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Indiana University School of Dentistry, Room S411
1121 West Michigan Street, Indianapolis, IN 46202-5186
Phone 317-350-4371, Fax: 317-852-3162
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Clinical Technique/Case Report

Minimally Invasive Multidisciplinary Restorative Approach to the Esthetic Zone Including a Single Discolored Tooth

A Tsujimoto • CA Jurado • J Villalobos-Tinoco • NG Fischer
S Alresayes • RA Sanchez-Hernandez • H Watanabe • F Garcia-Godoy

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Clinical Significance

A minimally invasive multidisciplinary approach in the esthetic zone, which includes internal bleaching using Washi, a gingivoplasty with a three-dimensional (3D) printed surgical guide, and ultrathin feldspathic porcelain veneers, resulted in successful esthetic improvements to anterior teeth, including a single discolored tooth.

SUMMARY

Objectives: The case report describes a minimally invasive, multidisciplinary approach to a single discolored anterior tooth, with internal bleaching using traditional Japanese paper (Washi), a gingivoplasty with a three-dimensional (3D) printed surgical guide, and ultrathin feldspathic porcelain veneers.

Clinical consideration: The patient's primary concern was improving her smile. After clinical

*Akimasa Tsujimoto, BDS, DDD, Department of Operative Dentistry, University of Iowa College of Dentistry, Iowa City, IA, USA

Carlos Alberto Jurado, DDS, MS, Texas Tech University Health Science Center El Paso, Woody L. Hunt School of Dental Medicine, El Paso, TX, USA

Jose Villalobos-Tinoco, DDS, Department of Oral Rehabilitation, Autonomous University of Queretaro School of Dentistry, Queretaro, Mexico

Nicholas G Fischer, PhD, Minnesota Dental Research Center for Biomaterials and Biomechanics, University of Minnesota School of Dentistry, Minneapolis, MN, USA

Saad Alresayes, DDS, MS, Department of Restorative Dentistry, King Saud University, Riyadh, Saudi Arabi

Ramon Alfredo Sanchez-Hernandez, dental technician, private practice, San Felipe, Baja California, Mexico

Hidehiko Watanabe, DDS, MS, Department of Restorative Dentistry, Oregon Health and Science University School of Dentistry, Portland, OR, USA

Franklin Garcia-Godoy, DDS, MS, PhD, Department of Bioscience Research, College of Dentistry, University of Tennessee, Health Science Center, Memphis, TN, USA

*Corresponding author: Department of Operative Dentistry, University of Iowa College of Dentistry, 801 Newton Rd, Iowa City, IA, 52242-1010, USA; e-mail: akimasa-tsujimoto@uiowa.edu

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evaluation, internal tooth bleaching for the discolored tooth and gingivoplasty with restoration of the maxillary anterior six teeth and first premolars was recommended. The internal tooth whitening was accomplished with sodium perborate mixed with 30% hydrogen peroxide impregnated in Washi and sealed in the root canal with glass ionomer. Once the tooth bleaching was completed, the 3D printed surgical guide was placed in the patient's maxillary anterior region and used to guide soft tissue recontouring. After 6 months, ultrathin feldspathic porcelain veneers were placed.

Conclusion: Well-planned restorative procedures combining internal tooth bleaching using Washi, gingivoplasty performed with electrosurgery using a 3D printed surgical guide, and ultrathin feldspathic porcelain veneers can achieve the desired results in the esthetic zone and remain successful for 4 years.

INTRODUCTION

Currently, patients demand dental improvements with high esthetic quality.[1] Esthetics in maxillary anterior teeth are particularly challenging due to high esthetic consciousness and demands of patients.[2] In many complex cases, optimal esthetic outcomes require an interdisciplinary approach from periodontists and restorative dentists to achieve gingival health, harmonious anatomy, and color, alongside restorative treatments.[3] Many kinds of esthetic restorative procedures are available as state-of-the-art techniques, such as bleaching,[4] periodontal surgery,[5] and veneers.[6] Although case reports combining the use of highly skilled techniques called multidisciplinary approaches have showed significant esthetic outcomes,[7] there is still room to improve those treatments with the benefit of current material development and new technical procedures.

Esthetic treatment of anterior teeth, including a single discolored tooth presents challenges,[8] especially if internal bleaching, gingival surgery, and veneers are planned. Internal tooth bleaching runs the risks of weakening the tooth structure[9] and cytotoxicity in the periodontal tissues.[10] Therefore, there is a demand for bleaching procedures that are both minimally invasive, limiting the detrimental effects on teeth and periodontal tissue, and effective. In addition, the esthetic harmony of maxillary anterior teeth depends on the gingival tissue level and gingival morphology.[11] Sometimes the gingival tissues surrounding a nonvital discolored tooth become irregular, and gingivoplasty is necessary to restore the esthetics. Further, as these teeth are nonvital, there is a possibility that the substrate will be weaker than that in a vital tooth.[12] Finally, the use of veneers, particularly thin veneers, places demands on the color and structural integrity of the underlying tooth.[13] Meeting all these requirements is challenging and reinforces the need for minimally invasive techniques. A further motivation for such an approach is the patients' desire to avoid extensive reduction in both nonvital and vital teeth. Given both these factors, restorative procedures that involve reduced tooth preparation are always in demand.

This clinical report describes a minimally invasive approach for the esthetic zone involving internal bleaching using a traditional Japanese paper (Washi), a gingivoplasty with a three-dimensional (3D) printed surgical guide, and an ultrathin feldspathic porcelain veneer placement.

CASE REPORT

A 40-year-old female patient presented to the clinic with the chief complaint of wanting to improve her smile (Figure 1). The patient was diagnosed with worn teeth from #5 to #12, uneven incisal edges of teeth from #7 to #10, and extensive discoloration of tooth #8, which had previously undergone root canal treatment followed by resin composite restoration. The periodontal pocket depths of teeth from #5 to #12 were less than 3.0 mm. The patient was offered an internal tooth bleaching, a gingivoplasty, and a veneer treatment. The patient requested that treatment start, beginning with internal bleaching of tooth #8, in anticipation of veneer treatment later.

A rubber dam (Nic Tone Dental Dam, MDC Dental, Guadalajara, Jalisco, Mexico) was placed, and the prior resin composite restoration was removed (Round #2, Patterson Dental Co, 1031 Mendota Heights Road, Saint Paul, MN 55120, USA) (Figure 2). Pulpal horns were exposed during removal of the existing resin composite to ensure optimal bleaching outcomes. A glass ionomer cement (GC Fuji GP, Tokyo, Japan) was placed (1 mm) over the existing gutta-percha (GP) to protect the periodontal ligaments from cytotoxic diffusion and allowed to set for 8 minutes. A mixture of sodium perborate and 30% hydrogen peroxide was wrapped in Washi (Washi Arts, Blaine, WA, USA) and then placed in the chamber (Figures 3 and 4). Finally, phosphoric acid-etched enamel margins were sealed with the glass ionomer cement. The patient was recalled at 2 weeks for assessment and repetition of the bleaching procedure. This step was repeated 2 weeks later. At this point, the discoloration had been removed,

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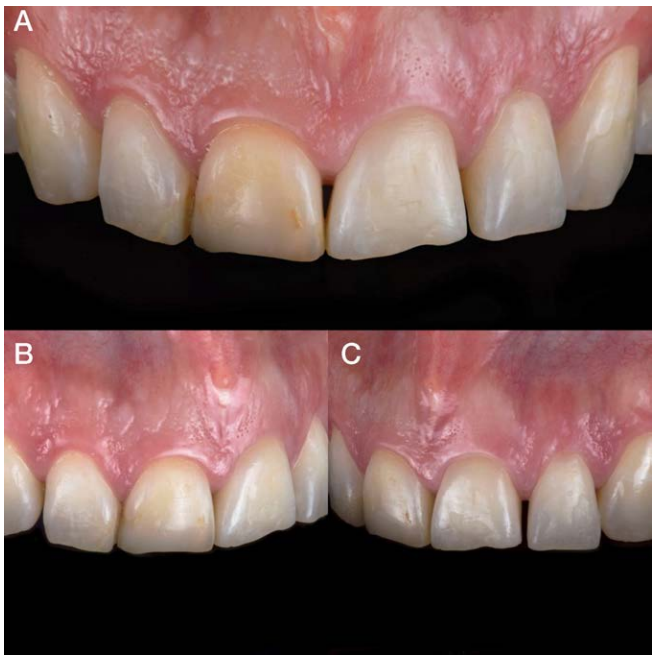

Figure 1. *Preoperative views. (A): Front view. (B): Side view (right). (C): Side View (left).*

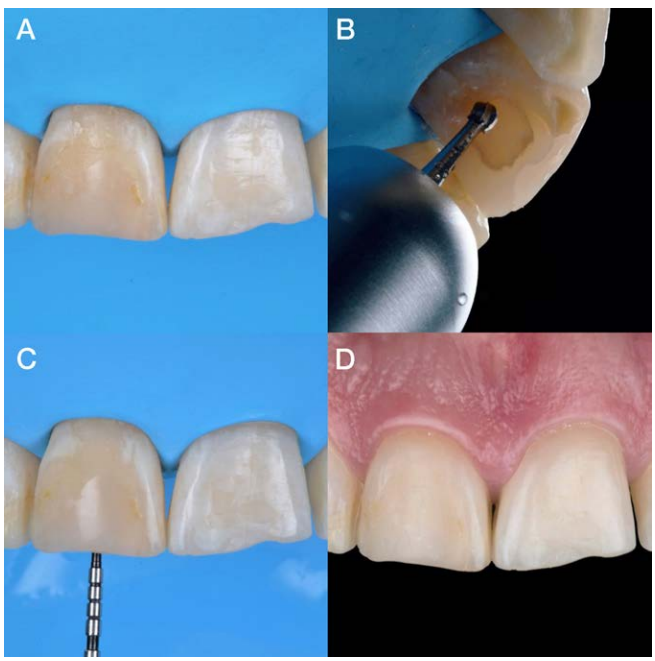

Figure 2. *Internal tooth bleaching using Washi. (A): Placing rubber dam. (B): Preparation of chamber space. (C): Confirmation of chamber depth. (D): Post internal bleaching.*

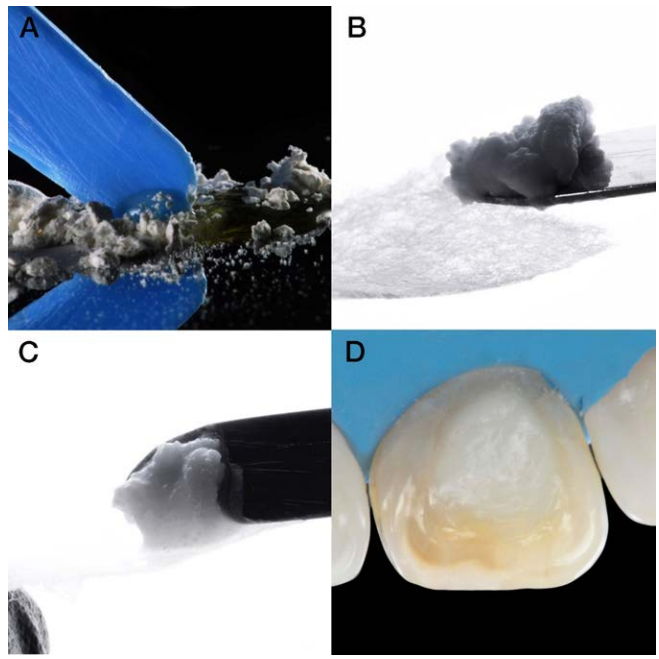

Figure 3. *Mixing bleaching material wrapped with Washi. (A): Mixing of materials. (B): Transfering to Washi. (C): Wrapping with Washi. (D): Temporary sealing.*

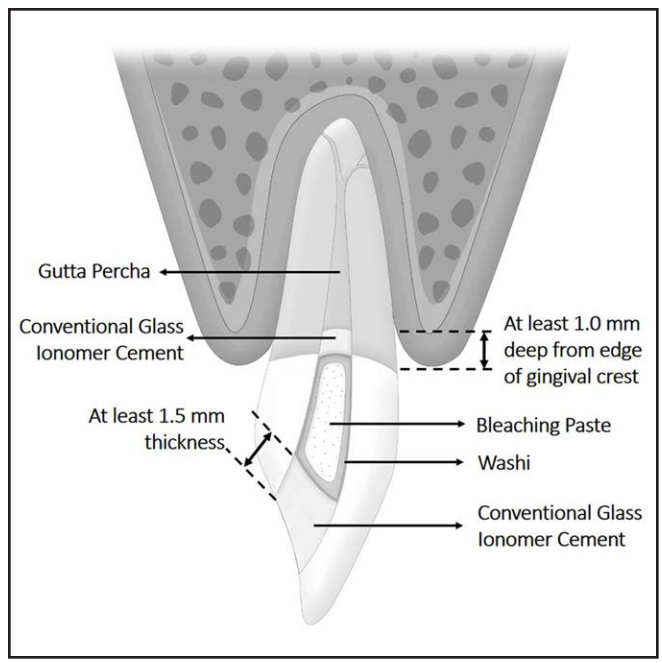

Figure 4. *Schematic drawing of internal bleaching using Washi.*

and the tooth's shade was enhanced. A conventional glass ionomer cement (GC Fuji GP) and flowable resin composite (G-ænial Universal Flow, GC) were used with a sandwich technique for filling the cavity. After the glass ionomer cement had set, 1 mm of the superficial surface of the ionomer filling was removed, the surface was etched with phosphoric acid, and the surface cavity was restored with universal adhesive and flowable composite. The patient was satisfied and agreed to continue treatment with the gingivoplasty.

A gingivoplasty was selected instead of crown lengthening, based on the adequate thickness of

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the attached gingiva. First, diagnostic casts were made, and a wax-up (Wax GEO Classic, Renfert, Hilzingen, Germany) was fabricated to provide the patient with a harmonious smile that met her desires. The diagnostic wax-up was scanned (D2000, 3Shape A/S, Copenhagen, Denmark), and a surgical guide was designed and printed out of resin (Dental LT Clear Resin V2, Form 2, FormLabs, Somerville, MA, USA) using a 3D printer (Form 3, FormLabs) (Figure 4). The surgical guide was placed over the teeth to provide guidance for the desired contour during gingivoplasty with an electrosurgical unit (Sensimatic 700SE Electrosurge, Parkell Inc, Edgewood, NY, USA) (Figure 5). The interproximal soft tissue was separated from the interdental gingiva with a gingivectomy knife (KB5/6 Buck Periodontal Knife, Hu-Friedy, Chicago, IL USA).

After 6 months, to allow for proper healing of the periodontal tissues, the mock-up was inserted in the patient's mouth, and the patient was satisfied. Depth grooves were cut (LVS1 FG Medium Depth Cutting Diamond 834.31.021, Brasseler Dental, One Brasseler Boulevard Savannah, GA 31419, USA). A clear reduction guide (0.5-mm thickness, Keystone Industries, 480 South Democrat Road, Gibbstown, NJ, USA) was made with a vacuum machine (Pro-Vac Machine 110V, Keystone Industries). Veneer preparations were performed on the six anterior teeth and first premolars. The guide was placed, and preparations were checked with hole-shaped perforations through which a periodontal probe was inserted to determine the reduction (Figure 6). A silicone putty reduction guide matrix was also fabricated to evaluate the reduction, again using a periodontal probe to measure the reduction (Figure 6). Afterwards, the teeth were polished and smoothed using discs (OptiDisc, Kerr, Orange, CA, USA).

A double cord impression technique was used in anticipation of the final impression. Cord #00 and then #0 (Ultrapak, Ultradent Products Inc, South Jordan, UT, USA) were packed. The final impression was taken using polyvinylsiloxane (Virtual 380, Ivoclar Vivadent AG, Schaan, Liechtenstein). Ultrathin ceramic veneers (less than 0.5-mm thick) were fabricated from feldspathic porcelain (Super Porcelain Ex-3, Kuraray Noritake Dental, Tokyo, Japan) (Figure 7). A try-in of the final ceramic veneers was performed to evaluate the fit and contours; the patient approved the final appearance. For the bonding of the veneers, isolation was performed with a rubber dam. The teeth receiving veneers were surface treated with 37% phosphoric acid (Total Etch, Ivoclar Vivadent) for 15 seconds and then rinsed with water (Figure 8). Adhese Universal (Ivoclar

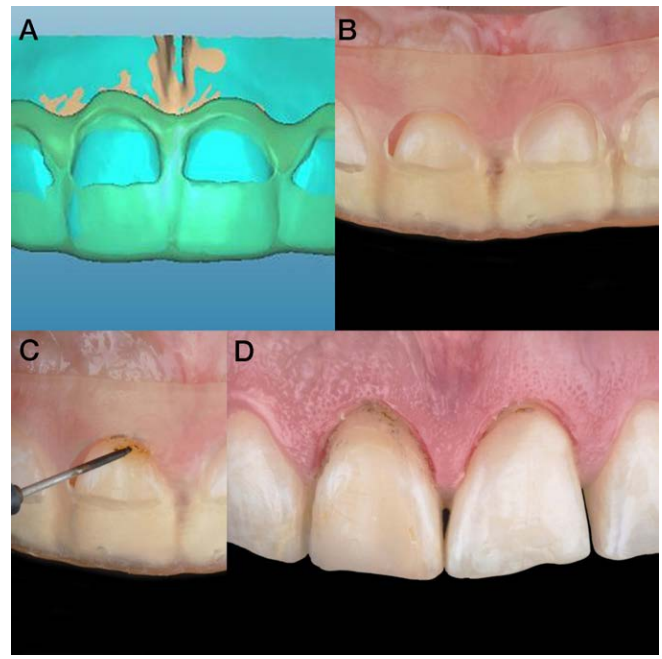

Figure 5. *Gingivectomy using a three-dimensional (3D) printed surgical guide over the teeth. (A): Digital designing for 3D printing surgical guide. (B): Placing a printed surgical guide. (C): Gingivoplasty using printed surgical guide. (D): Post surgery.*

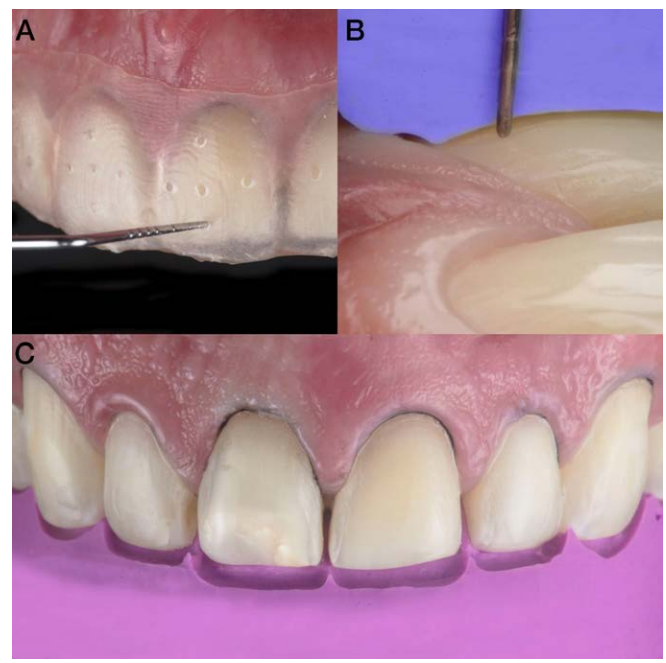

Figure 6. *Ultrathin veneer preparations. (A): Checking reduction depth with a clear reduction guide. (B): Checking reduction thickness with a silicone putty reduction guide. (C): Checking incisal reduction using a silicone putty reduction guide.*

Vivadent) was applied to the etched enamel surfaces. The intaglio surfaces of the ceramic restorations were etched with 5% hydrofluoric acid (IPS Ceramic Etching Gel, Ivoclar Vivadent) for 20 seconds, and Monobond

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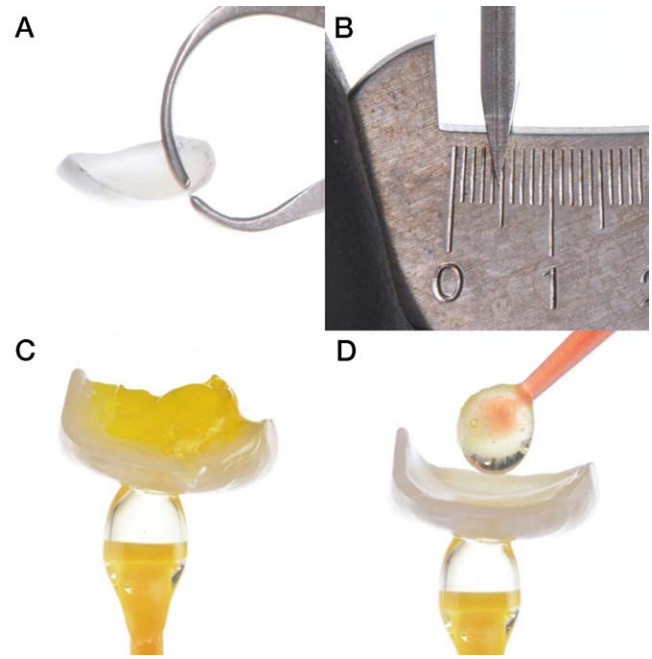

Figure 7. *Measurement for the thickness and pretreatments of veneers. (A): Checking a veneer thickness. (B): Measurement of a veneer thickness (less than 0.5 mm). (C): Hydrofluoric acid etching. (D): Primer applicaion.*

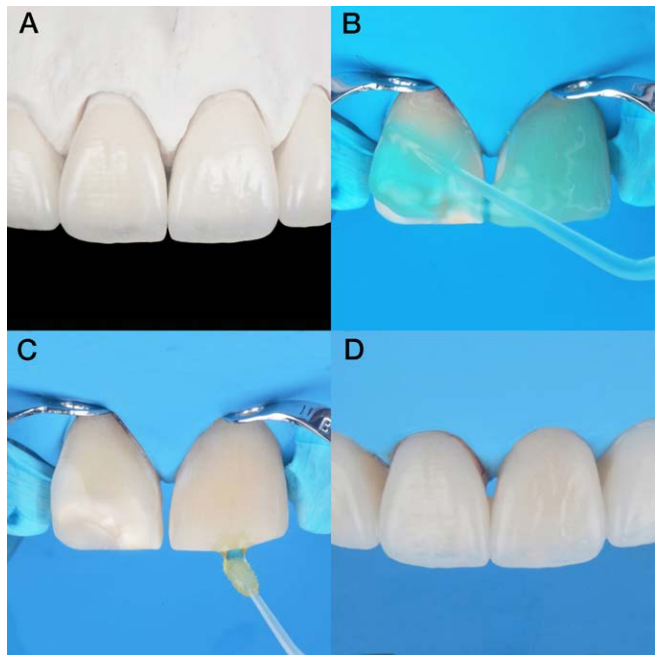

Figure 8. *Bonding ultrathin veneers. (A): Fabricated veneer.; (B): Phosphoric acid etching with rubber dam. (C): Adhesive application. (D): Cementation veneers with light-cured resin luting cement.*

Plus (Ivoclar Vivadent) was applied to the etched surfaces (Figures 7 and 8). Light-cured resin luting cement (Variolink Esthetic LC, Ivoclar Vivadent) was applied to the veneers, and they were seated. Excess cement was removed, and the restorations were cured using an LED light curing unit (VALO Cordless, Ultradent) on each surface (facial, palatal, mesial, and distal) for 40 seconds.

The patient approved the color, shape, and size of the final restorations, and the treatment fulfilled her esthetic requirements (Figure 9). An occlusal night guard was also provided in order to prevent any damage to the final restorations. At the patient's 4-year follow-up, she was highly pleased with the clinical outcome, including the closure of black triangles (Figures 9 and 10).

DISCUSSION

This clinical report presented a minimally invasive approach in the esthetic zone. The patient had two main complaints: spaces between teeth and a discolored tooth #8. The patient was informed of the need for nonvital tooth bleaching prior to any other treatment. The patient previously had an endodontic treatment of the tooth, and it has been demonstrated that, during endodontic therapy, blood content, such as hemosiderin, hemin, hematin, and memoidin, can penetrate the dentinal tubules causing discoloration of the tooth.[14] Internal tooth bleaching with a minimally invasive approach is needed, if thin ceramic veneers are planned. For this patient, internal tooth bleaching was provided with sodium perborate mixed with 30% hydrogen peroxide to form a paste, wrapped using Washi, and replaced every two weeks over a period of 6 weeks. Jurado and others[15] have reported a minimally invasive technique for nonvital tooth bleaching using Washi. Mixed bleaching paste wrapped with Washi, which is made using fibers from the inner bark of the gampi tree, the mitsumata shrub (*Edgeworthia chrysantha*), or the paper mulberry (kōzo) bush, can stay wet within the pulp chamber and release the ingredients slowly. This slow release minimizes the damage to organic and inorganic components of the tooth through the dentinal tubules and ensures that the peroxide does not reach the periodontal tissues, while providing an effective bleaching treatment. As in the previous case report,[15] the clinical results of the internal bleaching using Washi satisfied the clinician and patient without any side effects, such as external and internal resorption. This is a promising technique for minimally invasive bleaching. Another important merit of using Washi paper is that it is easier to apply the temporary sealing more accurately. Temporary sealing often debonds due to the moisture from the mixed paste. If the paste is enclosed in Washi paper, this can control the moisture level of the surface and

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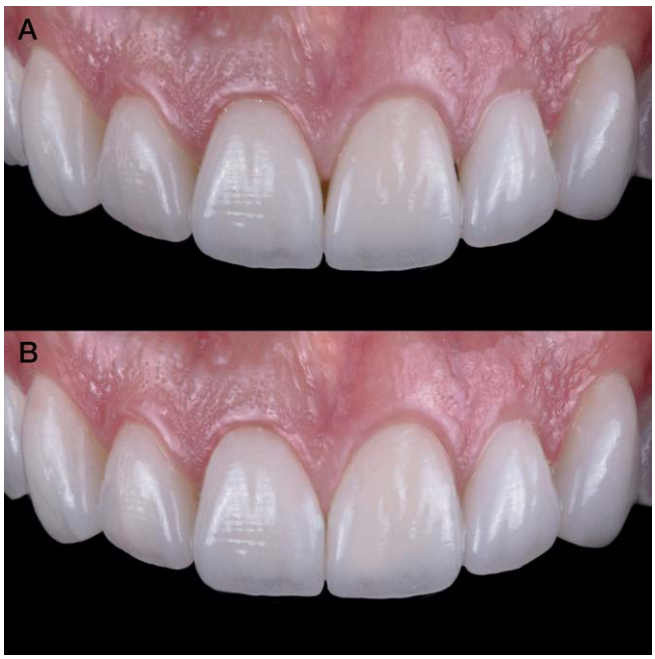

Figure 9. *Postoperative views and views of the restorations 4 years after cementation. (A): Postoperative view 1 week after cementation. (B): 4-year follow-up view.*

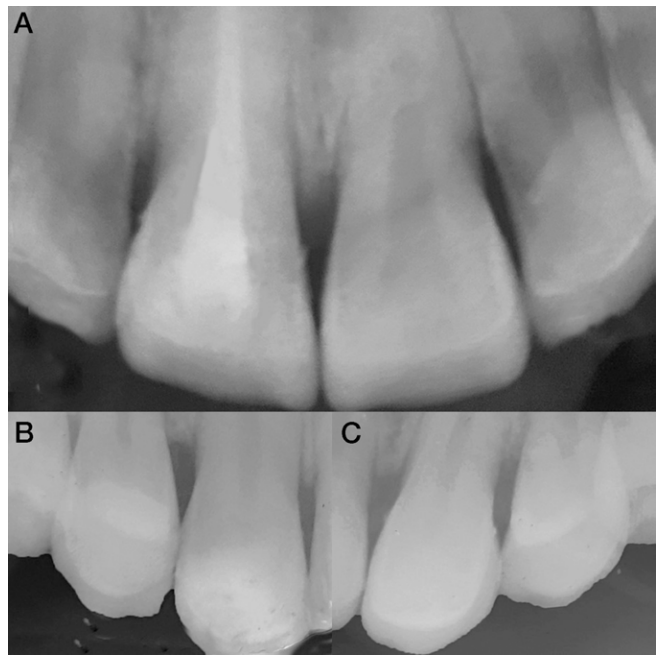

Figure 10. *Postoperative X-ray photos of restorations 4 years after cementation. (A): Front view. (B): Side view (right). (C): Side view (left).*

assist with temporary sealing. In this case, we did not see any debonding of the temporary sealing during treatment.

After achieving the desired tooth color, gingivoplasty was performed. Novel guides for improving the gingival architecture can be printed out based on a scanned diagnostic wax-up or based on bone level evaluation through cone beam computer tomography. Although some clinicians have reported creating a 3D printed surgical guide for crown lengthening, when cutting off the gingiva and trimming the alveolar bone,[16,17] there have been no reports of the use of a printed guide for gingivoplasty. For this patient, the diagnostic wax-up was scanned, and the gingivectomy guide was designed following its shape before being printed out in resin. 3D printing techniques can be used with computer-aided design and rapid prototyping, and applications of this technology are expanding in dentistry. In this case report, the use of a 3D-printed surgical guide helped the operating dentist perform precise surgery due to the good fit of the guide and also improved the patient's comfort during the gingivoplasty, as the guide was thinner. In this case, a stone model was used as the basis for the printed surgical guide, which could serve as a good transitional step to fully digital based surgical guides. Although fully digital based surgical guides will be the major form of guide in the future, clinicians have to become familiar with digital impressions and computer design. However, clinicians who are not familiar with digital dentistry can order guides from a stone model base mock-up. In addition, the printed guide showed good fitting and, thus, should be a good gateway to digital dentistry for clinicians who are not yet familiar with the technique.

Currently, the market offers a wide variety of dental ceramics, such as feldspathic porcelain, feldspathic porcelain reinforced with leucite and lithium dislicate.[18] Bonded veneer restorations to enamel have shown high survival rates with low failure numbers.[19] Moreover, laboratory techniques have evolved to produce ultrathin ceramic veneers from high-strength ceramic materials in recent years.[20] In this clinical case, a feldspathic porcelain was selected due to its high esthetic quality, but there is only a small number of clinical reports for ultrathin veneers made from feldspathic porcelain. One laboratory study reported that ultrathin ceramic veneers (less than 0.5 mm) were a potential option for clinical use from the fracture strength point of view.[21] However, every restoration is a combination of the restorative materials and the bonding system. Recently, the bonding and mechanical strengths of resin luting cement have been improved,[18,22] which makes the restoration stronger. This opened the possibility of using feldspathic porcelain of less than 0.5-mm thickness as an ultrathin veneer. Clinical monitoring of these ultrathin veneers confirmed satisfactory results over 4 years.

This case report combines three developments of existing techniques—the use of Washi in bleaching,

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the use of a printed guide for gingivoplasty, and the use of feldspathic porcelain ultrathin veneers—to successfully achieve minimally invasive and highly esthetic restoration of a difficult case.

CONCLUSIONS

Minimally invasive treatment involving internal bleaching with Washi, gingivoplasty with a 3D printed surgical guide, and ultrathin feldspathic porcelain veneers can achieve fully acceptable results in the esthetic zone for 4 years.

Regulatory Statement

This study was conducted in accordance with all the provisions of the human subjects oversight committee guidelines and policies of the Human Research Ethic Office of Centro de Estudios Odontologicos de Queretaro. The approval code issued for this study is DENT/0031-06152015.

Conflict of Interest

The authors have no financial interest in any of the companies or products mentioned in this article.

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Multidisciplinary Approach to Complicated Crown-root Fracture Treatment: A Case Report

MD Alves • MA Tateyama •NNO Pavan • AF Queiroz • MCP Nunes • MS Endo

Clinical Relevance

Multidisciplinary treatment is required in complex cases of crown-root fractures. Fragment reattachment is a viable approach, and in the case presented, the repair remained intact after two years of follow-up. Maintenance of the natural tooth has a positive impact on psychological and social issues.

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SUMMARY

Treatment of complicated crown-root fractures is one of the most challenging within the various types of dental trauma and requires a multidisciplinary approach. This paper reports the complicated crown-root fracture of a maxillary right central incisor, in which there was esthetic, functional, and biologic (endodontic and biologic width invasion) involvement. A 15-year-old male patient presented to the dental clinic one month after suffering trauma with a complicated crown-root fracture on tooth 8. The patient had previously undergone endodontic treatment and was sent to have periodontal surgery to reestablish the biological width on the palatal surface. Following the surgery, a fiberglass post was cemented, and the fragment was reattached. This approach allows the exposure of the cervical margin, adequate isolation, and subsequent fragment reattachment in the same clinical appointment. Fragment reattachment is a viable approach as it is a simple and conservative procedure that restores the natural esthetic of the tooth and has superior resistance compared to a composite restoration. The patient's cooperation in understanding the limitations of the treatment and maintaining adequate oral hygiene are very important to achieving a good prognosis of the case. After a 2-year clinical and radiographic follow-up period, the clinical protocol was found to

Morgana Ducatti Alves, DDS, State University of Maringa Health Science Center, Maringá, Brazil

*Mellissa Ayumi Tateyama, DDS, State University of Maringa Health Science Center, Maringá, Brazil

Nair Narumi Orita Pavan, PhD, State University of Maringa Health Science Center, Maringá, Brazil

Alfredo Franco Queiroz, PhD, State University of Maringa Health Science Center, Maringá, Brazil

Margareth Calvo Pessutti Nunes, PhD, State University of Maringa Health Science Center, Maringá, Brazil

Marcos Sergio Endo, PhD, State University of Maringa Health Science Center, Maringá, Brazil

*Corresponding author: State University of Maringa Health Science Center, Maringá, Brazil; e-mail: melissaatateyama@gmail.com

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be successful, and the tooth remained functional, esthetically favorable and asymptomatic.

INTRODUCTION

The maxillary central incisors are the teeth most affected by dental trauma, which occurs mainly in children and adolescents.[1,2,3] Crown-root fractures represent 5% of all trauma events[1,4] and can be classified as complicated when there is pulp involvement and non-complicated when they involve only enamel, dentin and cementum.[1,4,5] Their treatment requires a multidisciplinary approach[6,7] involving specialties such as restorative dentistry, endodontics and oral and maxillofacial surgery.[8,9] Which specialties will be involved in the treatment of a crown-root fractured tooth will depend on the fracture level.[1,2]

There are a number of treatment strategies for crown-root fractures, including orthodontic extrusion,[1,8,9,10,11,12] reattachment of the fragment,[3,9,11,13] surgical crown lengthening with osteotomy and/or gingivectomy,[14,15,16] intentional replantation -- surgical extrusion,[1,11,12,17] or extraction.[1,18]

It is important to emphasize that keeping the patient's own tooth in the alveolus favorably contributes to functional aspects, as it maintains enamel occlusion; to esthetic aspects, as it restores color, shape, texture, and alignment; and to psychological issues, maintaining the natural tooth.[19] The reasoning behind a conservative treatment in patients still too young for implant treatment is to allow maintenance of alveolar bone height and the possibility of surgery and prosthetic rehabilitation in the future.[20]

The aim of this case report is to present and discuss the multidisciplinary approach to a complicated crown-root fracture with endodontic involvement and biological width invasion in a maxillary right-central incisor.

CASE REPORT

A 15-year-old male patient in good general health presented to the dental clinic's emergency department reporting falling while playing sports one month previously and receiving urgent endodontic treatment in a private practice. The tooth fragment was temporally cemented to the adjacent teeth, but the fragment became loose and fell out. The patient stored it in saline solution and was referred to this treatment group. Clinical and radiographic examination led to the diagnosis of a complicated crown-root fracture involving enamel, dentin, cementum, and pulp, no alveolar fracture, and complete root development (mature tooth) with root filling material. The patient was also found to have gingivitis and biological width invasion on the maxillary right central incisor (tooth 8) (Figures 1A, 1B). The length of the fracture extended subgingivally in all surfaces of the tooth. After periodontal evaluation, it was determined that surgical crown lengthening on the palatal surface was necessary to restore biological width (Figures 2A, 2B, 2C).

DESCRIPTON OF TECHNIQUE

Surgical crown lengthening started with gingival marking using a North Carolina periodontal probe (Hu-Friedy, Rio de Janeiro, Rio de Janeiro, Brazil). A beveled sulcular internal incision was made along the facial and palatal surfaces with a 15-C scalpel blade (Feather Safety Razor Co Ltd, Seki, Gifu, Japan). Mucoperiosteal flap elevation was performed with a Molt 2/4 (Hu-Friedy), and approximately 1 mm of

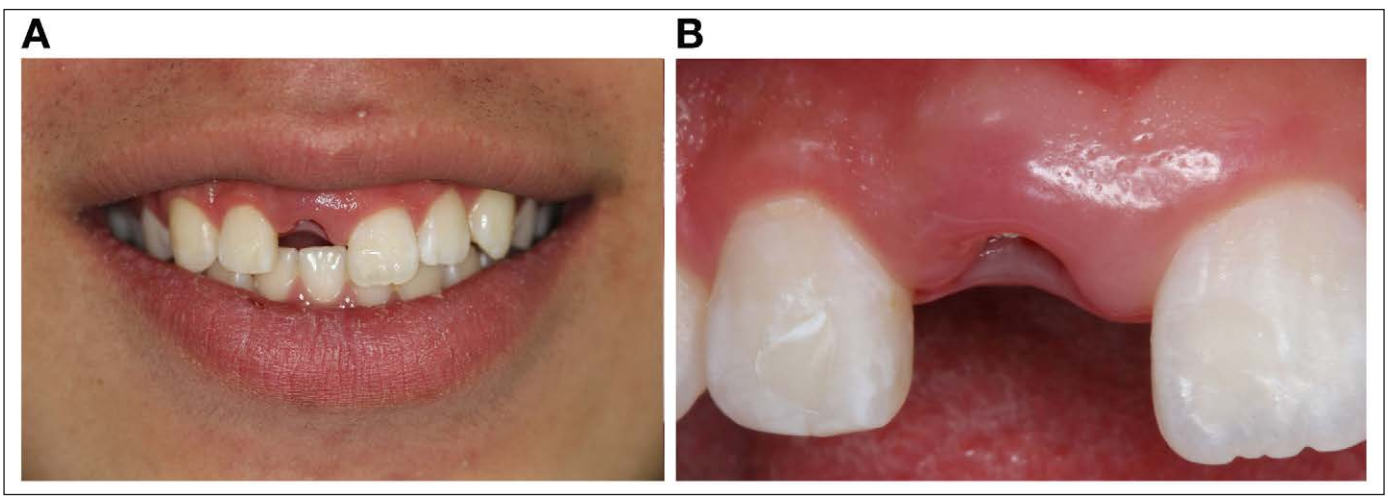

Figure 1. *(A) Front view of the crown-root fracture involving tooth 8; (B) Close front view showing excessive gingival growth and irregular gingival contour at the fracture area.*

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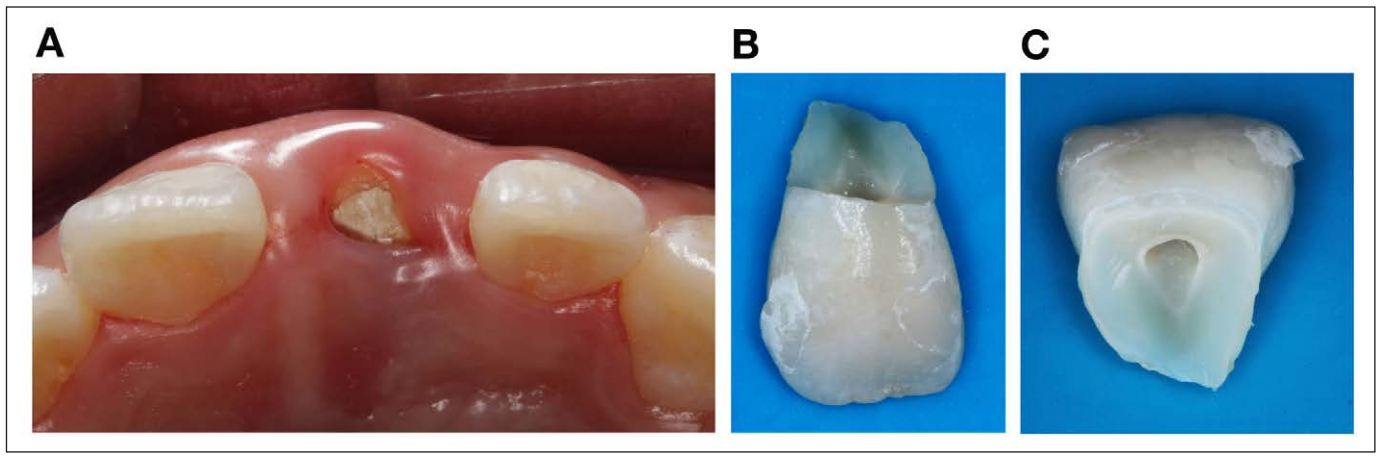

Figure 2. *(A) Occlusal view, biological width invasion by gingival tissue; (B) Front view of the fragment; (C) Palatal view of the fragment.*

tissue collar was removed, resulting in a new papilla formation in these surfaces. For a better adaptation of the coronal fragment, the alveolar crest was reduced approximately 1 mm on the palatal side using a Ochsenbein chisel (Hu-Friedy), and osteoplasty was later performed using a Rhodes chisel (Hu-Friedy) (Figure 3).

Next, the fragment was reattached. First, the root canal was prepared with a Largo drill 3 (Dentsply-Maillefer, Ballaigues, Switzerland) in the coronal two-thirds of the remaining root, maintaining the endodontic filling material in the apical third of the root canal for posterior cementation of a 3 fiberglass post (Angelus, Londrina, Paraná, Brazil), which was adjusted to create a groove with a diamond tip 1014 (KG Sorensen, Cotia, São Paulo, Brazil), and cemented with self-etching adhesive (Single Bond Universal, 3M, Sumaré, São Paulo, Brazil) and resin cement (RelyX Ultimate, 3M). The coronal fragment was gently cleaned, etched with 37% phosphoric acid (DFL, Curicica, Rio de Janeiro, Brazil) for 15 seconds, rinsed for 15 seconds and gently dried. A self-etching adhesive was applied (Single Bond Universal, 3M), and the fragment was reattached with the same cement used for the cementation of the fiberglass post (RelyX Ultimate 3M) (Figure 4). Once the reattachment procedure was completed and the correct adaptation of the fragment was verified, the area was closed using the mattress technique with 5.0 nylon suture (Procare, Lamedid Comercial e Serviços LTDA, Barueri, São Paulo, Brazil), Castroviejo needle holder (Hu-Friedy) and Dietrich forceps (Hu-Friedy) (Figure 5). Postoperatively, the patient was prescribed ibuprofen 600 mg every 8 hours for 3 days and mouthwash with 0.12% chlorhexidine digluconate every 12 hours for 10 days. Clinical instructions given to the patient and his guardian included warnings about harmful habits that could compromise treatment success, like biting food directly on the front teeth, especially hard food or foods like apples that require biting strength, or fingernail biting. The need to use a mouth guard during sports practice was also pointed out.

The patient underwent follow-up at 7, 14, 49, and 120 days and thereafter at 12-month intervals (Figures

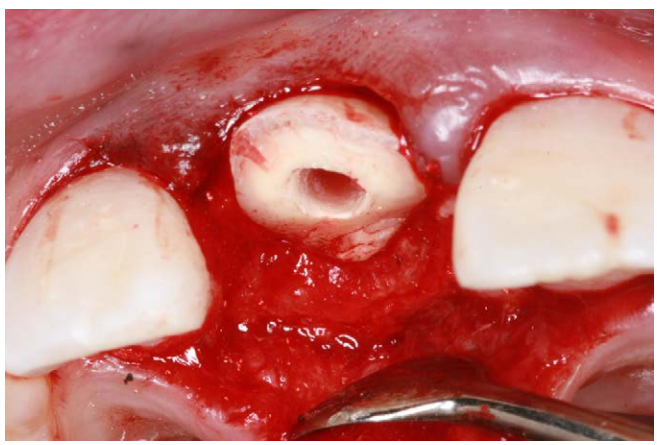

Figure 3. *Periodontal surgery. After mucoperiosteal flap elevation and alveolar crest bone reduction of 1 mm in the palatal region, it is possible to observe the cervical margin of the fracture.*

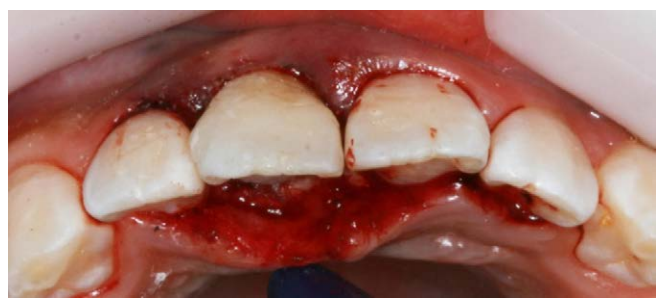

Figure 4. *Occlusal view showing correct adaptation of the coronal fragment.*

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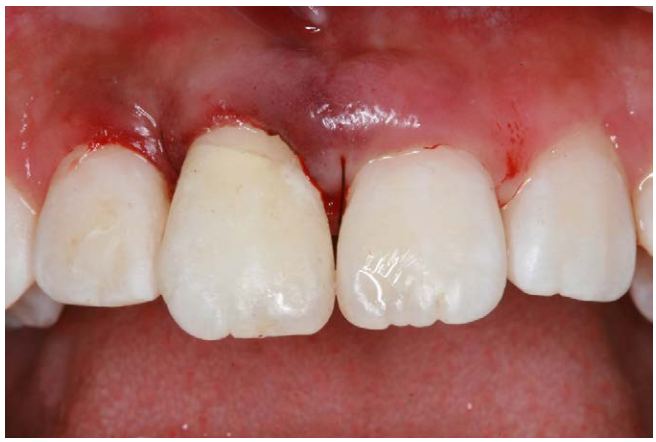

Figure 5. *Close-up view of the positioned fragment reattached after periodontal surgery, showing slight dental extrusion of tooth 8.*

6, 7, 8, 9, 10). Clinical and radiographic examinations were performed, which indicated stability and adaptation of the fragment. The fracture line is visible on the facial surface; however, when the patient smiles naturally, it cannot be seen, due to a low smile line. A satisfactory periodontal condition was observed, with 3 mm probing depths on all surfaces, slight extrusion of approximately 0.5 mm, likely due to the lack of occlusion in the one-month period after the injury, no sign of root resorption, and no painful symptomatology. The patient was satisfied with the esthetic effect. Two years have passed, and the patient is receiving annual clinical and radiographic follow-up.

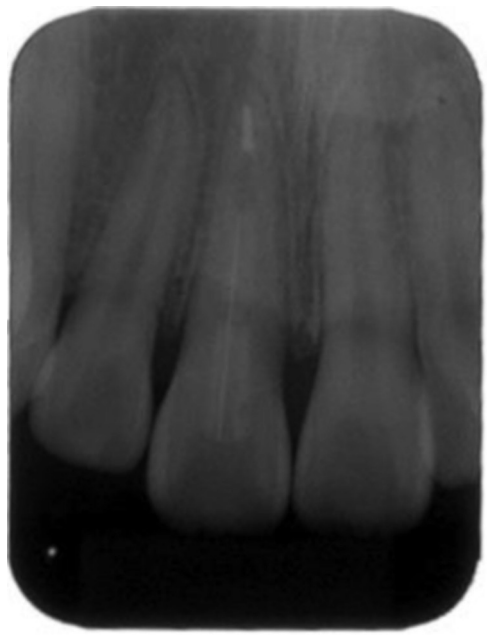

Figure 6. *Radiographic follow-up 7 days after surgery and fragment reattachment.*

DISCUSSION

The treatment of complicated crown-root fracture may involve a multidisciplinary approach, including oral and maxillofacial surgery, endodontics, orthodontics, pediatrics, radiology, and restorative dentistry.[8,9] Several factors should be considered during the treatment of traumatically injured teeth, such as length and shape of the fracture, pulp involvement, stage of root development, alveolar bone fracture, biological width invasion, gingival laceration, presence or absence of the coronal fragment, secondary traumatic injuries, occlusion, lip sealing, and esthetics.[1,21] The patient presented a favorable Class I occlusion with moderate overbite, complete root development, and an adequate crown-root ratio (<1:1), allowing endodontic treatment, intracanal post cementation, and fragment reattachment.

The determination of the treatment plan for crown-root fractures depends on the length of the fracture line.[1] Oblique fractures that extend below the gingival margin make restoration treatment difficult or impossible due to biological width invasion[22,23] and may extend below the bone level.[3,9,13] Thus, it is necessary to expose the fracture line either by means of orthodontic extrusion or by surgical access in order to facilitate rehabilitation treatment and reestablish the biological width. Surgical exposure of the fracture line in the present case allowed us to confirm the crown-root fracture diagnosis during the procedure; it was the preferred option over orthodontic extrusion since the attachment of an orthodontic button to the root fragment would be challenging because of the lack of tooth tissue available for an effective bonding procedure and the difficulty in isolating the surface to be bonded from gingival crevicular fluid and blood.[24,25]

Gingivectomy was performed on the palatal surface due to excessive gingival growth and the extensive oblique fracture in this region. As Olsburgh and others[1] have pointed out, in cases where there is a good adaptation of the fragment to the remnant, it is possible to perform gingivectomy and osteotomy only in areas where there is biological width invasion, removing just

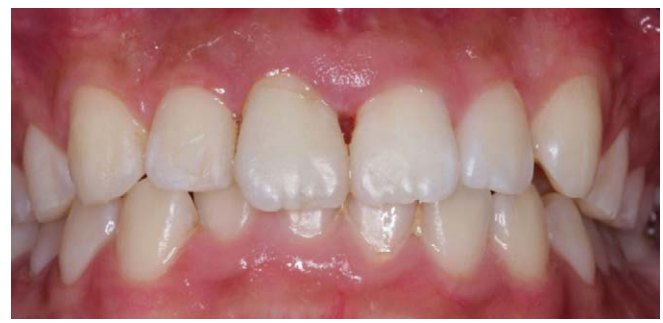

Figure 7. *Removal of suture 14 days after surgery.*

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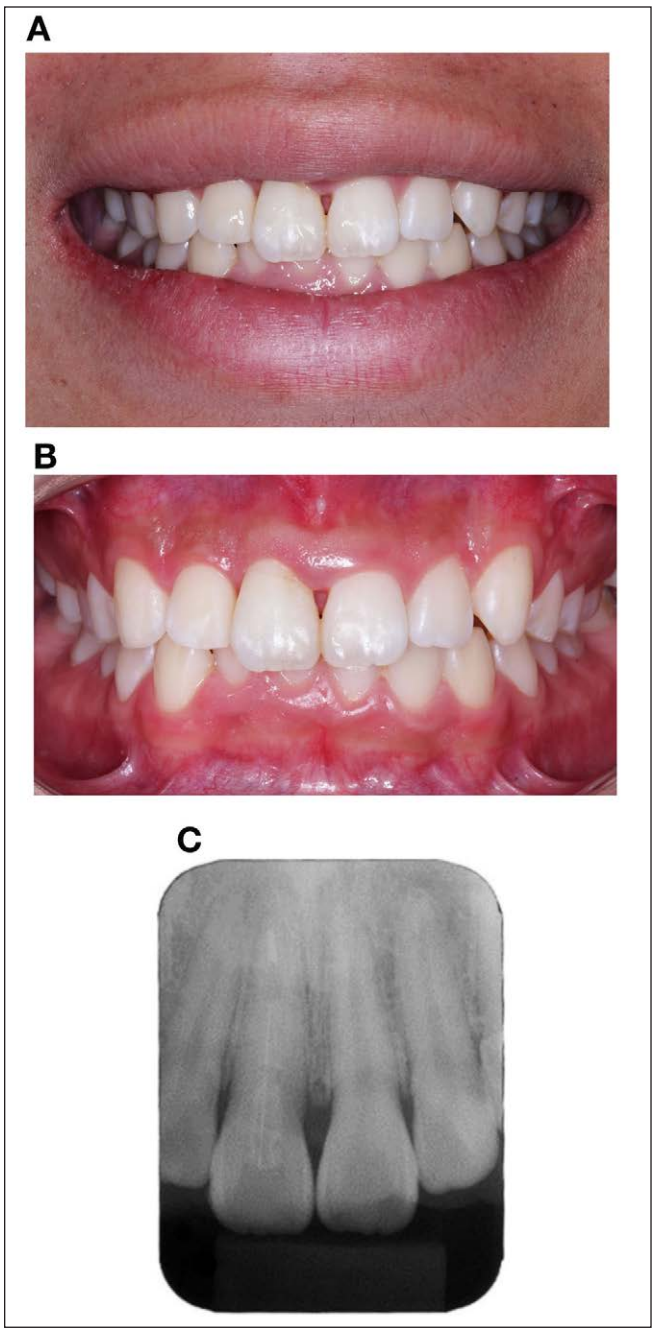

Figure 8. *Follow-up at 49 days. (A) Front view of the smile: the fracture line does not appear significantly; (B) Close front view; (C) Radiographic follow-up.*

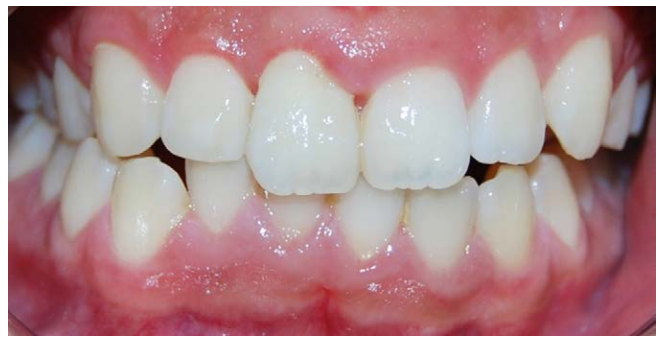

Figure 9. *Follow-up at 120 days. Front view.*

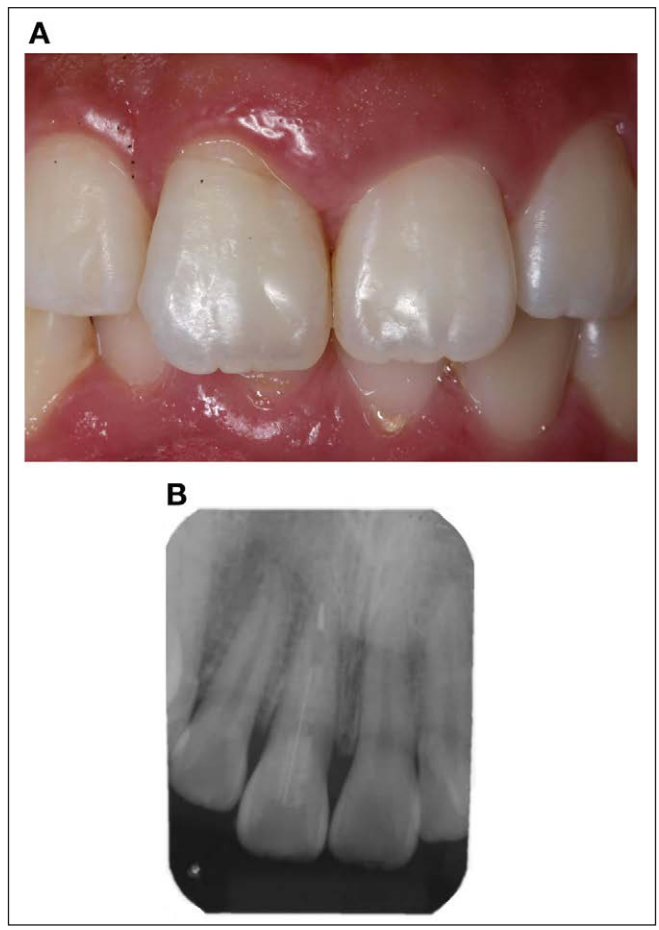

Figure 10. *Follow-up at 12 months. (A) Close-up front view showing subtle fracture line; (B) Periapical radiography attesting normality of the periapical tissues and good adaptation of the fiberglass post.*

enough bone to keep the cementation line 1 mm inside the bone. This approach allows the fragment to be reattached in the same appointment because it allows exposure of the cervical margin of the fractured tooth and adequate isolation of the operative field.[1]

The loss of the crown of a permanent incisor in a young patient can cause esthetic and functional problems, which in turn can lead to serious emotional problems.[24,25] Thus, when the fragment is present, reattachment is a viable approach[26,27] as it is a simpler, faster, and more conservative alternative that restores the natural esthetic of the tooth[3,21] and has better resistance than a composite restoration.[28,29,30] However, the patient should be informed about disadvantages and potential problems, such as the need to limit the function of the anterior teeth, the possibility of fracture

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recurrence, and the possibility that a visible line between the fragment and the remnant tooth structure will be noticeable[30,31]; the latter occurred in this case, but as the patient had a low smile line, the fracture line did not show when the patient smiles. Despite the limitations, fragment reattachment was the patient's preferred treatment option as it offered the possibility of maintaining his own tooth.[30]

In a fracture involving two-thirds or more of the crown, intracanal post systems are commonly used to increase resistance and reduce stress in the coronal fragment, since they interlock the crown and root fragments.[11,30,33] The fiberglass post has been recommended as effective in reducing tensile stress, which can lead to root fracture of endodontically treated teeth.[34,35,36] Fiberglass posts have a modulus of elasticity similar to dentin and are therefore preferable to cast metal posts.[11]

The patient's cooperation in understanding the limitations of the treatment and the need to maintain adequate oral hygiene is very important for a good prognosis of the case.[3] The patient described returned for follow-up after 7, 14, 49, and 120 days and 12 and 24 months; however, it has sometimes been a challenge to recall patients and keep them under observation for longer follow-up periods after crown-root fracture.[7]

CONCLUSION

In the present case, after 2-years of clinical and radiographic follow-up, the treatment protocol proved to be successful, and the tooth remains functional, esthetically favorable, and asymptomatic. Periodontally, there is no mobility, and probing depths are normal. Radiographically, the lamina dura is intact and there is normality of the periodontal tissues.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Dentistry Department, State University of Maringá.

Conflict of Interest

The authors have no financial interest in any of the companies or products mentioned in this article.

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Clinical Research

Reliability of Class II Bulk-fill Composite Restorations With and Without Veneering: A Two-year Randomized Clinical Control Study

D Kaisarly • M ElGezawi • R Haridy • A Elembaby
A Aldegheishem • R Alsheikh • KS Almulhim

Clinical Relevance

Veneering bulk-fill composites with conventional microhybrid composites is recommended for better clinical performance in Class II restorations.

SUMMARY

Bulk-fill composites are increasingly used in stress-bearing areas in posterior teeth, with a diversity of reports concerning their effectiveness and clinical reliability. The objective of this randomized clinical control study was to investigate the effectiveness of bulk-fill versus veneered bulk-fill Class II composite restorations. A double-blind split-mouth technique was employed in 80 subjects recruited for restoring Class II caries in one molar bilaterally in the same arch following respective inclusion and exclusion criteria and after obtaining written consent. While one molar was randomly restored with bulk-fill composite using the sealed-envelope technique, Tetric N-Ceram Bulk Fill (TBF), the contralateral was restored with a bulk-fill composite veneered with an increment of a heavy-body microhybrid

*Dalia Kaisarly, BDS, MDSc, PhD, University of Munich, Munich, Germany; Department of Restorative Dental Sciences, College of Dentistry, Imam Abdulrahman Bin Faisal University, Saudi Arabia

Moataz ElGezawi, BDS, MDSc, DDSc, Department of Restorative Dental Sciences, College of Dentistry, Imam Abdul Rahman Bin Faisal University, Dammam, Saudi Arabia

Rasha Haridy, BDS, MScD, PhD, Department of Clinical Dental Sciences, Princess Nourah Bint Abdel Rahman University, Saudi Arabia

Abeer Elembaby, BDS, MScD, PhD, Department of Restorative Dental Sciences, College of Dentistry, Imam Abdul Rahman Bin Faisal University, Dammam, Saudi Arabia

Alhanooof Aldegheishem, BDS, MScD, PhD, Department of Clinical Dental Sciences, Princess Nourah Bint Abdel Rahman University, Saudi Arabia

Rasha Alsheikh, BDS, MScD, PhD, Department of Clinical Dental Sciences, Princess Nourah Bint Abdel Rahman University, Saudi Arabia

Khalid S. Almulhim BDS, MScD, PhD, Department of Clinical Dental Sciences, Princess Nourah Bint Abdel Rahman University, Saudi Arabia

*Corresponding author: PO Box 1982, Dammam 31411, Saudi Arabia; e-mail: kaisarly@dent.med.uni-muenchen.de; dkaisarly@yahoo.com

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composite—Tetric-Ceram HB (TBF/V). Box-only cavities were prepared and received etch-and-rinse adhesive bonding and Tetric N-Bond treatment before composite insertion. Restorations were assessed at 24 hours, 2 weeks, 6 months, 12 months, and 24 months for esthetic, functional, and biological quality employing the FDI ranking criteria. Friedman repeated-measures analysis of variance, the McNemar test, and the Cohen's kappa statistical test were used for statistical analysis. Over a 24-month interval, none of the test restorations were ranked as clinically unsatisfactory. In terms of functional criteria, clinically excellent restorations were significantly more prevalent in TBF/V than in TBF ($p<0.05$). For long-term satisfactory performance of Class II bulk-fill composites, an occlusal veneering increment of conventional heavy body microhybrid composite appears to be favorable.

INTRODUCTION

Direct resin-based composite restorations constitute a basic aspect of modern, everyday practice of restorative dentistry. Millions of composite restorations are annually inserted around the world.[1,2] The use of resin composites for restoring cavities in load-bearing locations in posterior teeth has been increasingly popular and more clinically reliable, owing to the considerable contemporary upgrading in materials manufacturing aimed at improving their longevity and clinical performance.[3-5] Among the main limitations of composite restorations are their polymerization shrinkage and their degradation potential over time.[2] Much research has been conducted to improve the clinical long-term biomechanical and esthetic effectiveness of composite. The incremental insertion of direct composite has long been implemented to assure the optimal degree of curing light penetration and thus the degree of conversion, which is a prerequisite for optimal physical and mechanical properties as well as the biocompatibility of the composite.[6] Moreover, incremental insertion reduces the configuration factor, and, hence, the interfacial contraction stresses enhance better adaptation to cavity walls and inhibit pulling actions on cusps, thus reducing the cracking of teeth and possible postoperative hypersensitivity.[7] However, incremental insertion is time consuming and invites a greater risk of air void inclusion, with adverse consequences on restoration quality and clinical performance.[8,9]

Bulk-fill composites were introduced to simplify restorative procedures and reduce the time of application of composite restorations. The manufacturing technology of these materials included basic compositional modifications in the resin matrix and photoinitiator system to enable adequate degree of conversion at 4-5 mm thick bulk application without increasing the interfacial contraction stresses or compromising the tooth-restoration interfacial bonds.[3,8-11]

The reliability and performance of bulk-fill composites have been increasingly studied in different *in vitro* and *in vivo* investigations.[3,8-10,12-16] While an *in vitro* marginal integrity study did not find a significant difference between bulk and incremental fill composites,[16] another study showed that the internal adaptation of incremental composites is better than that of bulk-fill composites,[17] and a third study reported better bonding quality at the cervical interfaces of bulk-fill in comparison to incremental fill Class II composite restorations.[18] A diversity of *in vitro* studies of bulk-fill composite have been conducted over the past few years that focused on the degree of conversion and depth of cure as well as on the physicomechanical properties and degradation potential with increasing concerns regarding their long-term durability and effectiveness in clinical service. Ilie and others found that the mechanical properties of bulk-fill composites place them in a category between nanohybrid and microhybrid composites, which might indicate the inferior clinical behavior of bulk-fill composites.[12]

Leprince and others found it essential, after studying some of their physical and mechanical properties, to veneer bulk-fill composites with conventional microhybrid composite.[13] Sunbul and others also suggested a veneer bulk-fill composite with a more degradation-resistant composite.[14] Similar findings were reported by El Gezawi and others.[15] *In vivo* studies including clinical evaluation and ranking of restorations have been given the greatest value in evidence-based practice, meta-analyses, and systematic reviews, and are the basis of justifying specific clinical procedures and restoration techniques.[3]

Randomized clinical control trials are essential evidence for new materials and treatments, as they provide standardized clues of clinical predictability and judgment.[19] Clinical trials with longer follow-up periods provide more reliable clinical judgment and constitute a sound basis for evidence-based practice. A recent systematic review and meta-analysis based on clinical studies performed over 12-72 months found similar performance of bulk-fill and conventional composite restorations.[6] However, shorter-duration clinical trials can still provide faster dissemination of essential information needed for decision making in everyday clinical practice.[20,21]

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This study was designed to investigate the clinical reliability of Class II bulk-fill composite with and without a veneering layer of conventional microhybrid composite implementing the World Dental Federation (FDI) criteria for the ranking of restorations. The null hypothesis was that bulk-fill and veneered bulk-fill Class II resin composites perform similarly.

METHODS AND MATERIALS

This was a randomized clinical control study into the effectiveness of bulk-fill versus veneered bulk-fill Class II resin composite restorations employing the split-mouth technique. Eighty subjects were recruited following the inclusion and exclusion criteria listed. Patient recruitment, written consent, and follow-up procedures were performed in accordance with the ethical code and following the approval of the institutional review board of the university.

Sample Size Calculation

A total of 80 patients with a total of 160 Class II resin composite restorations divided into two study groups (n=80) were investigated. A sample size of 80 for each of the two study groups was considered satisfactory with respect to the previous reports of 3.2%-3.5% of annual failure by fracture of Class II resin composites, regarding two-tailed T statistics at α=0.05. An online free available sample size calculator was used to design our study sample size calculations (http://www.sample-size.net/means-effect-size/). Subjects were recruited from the outpatient clinic of the university, and follow-up occurred at five screening visits: 24 hours, 2 weeks, 6 months, 12 months, and 24 months after restoration.

Criteria

The inclusion criteria in this study were young adults (18-25 years): female (40) and male (40) patients with good oral hygiene, normal occlusion, no systemic disease, and regular use of a tooth brush twice daily. Based on the American Dental Association classification system, the selected molars, as viewed in digital bitewing radiographs indicated the presence of proximal caries extending into the DEJ beyond (D1) but not extending beyond the middle one-third of dentin (D2) (Figure 1A).[22,23] In each study subject, one molar on each side of the upper or lower arch was selected. Teeth selected for the study were in the same arch, with one molar on the right and the other on the left side following the split-mouth technique. Each of the molars selected for the study was in occlusion with natural sound antagonist occlusal tooth surfaces and each study restoration had proximal contact against a natural sound tooth surface.

The exclusion criteria were individuals with parafunctional clenching habits and bruxism. Furthermore, individuals with dry mouth, poor dietary habits of frequent consumption of carbohydrates (snacks more than three times a day), dental plaque index greater than 20%, multiple carious lesions, or frequent restorations were excluded from the study. Following many similar previous prospective clinical studies, caries risk assessment was not systematically performed in this study.[24-30]

Recruitment was performed after full-mouth screening by inspection using a mirror and explorer, DIAGNOdent Pen (Kavo, Biberach/Riß, Germany) carious lesion diagnosis, bitewing radiographs, and nonwaxed dental floss. DIAGNOdent Pen was used considering the clinical recommendations listed by Walsh.[31] Two independent calibrated investigators (RH, RA) carried out the screening exams and case selection. The purpose of the study was explained to the patients, and written consent with a time table showing the study intervals was signed by each patient. Before preparing the molars assigned for the study, recruited patients underwent full-mouth scaling and restoration of any carious lesions other than those included in the study. The procedures of cavity preparation, and restoration were performed bilaterally in the selected molars in one session.

A preliminary phase of manikin lab training of the three investigators (ME, RH, and AE) who participated in treating study subjects and the two follow-up evaluators (AA and KA) minimized human variables in cavity preparation, technique of restoration, and the clinical evaluation and ranking of restorations. A calibration was done between the independent screening examiners, operators, and evaluators using the Cohen Kappa (κ) index. Our κ interrater judgement scores for the different study aspects were $\kappa > 0.8$, indicating high levels of interinvestigator agreement.[32,33]

Cavity Preparation

Box-only Class II cavities were prepared on one proximal side of one right and one left molar tooth on the same arch after rubber dam isolation.[3] The preparation was started by gaining access through the enamel at the triangular fossa towards the proximal surface affected by caries using a round carbide bur number 1. The preparation was completed using a cylindrical diamond with a flat end. New burs were used for each study participant. Preparations were made using ultrahigh speed drills with abundant air–water cooling. The outline of the cavity was limited by caries extension and the need to free the proximal

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contact. The buccal, lingual, and gingival margins were placed in the corresponding embrasure buccally, lingually, and gingivally. The width of the gingival seat was dictated by caries extension. All cavity margins were butt joints (Figure 1C).

Cavity Restorations

The materials used in the study are presented in Table 1. All prepared cavities received the etch-and-rinse bonding approach using the Tetric N-Bond bonding system (Ivoclar Vivadent, Schaan, Liechtenstein). All light-curing procedures were carried out using Ortholux Luminous Curing Light (3M Unitek, Monrovia, CA, USA), which is a high-intensity LED of 1500 mW/cm^2 energy output with a wavelength of 430-480 nm and a peak of 455-610 nm. The bonding procedures were as follows: 37% phosphoric acid was used for etching the preparation walls for 30 seconds, followed by water rinsing for 10 seconds, and air drying with oil- and water-free compressed air for 5 seconds. Cavity walls were then painted with the bond using microsponges. Air thinning of the bond was performed for 5 seconds, followed by light-curing for 20 seconds. All restorations were built against a wedged sectional matrix (PalodentV3 sectional matrix system, Dentsply DeTrey GmbH, Konstanz, Germany). One bulk-fill resin composite material [Tetric N-Ceram Bulk Fill (TBF), Ivoclar Vivadent] was randomly used for filling one cavity (restoration TBF) as one bulk increment of 4-mm thickness, which was then light cured for 40 seconds from an occlusal direction. A second layer of the same resin composite material was used to completely fill the cavity. Gold-plated plastic instruments were used to anatomically shape the surface of the composite before occlusal light curing for 40 seconds. The remainder of the occlusal fissure system in both the restorations received fissure sealing treatment (Figure 1D).

The wedge and sectional matrix were then removed. The restoration then received additional light curing from the buccal and lingual directions for 40 seconds each.[8,24] Our restorative procedure implemented three-point curing—occlusal, buccal, and lingual, in order to optimize the degree of curing at the deepest parts of the restoration that is relatively distant from the light-curing tip on occlusal curing.[8,34,35]

Occlusion was then checked using articulating paper, and premature contacts were removed using white stones. The cavity on the other side of the arch was restored in a similar manner, except for veneering the bulk-fill composite with a layer of microhybrid composite Tetric Ceram HB (Ivoclar Vivadent) of approximately 2-mm thickness to completely fill the cavity occlusally (restoration TBF/V), following a technique recommended by Leprince and others,[13] Sunbul and others,[14] and El Gezawi and others.[15] The quality of proximal contacts was assessed using dental floss and bitewing radiographs (Figure 1B).

Randomization

The split-mouth technique was employed in our investigation following the recommendation of Hickel and others.[36] Randomization was carried out employing an opaque, sealed-envelope technique. To avoid disclosure, the envelope was opened only at the time of the restoration. The restoration technique was known by the operator but was blind for the participating subject and the evaluator at all study intervals.[36]

Restoration Evaluation

Subjects were examined for the FDI criteria of the Class II restorations of the study at 24 hours, 2 weeks, 6 months, 12 months, and 24 months for their esthetic, functional, and biological quality in accordance with the FDI World Dental Federation criteria of clinical ranking of restorations.[3,36,37] Marginal gaps were assessed postoperatively with the aid of loupes (X3.53) and two dental explorers with tip diameters of 150-250 μm (MEDSY 560-1, MEDSY, Maniago, Italy). The

Table 1: *Materials Used in This Study*

Material	Description	Lot Number	Manufacturer
Tetric Ceram HB	A light-curing fine-particle microhybrid material based on a moldable ceramic	N03283	Ivoclar Vivadent, Schaan, Liechtenstein
Tetric N-Ceram Bulk Fill (TBF)	Bulk-fill resin composite material that allows the curing of 4-mm- thick layers	R65898	Ivoclar Vivadent, Schaan, Liechtenstein
Tetric N-Bond	Light-cured primer and adhesive, total-etch adhesive	R52704	Ivoclar Vivadent, Schaan, Liechtenstein
Fine Etch, etchant	37% phosphoric acid gel	FE1242	Spident Co., Ltd, Incheon, Korea

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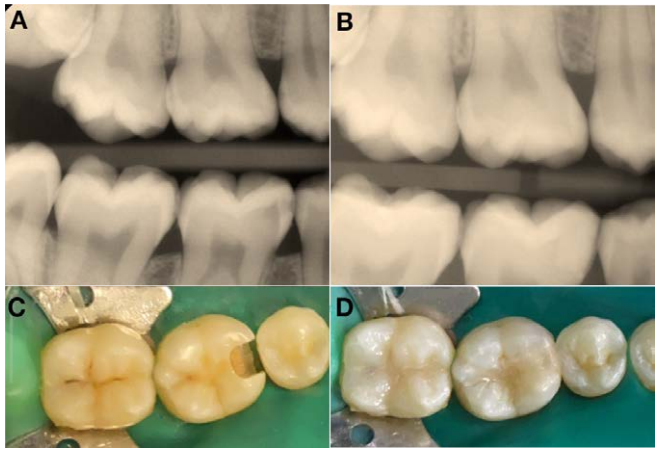

Figure 1. *Preoperative bitewing radiograph with proximal radiolucency D2 in tooth # 30 (A): postoperative bitewing radiograph, (B): box-only prepared cavity, (C): postoperative photograph of bulk-fill restoration (TBF), and (D): fissure sealing.*

marginal quality was ranked according to the FDI criteria;[16,37] see Table 2. Before each study interval, each explorer's tip diameter was measured by one investigator using a digital microscope (Hirox KH-7700, Tokyo, Japan) to assure accuracy. Blunted tip explorers were replaced by new ones.[38] Post-restoration hypersensitivity was ranked as a biological property, and the anatomic form and marginal discoloration were scaled as esthetic properties.

Patient Satisfaction Survey

A patient satisfaction survey was performed at each study interval by asking the patients to answer questions regarding their satisfaction with the restorations. A primary end point was determined by evidence of patient nonsatisfaction or clinically nonsatisfactory restoration, indicating the need for repair or remake.

At each study interval, each participating subject was asked to answer the following question: Are you satisfied with both the restorations? Answer-1: Yes, totally satisfied with both/one (right–left), answer-2: Yes, but one (right–left)/both show/shows slight sensitivity, food wedging between teeth, other, answer-3: No, I am not satisfied with one (right–left)/ both (sensitivity, food wedging between teeth, and other). Four investigators participated in restoration evaluation and data collection.

Demographic Data

The present study was conducted on 80 patients: 40 males (50%), and 40 females (50%), and the mean values for age were 23.1 (±4.6) years with a minimum of 18 and a maximum of 25 years.

Statistical Analysis

For each assessment criterion, the score numbers for restorations TBF and TBF/V were recorded for the respective study interval. The means and standard deviations were calculated and used for the statistical analysis. Differences in intergroup rankings after 24 months were analyzed using Friedman repeated-measures analysis of variance (α=0.05). Furthermore, differences in intragroup rankings at baseline and after 24 months were studied employing the McNemar test (a=0.05). Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0.

RESULTS

Qualitative data are presented as frequencies and percentages in Table 3. None of the test restorations at any of the study intervals was ranked as clinically unsatisfactory, necessitating repair or remake. Other than some reports of mild sensitivity or slight proximal wedging of food, none of the participating subjects reported a significant dissatisfaction, indicating the need for considerable intervention by restoration repair or replacement for any of the study restorations at any of the study intervals. Both study groups showed a time-dependent increase in the number of restorations showing deterioration in quality. Observations after 12 and 24 months showed that bulk-fill restorations (TBF) had significantly lower number of excellent restorations (Score I) and greater number of less quality scores than veneered bulk-fill restorations (TBF/V) in the incidence of fracture. Meanwhile, after 24 months of clinical service, bulk-fill restorations (TBF) showed significantly lower score I restorations with greater number of inferior quality scores than veneered bulk-fill restorations (TBF/V) regarding the quality of anatomical form and proximal contact.

Clinical Evaluation Outcome

Fracture

After 24 hours, 2 weeks, and 6 months, all restorations in the two groups had a score of I. After 12 and 24 months, TBF showed a significantly lower prevalence of restorations with a score of I with greater incidence of inferior quality scores than TBF/V (p=0.031, effect size=2.000, and p<0.001, effect size=1.692, respectively) denoting inferior performance of TBF. Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 12 as well as 24 months in each group (p<0.001, effect size=0.221 and p<0.001, effect size=0.094, respectively).

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Table 2: *Evaluation Criteria Following the FDI Ranking*

Study Intervals	**Evaluation Criteria**	**1-Fracture and retention**	**2-Marginal Adaptation**	**3- Anatomic form (marginal ridge continuity)**	**4- Tightness of proximal contact**	**5- Marginal Discoloration**	**6- Postrestoration Hypersensitivity**
24 hours 2 weeks 6 months 12 months 24 months	**Score I** Clinically excellent or very good	Restoration retained, no fractures or cracks	Harmonious outline, no gaps, no discoloration	Form is ideal	Normal contact point (floss or 25 µm metal blade can be inserted but not 50 µm blade)	No marginal or surface staining	No hypersensitivity, normal vitality
24 hours 2 weeks 6 months 12 months 24 months	**Score II** Clinically good	Small hairline crack	Marginal gap (<150 µm) Small marginal fracture removed by polishing	Form is only affected	Slightly too strong but no disadvantage	Minor marginal staining and/ or mild surface staining	Low hypersensitivity for a limited period of time, normal vitality
24 hours 2 weeks 6 months 12 months 24 months	**Score III** Clinically sufficient or satisfactory	Two or more or larger hairline cracks and/or chipping (not affecting the marginal integrity or proximal contact)	Gap <250 µm not removable Several small enamel or dentin fracture	Form differs but is not esthetically displeasing	Slightly too weak, no indication of damage to tooth, gingiva or periodontal structures (50 µm metal blade can pass easily, but not 100 µm)	Moderate marginal or surface staining	Premature/ slightly more intense Delayed or weak sensitivity; no subjective complaints, no treatment needed
24 hours 2 weeks 6 months 12 months 24 months	**Score IV** Clinically Unsatisfactory (but repairable)	Chipping fractures that damage marginal quality or proximal contacts; bulk fractures with or without partial loss (less than half of the restoration)	Gap > 250 µm or dentin/ base exposed Chip fracture damaging margin Notable enamel or dentin wall fracture	Form is affected and unacceptable esthetically. Intervention (correction) is necessary	Too weak (100-µm metal blade can pass) and possible damage (food impaction). Repair possible	Surface staining on the restoration, but not on the tooth. Restoration requires major correction	Premature/ very intense Extremely delayed/weak with subjective complaints Negative sensitivity. Intervention necessary but no replacement
24 hours 2 weeks 6 months 12 months 24 months	**Score V** Clinically Poor (replacement necessary)	Loss of restoration (partial or complete)	Filling is loose but in situ	Form is completely unsatisfactory and/or lost. Repair is not feasible or reasonable, replacement needed	Too weak and/or clear damage (food impaction) and/or pain or gingivitis, requires replacement	Surface staining is totally unacceptable, and the restoration needs to be replaced	Very intense, acute pulpitis or nonvital. Endodontic treatment is necessary, and restoration has to be replaced

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Table 3: *Descriptive Statistics and Results of McNemar's Test, Wilcoxon Signed-Rank Test and Friedman's Test for the Comparisons Between Groups and Within Each Group*

Criteria	Time	Score	Group A (n = 80)		Group B (n = 80)		p-value (Between groups)	Effect size
			N	%	N	%		
	24 hours	Score I	80	100	80	100	NC†	
Fracture	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	80	100	80	100	NC†	
	12 months	Score I	68	85	74	92.5	0.031*	*OR* =2.000
	12 months	Score II	12	15	6	7.5		
	24 months	Score I	58	72.5	71	88.8	<0.001*	*OR* =1.692
	24 months	Score II	22	27.5	9	11.3		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.221		0.094			
Marginal gap	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	75	93.8	78	97.5	0.250	*OR* =1.667
	6 months	Score II	5	6.2	2	2.5		
	12 months	Score I	67	83.8	70	87.5	0.250	*OR* =4.333
	12 months	Score II	13	16.3	10	12.5		*OR* =3.600
	24 months	Score I	62	77.5	67	83.8	0.063	*OR* =3.600
	24 months	Score II	18	22.5	13	16.3		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.165		0.128			
Anatomical form	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	80	100	80	100	NC†	
	12 months	Score I	80	100	80	100	NC†	
	24 months	Score I	62	77.5	73	91.3	0.001*	*OR*=1.636
	24 months	Score II	18	22.5	7	8.8		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.225		0.088			
Marginal discoloration	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	80	100	80	100	NC†	
	12 months	Score I	80	100	80	100	NC†	
	24 months	Score I	70	87.5	73	91.3	0.214	*r* = 0.139
	24 months	Score II	6	7.5	4	5		
	24 months	Score III	4	5	3	3.8		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.125		0.088			

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Table 3: *Descriptive Statistics and Results of McNemar's Test, Wilcoxon Signed-Rank Test and Friedman's Test for the Comparisons Between Groups and Within Each Group (Continued).*

Criteria	Time	Score	Group A (n = 80)		Group B (n = 80)		p-value (Between groups)	Effect size
			N	%	N	%		
Proximal contact quality	24 hours	Score I	80	100	80	100	NC†	
	2 weeks	Score I	80	100	80	100	NC†	
	6 months	Score I	76	95	77	96.3	1.000	*OR*=4.000
	6 months	Score II	4	5	3	3.8		
	12 months	Score I	72	90	70	87.5	0.500	*OR*=0.028
	12 months	Score II	8	10	10	12.5		
	24 months	Score I	55	68.8	62	77.5	0.007*	*r* = 0.304
	24 months	Score II	11	13.8	13	16.3		
	24 months	Score III	14	17.5	5	6.3		
	p-value (within group)		<0.001*		<0.001*			
	Effect size (*w*)		0.232		0.168			
Postrestoration hypersensitivity	24 hours	Score I	72	90	74	92.5	0.500	*OR* =4.000
	24 hours	Score II	8	10	6	7.5		*OR* =2.500
	2 weeks	Score I	75	93.8	77	96.3	0.500	*OR* =2.500
	2 weeks	Score II	5	6.3	3	3.8		*OR* =4.000
	6 months	Score I	76	95	77	96.3	1.000	*OR* =4.000
	6 months	Score II	4	5	3	3.8		*OR* =0.013 *OR =0.013*
	12 months	Score I	77	96.3	76	95	1.000	*OR* =0.013
	12 months	Score II	3	3.8	4	5		
	24 months	Score I	69	86.3	72	90	0.250	*OR* =3.667
	24 months	Score II	11	13.8	8	10		
	p-value (within group)		<0.001*		0.006*			
	Effect size (*w*)		0.067		0.045			

** Significant at p ≤ 0.05, NC† = not computed, because the variable is constant.*

Marginal Gap

After 24 hours and 2 weeks, all restorations in the two groups had a score of I. After 6, 12, and 24 months, there was no statistically significant difference between the two groups (p=0.250, effect size=1.667; p=0.250, effect size=4.333; and p=0.063, effect size=3.600, respectively). Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 6, 12, and 24 months in each group (p<0.001, effect size=0.165 and p<0.001, effect size=0128, respectively).

Anatomical Form

After 24 hours, 2 weeks, and 6 as well as 12 months, all restorations in the two groups had a score of I. After 24 months, TBF showed a statistically significant lower prevalence of restorations with a score of I and greater incidence of inferior quality scores than TBF/V (p=0.001, effect size=1.636) denoting inferior performance of TBF. Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater inferior quality scores after 24 months in each group (p<0.001, effect size=0.225 and p<0.001, effect size=0.088, respectively).

Marginal Discoloration

After 24 hours, 2 weeks, and 6 as well as 12 months, all restorations in the two groups had a score of I. After 24 months, there was no statistically significant difference between the two groups (p=0.214, effect size=0.139).

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Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I after 24 months with greater incidence of inferior quality scores in each group (p<0.001, effect size=0.125 and p<0.001, effect size=0.088, respectively).

Proximal Contact Quality

After 24 hours and 2 weeks, all restorations in the two groups had a score of I. After 6 and 12 months, there was no statistically significant difference between the two groups (p=1.000, effect size=4.000 and p=0.500, effect size=0.028, respectively). After 24 months, TBF showed a statistically significantly lower prevalence of scores I and II with greater incidence of inferior quality scores than TBF/V (p=0.007, effect size=0.304) denoting inferior performance of TBF. Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 6, 12, and 24 months in each group (p<0.001, effect size=0.232 and p<0.001, effect size=0168, respectively).

Postrestoration Hypersensitivity

After 24 hours, 2 weeks, and 6, 12, and 24 months, there was no statistically significant difference between the two groups (p=0.500, effect size=4.000; p=0.500, effect size=2.500; p=1.000, effect size=4.000; p=1.000, effect size=0.013; and p=0.250, effect size=3.667, respectively). Regarding the changes by time, there was a statistically significant decrease in the prevalence of score I with greater incidence of inferior quality scores after 24 months in each group (p<0.001, effect size=0.067 and p=0.006, effect size=0.045, respectively).

Patient Satisfaction Survey

There was a statistically significant change in patient satisfaction by time (p<0.001, effect size=0.215). Total satisfaction with both the restorations was 90% after 24 hours, which increased to 93.8% after 2 weeks and 95% after 6 months. After 12 months, total satisfaction with both restorations decreased to 87.5%, and a further decrease was observed after 24 months to 66.3% (Figure 2).

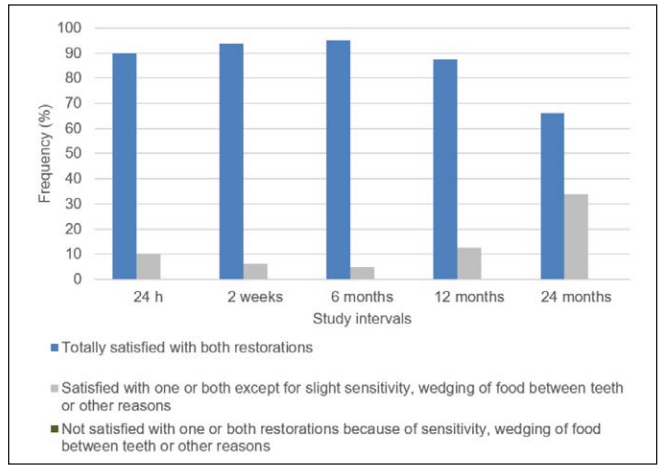

Figure 2. *Patient satisfaction through the study intervals. Abbreviation: h=hours.*

DISCUSSION

Our double-blind randomized clinical control study was performed over a 24-month follow-up because of strong limitations regarding patient availability over a longer duration. Nevertheless, longer duration follow-up might have provided more reliable outcomes. Another limitation of this study is the small size of the study restorations. More complex restorations would have been more prone to clinical failure and might have provided a broader image of restoration performance.[6]

In spite of previous reports indicating no gender differences in failure rate of dental restorations,[39] others listed age and gender among factors affecting longevity of restorations.[40,41] Furthermore, studies confirmed variations in values of biting forces in different gender and age groups, which might indicate different functional behavior of restorations in different genders.[42,43] One study assumed that the incidence of significantly more prominent wear of teeth in males than females is because of the ability of males to use heavier masticatory forces in addition to differences in life stresses and type of diet.[44] In our study design, we expected a gender ratio of the population close to 50/50.[45] Using equal gender distribution of participants might not be the best way to eliminate gender bias in clinical trials for different clinical disciplines.[46,47] However, we tried to provide a balanced interpretation of results and avoid possible age and gender influences by using a narrow age range, and equal number of male and female subjects.

Although previous reports have indicated low specificity of DIAGNOdent Pen, as it might give false positive readings with existing restorations or foreign substances, our study used DIAGNOdent Pen as a diagnostic aid for its reported validity, reliability, and high sensitivity as well as its *in vivo* fair positive correlation with radiographic scores.[48-50] The sensitivity of bitewing radiographs in detecting any proximal lesion was only 42%, which indicates the need for having an additional diagnostic tool. The accuracy of DIAGNOdent Pen in diagnosing proximal cavitated or noncavitated proximal caries in posterior teeth was found to be superior to digital bitewing radiography.[31]

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During our screening, DIAGNOdent Pen was particularly helpful in diagnosing small proximal carious lesions where the DIAGNOdent Pen readings were confirmed by bitewing radiographs. This confirmed selecting only molars with proximal lesions extending beyond D1 but not beyond D2 for the current study purpose, avoiding unnecessary exposure to X-rays in case of absence of proximal lesions or overtreatment in cases of less extending lesions treatable by noninvasive approaches.[23,48,51,52] Furthermore, it was useful in screening occlusal surfaces to justify box-only preparations used in the current study.[31]

While Tetric N-Ceram is a bulk-fill resin composite with Ivocerin photoinitiator technology, and with 61% inorganic filler and 17% polymer filler with a total of 68% inorganic filler content by weight,[53,54] Tetric Ceram HB is a high-viscosity, heavy body, microhybrid composite with high filler loading of 81% by weight. Reports on Tetric Ceram HB claim that this composition and heavy body helps in packing and producing tight proximal contact and high wear resistance.[55-57]

Our findings indicated that Class II bulk-fill composite restorations show a satisfactory performance whether veneered with conventional microhybrid composite or not. None of the restorations used showed clinical failure necessitating repair or remake. This is in agreement with the previous findings of Loguercio and others,[19] who studied the clinical performance of Class II bulk-fill composites placed incrementally or as one bulk over 72 months. Moreover, these results are also in line with the meta-analysis of Veloso and others.[58]

Our results confirmed the time-dependent deterioration in restoration quality regardless of the technique of application. Although our two studied groups, TBF and TBF/V, showed similar excellent performance after 24 hours and 2 weeks, gradual significant deterioration in quality indicated by a reduction in the number of restorations ranked as Grade I was recognized thereafter in all assessment criteria. This is again in harmony with the previous findings of Loguercio and others[19] and Veloso and others.[58] Time-dependent degradation of both resin composite and resin adhesive bonds to tooth structure has been reported by many *in vitro* and *in vivo* studies.[4] Exposure to oral environmental conditions of humidity, functional mechanical loading, thermal cycling, pH cycling, and bacterial biochemical products as well as endogenous degrading enzymes, such as endogenous matrix metalloproteinases, progressively deteriorates the internal structure of resin dentin bonds and the collagen hybrid layer.[4,59] This biodegradation damages the polymeric matrix of resin structures and breaks down their bonds with the silane coupling agents due to the hydrolysis of Si-O-Si bonds of the silane.[60] This process leads to downgrading of the physical and mechanical properties of resin composite as well as the interfacial bonds to tooth structure.[4,59] Fatigue, chemical degradation, and worsening of mechanical properties, such as microhardness fracture toughness and flexure strength of resin composite as well as loss of fillers of the composite structure, are potential predisposing factors for clinical consequences of fracture, loss of occlusal anatomy, and tightness of proximal contacts. Similarly, a consistent time-dependent degradation in the quality of the restoration-tooth structure bonding might predispose marginal and interfacial gaps with greater potential for marginal discoloration, hypersensitivity, and recurrent caries.[60,61]

On the other hand, the degradation of resin bonds to tooth structure predisposes patients to leakage, marginal deterioration, and recurrent caries.[4,12,15,17,18] Factors such as the chemical make-up of the polymer matrix, filler size and size distribution, degree of polymerization, and quality of matrix systems used during insertion of resin composite have been listed among the factors influencing the form and function of resin composite restorations.[53] The significant correlation between surface microhardness and volume fraction of the fillers of resin composite has been reported by Leprince and others[13] as a basis explaining the inferior mechanical performance of bulk-fill composites in comparison to conventional composites. They reported variations in the mechanical properties of different bulk-fill composites relative to conventional resin composites. In their study, Tetric EvoCeram Bulk Fill showed similar properties to those of its conventional counterpart from the same manufacturer—Tetric EvoCeram. In our study, TBF was compared to TBF veneered with Tetric Ceram HB conventional microhybrid composite.[13]

Al-Nahedh and Alawami showed that the fracture resistance of Tetric-N Ceram Bulk Fill Class II composite restorations capped with a layer of conventional nanohybrid resin composite is greater than that of the uncapped Tetric-N Ceram bulk-fill restorations. However, they demonstrated that the performance of bulk-fill composites is material dependent.[62]

Changes in the occlusal anatomy and tightness of proximal contact occur due to wear of the resin composite. Fatigue wear, adhesive wear, abrasive wear, and corrosive wear are among the mechanisms reported for the wear of resin composite.[63] Accordingly,

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variations in composition and chemical make-up as well as depth of cure in different resin composites have a deciding influence on the resistance of the respective resin composite to wear and hence on the clinical performance of resin composite restorations with respect to occlusal anatomy and tightness of proximal contact.[18,59] The high filler content of the high-viscosity Tetric Ceram HB claimed to superior packability might explain the superior functional performance of restoration B, where TBF has been veneered by an increment of approximately 2-mm thickness of Tetric Ceram HB relative to Restoration A of Tetric N-Ceram Bulk-Fill composites at 12 and 24 months follow-ups, respectively.[55] Recent reports indicated that the tightness of proximal contacts of bulk-fill composites is material dependent.[64]

The results of the current study indicated that none of the investigation subjects were unsatisfied with any of the study restorations. None of the studied restorations showed marked deterioration in any of the employed assessment criteria to the degree necessitating repair or remake at any of the study intervals. This is in line with the previous findings of Loguercio and others.[12]

Our results of the criteria for fracture, anatomical form, quality of proximal contact after 12- and 24-month intervals, which showed a significantly lower number of grade I, and excellent restorations in TBF relative to TBF/V might support the previous *in vitro* findings that the mechanical properties of bulk-fill composites of Ilie and others,[12] Leprince and others,[13] Sunbul and others[14] are inferior in mechanical properties, such as the elastic modulus and the flexure strength, to conventional composites due to the swelling behavior of bulk-fill composite and their greater degradation tendency over time compared with conventional composites.[13-15] An abrasive wear study showed that bulk-fill composites vary in their wear behavior, and no common conclusion can be drawn to include the entire brand of materials.

Other reports have shown that the differences between bulk-fill and conventional composites arise mainly from the greater depth of cure because of the increased translucency of bulk-fill composites, and that more clinical studies are needed to demonstrate the clinical performance of bulk-fill composites, particularly in large cavities where wear and fracture resistance are of primary interest.[14,65] According to our results, the given null hypothesis that TBF and VBF perform similarly was rejected, since VBF performed better than TBF restorations. Although the simplicity and application time savings in addition to minimizing the risks of air void incorporation between successive increments are reported objectives of employing bulk-fill composites, this should never be at the expense of the quality of clinical performance and long-term degradation resistance.[12,66,67]

The authors of the current investigation, based on their findings, recommend the veneering of bulk-fill composites in posterior stress-bearing locations with an increment of conventional microhybrid composite. Future studies should consider recurrent caries that have been reported together with fracture as the most common modes of failure of posterior composites.[14] Three years of clinical service has been recommended for such evaluation.[14] Accordingly, longer duration clinical trials are needed to confirm our findings over longer durations of clinical service and to consider the criterion of recurrent caries.[14] Systematic caries risk assessment models employing true risk factors is an element of consideration in studying the criterion of caries recurrence in future research.[28] Further clinical investigations should assess different bulk-fill composites before generalized conclusions can be drawn.

CONCLUSIONS

Within the limitations of the current study, the following conclusions can be drawn:

1. Both bulk-fill and veneered bulk-fill Class II restorations perform satisfactorily over 24 months of clinical service with no need for repair or remake.
2. Veneering bulk-fill composites with a layer of high-viscosity conventional microhybrid composite appears to be a better clinical practice for improved clinical performance.

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Regulatory Statement

The author represents that this study was conducted in accordance with all the provisions of the human subjects' oversight committee guidelines and policies of Imam Abdulrahman Bin Faisal University, Dammam, Saudi Arabia.

Conflict of Interest

The authors of the present study certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in the present article.

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Survival Rate of CAD–CAM Endocrowns Performed by Undergraduate Students

ML Munoz-Sanchez • M Bessadet • C Lance • G Bonnet
JL Veyrune • E Nicolas • M Hennequin • N Decerle

Clinical Relevance

Computer-aided design–computer-aided manufacturing (CAD–CAM) endocrown restorations could be carried out by undergraduates on posterior endodontically treated teeth with a low risk of failure. A minimum 2 mm ceramic thickness and a rigorous bonding protocol are two key prerequisites for the success of these restorations.

SUMMARY

Objectives: This study aimed to evaluate the success of computer-aided design–computer-aided manufacturing (CAD–CAM) endocrown restorations of endodontically treated teeth (ETT) performed by supervised undergraduate students. The study also intended to identify possible factors that may lead to failures.

Methods and Materials: This observational open cohort study was based on clinical data from endocrown restorations performed by residents and undergraduate students in their 4th, 5th, and 6th year from July 2011 to May 2018. The presence of a tooth with an endocrown on the arch was the main criteria used to calculate the survival rate of restored teeth. The quality of the remaining endocrowns was evaluated referring to the FDI criteria. The cases of failure were categorized into either favorable or unfavorable.

Results: A total of 343 ETT were restored with endocrowns in 315 patients. Among them, 199 patients encompassing 225 endocrowns were followed during a 56 ± 26 month period. The survival rate of restored teeth was found to be 81.8%, the estimated Kaplan–Meier survival rate being 71.8% at 9 years. Among the 41 failed cases, 32 were favorable (debonding and/or ceramic fractures) and 9 were unfavorable.

Marie Laure Munoz-Sanchez, DDS, University Clermont Auvergne CHU de Clermont-Ferrand, France
Marion Bessadet, DDS, PhD, University Clermont Auvergne CHU de Clermont-Ferrand, France
Cindy Lance, DDS, PhD, University Clermont Auvergne CHU de Clermont-Ferrand, France
Guillaume Bonnet, DDS, PhD, University Clermont Auvergne CHU de Clermont-Ferrand, France
Jean Luc Veyrune, DDS, PhD, HDR, University Clermont Auvergne CHU de Clermont-Ferrand, France
*Martine Hennequin, DDS, PhD, HDR, University of Clermont Auvergne, Clermont-Ferrand, France
Emmanuel Nicolas, DDS, PhD, HDR, University Clermont Auvergne, CHU de Clermont-Ferrand, France
Nicolas Decerle, DDS, PhD, University Clermont Auvergne CHU de Clermont-Ferrand, France
*Corresponding author: UFR d'Odontologie, 2 rue de Braga, 63000 Clermont-Ferrand, France; e-mail: martine.hennequin@uca.fr
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Conclusion: Endocrown restorations of posterior ETT using CAD–CAM technologies could be carried out by undergraduates with a low risk of failure. Teacher supervision could be reinforced, covering all steps of each endocrown procedure in order to avoid failures due to insufficient thickness or loss of retention.

INTRODUCTION

Training in the restoration of severely damaged posterior teeth remains a key area of interest, particularly in the treatment of endodontically treated teeth (ETT). Previously, the most common proposal was the use of a complete crown with a radicular anchorage (including cast and prefabricated post and cores). However, in the long term, high risks for tooth fracture were reported.[1] Direct restorations, full or partial crowns, offer alternative proposals to radicular anchorage. Two reviews reported that there was insufficient reliable evidence to determine which treatments would be more effective.[2,3]

In 1995, Pissis proposed an original indirect restoration designed as a monobloc crown, in order to eliminate the radicular anchorage.[4] The concept was then improved by Bindl and Mörmann, who labelled the "endocrown" as an adhesive monolithic ceramic restoration anchored in the pulp chamber, exploiting the mechanical retention properties of the pulp chamber walls.[5] Several studies reported that the design for endocrown preparations was compatible with computer-aided design–computer-aided manufacturing (CAD–CAM) system applications.[5,6] Many evaluations of this new type of restoration have been carried out;[5,7-9] but all studies were difficult to compare due to differences in materials, tooth type, or procedure. Recently, a systematic review was conducted to state whether endocrowns were an appropriate restorative option with a predictable outcome for extensively damaged ETT.[10] Eight clinical studies were included, reporting survival rates varying between 69% and 100%, depending on tooth type (molar or premolar) and a mean follow-up period ranging from 6 to 116 months.[10]

Recent studies reported optimistic long-term results for CAD–CAM endocrowns[8,9] that suggested such treatments would be furthered developed for the treatment of severely damaged posterior ETT. Therefore, it seems necessary to train both undergraduates and postgraduates on how to use these new technologies. In the latest studies into endocrown evaluations, the operators were experienced practitioners, and there was no evidence of students (especially undergraduates) possessing the clinical competencies required in order to successfully provide endocrown treatment. Introducing new procedures during the clinical stage of dental studies raises the issue of quality of care, even if students treat patients while under the teachers' supervision. Particularly in the case of prosthodontic care, failures occurred late, usually when students had completed their studies. That could lead to insurance claims and requests for reimbursements from the establishments. Indeed, assessing the quality of endocrowns would help to update information about the quality of prosthodontic care, which should be readily available to patients treated by dental students.

In this way, this study aimed to evaluate the success of CAD–CAM endocrown restorations of root-filled teeth carried out by supervised undergraduate students and to search for possible factors that may lead to failures.

METHODS AND MATERIALS

Type of Study

This was an observational open cohort study based on clinical data from therapeutic procedures, the use of which was authorized by the local ethics committee. All patients were informed about the study and gave their consent to participate. From July 2011 to May 2018, any adult patient attending the University Dental Hospital of Clermont-Ferrand was invited to participate if he or she had received indication to restore a permanent posterior ETT with an endocrown. After enrolment, the patient was given an appointment for the tooth restoration procedure.

Procedure

Operators — CAD–CAM technologies for prosthodontics are organized as a routine procedure. Residents and undergraduate students in their 4th, 5th, or 6th year worked under the supervision of four teachers who checked each of the six following steps: 1) indication for the endocrown restoration; 2) dental preparation; 3) digital scan; 4) computer designs of the restoration; 5) bonding and sealing; and 6) occlusal adjustment and polishing.

Tooth Preparation — Endocrowns are restorations guided by conservative principles[11,12] that preserve the maximum amount of tooth surface for bonding. Tooth preparation consisted of a circular cervical butt margin and a central retentive cavity in the pulp chamber, without root anchoring (Figure 1).[5] Intraradicular extension of the endocrown preparation negatively

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affected both the marginal adaptation and the internal fit of the final restoration.[13] Endocrown pulp chamber extension depth was not greater than 2 mm.[14] A minimum thickness of 2 mm had to be achieved under the entire occlusal surface in order to create sufficient space for the restorative material in a full cuspal coverage objective. The axial preparation was carried out to permit continuity between the access cavity and pulp chamber, with a total occlusal convergence angle of 7; and, always in the interest of maximum preservation of residual tissue, any undercut would be filled with a resin composite to avoid unnecessary overpreparation of the cavity. The use of a small resin composite supply may be useful to provide enhanced geometry and remove undercuts from the endodontic preparation.[15] All internal line angles were rounded. The endocrown restored the occlusal surface and occlusal part of the dental walls, as is also achieved with an overlay. There was no peripheral preparation. The preparation was to be supragingival to facilitate digital scanning and bonding. If the occlusal part of the residual walls was less than 2 mm thick, the walls were then reduced in height until reaching 2 mm.

Endocrown Materials — Two reinforced glass-ceramics from Ivoclar Vivadent (IPS Empress CAD [with leucite crystals] and IPS e.max CAD [with lithium disilicate]) were used for milling endocrowns, depending on the supervisor indications.

Milling — For the duration of the study, a Bluecam system with Cerec 3D and Cerec SW 4, then an Omnicam system with Cerec Omnicam 4.4 and Cerec Omnicam SW 4.5 were used for digital scanning and endocrown milling. Crystallization was achieved within 20 minutes for IPS e.max CAD restorations (Programat CS, Ivoclar Vivadent). IPS Empress CAD pieces were oven glazed.

Etching — After milling, ceramic pieces were etched with 9.5% hydrofluoric acid (Porcelain Etch, Ultradent), according to the manufacturer's recommendations, for different durations (60 sec for IPS Empress CAD, 20 sec for IPS e.max CAD). A silane was then applied to the intaglio surface of the endocrown (Monobond Plus, Ivoclar Vivadent).

Bonding — Two bonding procedures were followed. For cases being treated without the use of a rubber dam, a selective etching was made, limited to enamel, and an auto-adhesive cement (RelyX Unicem, 3M Oral Care) was used for sealing the endocrown. For teeth being treated using a rubber dam, enamel was etched for 30 seconds and dentin for 15 seconds. A dual cure adhesive (Excite DSC, Ivoclar Vivadent) and a resin cement (Variolink II, Ivoclar Vivadent) were used for bonding and sealing, respectively.

Finishing — Proximal contacts were checked with dental floss. Control for occlusion was made with finishing burs and using 200 µm occlusion paper.

Study Criteria

Primary Criteria — The presence of the tooth with the endocrown was the main criteria used to calculate the survival rate of restored teeth. Survival was defined as the tooth remaining in the arch and the restoration of the tooth with or without modifications made during the observation period.[16]

Secondary Criteria — The quality of the surviving endocrowns was evaluated, referring to the FDI criteria.[17] Two independent investigators assessed according to the FDI calibration procedure, adapted for a visual assessment. They proceeded to the evaluation of 14 of the 16 FDI criteria at each control session. At each step of evaluation, the investigators were blinded from the operator, the materials and procedures, and the follow-up duration.

FDI criteria are grouped into three categories: 1) Aesthetic properties (condition surface, surface coloring, color and translucency stability, and anatomical shape); 2) Functional properties (fracture and retention, marginal adaptation, contouring occlusal and wear, proximal contact point/food blockage, radiographic examination, and the patient's point of view); and 3) Biological properties (postoperative hypersensitivity and pulp vitality, recurrent decay/erosion/abfraction,

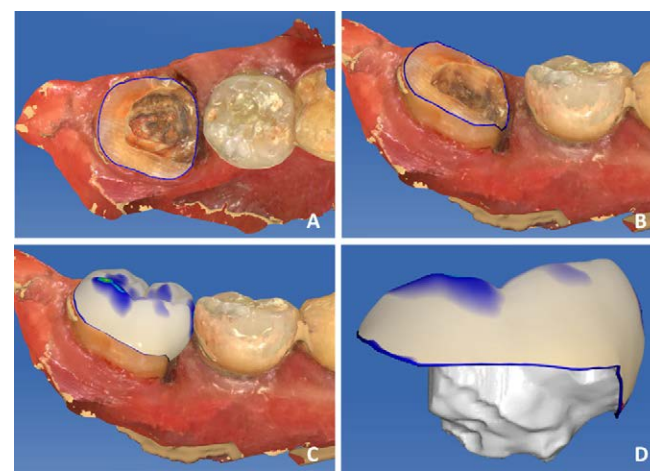

Figure 1: *Cerec screenshots for computer design of the endocrown: A) Occlusal view of the preparation; B) buccal view of the preparation; C) buccal view of the Cerec endocrown model before milling; D) endocrown model before milling.*

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tooth integrity, periodontal response, adjacent mucous membrane, and oral or general health). The criteria for postoperative/pulp vitality and for occlusal contour/wear were not applicable in this study. Each criteria was scored from 1 to 5—the highest values signifying poor quality (score 1 is "clinically excellent/very good", score 2 is "clinically good", score 3 is "clinically sufficient/satisfactory", score 4 is "clinically unsatisfactory," and score 5 is "clinically poor.").

The causes for failure were categorized into two types[18,19]: i) Unfavorable or catastrophic failure—the tooth was lost or unrestorable due to fracture below the height of bone level simulation; ii) favorable failure—the endocrown was partially or totally lost (debonding), but the tooth was still restorable with another endocrown or other type of restoration, or the endocrown was fractured without fracture of the tooth.

For each unfavorable failure case, Cerec computer designs of the restorations were collected and analyzed by the blinded investigators. The minimal thickness of each piece was measured using the "cut" and "measure" tools of the Cerec software. Thickness default was recorded for the pieces with a minimal thickness of lower than 2 mm. The continuity of the peripheral limit, which was selected to proceed to milling, was analyzed. The defaults in limits position were checked in accordance with the literature.[20]

Follow-up

The first evaluation was carried out during the endocrown bonding session for the cases without rubber dam use and one week later for the cases bonded under rubber dam. The one-week delay was related to the use of rubber dam, which could alter the degree of rehydration in the tooth and, in turn, its color. The clamp could also induce gingival bleeding. This could influence evaluation of the corresponding FDI criteria: "color and translucency stability," "periodontal response," and "adjacent mucous membrane". The patient was then scheduled for further appointments 6 months post-treatment, and every year thereafter. Clinical examinations were conducted to assess the survival of the tooth at the arch, the presence of the endocrown, and, where relevant, its quality using FDI criteria.

Investigators

Two investigators were trained on an online training and calibration site (www.e-calib.info) in December 2011 (MLMS, ND). Each of them evaluated each restoration independently at each study step. After both evaluations, the scores were compared. When evaluations ranged from 1 to 3, both the values were averaged. When at least one investigator scored 4 or 5, a consensual value was then obtained after re-examination of the patient.

Statistical Analysis

The statistical tests were carried out with the software SPSS 22.0. The survival probabilities were estimated with Kaplan–Meier method. The FDI score criteria were compared between the first and the last evaluation, with paired student's *t*-test.

To evaluate the impact of the follow-up duration, data for the FDI criteria being significant after student's *t*-test were subcategorized into four equivalent quartiles based on the values of the follow-up duration. ANOVA was applied for intergroup comparisons. Log-rank testing was applied to compare survival probabilities, according to tooth type and the rubber dam utilization linked with the bonding system used.

RESULTS

From July 2011 to May 2018, 343 root-filled molar or premolar teeth were restored with endocrowns in 315 patients. Among them, 199 patients were included in the cohort. Fifty-seven patients were lost to follow-up, one patient was deceased, and 56 missed the last appointment. The flow diagram of the cohort is presented in Figure 2.

Overall, 225 endocrowns were evaluated during 56.11 ± 25.94 months, 113 being recalled from 6 months to 4 years and 112 being recalled from 5 years to 9 years. The distribution of endocrowns per student year was 18.7% in 4th year, 41% in 5th year, 20.9% in 6th year, and 19.4% were residents. The distribution of endocrowns per student gender was 43.9% male students and 56.1% female students.

The survival rate of restored teeth was of 81.8%. The estimated Kaplan–Meier survival rate was 71.8% at 9 years (Figure 3). The survival rates were not affected by tooth type, use of rubber dam, or bonding system. The estimated Kaplan–Meier success rate was 58% at 9 years (Figure 4).

The comparisons of mean scores for FDI criteria between initial and final evaluation in the group of successful endocrowns are presented in Table 1. A statistically significant degradation could be noted for the criteria "surface staining," "color stability and translucency," and "patient's view," whereas the "anatomic form" and "oral and general health" criteria showed a statistically significant improvement over time. Color stability and translucency was the single variable varying differently with follow-up duration

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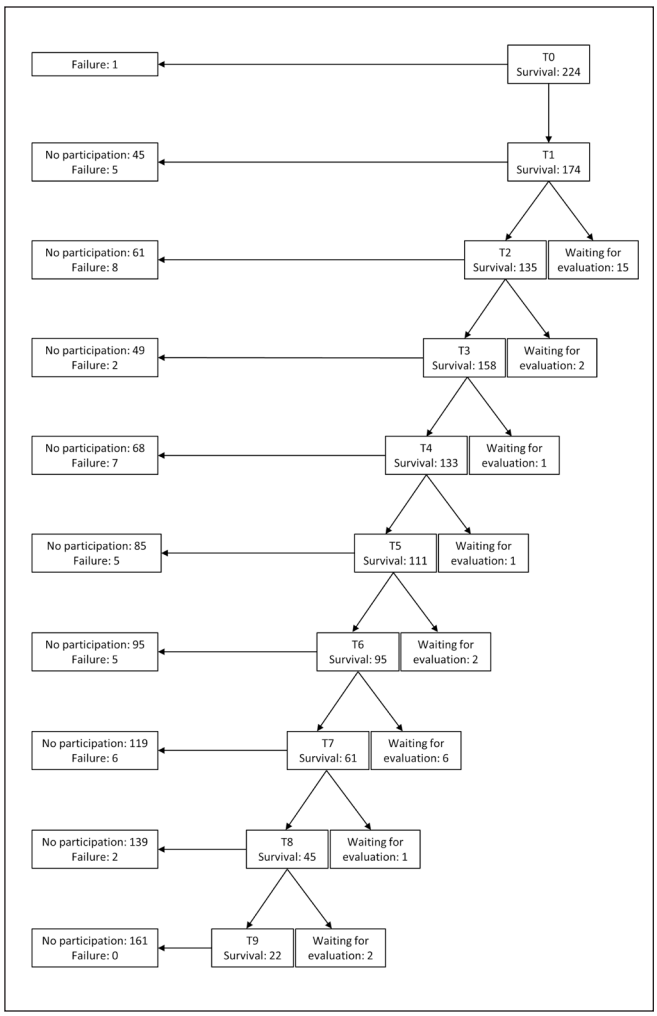

Figure 2: *Flow diagram of the endocrown cohort.*

(Table 2). Mean FDI score value for Quartile 1 with short duration follow-up was significantly lower than the three other groups with longer duration follow-up.

The distribution of the retrospective evaluation results, of 41 cases of failure on captured images in the Cerec system, is presented in Table 3. The analysis of failures showed that almost all failed restorations could be explained by the ceramic thickness or by an error in the preparation limits previously defined by the student on the digital scan.

DISCUSSION

Endocrown restorations of posterior ETT using CAD–CAM technologies could be carried out by undergraduates with a low risk of failure before five years. Exposing the students to the outcome of their work would be a matter to be covered in teaching. However, students who had treated their patients for 2

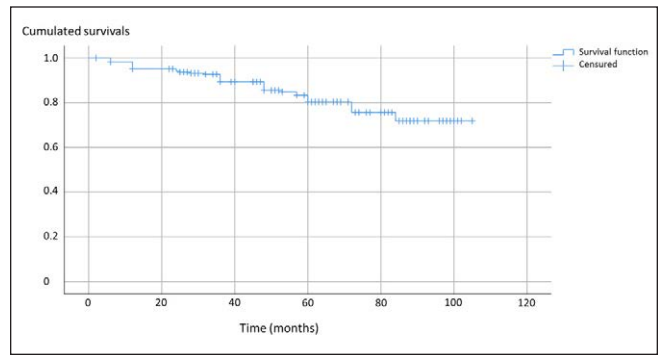

Figure 3: *Survival function of endocrowns carried out by students on root-filled molars and premolars.*

or 3 years and then left university could not experience the long-term results of their prosthetic work. The representations they have of the success, failures, and limits of the dental treatments were not based on self-experimentation. It is, therefore, important to analyze the clinical activities of the students in order for new classes of students to be able to appreciate the possible differences between literature data and the realistic outcome of their activities. Introducing new procedures into the dental curriculum required discussions on several points: i) which improvements the new procedure is supposed to bring to professional practices; ii) are the survival rates of endocrowns performed by students comparable to those of conventional peripheral crowns performed by students and to those of endocrowns performed by experimental operators?; iii) what could be learned from the failure of endocrowns performed by students?; iv) what should be changed in the endocrown operative protocol in order to attenuate the impact of time on FDI criteria and, in particular, on color stability and translucency.

Providing teaching on endocrowns rather than conventional crowns to students has several

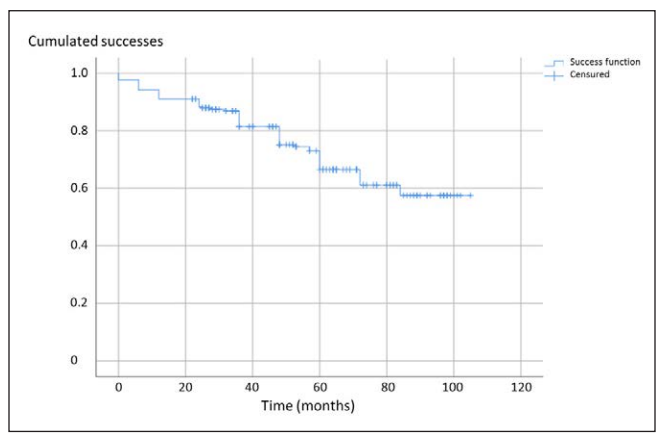

Figure 4: *Kaplan–Meier success curve of endocrowns carried out by students on root-filled molars and premolars.*

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Table 1: *Comparison of the Mean FDI Scores Values (±SD) for Each Clinical Criteria Between Initial and Final Evaluation in the Group of Successful Endocrowns (n=184)*

	Initial Evaluation	Final Evaluation	Comparison (Paired Student's t- Test)
Surface luster	1.08±0.23	1.04±0.21	NS
Surface staining	1.04±0.17	1.11±0.34	p=0.008
Color stability and translucency	1.93±0.63	2.24±0.79	p<0.001
Anatomic form	1.51±0.64	1.32±0.57	p<0.001
Fracture and retention	1.01±0.12	1.04±0.28	NS
Marginal and adaptation	1.51±0.70	1.55±0.66	NS
Contact points			
Mesial contact point	1.37±0.64	1.54±0.88	NS
Distal contact point	1.49±0.82	1.48±0.92	NS
Radiographic examination	1.38±0.85	1.34±0.77	NS
Patient's view	1.08±0.36	1.21±0.66	p=0.008
Recurrence of caries, erosion, abfraction	1.01±0.07	1.03±0.26	NS
Tooth integrity	1.01±0.07	1.01±0.08	NS
Periodontal response	1.23±0.52	1.21±0.51	NS
Adjacent mucosa	1.01±0.08	1.01±0.07	NS
Oral and general health	1.01±0.08	1.00±0.00	p=0.02

FDI criteria scores: 1: clinically excellent/very good; 2: clinically good; 3: clinically sufficient/satisfactory; 4: clinically unsatisfactory; 5: clinically poor.

advantages. Firstly, it could be performed immediately or during the consecutive session following endodontic treatment, reducing the number of patient visits. Moreover, it has been reported that early placement of permanent coronal restoration increases the longevity of ETT.[21] Since the advent of the chairside CAD–CAM system, endocrowns can be bonded in one session. However, conventional crowns take at least 3 sessions. Secondly, compared to conventional restoration with root anchorage and peripheral metal or ceramic crown, the endocrown restoration represents only one single bonding interface. It forms an adhesively luted ceramic restoration–composite cement–residual tooth structure biomechanical unit.[22] Limiting the number of bond interfaces rends the restoration less susceptible to the adverse effects of degradation of the hybrid layer.[23]

The survival rate of endocrowns assessed in the present study (71.8% at 9 years) is similar to that of a recent study on classical peripheral crowns, with or without post, made by 4th and 5th year students in Saudi Arabia (76% at 8 years).[24] The practitioner's experience seems to have an impact on the survival rate of indirect coronal restoration, whatever its type. It was reported that teeth that were treated by 4th year students were more likely to be extracted than those treated by 5th year students.[24] It could be argued that students with less knowledge and/or motor skills have a higher risk of unfavorable or catastrophic failures leading to extractions.

If there was already an impact of the level of experience (between the 4th and 5th year of study) on the survival rate of endocrowns, it, therefore, seems normal to find a noticeable difference between the survival rates of restorations carried out by students and those carried out by experienced practitioners. Endocrown restorations performed by specialized practitioners showed a success rate of 99.8% to 4.5 years on average, which is higher than the results of the present study (81.8% for a similar average follow-up time).[8] This difference is also reflected in the success rate of conventional crown restorations performed by specialists (98.7%) compared to the same restorations performed by students (76%).[24]

Failure cases among endocrowns performed by the students are higher than among those carried

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Tables 2: *Comparison of FDI Mean Scores (±SD) for Clinical Criteria Between Initial and Final Assessment at Different Follow-up Duration in the Group of Successful Endocrowns (n=184)*

Quartiles of Follow-up Duration (Months)	**Quartile 1 n=46**		**Quartile 2 n=46**		**Quartile 3 n=46**		**Quartile 4 n=46**		**Comparisons**	
Mean ± SD	29.0±10		51.0±17		71.5±12		133.0±17			
Min – Max	22–36		39–63		64–80		81–105			
Mean scores ± SD for FDI criteria	Initial	Final	Initial	Final	Initial	Final	Initial	Final	F	Risk alpha
Surface staining	1.02 ±0.10	1.08 ±0.26	1.0 2±0.10	1.10 ±0.27	1.00 ±0.00	1.13 ±0.45	1.11 ±0.28	1.14 ±0.34	ns	
Color stability and translucency	1.73 ±0.60	1.87 ±0.62	2.10 ±0.59	2.35 ±0.82	2.12 ±0.73	2.31 ±0.86	1.77 ±0.50	2.42 ±0.75	5.001	p=0.002
Anatomic form	1.28 ±0.47	1.16 ±0.37	1.70 ±0.72	1.40 ±0.57	1.63 ±0.74	1.26 ±0.51	1.43 ±0.53	1.43 ±0.73	2.837	p=0.039
Patient's view	1.01 ±0.07	1.21 ±0.72	1.07 ±0.23	1.15 ±0.43	1.23 ±0.66	1.26 ±0.83	1.02 ±0.10	1.22 ±0.63	ns	
Oral and general health	1.00 ±0.00	1.00 ±0.00	1.01 ±0.07	1.00 ±0.00	1.00 ±0.00	1.00 ±0.00	1.04 ±0.14	1.00 ±0.00	ns	

Abbreviation: ns = not significant.

Table 3: *Retrospective Evaluations of 41 Cases of Failures on Captured Images in the Cerec System*

Failure Type	**Criteria**	**Correct**	**Ceramic Thickness Less Than 2 mm (A)**	**Peripheral Limits (B)**	**A+B**
Favorable failure	Endocrown fracture	0	7	4	3
	Debonding	2	2	1	5
	Periodontal failure	1	0	0	0
	Recurrent Carious Lesion	0	1	0	0
	Endodontic Retreatment	1	0	0	2
	Operator's mistake	0	1	0	1
	Dental fracture	0	1	0	0
	Subtotal	**4**	**28**		
Unfavorable failure	Endocrown fracture	0	1	2	0
	Periodontal failure	0	0	1	0
	Recurrent Carious Lesion	0	0	0	2
	Tooth fracture	1	1	0	1
	Subtotal	**1**	**8**		

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out by experimental practitioners in previous studies (Table 4). This provided the opportunity to analyze the reasons behind endocrown failures. Reasons for failure were reported in a recent systematic review that included eight studies of variable follow-up period duration: the unsuccessful restorations were mainly due to loss of retention (53%) and fracture (14%).[10] The rate of debonding occurrence varied between 0% and 16%. Generally, insufficient bonding protocol is often evoked to explain ceramic pieces debonding.[10,25,26] It

Table 4: *Survival and Failures Rates of Endocrowns on Endodontically Treated Teeth (ETT) Reported in Previous Studies According to the Sealing Protocols*

Study	Number	Bonding Protocol	Rubber Dam Use	Survival Rate	Follow-up Period (Months)		Failures		
					Mean	Range	Debonding	Fracture	
								Endo-crown	Tooth
Bindl and Mörmann (1999)[5]	19	Tetric Ivoclar Vivadent; Panavia 21 TC, Kuraray Noritake	Yes : 4 cases No: 15 cases	All: 95% M: 93.3% PM: 100%	26±6	14–35.5	5.3%	0	0
Otto (2004)[33]	10	Duo Cement Plus, Coltène	Yes	All: 100%	15±ND	12-16	0	0	0
Bindland others (2005)[7]	86	Tetric Ivoclar Vivadent	No	M: 87.1% PM: 68.8%	52±15	ND	16.3%	0	2.3%
Bernhart and others (2010)[34]	20	Panavia F2.0, Kuraray Noritake	Yes	M: 90%	ND	max: 24 ± 2	0	5%	5%
Decerle and others (2014)[17]	16	RelyX Unicem, 3M	Yes	M: 90.9% PM: 100%	6	ND	0	0	0
Otto and Mörmann (2015)[35]	25	Duo Cement Plus, Coltène	Yes	M: 90.5% PM: 75%	116±ND	109-146	8%	4%	0
Belleflamme and others (2017)[9]	99	Variolink II, Ivoclar Vivadent	ND	All: 99%	44.7±34.6	ND	2%	0	1%
Fages and others (2017)[8]	235	RelyX Unicem, 3M	No	M: 99.8%	55.2±5.13	ND	0	0.43%	0
Present study	178	RelyX Unicem, 3M	No	All: 78.7%	61.0±24.5	2-105	5.6%	9 %	1.7%
	47	Variolink II, Ivoclar Vivadent	Yes	All: 93.6%	37.6±22.9	6-98	0	2.1%	2.1%

Abbreviations: M = molars; ND = no data; PM = premolars.

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could be suggested that the use of a rubber dam could influence the survival rate of endocrowns by reducing the number of failures due to debonding. In fact, Table 4 shows that four out of the eight studies reported the use of a rubber dam, but their success rates for endocrown did not differ from those which did not use it. In addition, many studies have not found a causal link between rubber dam use and improvement of performances of direct adhesive restorations.[27-29] The analysis of endocrown failures by fracture reported a variation ranging from 0% to 9%. One recent literature review showed a link between a thickness inferior to 2 mm and failure of ceramic onlay.[25] The present study reports that insufficient preparation thickness is also a cause for fractured endocrowns, when students are operators. Teacher supervision could be reinforced, covering all steps of the endocrown procedures. In particular, captured image analysis for the design of the finish line and the expected ceramic thicknesses could be awarded more attention. Teaching students how to use the digital tools of CAD–CAM software to evaluate the thickness of future restoration could prevent failures.

Among the FDI criteria associated with time, some improved and others worsened between the initial and the final evaluations. The improvement of anatomical form could be explained by physiological wear of the prosthodontic part and/or by the occlusal setting that occurs spontaneously during the first weeks postoperatively. Degradation of the "patient's view" could be linked to the "color stability and translucency" and "surface staining" criteria. It was already shown that the color of root-filled teeth changed with time,[30] and the criteria "color stability and translucency" is time-dependent appearing after several years (Table 2). Three proposals were reported to improve CAD–CAM restoration aesthetics. First, nonvital bleaching carried out before the restoration was recommended to prevent discolorations over time[31]; however, the long-term results are limited. Second, changing the design of the preparation finish line would have more predictable aesthetic results. A shoulder preparation design or the positioning of the circular, cervical butt margin near the gingival margin are described protocals that result in less enamel thickness, in turn, altering the quality of bonding. A 45° bevel design for the preparation finish line resulted in a better esthetic integration limiting the loss of tissue. This design would be more favorable in terms of bonding and resistance.[22] This was indicated for endocrowns where aesthetic requirements are met. Third, when the endocrown was made into composite blocks, a discrete double bevel on both the restoration limit and the enamel border was created with a fine diamond cutting rotary instrument to 1.5-mm thickness. This minimal preparation could then be filled with a resin composite layer in order to improve the aesthetics of the restoration-tooth transition.[32]

This study had some limitations. Firstly, the return rates of the patients decreased with time, half of the endocrown cohort being lost to follow-up after 5 years. The limited number of trained investigators could partially explain this low rate. Their presence in the service was limited to some days, and some evaluations were probably lost for this reason. However, return rates in open cohorts are often low, particularly for studies conducted on routine care. The ethical frame of studies on routine care did not allow any changes in the organization nor the observed dental procedure. For this reason, it was not possible to recall the patients for evaluation appointments. Secondly, endocrown evaluations were only taken on by calibrated investigators. Comparisons of T0 evaluations between calibrated investigators and students would be possible. Asking the student operator to evaluate the endocrown he/she carried out at T0 would be interesting, as that would allow him/her to use the evaluation criteria, and to then ask themselves what the outcome of the treatment should be. Moreover, this could prepare the students for self-evaluation of professional practices, giving them tools to compare direct or indirect restorations, for example.

CONCLUSIONS

Undergraduate students could be trained to restore root-filled posterior teeth with CAD–CAM endocrowns. Teacher supervision should cover all steps of carrying out endocrown procedures in order to limit the number of failures. The evaluation criteria of this study could be referred to any practitioner or teacher aiming to evaluate the professional practices according to the Deming cycle method.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the human subjects' oversight committee guidelines and policies of Comité d'Ethique des Centres d'Investigation Clinique del'inter-région Rhône-Alpes-Auvergne. The approval code issued for this study is CE-CIC-GREN-11/17.

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Conflict of Interest

The authors of the present study certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in the present article.

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Three-year Randomized Prospective Clinical Trial of Class II Restorations Using Flowable Bulk-fill Resin Composites

MD Moda • AF Briso • IAE Hoshino • SMB Frascino • PH Santos
DM Gonçalves • TC Fagundes

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Clinical Relevance

Initial marginal discoloration was observed more frequently in class II restorations performed using flowable bulk-fill resin composites. All restorative systems had decreased proximal contact strength over time.

SUMMARY

Objectives: This randomized, prospective, and split-mouth study aimed to evaluate flowable bulk-fill resin composites in class II restorations and to compare with a conventional layering technique after a 3-year follow-up.

Methods and Materials: Fifty-three subjects received three class II restorations according to the restorative systems: conventional microhybrid resin composite (PA, Peak Universal + Amelogen Plus, Ultradent), flowable bulk-fill and nanoparticulate resin composites (ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT, 3M Oral Care), and flowable bulk-fill and microhybrid resin composites (XST, XP Bond + SDR + TPH3, Dentsply). The clinical performance and interproximal contacts were evaluated. Statistical

Mariana Dias Moda, DDS, MS, PhD, Department of Preventive and Restorative Dentistry, São Paulo State University, School of Dentistry, Araçatuba

André Fraga Briso, DDS, MS, PhD, associate professor; Department of Preventive and Restorative Dentistry, São Paulo State University, School of Dentistry, Araçatuba

Isis Almela Endo Hoshino, DDS, MS, PhD student, Department of Preventive and Restorative Dentistry, São Paulo State University, School of Dentistry, Araçatuba

Sandra Meira Borghi Frascino, DDS, MS, Department of Preventive and Restorative Dentistry, São Paulo State University, School of Dentistry, Araçatuba

Paulo Henrique dos Santos, DDS, MS, PhD, associate professor, Department of Dental Materials and Prosthodontics, São Paulo State University, School of Dentistry, Araçatuba

Diego Mardegan Gonçalves, DDS, MS student, Department of Preventive and Restorative Dentistry, São Paulo State University, School of Dentistry, Araçatuba

*Ticiane Cestari Fagundes, DDS, MS, PhD, assistant professor; Department of Preventive and Restorative Dentistry, São Paulo State University, School of Dentistry, Araçatuba

*Corresponding author: Rua José Bonifácio, 1193 Vila Mendonça, Araçatuba, São Paulo, Brazil, 16105-050; e-mail: ticiane.fagundes@unesp.br

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analyses were performed using the equality test of two proportions, Logistic regression analysis, Friedman, Wilcoxon, Kruskal-Wallis, and Mann-Whitney tests (a=0.05).

Results: Forty-seven patients were evaluated at 3 years. XST bulk-fill restorative system presented higher marginal discoloration than PA, and the opposite occurred for surface staining. All restorative systems resulted in decreased interproximal contacts, occurring early for XST.

Conclusions: Although the restorative system using incremental technique presented better performance for marginal discoloration, one of the restorative systems that used flowable bulk-fill resin composite (XST) showed the lowest surface staining. All restorative systems had decreased proximal contact over time.

INTRODUCTION

Resin composites became the most employed material for restoration of dental elements and has also been used for replacement of unsatisfactory amalgam restorations or for esthetic reasons. The improvement of restorative adhesive systems has avoided the incidence of secondary caries and fracture.[1] To improve the success of these restorations, factors related to the patient and operator are fundamental.[1]

However, the main challenge for the professional is the correct technique required by this material. Another difficulty in direct resin composite restorations is the reconstruction of posterior large cavities, such as those involving the posterior proximal wall, to achieve adequate proximal contacts.[2] The literature recommends inserting the resin composite on the inner proximal surface of the matrix band, from gingival to occlusal, to minimize the c-factor, polymerization shrinkage, and formation of marginal gaps.[3,4] Another important factor is the amount of energy that must be supplied at the correct wavelengths to achieve a satisfactory degree of conversion of the resin material.[4] Furthermore, to achieve success of conventional resin composite, it is fundamental to use the 2-mm layering technique. However, the insertion of 2-mm increments and their correct light curing require more clinical time and patient discomfort. In this context, newer bulk-fill restorative resins allow the insertion of increments up to 4 mm, optimizing the clinical time and reducing the technique sensitivity by the professional.[5]

The bulk-fill composites have monomers with a high molecular weight to reduce the shrinkage stress.[6] The first generation of bulk-fill materials had flowable consistency, requiring a final increment with conventional composites.[7] Some clinical studies and meta-analysis demonstrated that bulk-fill composites have shown similar results to conventional resin composites until 6-year follow-up.[6,8-13] However, more randomized clinical trials (RCT) with longer periods are still necessary, as well as studies evaluating the maintenance of interproximal contact over time.

Thus, the main outcome of this RCT was to compare the clinical performance and interproximal contact of incremental resin composite and two flowable bulk-fill restorative systems. The null hypotheses tested were that there would be no difference between the three restorative systems for the clinical parameters and that there would be no differences for the same restorative strategy over time.

METHODS AND MATERIALS

Study Design

This clinical trial was a prospective, randomized, double-blind (volunteers and examiners), and split-mouth model. It was registered and conducted according to CONSORT guidelines (Figure 1). Three restorative systems were used: microhybrid conventional resin composite, considered the control group (PA, Peak Universal + Amelogen Plus, Ultradent, South Jordan, UT, USA); flowable bulk-fill and nanoparticulate resin composites (ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT, 3M Oral Care, St Paul, MN, USA); and flowable bulk-fill and microhybrid resin composites, (XST, XP Bond + SDR + TPH3, Dentsply, Caulk Milford, DE, USA); the two latter restorative systems were considered as test groups.

Patient Selection

During the period from March to June 2015, all patients attending the undergraduate clinic who needed three class II restorations were asked to participate in the study.

The sample power for two proportions, considering 95% success achieved for the control group and 80% for the test group, indicated that an experimental sample with 159 restorations had a high power of 98.3%.

The following inclusion criteria were used: patients presenting at least three unsatisfactory class II restorations with minimum depth of 3 mm in permanent premolar or molar with an adjacent tooth, patients with good periodontal health, and patients with no clinical history of allergies to dental products. The exclusion criteria were pregnant or lactating women, patients receiving orthodontic treatment, a tooth without an antagonist, and endodontically treated teeth.

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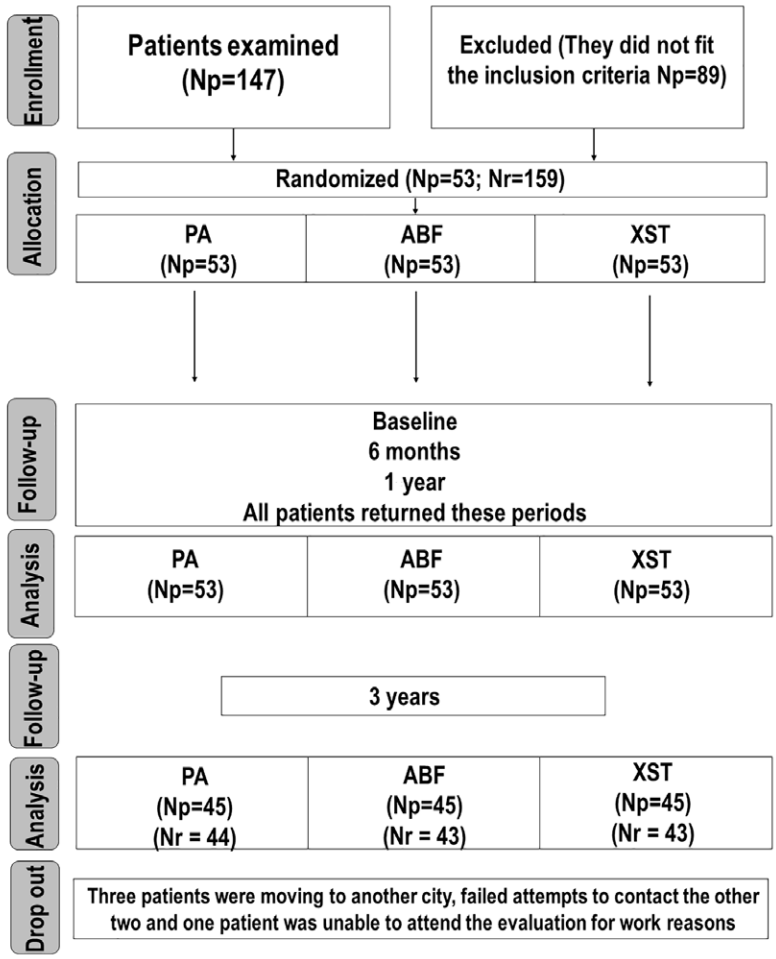

Figure 1. *Flowchart of patients. Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; Np, number of patients; Nr, number of restorations; PA, Peak Universal + Amelogen Plus; XST, XP Bond + SDR + TPH3.*

Fifty-three subjects were selected from the local undergraduate clinic, and patients were submitted to clinical and radiographic examination after signing the informed consent.

Calibration and Randomization

Two calibrated operators (residents), with clinical experience of 19 years and 1 year, were trained by a faculty member specialized in restorative dentistry to perform the restorative procedures. For calibration, each operator performed two restorations for each group in patients not selected for the research. The operators were identified on the procedure sheets. Visible plaque index; gingival bleeding index; and decayed, missing and filled teeth index were assessed at baseline. The subjects then received oral hygiene instructions, and initial photographs were taken.

All subjects received local anesthesia prior to restorative procedures. Randomization was performed by putting numbers in a sealed envelope and drawing which restorative procedure would be performed on each of the selected teeth. Each subject received three restorations, one from each group in the same clinical appointment.

Restorative Procedures

The complete restorative procedures have been described in our previous study.[14] The cavity preparations were performed using round diamond burs (#1015-1017; KG Sorensen, Barueri, SP Brazil). When there was carious tissue, smooth round carbide burs (#1/2-4, Dentsply-Maillefer, Ballaigues, Switzerland) were also used in slow-speed handpiece. Isolation of the operative field was performed with a rubber dam. A probe with one side being a periodontal tip was used to measure the deeper region of the cavity.

Then, 35% phosphoric acid gel (Ultra-etch, Ultradent Products Inc) was used for 30 seconds on enamel and 15 seconds on dentin for all groups. Subsequently, adhesive systems and restorative materials were applied,

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Table 1: *Products (Material, Manufacturer, Composition and Mode of Application) Used in this Study*

Group	Material	Manufacturer	Composition	Application
Control PA	Peak Universal	Ultradent (South Jordan, UT, USA)	Ethyl alcohol and 2-hydroxyethyl methacrylate	Dental surfaces were rinsed thoroughly for 5 seconds and lightly dried using the air/water syringe. The adhesive was applied with a microbrush by rubbing on the cavity for 10s. Adhesive was air dried for 10s and photoactivated for 10s.[a]
	Amelogen Plus		Organic matrix: Bis-GMA, TEGDMA. Filler: silica dioxide and silicate particles (76% wt)	Oblique 2-mm increments were inserted and photoactivated for 20s. The last increment was photoactivated for 40s.[b]
Test ABF	Adper Single Bond 2	3M Oral Care Dental Products TM (St Paul, MN, USA)	Water, ethanol, Bis-GMA, HEMA, UDMA, bisphenol A glycerolate, sílica nanofillers treated with acid copolimer, dimetacrylate	Dentin was left slightly moist. The adhesive was applied with a microbrush and air dried for 5s. A second layer of the adhesive was applied and air dried for 5s. Photoactivation was performed for 20s.[c]
	Filtek Bulk Fill Flow		Organic matrix: Bis-GMA, Bis-EMA, UDMA, Procrylat. Filler: ytterbium trifluoride filler with a range of particle sizes from 0.1 to 5.0 microns and zirconia/ silica with a particle size range of 0.01 to 3.5 μm (64.5% wt)	A single increment was inserted in the cavity without submerging the tip of the syringe in the material already dispensed and photoactivated for 40s. Material was kept 2 mm below the occlusal margin.[d]
	Filtek Z350XT		Organic matrix: Bis-GMA, Bis-EMA, UDMA and TEGDMA. Filler: agglomerated silica nanofillers and nanoagglomerated zirconia/ silica (78.5% wt)	Oblique increments of up to 2 mm were inserted, finishing the restorations. Each increment was photoactivated for 20s and the last increment for 40s.[e]

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; Bis-EMA, bisphenol A ethoxylate methacrylate; Bis-GMA, bisphenol A glycidyl methacrylate; CQ, camphorquinone; EBPADMA, bisphenol A ethoxylated dimethacrylate; EDAB, ethyl-4-dimethylamino benzoate; PA, Peak Universal + Amelogen Plus; TEGDMA, triethylene-glycol dimethacrylate; UDMA, urethane dimethacrylate; XST, XP Bond + SDR + TPH3.

[a] *https://downloads.ctfassets.net/wfptrcrbtkd0/720cc075-a5d8-4113-8f12-8c58a6c9c80b/212e0f1d907a848f628f3b5e8b361593/Peak_Universal_BondBottle_-Peak_SE.pdf*

[b] *https://assets.ctfassets.net/wfptrcrbtkd0/7d495004-256c-4100-9c4d-bedb272215f4/434abf25dddd417d033c0c3a14da67e6/Amelogen_Plus_Singles.pdf*

[c] *https://multimedia.3m.com/mws/media/276868O/adper-single-bond-2-technical-profile.pdf*

[d] *https://multimedia.3m.com/mws/media/792321O/filtek-bulk-fill-flowable-restorative-technical-product-profile.pdf*

[e] *https://multimedia.3m.com/mws/media/631547O/filtek-z350-xt-technical-product-profile.pdf*

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Table 1: *Products (Material, Manufacturer, Composition and Mode of Application) Used in this Study (cont.)*				
Test XST	XP Bond2	DENTSPLY (Caulk Milford, DE, USA)	PENTA, UDMA, dimethacrylate modified by carboxilic acid (TCB resin), triethileneglycol dimethacrylate, hydroxyethylmethacrylate, canphoroquinone, ethyldimethylaminebenzoato, tert-butylhydroquinon,silica, tert-butanol (T-butanol)	Dentin was left slightly moist. One drop of XP Bond was applied with a microbrush, allowed to sit for 20s, air dried for 5s, and photoactivated for 20s.[f]
	SureFil SDR		Organic matrix: SDR-UDMA, EBPADMA, TEGDMA, CQ, butyl hydroxy toluene; stabilizers UV, titanium dioxide; iron oxide pigments. Filler: Barium glass fluoride aluminum silicate, strontium glass, with average particle size of 4.2 μm (68% wt).	A single increment was inserted using a constant and slow pressure in the deepest part of the cavity, keeping the tip inside the material until an increment of not more than 4 mm was obtained. The material was kept 2 mm below the cavosurface angle for posterior insertion of the universal resin and photoactivated for 40s.[g]
	TPH3		Organic matrix: Bis-GMA, Silica Dimethacrylate; EDAB and others. Filler: Silanized barium glass aluminum borosilicate; silanized barium glass, fluoride, aluminum borosilicate (75% wt)	Resin was placed using the incremental technique, and each increment was photoactivated for 20s. The last increment was photoactivated for 40s.[h]

[f] *https://media.dentalcompare.com/m/25/Downloads/XP%20Bond%20Universal%20Total%20Etch%20Adhesive%20Directions%20for%20Use.pdf*

[g] *https://assets.dentsplysirona.com/flagship/en/explore/restorative/sdr_flow_plus_eu-version/SM%20SDR%20FlowPlus%20V01%202017-12-08.pdf*

[h] *https://www.dentsply.de/directions-for-use?ifufile=SpectrumTPH3_IFU.pdf*

following the recommendations of the respective manufacturers. Table 1 presents the specifications for each group.

To restore the shape of proximal walls, wooden wedges, preformed metal matrices, and rings (Unimatrix sectional matrix system, TDV Dental Ltda, Pomerode, SC, Brazil) were used. Adhesive and resin composites were light-cured with a curing light (Valo, Ultradent Products Inc), in the standard application mode and an output of 1000 mW/cm^2. In the experimental groups, the top layer was standardized with a 2-mm capping layer with a conventional composite resin. When the height of the proximal cavity was greater than 4 mm, the bulk-fill resin was inserted in two layers. Fine and ultrafine diamond burs (#1190F, 3118F, 1190FF, 3118FF; KG Sorensen, Cotia, SP, Brazil) were used to finish the restorative procedures. All restorations were polished with polishing points (Jiffy, Ultradent Products Inc).

Evaluation

Two independent and calibrated examiners, neither of which placed the restorations, were responsible for the clinical evaluations. The examiners were kept blind in the assessments. The clinical performance of restorations was assessed by visual and tactile inspection, using a flat dental mirror and a probe with one side with explorer tip.

After 3-year follow-up, the restorations were evaluated using the modified US Public Health Service (USPHS) criteria, as described in Table 2. The tightness of the proximal contact was determined based on the

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Table 2: *Modified USPHS Criteria Rating System for Clinical Evaluation of the Restorations*
Retention
Alpha (A): Presence of the restoration Bravo (B): Partial absent of the retention, less than one-third of the restoration Charlie (C): More than one-third or total absent of the retention
Marginal Integrity
Alpha (A): There is no visual evidence of marginal fracture, and the tip of the dental probe is not trapped in the tooth/restoration interface. Bravo (B): There is visible and tactile evidence of a cleft, but the dentin and/or base is not exposed, nor does the restoration present mobility. Charlie (C): The dental probe penetrates the tooth/restoration interface, presenting exposed dentin and/or base, but the restoration is not mobile, fractured, or lost.
Marginal Discoloration
Alpha (A): There is no visual evidence of marginal discoloration at the tooth/restoration interface. Bravo (B): There is visual evidence of marginal discoloration at the tooth/restoration interface, which can be removed with polishing. Charlie (C): There is visual evidence of deep marginal discoloration at the tooth/restoration interface, which cannot be removed with polishing.
Surface Texture
Alpha (A): Smooth and shiny, similar to enamel Bravo (B): Slightly rough Charlie (C): High roughness, not reflective
Wear
Alpha (A): No wear, continuous interface Bravo (B): Discontinuous interface, no exposed dentin Charlie (C): Discontinuous interface, exposed dentin
Secondary Caries
Alpha (A): There is no visual evidence of tooth decay at the tooth/restoration interface. Charlie (C): There is visual evidence of tooth decay at the tooth/restoration interface.
Anatomical Form
Alpha (A): The restoration presents continuity with the anatomical form of the existing tooth. Bravo (B): The restoration has a slight overcontour or undercontour. Charlie (C): There is loss of restorative material leading to exposure of dentin and/or base.
Surface Staining
Alpha (A): Absent Bravo (B): Present
Color
Alpha (A): Nonapparent interface with the tooth Bravo (B): Subtle visualization between tooth and restoration Charlie (C): Clear visualization between tooth and restoration
Gingival Tissue
Alpha (A): No inflammation Bravo (B): Mild inflammation Charlie (C): Severe inflammation
Abbreviations: USPHS, United States Public Health Service.

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resistance to dental floss (Sanifill, São Paulo, SP, Brazil) between the restored surface and the adjacent tooth. The following scores were used: 0, no contact; 1, minimum contact; 2, ideal contact; 3, tight contact; 4, very tight contact.[15] In cases where more than one proximal surface was involved, the worst score of the two contacts was recorded.

Statistical Methods

The Kappa index was used to measure the degree of agreement between evaluators. The equality test of two proportions was used to evaluate clinical performance. The Friedman and Wilcoxon tests were used to evaluate interproximal contacts within each group, and the Kruskal-Wallis and Mann-Whitney tests were used within the same evaluation period.

The Hosmer-Lemeshow test was applied to evaluate the efficacy of the logistic regression model. Logistic regression analysis was performed to predict the probability of total success (alpha score) of the clinical performance results at 3 years, using the characteristics cited in Table 3. All tests were performed at a significance level of 0.05%.

RESULTS

The mean age of the 53 subjects was 48.3 (±10.0) years. A total of 65 molars and 94 premolars were restored (159 restorations). The characteristics of preparations and restorative procedures are described in Table 3. Forty-seven (88.6%) subjects and 130 restorations were evaluated at 3-year follow-up.

Table 3: *Characteristics of the Cavities and the Restorative Procedures*

Variables	**Characteristics**	**n**	**Groups**		
			PA	**ABF**	**XST**
Operator	1 (experience of 19 years)	81	27	27	27
	2 (experience of 1 year)	78	26	26	26
Teeth	Maxillary premolar	67	22	23	22
	Maxillary molar	34	11	13	10
	Mandibular premolar	27	7	9	11
	Mandibular molar	31	13	8	10
Restored faces	2	87	30	30	27
	3	67	20	23	24
	4	5	3	0	2
Previous condition	Unsatisfactory amalgam	106	39	35	32
	Unsatisfactory resin composite	52	14	18	20
	Primary caries lesions	1	0	0	1
Depth of the cavity	3 mm	29	12	9	8
	≥4 mm	61	17	19	25
	≥5 mm	69	24	25	20
Previous dentin before restoration	Normal	34	10	15	9
	Sclerotic	125	43	38	44
Anesthesia	Yes	156	52	52	52
	No	3	1	1	1
Restorative time	≤10 min	133	43	45	45
	≤20 min	26	10	8	8
Operator perception	Easy	113	39	38	36
	Medium	38	13	12	13
	Difficult	8	1	3	4

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; PA, Peak Universal + Amelogen Plus; XST, XP Bond + SDR + TPH3.

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There was statistically significant agreement among evaluators at the periods analyzed ($p<0.001$), showing an excellent Kappa agreement (baseline=0.79, 6 months=0.91, 1 year=0.89, 3 years=0.92).

Data from the USPHS criteria are presented in Table 4. All failure data were accumulated even if the patient did not return at the evaluation. Also, in the first evaluation in which the restoration failed, all other criteria were evaluated if possible; however, only the criterion that failed was considered at following evaluations.

Concerning the analysis between groups, statistically greater marginal discoloration was observed for XST compared to PA; the opposite occurred for surface staining. The ABF group was similar to other restorative systems for those two criteria. No differences were found between groups for other criteria.

When comparing the evaluation periods for each group, no statistically significant difference was found for secondary caries, anatomical form, and gingival tissue for all groups. Other criteria had decreased alpha score at 3 years, except for retention (XST) and color (ABF and XST). Representative images from each group can be seen in Figure 2.

Data on interproximal contacts are shown in Table 5. There was no significant difference between groups. However, all restorative systems resulted in decreased interproximal contacts, occurring from 1 year for XST.

The probability of success was influenced by the number of tooth surfaces involved in the restoration and the presence of sclerotic dentin for marginal integrity. The same was observed for cavity depth and operator for marginal discoloration.

Table 4: *Clinical Evaluation of Resin Composite Restorations (USPHS)*[a]

Category	**Groups**	**Baseline**[b]	**6 Months**[b]
Retention	PA	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0C) Aab
	ABF	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
Marginal integrity	PA	100% (53-A/0-B/0-C) Aa	92.5% (49-A/4-B/0-C) Ab
	ABF	100% (53-A/0-B/0-C) Aa	94.3% (50-A/3-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	94.3% (50-A/3-B/0-C) Aa
Marginal discoloration	PA	98.1% (52-A/1-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	ABF	98.1% (52-A/1-B/0-C) Aa	83.0% (44-A/9-B/0-C)Bb
	XST	100% (53-A/0-B/0-C) Aa	96.2% (51-A/2-B/0-C) Aa
Surface texture	PA	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	ABF	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
Wear	PA	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	ABF	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aab
Secondary caries	PA	100% (53-A/0-C) Aa	100% (53-A/0-C) Aa
	ABF	100% (53-A/0-C) Aa	100% (53-A/0-C) Aa
	XST	100% (53-A/0-C) Aa	100% (53-A/0-C) Aa
Anatomical form	PA	98.1% (52-A/1-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	ABF	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	100% (53-A/0-B/0-C) Aa
Surface staining	PA	100% (53-A/0-B) Aa	96.2% (51-A/2-B) Ba
	ABF	100% (53-A/0-B) Aa	86.8% (46-A/7-B) Bb
	XST	100% (53-A/0-B) Aa	100% (53-A/0-B) Aa
Color	PA	71.7% (38-A/13-B/2-C) Ba	75.5% (40-A/12-B/1-C) Ba
	ABF	92.5% (49-A/3-B/1-C) Aa	90.6% (48-A/4-B/1-C) Aa
	XST	92.5% (49-A/4-B/0-C) Aa	94.3% (50-A/3-B/0-C) Aa
Gingival tissue	PA	98.1% (52-A/0-B/1-C) Aa	98.1% (52-A/0-B/1-C) Aa
	ABF	96.2% (51-A/2-B/0-C) Aa	98.1% (52-A/1-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	98.1% (52-A/0-B/1-C) Aa

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Table 4: *Clinical Evaluation of Resin Composite Restorations (USPHS) (cont.)*[a]

Category	Groups	1 Year[b]	3 Years[b]
Retention	PA	94.3% (50-A/2-B/1-C) Aab	91.5% (43-A/1-B/3-C) Ab
	ABF	98.1% (52-A/0-B/1-C) Aa	87.0% (40-A/3-B/3-C) Ab
	XST	96.2% (51-A/0-B/2-C) Aa	95.6% (43-A/0-B/2-C) Aa
Marginal integrity	PA	71.7% (38-A/15-B/0-C) Ac	56.8% (25-A/18-B/1-C) Ac
	ABF	73.6% (39-A/14-B/0-C) Ab	58.1% (25-A/16-B/2-C) Ab
	XST	83.0% (44-A/9-B/0-C) Ab	67.4% (29-A/13-B/1-C) Ab
Marginal discoloration	PA	73.6% (39-A/14-B/0-C) Ab	68.2% (30-A/14-B/0-C) Ab
	ABF	73.6% (39-A/14-B/0-C) Ac	55.8% (24-A/17-B/2-C) ABc
	XST	77.4% (41-A/12-B/0-C) Ab	44.2% (19-A/23-B/1-C)Bc
Surface texture	PA	96.2% (51-A/2-B/0-C) Aab	90.9% (40-A/4-B/0-C) Ab
	ABF	94.3% (50-A/3-B/0-C) Aa	79.1% (34-A/9-B/0-C) Ab
	XST	92.5% (49-A/4-B/0-C) Aab	81.4% (35-A/8-B/0-C) Ab
Wear	PA	98.1% (52-A/1-B/0-C) Aa	75% (33-A/11-B/0-C) Ab
	ABF	98.1% (52-A/1-B/0-C) Aa	76.7% (33-A/10-B/0-C) Ab
	XST	98.1% (52-A/1-B/0-C) Aab	90.7% (22-A/9-B/0-C) Ab
Secondary caries	PA	100% (53-A/0-C) Aa	100% (44-A/0-C) Aa
	ABF	98.1% (52-A/1-C) Aa	97.7% (43-A/1-C) Aa
	XST	98.1% (52-A/1-C) Aa	95.6% (43-A/2-C) Aa
Anatomical form	PA	98.1% (52-A/1-B/0-C) Aa	97.7% (43-A/1-B/0-C) Aa
	ABF	98.1% (52-A/1-B/0-C) Aa	97.6% (42-A/1-B/0-C) Aa
	XST	100% (53-A/0-B/0-C) Aa	100% (43-A/0-B/0-C) Aa
Surface staining	PA	84.9% (45-A/8-B) Ab	63.6% (28-A/16-B) Bc
	ABF	66.0% (35-A/18-B) Bc	67.4% (29-A/14-B) ABc
	XST	94.3% (50-A/3-B) Aab	83.7% (36-A/7-B) Ab
Color	PA	84.9% (45-A/8-B/0-C) Ba	95.5% (42-A/2-B/0-C) Ab
	ABF	92.5% (49-A/4-B/0-C) Ba	95.3% (41-A/2-B/0-C) Aa
	XST	96.2% (51-A/2-B/0-C) Aa	97.7% (42-A/1-B/0-C) Aa
Gingival tissue	PA	96.2% (51-A/1-B/1-C) Aa	100% (44-A/0-B/0-C) Aa
	ABF	96.2% (51-A/2-B/0-C) Aa	100% (43-A/0-B/0-C) Aa
	XST	98.1% (52-A/1-B/0-C) Aa	100% (43-A/0-B/0-C) Aa

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; PA, Peak Universal + Amelogen Plus; USPHS, US Public Health Service; XST, XP Bond + SDR + TPH3.
[a]*Percentage values of A score and numbers of A, B, and C scores in parentheses, respectively.*
[b]*Different letters represent statistical differences (*p<*0.05). Uppercase letters compare different restorative systems, and lowercase letters compare evaluation periods.*

DISCUSSION

The present study represents a prospective, randomized, double-blind, and split-mouth clinical trial, allowing analysis of the test and control groups under the same conditions, increasing the statistical efficiency and decreasing the number of patients required for the study.[16] Furthermore, the distribution of restorations (maximum of three pairs in the same patient) is in accordance to the American Dental Association guidelines when testing a new material.[17] The number of 159 restorations in the present study was superior to that estimated by van Dijken and others,[9] allowing to determine significant differences between groups treated with distinct materials in similar evaluations of intra-individual comparison design with a power of 98.3%. In addition, 138 restorations were evaluated at the 3-year follow-up, maintaining the possibility of detection of statistical differences between groups.

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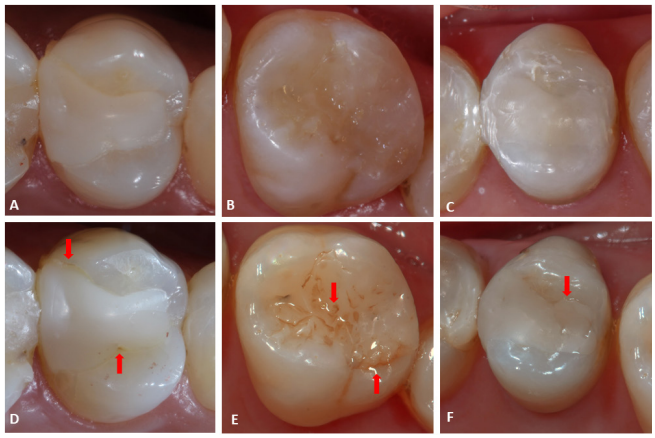

Figure 2. *Representative clinical images from all groups. (A): First premolar of the PA group with alpha scores for all criteria at baseline. (B): First molar of the ABF group with alpha scores for all criteria at baseline. (C): Second premolar of the XST group with alpha scores for all criteria at baseline. (D): First premolar representative of the PA group with bravo scores for only marginal integrity and marginal discoloration as pointed with arrows, at 3-year follow-up. (E): First molar of the ABF group with bravo scores for only marginal discoloration and surface staining as pointed with arrows, at 3-year follow-up. (F): Second premolar of the XST group with bravo scores for only marginal integrity as pointed with arrows, at 3-year follow-up.*

The method used for the performance of restorations was USPHS, commonly used in several clinical trials,[9,11,12,18,19] although there are other criteria for the clinical evaluation of restorations, such as those used by the World Dental Federation (FDI criteria).[13] It is worth mentioning that the kappa test revealed increased and excellent agreement between the evaluators over time.

These resin composites were selected to compare the clinical behavior of conventional resin using incremental technique and flowable bulk-fill resin composites. Retention, marginal integrity, and marginal discoloration are directly related to the stress produced at the tooth/restoration interface, which may be influenced by the cavity geometry, adhesive systems, viscosity of restorative materials, and placement technique.[19]

Concerning retention, no statistical difference between conventional resin composite and bulk-fill resin composites was found; however, the XST group presented two charlie scores after 1-year follow-up, and three bravo and three charlie scores were found for the ABF group at 3-year follow-up. A clinical trial that evaluated the SDR bulk resin found one fractured restoration only after 5 years.[9] In the case of bulk-fill resin composites, although they present similar percentage of filler particles (64.5% for ABF and 68% for XST), the monomers of Filtek Bulk Fill Flow present similar structure to conventional resins, while Surefil SDR has a patented monomer (SDR-UDMA).[20,21] A study comparing conventional resins to flowable and full-body bulk-fill resin composites, by tomography analysis, concluded that flowable bulk-fill resins can promote increased voids in class II restorations, and this appears to be more related to voids present inside the material syringe than to the use of incremental or bulk-fill restorative techniques.[22]

Regarding marginal integrity, there were no differences between groups in all evaluations. Corroborating with this study, similarity in marginal adaptation among incremental and bulk-fill techniques after thermomechanical cycling was found using FDI criteria.[23] This fact can probably be explained by the presence of enamel margins and the low modulus of elasticity of bulk materials, reducing the stresses generated by the polymerization shrinkage and thus maintaining the marginal integrity.[23,24] Another study comparing the same flowable bulk-fill resin composites used in this study showed similar polymerization shrinkage between them using microtomography in class II cavities.[25] It was evident that the higher number of bravo scores began at 6-month follow-up, and statistical increase occurred at 1 and 3 years for the PA group, or ABF and XST groups began at 1 year and remained statistically similar between 1 and 3 years. In another study comparing conventional and bulk-fill composites in class II cavities, increased bravo scores were found only for conventional microhybrid composite at 2 years; however, the full-body Filtek Bulk Fill was used instead of the flowable version.[11] All restorative flowable bulk-fill systems also presented an increased number of bravo scores after 2 years, but one of the flowable bulk-fill composite (everX Posterior + G-aenial Posterior) had twice as much slight marginal misfits than the other restorative system (SureFil SDR flow + Ceram.X mono).[12]

In relation to marginal discoloration, the differences between performances of the resin composite systems became more evident after 3 years, where XST presented greater marginal discoloration than the conventional. When the percentage of restorations with marginal gaps for the same three resin composites after artificial ageing was studied, the conventional resin composite may be superior regarding marginal gap formation in enamel than flowable bulk-fill resin composites.[26] Flowable bulk-fill composites also had more imperfect margins than the full-body bulk-fill[25,27] and conventional microhybrid composites in class II restorations performed in an *in vitro* study.[27] The viscosity of the bulk-fill restorative material also influenced the proportion of gap-free marginal interface in dentin.[28] One meta-analysis demonstrated that only marginal adaptation after 12 months showed

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Table 5: *Means (SD) of the Interproximal Contacts for Groups and Evaluation Periods*[a]

Groups	Evaluation Periods			
	Baseline	6 Months	1 Year	3 Years
PA	*1.92 (0.51) Aa*	*1.87 (0.48) Aa*	*1.79 (0.49) Aa*	*1.48 (0.59) Ab*
ABF	*1.85 (0.45) Aa*	*1.79 (0.41) Aa*	*1.79 (0.41) Aa*	*1.55 (0.69) Ab*
XST	*1.94 (0.41) Aa*	*1.83 (0.38) Aa*	*1.73 (0.44) Ab*	*1.54 (0.64) Ac*

Abbreviations: ABF, Adper Single Bond 2 + Filtek Bulk Fill Flow + Filtek Z350XT; PA, Peak Universal + Amelogen Plus; XST, XP Bond + SDR + TPH3.

[a]*Uppercase letters compare groups within a same evaluation period (columns), and lowercase letters compare the periods of each group individually (lines).*

statistically significant outcomes in which conventional composites presented significantly better results than resin composites containing modified monomers.[6]

However, in other clinical trials evaluating posterior restorations, no marginal discoloration was found in 100% and 89.2% restorations with flowable bulk-fill resin composite (Surefil SDR) at 3- and 6-year follow-up, respectively;[9] furthermore, superior discoloration and marginal adaptation were found for conventional nanofill (Filtek Ultimate) compared to full-body bulk-fill composite (Tetric EvoCeram Bulk Fill) at 3 years.[18] A superiority of the etch-and-rinse adhesive technique was seen compared to self-etch approach for marginal discoloration *in vivo* and adaptation *in vitro*, irrespective of the composite used.[13,29] It is important to emphasize that in our study, phosphoric acid gel was applied for all groups. Furthermore, the two operators performing the restorations had different times of clinical experience, reflecting the actual clinical practice; however, in those clinical trials,[9,18] only one operator performed all restorations, improving the results.[1] Decreased alpha scores for marginal discoloration occurred over time for all groups, corroborating other studies in which bulk resins were evaluated.[9,11-13,18]

The next criteria that will be discussed involve the resins used as the top layer. PA and ABF presented a high number of bravo scores for surface staining, since only TPH resin does not include tryethylene glycol dimethacrylate (TEGDMA) monomer in its composition.[30,31,32] The presence of the TEGDMA monomer, which has an aliphatic chain, increases the susceptibility to the constant challenges of the oral cavity, such as water absorption and acid environment.[30,31] Furthermore, all restorative systems studied had statistical differences for surface texture and wear over time; however, one of the resins used as the top layer, which contains TEGDMA, had initial surface staining from 6 months.

The literature is scarce in clinical work evaluating the intensity of proximal contacts of posterior flowable bulk resin composite restorations. Only one recent study assessed the proximal contact of a full-body bulk-fill resin composite in class II restorations where all teeth restored with conventional and bulk resin had alpha score for this criterion after 2 years.[11] The current study also found no difference between groups; however, all restoratives showed decreased proximal contact over time, occurring early for XST. Manufacturers of both flowable bulk-fill composites studied recommend a 2-mm capping layer with a conventional composite resin; however, the bulk-fill composite may extend to reestablish the proximal contacts in a clinical situation. Therefore, it is difficult to state which type of resin the proximal contact was established clinically. Algamaiah and others[25] report that volumetric changes of flowable bulk-fill composites may compromise the precision of proximal contacts, leaving a space between adjacent teeth for food impaction. Our findings showed that a mean of 1.9 was detected for all proximal contacts at baseline because the operators carefully observed if the contact was established after final curing. It is important to highlight that, if the patient complained about food impaction, the restoration was classified as 0 score and was repaired.

According to the logistic regression analysis, some factors influenced the results. The number of restored surfaces influenced the marginal integrity, and the depth of cavities influenced the marginal discoloration. It is known that the greater the volume of material, the greater the shrinkage, contributing to increasing the chance of failures in the margins.[33] Presence of sclerotic dentin also affected the marginal integrity, since it can reduce the bond strength,[34] interfering with marginal integrity. The operator with 1 year of experience had 40 restorations classified with alpha score, while the operator with 19 years of experience had 33 restorations with the same score. It is speculated that the younger operator would be more updated than the other, mainly about the care during evaporation of the adhesive solvent. Technique-related aspects of a posterior restoration rely on the knowledge and sufficient skills of the operator.[1]

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A limitation of the present study is the greater extension of cavities with very thin remaining cusps for many teeth. Additionally, the proximal contact strength is not a constant value and can be affected by a variety of factors, such as patient position and time of day.[35] Then, future studies are necessary to evaluate the accuracy of clinician evaluation of interproximal contacts after bulk restorations using different methods, such as with the use of a shim stock.[36] It is also important to highlight that the gingival floor of the proximal box and pulpal floor of the cavity had higher imperfect margin percentage than the buccal and lingual walls of the proximal box.[27] In the current study, radiographs were taken at all evaluation periods to help the diagnosis when visual examination only was not sufficient to define the scores. However, only standardized radiographs will be used in a future study, and clinical analysis with a longer evaluation period will be performed.

CONCLUSION

Although the restorative system using incremental technique presented better performance for marginal discoloration, one of the restorative systems that used flowable bulk-fill resin composite (XST) showed the lowest surface staining. All restorative systems had decreased proximal contact after 3 years.

Acknowledgement

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Regulatory Statement

This study was conducted in accordance with all provisions of the human subjects oversight committee guidelines and local institutional review boards. The approval code for this study is 1.235.100.

Conflicts of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Laboratory Research

Effect of Deep Margin Elevation on Interfacial Gap Development of CAD/CAM Inlays after Thermomechanical Cycling

W Moon • SH Chung • J Chang

Clinical Relevance

The margin elevation technique using RMGI can be used as an adjunct procedure to enhance interfacial adaptation of CAD/CAM lithium disilicate inlays with deep margins. The technique may be beneficial for long-term clinical services for CAD/CAM intracoronal restorations with large internal spacing.

SUMMARY

The aim of this study was to evaluate interfacial gap formation of CAD/CAM lithium disilicate inlay margins before and after thermomechanical loading.

Methods and Materials: Mesio-occlusal-distal cavities were prepared on 12 extracted mandibular molars. The gingival margin of one proximal box was elevated with resin modified glass ionomer (RMGI) by a height of 2 mm (Group E [elevation]), and the margin of the other side served as a control (Group NE [no elevation]). Lithium disilicate computer-aided design and computer-aided manufacturing (CAD/CAM) inlays were fabricated and bonded with a self-adhesive resin cement. An aging process was simulated on the specimens under thermomechanical cycling by using a chewing simulator. Marginal integration was evaluated under scanning electron miscroscopy (SEM) using epoxy resin replicas before and after cycling. Marginal areas were stained with silver nitrate solution, and the volumetric gap was measured at the bonded interfaces using micro-computed tomography (CT) before and after cycling. Statistical analyses were performed using paired *t*-tests, the Wilcoxon signed rank test, and the Mann–Whitney test (a<0.05).

Results: SEM showed marginal discontinuities in Group NE that increased after thermomechanical cycling. Micro-computed tomography exhibited three-dimensional dye-penetrating patterns at the interfaces before and after cycling. Interfacial

Wonjoon Moon, DDS, PhD candidate, Department of Dental Biomaterials Science, School of Dentistry and Dental Research Institute, Seoul National University, Seoul, Republic of Korea

Shin Hye Chung, DDS, MSD, PhD, associate professor, Department of Dental Biomaterials Science, School of Dentistry and Dental Research Institute, Seoul National University, Seoul, Republic of Korea

*Juhea Chang, DDS, MSD, PhD, clinical professor, National Dental Care Center for Persons with Special Needs, Seoul National University Dental Hospital, Republic of Korea

*Corresponding author: 101 Daehak-ro, Jongno-gu, Seoul 03080, Republic of Korea; e-mail: juhchang@snu.ac.kr

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disintegration was larger in Group NE before cycling ($p<0.05$). Thermomechanical cycling increased the gaps in both Groups NE and E ($p<0.05$). The gap increment from thermomechanical cycling was larger in Group NE ($p<0.05$).

Conclusions: Thermomechanical cycling induced interfacial disintegration at the lithium disilicate CAD/CAM inlays, with deep proximal margins. Margin elevation with RMGI placement reduced the extent of the interfacial gap formation before and after the aging simulation.

INTRODUCTION

With advancements in digital dentistry and adhesive techniques, computer-aided design and computer-aided manufacturing (CAD/CAM) inlays have shown favorable outcomes as a minimally invasive restorative regimen.[1] In a stress-bearing area, lithium disilicate ceramic can be the optimal choice, with its high characteristic strength among the diverse composition of CAD/CAM restorative materials.[2] Several previous studies have evaluated the mechanical properties and internal adaptation of CAD/CAM fabricated restorations, with lithium disilicate glass ceramics serving as the control groups to be compared among various polymer-infiltrated ceramics and other types of glass ceramics.[3,4] From a clinical perspective, CAD/CAM inlays of lithium disilicate glass ceramics have had a 100% survival rate for 2 years, which is also highly rated by modified criteria of the United States Public Health Service Commissioned Corps.[5]

In multiple workflows for CAD/CAM restorations that include tooth scanning, restoration designing, block milling, crystallization firing, and final finishing and polishing, each individual step can affect the quality of marginal and internal adaptation.[6] The interfacial gap formation between the restoration and tooth surfaces is inevitable, and the space is filled with luting cement that is susceptible to mechanical, physical, and thermal stresses. According to a systematic review of the marginal and internal fit of CAD/CAM inlay/onlay restorations, the values for the marginal fit largely ranged between 36 μm and 222.5 μm, and ranged between 23 μm and 406.5 μm for the internal fit.[3] When the aging process was simulated, a gap increment was prevalent regardless of the variation in experimental settings. Particularly, when inlay restorations include extended mesio-occlusal-distal (MOD) cavities, the margins of deep proximal boxes are not surrounded by enamel for durable bonding. Moreover, deep proximal boxes of CAD/CAM inlays complicate the clinical steps throughout cavity preparation, optical scanning, margin readings, adhesive cementation, finishing, and polishing. Therefore, a deep margin elevation technique can be considered to position the margins to a more manageable, supragingival level by applying base materials in the bottom of proximal boxes.[7] However, a literature review on deep margin elevation in indirect adhesive restorations revealed conflicting results, and studies included in the review had mainly applied conventional measurements for marginal adaptation by scanning electron microscopy (SEM) using epoxy replicas.[8] Further, limitations exist for percentile measurement of continuous margins on the restoration surfaces in a two-dimensional (2D) plane.

Inlays have a more complex geometry than full-coverage crowns and provide interfacial clearance sufficient for internal adjustment.[3] A CAD/CAM workflow that incorporates multiple digitalized steps tends to accumulate interfacial spacing that results in both marginal and internal gap increments at the final step. Recently, three-dimensional (3D) measurements using micro-computed tomography (micro-CT) has been advocated as a useful tool to evaluate numerous points of the interfacial areas between restoration and tooth surfaces. Using micro-CT, multiple sectional images can be constructed, and virtual cement spaces under inlays can be measured for quantitative analysis.[9] Moreover, an unaltered observation setting enables timewise observation to confirm the interfacial disintegration induced by the aging simulation.[10]

The purposes of this study were (1) to determine 2D and 3D gap formation using SEM and micro-CT, (2) to compare the interfacial gap formation in the CAD/CAM lithium disilicate MOD inlays with and without margin elevation, and (3) to evaluate the interfacial gap increment after thermomechanical loading. The null hypothesis was that the margin elevation of CAD/CAM MOD inlays with RMGI would not affect interfacial gap formation before and after thermomechanical cycling.

METHODS AND MATERIALS

Specimen Preparation

Twelve freshly extracted mandibular molars were used to prepare MOD cavities (4 mm in bucco-lingual width, 3 mm in occlusal depth, and 4 mm in axial depth of the proximal box). All gingival margins of proximal boxes were located beneath the cementoenamel junction. Either a mesial or distal proximal box was randomly selected (Group E [elevation]), and its gingival margin was elevated by 2 mm by layering RMGI cement (Fuji II LC; GC, Tokyo, Japan). The

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gingival margin at the other side (Group NE [no elevation]) was not elevated (Figure 1). The proximal cavities were cleansed with polyacrylic acid (dentin conditioner; GC, Tokyo, Japan) and layered with a RMGI cement. After placement of the RMGI cement, the cavity forms were finished with fine diamond burs (Komet Inlay-Preparation Set 4261; Gebr. Brasseler GmbH & Co. KG, Lemgo, Germany). Specimens were embedded in an epoxy resin (Cold Mounting Systems Epoxy Systems; Metallurgical Supplies, Buffalo, NY, USA) that exposed the coronal portion of the teeth. Each cavity was scanned using CEREC Omnicam (Dentsply Sirona, Hanau-Wolfgang, Germany) and an MOD inlay was designed with the cement space set by 150 μm. A lithium disilicate CAD block (MAZIC Claro CAD, Vericom, Chuncheon, Korea) was milled using a milling machine (CEREC MC XL; Dentsply Sirona) and went through crystallization in a firing furnace (Multimat Cube; Dentsply Sirona). The inlay specimens were then etched with a 4% hydrofluoric acid (Porcelain Etchant; Bisco, Schaumburg, IL, USA), treated with a primer (Porcelain Primer; Bisco), and bonded with a resin cement (RelyX U200; 3M Oral Care, St. Paul, MN, USA). The cemented specimens were stored in 37°C water for 24 hours.

Thermomechanical cycling

All specimens underwent thermomechanical aging simulation that consisted of 1,000,000 cycles of mechanical loading and 8,836 cycles of thermal alterations (40 seconds at 5°C and 55°C, respectively) in a chewing simulator (Chewing Simulator CS-4; SD Mechatronik, Feldkirchen-Westerham, Germany). The load was applied at the central fossa with a 1-mm round-ended cylindrical steel tip. The loaded weight was chosen as 5 kg, equivalent to an effective loading force of 49 N.[11]

Two-dimensional Interfacial Analysis Using SEM

Before and after thermomechanical cycling, silicone impressions of the mesial and distal margins of all specimens were taken with putty (Exafine Putty Type; GC) and light-body impression materials (Examixfine; GC) to observe 2D marginal integration. Based on the impression, epoxy models were fabricated to be observed under a field emission SEM (FE-SEM JSM-7401F; JEOL, Tokyo, Japan) at 100x magnification. Along the gingival margin of the proximal box, the percentage of marginal discontinuity was calculated using ImageJ software (ImageJ; NIH, Bethesda, MD, USA). The same measurement was repeated on all specimens after thermomechanical cycling.

Three-dimensional Interfacial Analysis Using Micro-CT

After silicone impressions were taken, the specimens were immersed in a radiopaque dye, 50% w/w silver nitrate ($AgNO_3$) solution (pH = 8.48), for 6 hours in the dark at room temperature. Specimens were scanned using a micro-CT scanner (Skyscan 1172; Bruker, Kontich, Belgium). The scanning parameters were 100kV and 100μA using an aluminum and copper filter, with an exposure time of 1,180 ms. The pixel size was 8.85 μm, with a rotation of 0.40 and an average frame of 3. 3D images were acquired by 3D reconstruction (NRecon; Bruker), 3D modeling (CTAn; Bruker), and 3D analysis (CTVol; Bruker). To detect and confirm the presence of silver nitrate, the dye solution was scanned under the same condition. Then, standard parameters and thresholds for silver nitrate were determined and the volume of dye penetration was calculated for summation. For the volumetric calculation, sagittal images were obtained from the surface of the proximal

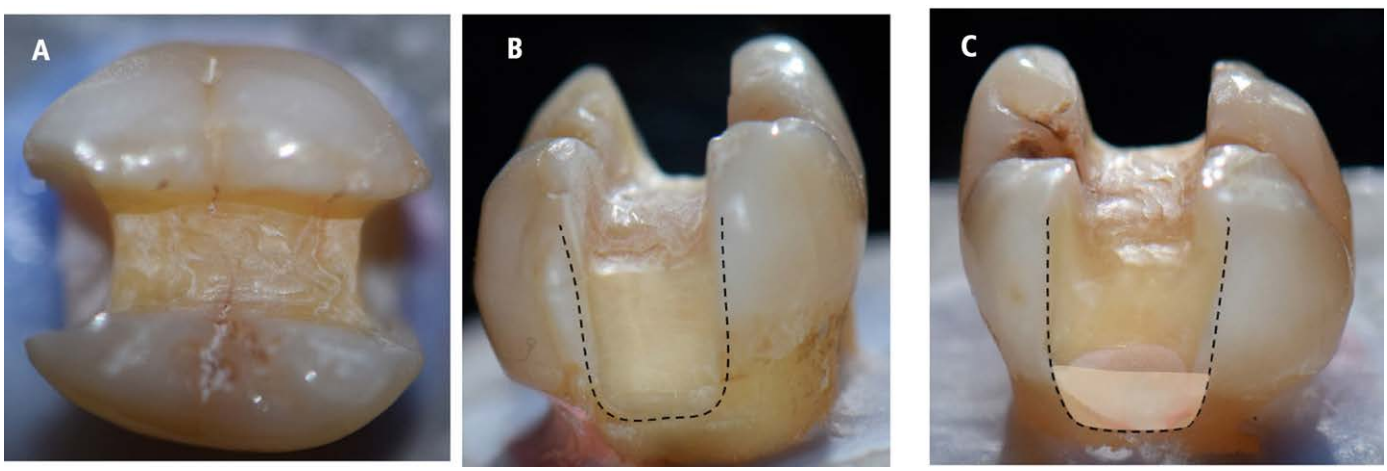

Figure 1. *(A): Tooth specimen with a mesio-occlusal-distal inlay cavity. A proximal box without margin elevation (B) and with margin elevation by resin modified glass ionomer layering (C).*

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box to the axial wall. Additionally, cross-sectional images were obtained to analyze the interfaces between dentin and inlay in Group NE, and those between RMGI and inlay in Group E. The above procedures were repeated after thermomechanical cycling, and the corresponding interfacial configuration was analyzed in the same manner.[12]

Statistical Analysis

The volume of silver nitrate penetration was analyzed as follows. Data from before and after thermomechanical cycling was compared using the Wilcoxon signed rank test and paired *t*-tests based on the normality tests. To compare Groups E and NE, the Mann–Whitney U test was used, as the data did not follow the normal distribution. SPSS Statistics for Windows (version 26.0; IBM, Armonk, NY, USA) was used with the significance level set at $a<0.05$. The sample size was determined based on previous studies that reported the means and standard deviation (SD) for the interfacial gap volumes of MOD inlays evaluated by micro-CT.[10,13]

RESULTS

Based on the SEM evaluation before and after thermomechanical cycling, percentile marginal discontinuities were observed in 12 specimens in each group (Figure 2). Before thermomechanical cycling, 6 specimens showed marginal discontinuity (mean [SD] = 30.3 [40.8] %) in Group NE, while all margins were intact in Group E. After cycling, discontinuity increased in Group NE (mean [SD]=39.5 [42.0] %) and all margins stayed intact in Group E.

Micro-CT analysis before and after thermomechanical cycling determined the volumes of interfacial dye penetration (Figure 3). Proximal boxes with margin elevation revealed significantly less interfacial gap volume compared with those without margin elevation (Table 1; Figure 3A, $p<0.05$). After cycling, the volumetric gap increased in both groups, but the increment was less in Group E (Figure 3B, $p<0.05$). The reconstructed images of the dye-penetrated interfaces exhibited a lesser degree of penetration in Group E (Figure 4). The penetration was extended in both groups after cycling.

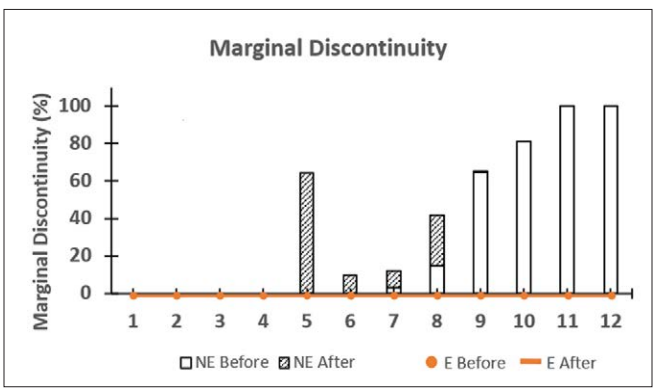

Figure 2. *Marginal discontinuity (%) at the gingival margins with and without elevation determined before and after thermomechanical cycling. Abbreviations: E, elevation; NE, no elevation.*

Figure 5 shows the cross-sectional images of micro-CT taken at the interfaces for evaluation. The white images represent the presence of silver nitrate at the interface between the inlay and the deep gingival floor in Group NE and between the inlay and RMGI base in Group E. Before cycling, the interfaces exhibited minimal penetration of silver nitrate. After cycling, the presence of dye was slightly increased at the marginal surfaces in both groups but was not noticeably extended into the internal areas.

DISCUSSION

This study evaluated the interfacial gap developed under CAD/CAM MOD inlays made of lithium disilicate ceramic to determine the effect of deep margin elevation, and to also evaluate the impact of thermomechanical cycling on gap formation. The 3D analysis using micro-CT showed that the margin elevation using RMGI lessened the interfacial gap at the deep gingival margins and reduced the gap increment under thermomechanical cycling. Therefore, the null hypothesis that margin elevation with RMGI would not affect interfacial gap formation before and after thermocycling was rejected.

The margin elevation technique is a direct adhesive restoration that functions as a base under an indirect restoration to enhance the marginal adaptation at deep margin areas.[14] It came from the open sandwich

Table 1: *Volumetric Measurement of Interfacial Gap Formation Determined by Micro-CT Evaluation*

Groups	Interfacial Gap Volume (mm^3) Mean (SD)		*p*-values
	Before Cycling	After Cycling	
Group NE (No elevation)	0.098 (0.097)	0.178 (0.165)	0.002[a]
Group E (Elevation)	0.021 (0.025)	0.054 (0.053)	0.003[b]
p-values	0.007[c]	0.017[c]	

Abbreviation: SD, standard deviation.
[a] *Wilcoxon signed rank test.*
[b] *Paired* t*-test.*
[c] *Mann-Whitney test.*

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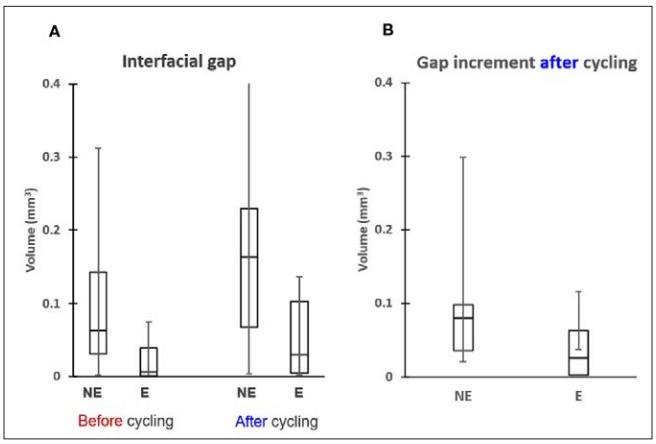

Figure 3. *Volumetric measurement of interfacial gap formation determined by micro-computed tomography evaluation. Abbreviations: E, elevation; NE, no elevation.*

technique that places base material at the bottom of open proximal boxes to reduce polymerization shrinkage of overlying composite resins.[15] Among various adhesive restorative materials, RMGI was shown to be an optimal material for this purpose, benefited by not only the chemical adhesion to deep dentin and hygroscopic expansion in the humid oral environment, but also by mechanical and adhesive properties enhanced with resin-based components. Composite resins are an alternative option that exhibit satisfying results, particularly for CAD/CAM glass-ceramic restorations with high strength and large interfacial spacing.[15,16] However, in clinical circumstances, clean and sound dentin surfaces are difficult to obtain for optimal bonding in the deep marginal areas. Moreover, teeth with deep proximal defects often involve caries-affected dentin that has an inferior capability for hybridization in its tubular structures.[17] Alternately, application of RMGI at the deep proximal margin can be less affected by contamination issues in suboptimal operating conditions and is not as technique-sensitive to practitioners as composite resins are.[18] The proximal boxes with margin elevation using RMGI contained two different interfaces: one between the inlay and the RMGI base, and the other between the RMGI base and the deep dentinal floor. In our observations using SEM, both interfaces were intact before and after thermomechanical cycling. Micro-CT evaluation showed that the marginal and internal gaps were hardly detected at the interface between RMGI and dentin, while gaps were evident at the interface between RMGI and resin cement. So, the latter was selected for our measurement and analysis. We considered the chemical bonding between RMGI and dentin was relatively well maintained, and spatial compensation resulted from water resorption and hygroscopic expansion of RMGI, largely due to hydrophilic monomer components such as hydroxyethyl methacrylate.[19] This aspect seemed to contribute to diminishing the space between RMGI and resin cement, resulting in less space than that between dentin and resin cement.

A CAD/CAM fabrication system incorporates many digitized processes that are influenced by cavity

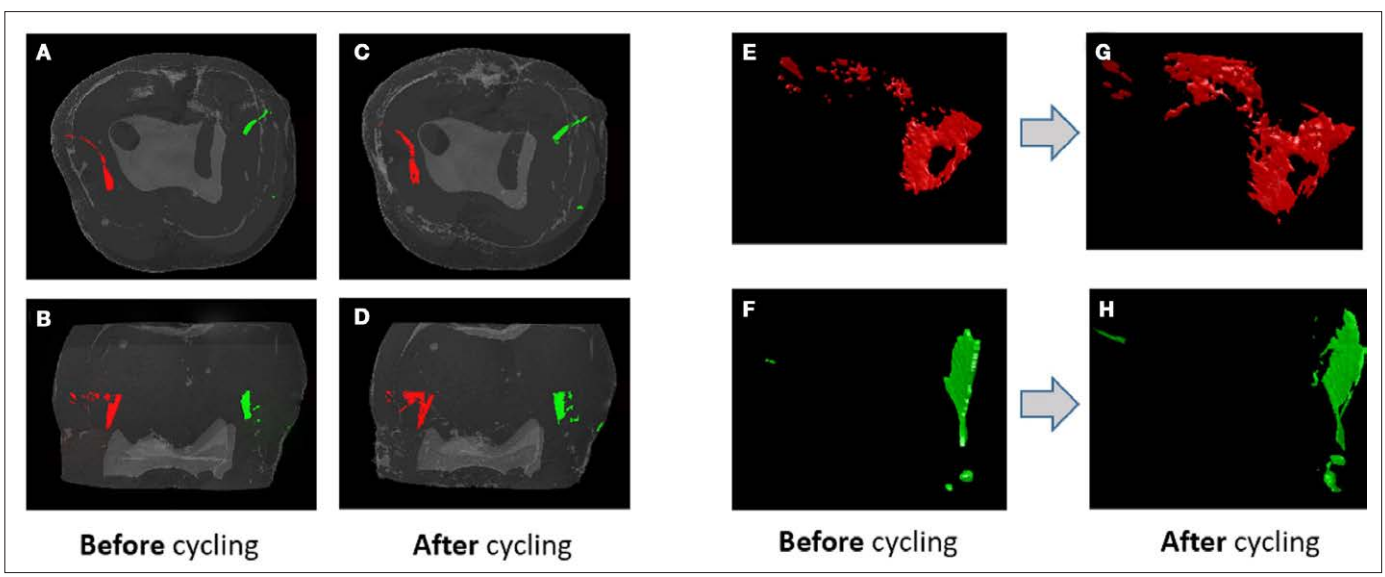

Figure 4. *Occlusal (A, C) and lateral views (B, D) of dye penetrating modes of a single representative specimen from three-dimensional reconstruction and modeling of micro-computed tomography data. The boxes showing margin elevation (red) shows a larger extent of dye penetration at the interfaces compared with that of the boxes showing margin elevation (green). Images before (A, B) and after (C, D) thermomechanical cycling showed an increase in the interfacial gap after cycling. Magnified views of dye penetration before (E, F) and after (G, H) thermomechanical cycling.*

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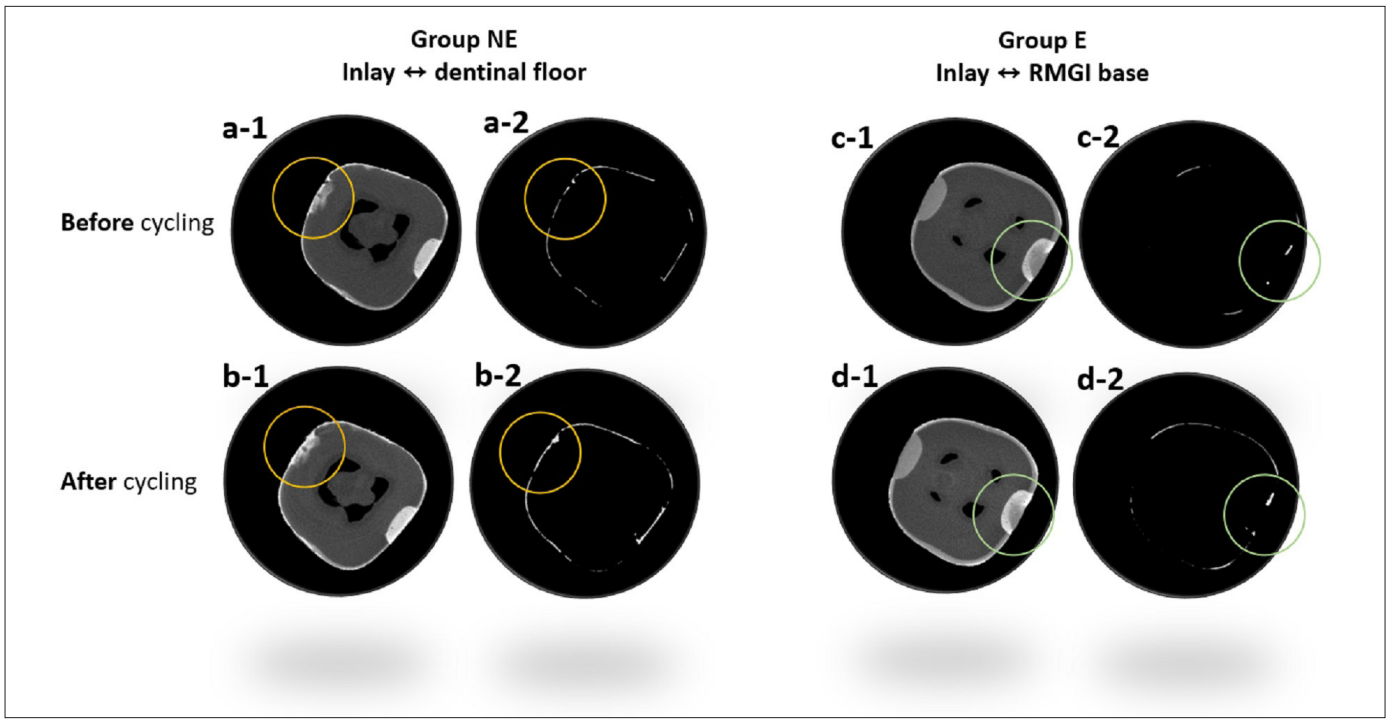

Figure 5. *Micro-computed tomography images indicating dye penetration at both proximal boxes of the same specimen. Circled images show the dye-penetrated interfaces between inlay and dentinal floor (Group NE) and between inlay and RMGI base (Group E). Paired images show the whole specimen (a-1, b-1, c-1, d-1) and the dye penetrants with surrounding substrates filtered out (a-2, b-2, c-2, d-2). In Group NE, almost no penetration was seen at the interface between the inlay and dentinal floor (a-1, a-2), which was minimally increased after cycling (b-1, b-2). In Group E, the presence of silver nitrate was not detectable at the interface between the inlay and the RMGI base (c-1, c-2), and it was not penetrated after cycling (d-1, d-2). Abbreviations: E, elevation; NE, no elevation; RMGI, resin modified glass ionomer.*

preparation, optical impression, design algorithms, material types, milling tools, and milling machines.[20] When an optical impression is directly captured from the mouth, it is especially difficult to detect deep proximal margins.[21] Also, caries-affected tooth surfaces are often plaque retention areas prone to gingival bleeding that induce marginal contamination. Consequently, marginal inaccuracy can affect the internal fit of restorations and increase the overall cement spaces. In addition, high strength ceramics such as lithium disilicate are more sustainable in stress-bearing posterior dentition, but they have lower machinability compared with variants of polymer-based glass ceramic blocks.[3] For ease of insertion into the complex geometry of inlay preparation, sufficient clearance needs to be provided under the restoration. Altogether, inherently large interfacial spaces are gained and filled with luting cement that adjoins heterogeneous substrates with superior strength (enamel, dentin, and ceramics). Clinically, the main failures reported in class II ceramic inlays are bulk fractures rather than marginal fractures.[16] Within a thick cement layer, macro- and micro-level defects are easily created that initiate crack propagation, dislodge the inlays, and eventually lead to early failure modes.[22] The prefracture stage of internal defects is hardly detectable because it occurs in the unseen part of the restoration. Therefore, observation of marginal leakage is not a viable measure to predict restoration failures, especially when visible margins are tightly bound to sound tooth structures. As shown in Figure 5, adhesive interfaces at the tooth surfaces, which were the observation points in conventional leakage tests, were minimally affected even after aging simulation. Instead, gap development mostly occurred deep inside the cavities (Figure 4).

In previous micro-CT studies of the marginal and internal adaptation of CAD/CAM intracoronal restorations, the gap values equivalent to cement thickness was used as the outcome measures for experimental variables.[3,9,10,14,23] We focused on spatial defects that were initially produced and gradually progressed not only at the adhesive interfaces but also within the cement layer. So, silver nitrate dye was selected to distinguish the penetrant occupied spaces within a multigray-scaled component because current resin luting cements are variously comprised of monomers and fillers of dissimilar radiopacities. We evaluated silver nitrate penetration into all vacancies

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that represented the structural defects potentiating fatigue-based failures. The quantitative comparisons using 3D reconstruction of selected images clearly showed the changes induced from thermal and mechanical impacts.

As in other studies evaluating the efficacy of the margin elevation of CAD/CAM MOD inlays, we prepared standardized sizes of MOD cavities. Although the natural human molars used in this study provided the highest clinical relevance among other alternatives, the anatomical configuration of the remaining tooth structures and histophysiology of dentin substrates differed among specimens, which was attributed to a large variation of the outcome values. Moreover, as demonstrated in a study comparing the internal fit between pressed versus milled ceramic inlays,[22] CAD/CAM inlays are vulnerable to imperfect preparation geometry and provide larger compensating clearance in the interfaces through milling processes. The interfacial gap may be more accentuated in a long and narrow configuration such as deep proximal boxes. Our study also showed that Group NE revealed larger gap values with higher variances than Group E. Considering interspecimen variabilities, we performed paired tests to compare both proximal boxes within the same specimen, and simplified parameters were put into the analyses (margin elevation versus none, and before versus after cycling). Additional approaches would be needed to improve the current experimental settings. For instance, an increase in sample size would make it possible to incorporate more variables to determine the optimal clinical technique to minimize interfacial disintegration of CAD/CAM ceramic inlays. Also, 3D printing of tooth models may enable researchers to standardize experimental protocols for consideration in future studies.

CONCLUSION

Based on the results of this study, deep margin elevation with RMGI can be an adjunct technique to decrease interfacial gap formation in CAD/CAM lithium disilicate inlays. Margin elevation decreased the initial gap formation and reduced the gap increment after thermomechanical cycling. The interfacial disintegration mainly occurred in the deep areas of proximal cavities, while surface margins remained integrated through the aging processes.

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Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Impact of Resin Composite Viscosity and Fill-technique on Internal Gap in Class I Restorations: An OCT Evaluation

KR Kantovitz • LL Cabral • NR Carlos • AZ de Freitas • DC Peruzzo • FMG Franca
FLB do Amaral • RT Basting • RM Puppin-Rontani

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Clinical Relevance

Although bulk-fill, resin-based composites are attractive for direct posterior Class I restorations, conventional resin-based composites with incremental-fill technique resulted in better internal adaptation, even after being exposed to thermal fatigue.

SUMMARY

The aim of this *in vitro* study was to quantitatively evaluate the internal gap of resin composites of high- and low-viscosity used in single- and incremental-fill techniques in Class I cavities exposed to thermal cycling (TC) using optical coherence tomography (OCT). Cavities of 4-mm depth and 3-mm diameter were prepared in 36 third molars randomly distributed into four groups, according to viscosity of restorative resin-based composite (high or low viscosity, all from 3M Oral Care) and technique application (bulk or incremental fill)

[*]Kamila Rosamilia Kantovitz, DDS, MS, PhD, Faculdade São Leopoldo Mandic, Dental Material Area Campinas, SP, Brazil. State University of Campinas (UNICAMP), Piracicaba Dental School, Department of Pediatric Dentistry, Piracicaba, SP, Brazil

Lais Lemos Cabral, DDS, MS, Faculdade São Leopoldo Mandic, Dental Material Area Campinas, SP, Brazil. University Center Tiradentes (UNIT), Restorative Dentistry Area, Maceió, AL, Brazil

Natalia Russo Carlos, DDS, MS, PhD student, Faculdade São Leopoldo Mandic, Dental Material Area Campinas, SP, Brazil

Anderson Zanardi de Freitas, PhD, Nuclear and Energy Research Institute, IPEN-CNEN/SP, Department of Center of Lasers and Applications, Sáo Paulo, SP, Brazil

Daiane Cristina Peruzzo, DDS, MS, PhD, Faculdade São Leopoldo Mandic, Periodontics Area, Campinas, SP, Brazil

Fabiana Mantovani Gomes Franca, DDS, MS, PhD, Faculdade São Leopoldo Mandic, Restorative Dentistry Area, Campinas, SP, Brazil

Flavia Lucisano Botelho do Amaral, DDS, MS, PhD, Faculdade São Leopoldo Mandic, Restorative Dentistry Area, Campinas, SP, Brazil

Roberta Tarkany Basting, DDS, MS, PhD, Faculdade São Leopoldo Mandic, Restorative Dentistry Area, Campinas, SP, Brazil

Regina Maria Puppin-Rontani, DDS, MS, PhD, State University of Campinas (UNICAMP), Piracicaba Dental School, Department of Pediatric Dentistry, Piracicaba, SP, Brazil

[*]Corresponding author: Faculdade São Leopoldo Mandic, Dental Research Center, Dental Material Area Campinas, SP, Brazil; Rua José Rocha Junqueira, 13 - 13045-755, Campinas, SP, Brasil; e-mail: kamilark@yahoo.com.br; kamila.kantovitz@slmandic.edu.br

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used (n=9): RC, high-viscosity, incremental-fill, resin-based composite (Filtek Z350 XT Universal Restorative); BF, high-viscosity, bulk-fill, resin-based composite (Filtek One Bulk Fill); LRC, low-viscosity, incremental-fill, resin-based composite (Filtek Z350 XT Flowable Universal Restorative); and LBF, low-viscosity, bulk-fill, resin-based composite (Filtek Flowable Restorative). Single Bond Universal Adhesive system (3M Oral Care) was used in all the experimental groups. The incremental-fill technique was used for RC and LRC groups (2-mm increments), and a single-layer technique was used for BF and LBF groups, as recommended by the manufacturer. The internal adaptation of the resin at all dentin walls was evaluated before and after TC (5000 cycles between 5°C and 55°C) using OCT images. Five images of each restored tooth were obtained. Images were analyzed using ImageJ software that measured the entire length of the gaps at the dentin–restoration interface. The length of gaps (μm) was analyzed using two-way repeated measures ANOVA and the Tukey tests (α=0.05). There was a significant interaction between material types and TC (p=0.006), and a significant difference among all material types (p<0.0001), before and after TC (p<0.0001). Increased internal gaps at the dentin–restoration interface were noticed after TC for all groups. RC presented the lowest value of internal gap before and after TC, while LBF showed the highest values of internal gap after TC. In conclusion, TC negatively affected the integrity of internal gap, whereas high-viscosity, incremental-fill, resin-based composite presented better performance in terms of internal adaptation than low-viscosity, bulk-fill materials in Class I cavities.

INTRODUCTION

Resin-based composites are the primary choice for direct restorations on posterior and anterior teeth, as their technological development led to improved physical properties and greater restoration longevity.[1] Although significant progress has been made towards the use of resin-based composite restorations, limitations have been reported leading to clinically relevant problems as recurrent caries and restoration fractures.[2] Furthermore, resin-based composite polymerization shrinkage stress may cause cusp deflection, postoperative sensitivity, and marginal and internal gaps at the dentin–resin-based composite bonding interface that lead to potential development of caries lesions around the restoration.[3-6] Several factors, including cavity preparation, operative technique, and material properties have been described to be associated with internal adaptation of resin-based composite restorations,[3,7,8] and their impact has been suggested to be strongly dependent on cavity size and configuration (C-factor), filler content in resin-based composite, formulation of organic matrix, elastic modulus, viscosity, and bond strength of resin-based composite materials to the walls of the cavity preparation.[3,7,9-12] Clinical strategies have been proposed to reduce polymerization stress, including the use of incremental-fill techniques, or modifications of the light-activation protocol. However, they are time consuming and technically demanding.[13,14]

Bulk-fill, resin-based composites were originally developed to reduce clinical time without affecting light-induced conversion rate and polymerization shrinkage stress on the adhesive interface.[15] In addition, bulk-fill, resin-based composites provide low elastic modulus.[16,17] Most of them have increased translucency to create deeper light penetration and also incorporate additional photoinitiators.[17] Compared to incremental-fill, single-fill (bulk) resin-based composites display up to 60% reduction of polymerization stress.[12] However, effective polymerization of resin-based composite materials in deeper layers remains controversial.[18] Inefficient polymerization associated with thermal and mechanical stresses may result in cracks, marginal leakage, and internal gaps ultimately causing decrease in restoration performance.[8] In this context, viscoelastic flow behavior and reaction kinetics have been shown to play a key role affecting polymerization shrinkage stress.[9,13,19-21] Contradictory studies have been reported on the potential benefit of using low-viscosity, resin-based composite as an intermediate layer to act as a stress-absorbing layer to relieve the polymerization shrinkage stress at the tooth–resin-based composite bonding interface, and reduce microleakage and internal gaps.[11,21-26]

To predict resin-based composite restoration performance inside a tooth cavity, *in vitro* studies including thermal cycling (TC) and optical coherence tomography (OCT) have been proposed. TC simulates oral environment stress promoting temperature changes that lead to deleterious impact to the tooth–resin-based composite restoration bonding interface,[27,28] whereas OCT is a well-established nondestructive method used to assess internal adaptation of a given restorative material without specimen cross-sectioning.[4,6,29,30] OCT is a method similar to ultrasound, in the sense that the backscattered light from the internal tissue structures contains the information to be analyzed. The OCT technique is based on interferometry using

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a broadband light source. This interferometer is composed by two arms—the reference and the sample arms; the broadband light source is split between the two arms. The light that comes back from the reference arm and the sample arm is combined, giving rise to an interference pattern that depends on the position of the reference arm; knowing the position of that arm, it is possible to determine which depth of the sample the light comes from in that incident point. Making a lateral scan in the sample, it is possible to generate two-dimensional or three-dimensional (2D or 3D) images.[6,24,29,30] Although a number of studies have evaluated the internal adaptation of bulk-fill, resin-based composite restorations, very few have assessed the effect of TC on the internal gaps of these materials in Class I and II cavities.[5,6,31,32] Therefore, the aim of this laboratory study was to quantitatively evaluate the internal gaps of high- and low-viscosity, bulk- and incremental-fill, resin-based composite materials exposed to TC in Class I cavities, using the OCT approach. The null hypothesis was that there is no difference in the presence of internal gaps in Class I direct restorations performed with different resin-based composite material viscosities combined with the application technique and submitted to restoration aging (TC fatigue).

METHODS & MATERIALS

Experimental Design

This was a simple, parallel, randomized study. The factors in the study were: 1) Types of resin-based composite materials combined with different techniques (high and low viscosity in single or incremental fills); and 2) Thermal cycling (before and after TC). Thirty-six sound human third molars were randomly divided into four experimental groups (n=9/group). Sample size was defined based on a pilot study to obtain statistical power of 0.8. Restoration internal gap was determined (μm) before and after TC by OCT, and the results were presented as the internal gap of restorations in resin-based composites before and after TC—the variation of the internal gap (Δ Gap) and the proportional difference between before and after TC (%). Figure 1 illustrates a schematic of workflow used for data collection.

Selection of teeth

All teeth were examined under 40× magnification (Eikonal Equip, model EK3ST, São Paulo, SP, Brazil) to exclude those with enamel defects or dental deformities. Their roots were removed 2 mm below the cementoenamel junction using a double-face diamond

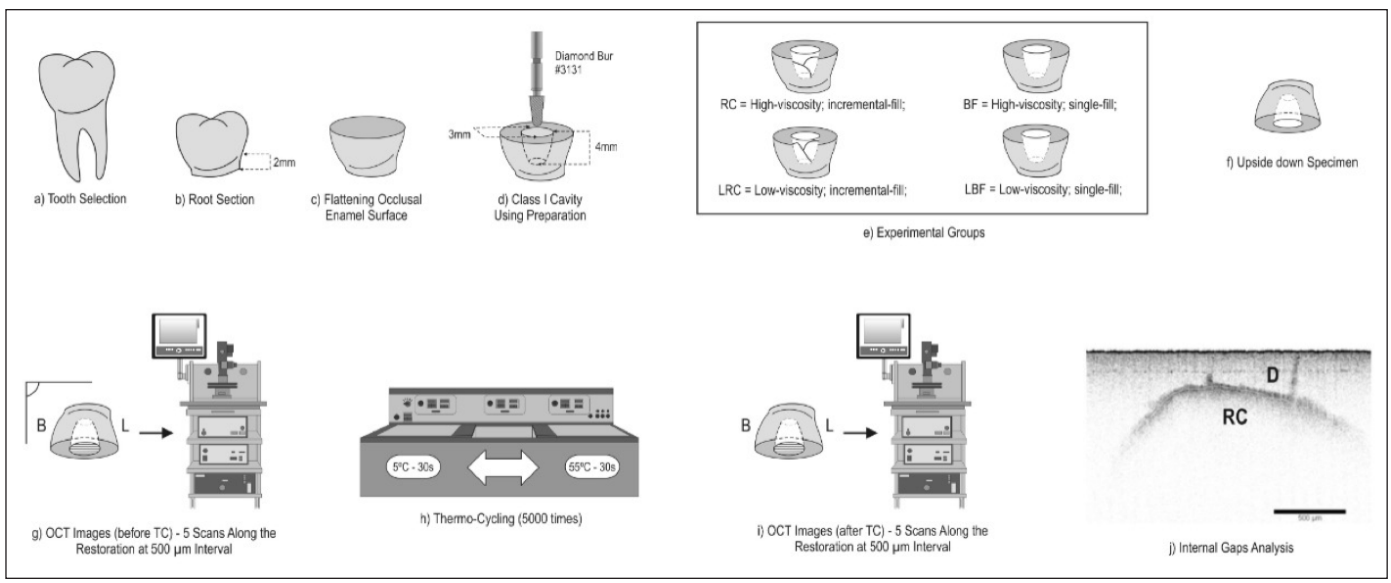

Figure 1. *Representative schematic illustration of the methodological approach for measuring percentage (%) internal adaptation of resin composites: (a) Tooth selection; (b) root section; (c) flattening occlusal enamel surface; (d) Class I cavity preparation (3-mm deep × 4-mm deep); (e) application of resin composites (RC—high viscosity, incremental fill; BF—high viscosity, incremental fill; LRC—low viscosity, incremental fill; LBF—low viscosity, single fill); (f) given the imaging depth limitation of OCT (Model OCS930RS), the images were taken with specimens placed upside down in order to evaluate the interface of the cavity floor; (g) OCT image before TC (thermal-cycling) at 500-μm interval; (h) thermal cycling (5000 times of 30 seconds in each bath of 5oC and 55oC water, with an interval of 30 seconds in a 37oC bath); (i) OCT image after TC (thermal cycling) at 500-μm interval; (j) analysis of interval gap percentage (%) using ImageJ program. The variations of internal dentin gap percentage were calculated as follows: D%Gap = [(%G2–%G1) × 100]/ %G2. G1, dentin gap percentage before TC (Baseline) and G2, dentin gap percentage after TC.*

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saw disk and discarded (KG Sorensen; São Paulo, SP, Brazil) (Figure 1a,b).

Class I Cavity Preparation

Each tooth was fixed in polyvinyl tubes (Amanco–Mexichem Brazil, Suape, PE, Brazil) using silicone (Express XT, 3M Oral Care, Sumaré, SP, Brazil). Occlusal enamel surfaces (cusps) were flattened on a water-cooled mechanical grinding machine (Aropol 2V, Arotec Indústria e Comércio, São Paulo, SP, Brazil) using 80-grit sandpaper (Buehler, Lake Bluff, IL, USA). Standardized Class I cavities were prepared at the center of the occlusal surface (4-mm depth and 3-mm diameter) in dentin. Care was taken not to expose the pulp chamber. The cavity preparation machine (Federal University of Uberlândia, MG, Brazil) was used with a high-rotation turbine (Kavo Dental Excellence, Joinville, SC, Brazil) using diamond bur #3131 (Microdont, São Paulo, SP, Brazil) under water cooling (Figure 1).[33] Each bur was replaced after the preparation of five cavities. To prepare teeth for OCT analysis, the root portion of each tooth was flattened to within 0.1-mm of the pulp chamber with 320-grit sandpaper (3M Oral Care) (Figure 1c,d). A millimeter caliper (Golgran, São Caetano do Sul, SP, Brazil) was used to measure the depth and thickness of the cavities. Subsequently, they were randomly distributed into four groups according to resin-based composite material (high and low viscosity) and technique application (Figure 1).

Restorative Procedure

Enamel was etched with 37% phosphoric acid for 30 seconds (Condac 37, FGM Dental Products, Joinville, SC, Brazil) and then rinsed with water for 30 seconds. A moist dentin surface was maintained by using an absorbent paper pellet. Next, cavities were bonded using a universal adhesive system (Single Bond Universal, 3M Oral Care) to improve marginal sealing.[34] The adhesive system was applied by rubbing the internal area of the cavity for 20 s with a fully saturated microbrush (FGM Dental Products). Subsequently, a gentle air spray was applied for 5 seconds to evaporate the solvent, and light cure was done for 10 seconds. Both, the adhesive system and resin-based composites were photoactivated using a light-emitting diode curing light at 1000 mW/cm^2 intensity, set up in a standard power, with 9.6 mm lens diameter, wavelength of 395-480 nm, and kept plugged to an electrical outlet (VALO, Ultradent Products, South Jordan, UT, USA). For all restorations, the curing light tip was fixed perpendicularly to the occlusal cavity at the cavosurface margins to ensure that all layers of the restoration were reached by the curing light in a standard way for all experimental groups. Light-curing times were adjusted according to the manufacturer's instructions, as described in Table 1, and restorations were performed by the same operator to control for technical bias.

Filtek Z350 XT Universal Restorative high-viscosity and Filtek Z350 XT Universal Restorative flowable low-viscosity, resin-based composites (3M Oral Care) were inserted with a 2 mm oblique incremental technique. While, Filtek One Bulk Fill (high-viscosity) and Filtek Bulk Fill low-viscosity, resin-based composites (3M Oral Care) were inserted into the cavity in a 4-mm single-layer increment. Careful deposition of increments was taken to avoid interfacial gaps and porosity between layers. Resin-based composites were light cured using a previously describe methodology that is described in Table 1. Finishing and polishing were performed using a sequence of medium, fine, and superfine aluminum-oxide abrasive disks (Sof-Lex Pop-on, *3M Oral Care*) for 15 seconds each., and teeth were stored for 24 hours at 37°C in a humid environment (Figure 1e).

Optical Coherence Tomography (OCT)

The analysis of internal dentin/restoration gap in the cavity floor was performed by OCT (Thorlabs, Inc., Model OCS930RS, Newton, NJ, USA), operating in a 930 nm with 6.0 μm resolution in air. A silicone specimen holder (Speedex, Vigodent, Rio de Janeiro, RJ, Brazil) was fabricated for each tooth to individually fix it to the OCT worktable, and allow identical assessment of each tooth before and after TC. Next, transverse 2D images were obtained by scanning the occlusal surface in the mesiodistal direction over the restoration, and five images were obtained every 500 μm (Figure 1f,g,i), as previously described.[4]

Thermal Cycling (TC)

After baseline OCT analysis of internal gap, all teeth were subjected to TC for 5000 cycles (30 seconds in each bath of 5°C and 55°C water, with an interval of 30 seconds in a 37°C bath) in a TC simulator machine (TCMD-3, ElQuip, São Carlos, SP, Brazil) (Figure 1h), which corresponded to approximately 6 months of *in vivo* clinical service.[27,28] Then, internal gap analysis was carried out again, using the same parameters and locations as the baseline, to obtain gap percentage.[4]

Internal Gap Percentage Calculation

Images were quantitatively analyzed using ImageJ software (ImageJ 1.45, NIH, Bethesda, Maryland, MD, USA) (Figure 1j). The dentin internal gap was linearly measured along the interface of the dentin–resin-based composite restoration. The internal gap was defined as any space between the dentin and restoration. First, the total length of the interface between the tooth structure

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Table 1: *Material Type and Classification, Composition, Protocol, Manufacturer, and Batch Number Used in this Study*

Classification	Material/ Abbreviation	Composition and (Shade)[a]	Filler Composition Filler Amount (wt/vol.%)[a]	Protocol[b]	Manufacturer/ Batch #
Phosphoric acid	Condac 37	37% phosphoric acid, thickener, dye and deionized water	—	a,b	FGM Dental Products, Joinville, SC, Brazil/ 20418
Adhesive system	Single Bond Universal	Bis-GMA, Ethanol, Water, Camphorquinone, Dimethylbenzocaine, Polyalkenoic acid copolymer, Photoinitiators	Silica	a,b,c	3M Oral Care, Sumaré, SP, Brazil/ 645026
Incremental oblique layered, resin-based composite: High viscosity	Filtek Z350 XT/RC	Silanized Ceramic, Bis-GMA, Bis-EMA, UDMA, TEGDMA, Zirconium, Polyethylene Glycol (A2 body)	Silica (66.3 vol%)	a,b,c,d	3M Oral Care, Sumaré, SP, Brazil/ 646748
Incremental oblique layered, resin-based composite: Low viscosity	Filtek Z350 XT Flow/LRC	Silanized Ceramic, BisGMA, Bis-EMA, TEGDMA, EDMAB, YbF, Polymer, Benzotriazole, Diphenyliodonium (A2)	Silica (46 vol%)	a,b,c,d	3M Oral Care, Sumaré, SP, Brazil/ 838190
Bulk-fill, single-layer, resin-based composite: High viscosity	Filtek One Bulk Fill/BF	Silanized Ceramic, AUDMA, UDMA, DDDMA, YbF3, Zirconium, Water (A2)	Silica (58.4 vol%)	a,b,c,d	3M Oral Care, Sumaré, SP, Brazil/ 685666
Bulk-fill, single-layer, resin-based composite: Low viscosity	Filtek Bulk Fill Flow/LBF	Silanized Ceramic, Bis-GMA, Bis-EMA-6, UDMA, YbF, Benzotriazole, TEGDMA (A2)	Silica (42.5 vol%)	a,b,c,d	3M Oral Care, Sumaré, SP, Brazil/ 913202

[a]*Information provided by the manufacturer; Bis-GMA, bisphenol A-glycidyl dimethacrylate; Bis-EMA, ethoxylated bisphenol-A dimethacrylate; UDMA, Urethane dimethacrylate; TEGDMA, triethylene glycol dimethacrylate; EDMAB, Amine compound ethyl-4-(dimethylamino) benzoate; AUDMA, aromatic urethane dimethacrylate; DDDMA, dodecanediol dimethacrylate;*

[b]*Application Protocol: (a) Selective acid etching only to the enamel surface for 30 seconds; (b) washing for 30 seconds and drying the cavity with an absorbent paper pellet; (c) applying the self-etch function of the Single Bond Universal Adhesive system to the prepared tooth and rubbing it in for 20 seconds, gentle air spray for 5 seconds to evaporate the solvent, and light cure for 10 seconds. (d) Insertion of the restorative composite according to the manufacturer's guidelines (incremental oblique layer or single layer).*

(dentin) and the restoration was measured. Then, the percentage of dentin internal gap was calculated as follows: 1. Dentin gap percentage before TC (Baseline): $\%G_1 = (ld/Ld) \times 100$, where *Ld*=Total Dentin Internal Length and *ld*=Dentin Internal Gap Length; 2. Dentin gap percentage after TC: $\%G_2=(ld/Ld) \times 100$; 3. Dentin internal gap percentage: $\%Gap=\%G_{2-}\%G_1$; 4. The variation of internal dentin gap percentage (D%Gap): $D\%Gap=(\%Gap \times 100)/\%G_2$.[4] Out of the total five measurements obtained every 500 μm per specimen, the least adapted region was used for statistical analysis, as previously reported.[4] The images obtained were always analyzed by a blind and calibrated operator.

Statistical Analysis

After exploratory data analysis of internal gap percentages by Shapiro–Wilk test and Levene tests ($p>0.05$), two-way repeated measures ANOVA

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(4x2) and Tukey tests were used to compare the internal gap for study factors—the types of resin-based composite materials combined with different techniques and the time (before and after TC). The data of variation of internal gap (in μm) were subjected to Kruskal–Wallis and Dunn tests. All tests employed a 0.05 level of statistical significance, and all statistical analyses were carried out with the statistical package SPSS 21 (Chicago, IL, USA).

RESULTS

There was a significant interaction between the factors: material types/techniques and TC (p=0.006) (Table 2). All material types/techniques showed an increase in internal gap compared to before TC (p<0.0001). The lowest values of internal gaps were observed for RC, while LBF presented the highest internal gap values. There were no statistically significant differences between BF and LRC internal gap values before and after TC (p<0.0001). Considering the variation of internal gap, LBF group showed the lowest variation of internal gap (10.5%) (p<0.05). While, the highest variation of internal gap was seen for the BF group (31.4%) (Table 2). There were no significant differences of internal gaps variation values between RC and LRC groups. Figure 2 represents the OCT images of the internal gap of experimental groups before and after thermal cycling.

DISCUSSION

The internal adaptation of Class I resin-based composite restorations was assessed instead of its marginal microleakage, as it is more challenging for the material to adapt to the deepest cavity's areas compared to other interface locations.[5,8,9,11,31] In this study, the methodology used to simulate restoration aging included 5000 cycles of TC to challenge thermal fatigue in the bonding dentin–restoration integration, as it has been reported to represent approximately 6 months of clinical service.[27,28] Others' laboratory studies have used long-term water storage to determine restoration bonding durability.[28,35,36] In this context, the null hypothesis, that thermal stress would not affect internal gaps amplitude of resin-based composite in Class I cavities, was rejected. The specimens submitted to TC had internal adaptation loss up to 31.4% (Table 2). These findings are in accordance with previous studies, which also found that TC significantly reduced material's bonding or internal adaptation.[28,31] Taken together, these findings strongly suggest that the thermal stress and the potential action of water on the restoration interface may be caused by temperature changes on the bonded materials. This is because there is a different between the expansion coefficients and thermal conductivity rates of the resin material and of the tooth.[37] Additionally, TC may produce interface degradation and debonding, and may change the stress or strain levels transferred to the interface, therefore, decreasing bond strength by hydrolytic degradation of interface components.[11,27,28]

Higher variation of internal gap in percentage was seen by high-viscosity, resin-based composite RC (25.6%) and BF (31.4%) groups, which suggests that TC jeopardized the dentin–restoration interface when cavities were filled with these material and technique application combinations, while low-viscosity resin composites—LRC (11.6%) and LBF (10.5%) groups—showed lower internal gap variation percentage (Table

Table 2: *Mean (Standard Deviation) of the Internal Gap of Restorations in Resin-based Composites/Techniques Before and After Thermal Cycling (TC), the Median (Minimum–Maximum) of Internal Gap Variation (D Gap), and the Percentage of Internal Gap Variation of the Resins/Techniques After TC*[a]

Experimental Groups	Internal Gap (μm)		Variation of Internal Gap (D Gap in μm)	Variation of Internal Gap in Percentage (D% Gap)
	Before TC	After TC		
RC	591.6 (98.9) Aa	795.4 (108.3) Ab	200.8 (80.2-347.3) AB	25.6
BF	859.4 (150.1) Ba	1252.2 (204.2) Bb	424.6 (14.6-687.3) A	31.4
LRC	1083.3 (154.1) BCa	1226.2 (139.0) Bb	142.9 (33.2-335.8) AB	11.6
LBF	1186.9 (244.2) Ca	1326.7 (135.9) Cb	139.7 (0.61-335.8) B	10.5

[a]*Different letters (uppercase letters vertically and lowercase horizontally) indicate significant differences by ANOVA two-way repeated measures and Tukey tests (internal gap data before and after TC). There was an interaction between material types and TC (p=0.006). Different uppercase letters vertically indicate significant diferences by Kruskal–Wallis and Dunn tests (variation of internal gap) (p<0.05). BF, Filtek One Bulk Fill; D%Gap = [(%G2 – %G1)×100)]/%G2; G1, Dentin Gap% before TC; G2, Dentin Gap% after TC; LBF, Filtek Bulk Fill Flow; LRC, Filtek Z350 XT; RC, Filtek Z350 XT Universal Restorative.*

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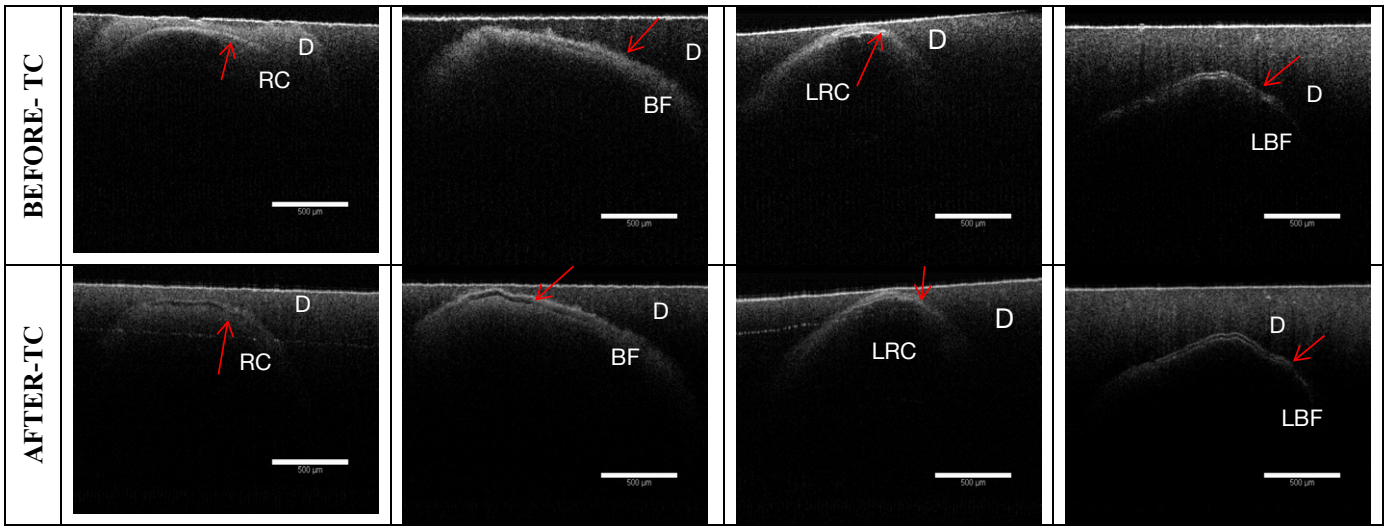

Figure 2. *OCT images of the internal gap (µm) of experimental groups before and after thermal cycling (TC). RC, Filtek Z350 XT Universal Restorative; BF, Filtek One Bulk Fill; LRC, Filtek Z350 XT Flow; LBF, Filtek Bulk Fill Flow; D, dentin. Red arrows indicate the internal gap in the resin-based composite–dentin interface observed by OCT.*

2). This might be attributed to the modified polymer chains of the low-viscosity resin composites, which are very flexible in the pregelation phase. This highly stress-relieving internal monomer might delay the gel point, which could allow more time to compensate for the shrinkage; consequently, polymerization shrinkage and internal gaps would be reduced.[16,38]

Considering the type of resin-based composite materials used in this study, the lowest values of internal gap were observed for RC (Table 2). The volume of material (2 mm increments)[39] applied to a high C-factor cavity (Class I), reducing the shrinkage generated by each increment, may explain the results obtained.[5,13,39] Thus, polymerization shrinkage stress is reduced, and the C-factor is minimized, reducing the incidence of internal gaps.[13] It is also reported that the use of incremental layers is one of the main methods to reduce polymerization stress, and that there is a statistically significant correlation between the percentage of internal interfacial gaps formed and the polymerization contraction.[13,14,31,40] However, finite element analyses demonstrated that increasing the number of increments and high postgel shrinkage and/or elastic modulus values caused higher stress in the remaining tooth structure and tooth–restoration interface.[41] Considering the viscosity of the resin-based composites that were used with the same application technique (incremental fill), the present study showed the LRC group had a greater content of triethylene glycol dimethacrylate (TEGDMA—a low-molecular-weight diluent monomer) than RC, which may have contributed to an increase in volume shrinkage and polymerization stress, jeopardizing the integrity of the resin-based composite–dentin interface.[13,40] The present result is supported by other studies reporting that an incremental-layer technique improved the adaptation of a composite to the cavity floor, as compared to a single-fill technique.[11,31,40]

The low-viscosity, single-layer, resin-based composite (LBF group) exhibited the highest values of internal gap, corroborating previous studies using Class I[3,21,42] or Class II cavities.[5] Typically, low-viscosity, resin-based composites have higher content of organic matrix, lower filler content, and consequently higher polymerization shrinkage than the conventional resin-based composites,[7,8,10,19,24] and, consequently, a higher percentage of interfacial gap formation.[21,40] The types and ratios of matrix monomers present in the composition can strongly influence the polymerization shrinkage.[10] The increase of *Bis*-GMA:TEGDMA ratios in composition of resin-based composite were shown to significantly decrease elastic modulus, most specifically for the filler contents above 50% that negatively compromised restoration internal adaptation.[10]

Besides the present study's affirmation that viscosity and technique application are factors that play a role in internal adaptation of resin-based composite in high C-factor (Class I) cavities, changes in monomer structure or chemistry and modification of polymerization dynamics have been regarded as contributing factors to influence the elastic modulus and polymerization and, consequently, to impact internal gaps.[13,16] In the current study, we aimed at assessing whether interfacial gaps, most likely formed due to polymerization shrinkage and stress during and soon after polymerization, were impacted by TC. Data analysis revealed that LRC

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exhibited similar internal gaps to BF, while BF (58.4 vol%) had a higher filler content by volume percentage than LRC (46 vol%). More highly filled resins have less matrix monomer available to contribute to the polymerization process, and need the inclusion of low-molecular-weight monomers (UDMA with 470 g/mol) to ensure a proper handling viscosity, thus increasing the shrinkage and internal gaps. On the other hand, the composition of resin composite also affects its elastic modulus. The elastic modulus of dimethacrylate polymers can be ranked as follows: TEGDMA<*Bis*-EMA<UDMA<*Bis*-GMA.[43] Therefore, low molecular-weight TEGDMA decreases the viscosity and contributes to higher polymerization shrinkage than BF, which contains high-molecular-weight monomers, such as UDMA and *Bis*-EMA.[43] It suggests that LRC and BF resin composites are comparable due to a balance of their flexural modulus and filler loading.[7] Another concern raised with the use of the single-layer technique is that the material may suffer from reduced polymerization at the deeper layer of the increment due to light attenuation.

OCT images differentiate the tissue optical properties, which include the effects of optical absorption and scattering.[4,6] It can successfully measure internal gaps between cavity floor (pulpal wall) and resin composite in Class I , II, and V cavities and provide nondestructive information on the dental performance.[4,6,30,44] Although OCT is a promising technology for clinical and laboratory applications, some limitations should be considered, including the depth limit for the acquisition of images to be analyzed, which depends on the specificity of the equipment.[29] Furthermore, when analyzing images, the internal adaptation was determined by a critical grayscale threshold of OCT images and the definition of the threshold level is somewhat subjective; therefore, the measurements of the imperfections do not represent absolute values. Future laboratory and clinical studies should be considered to further define the impact of aging on the internal adaptation and long-term success rate of resin-based composite restorations.

CONCLUSIONS

It can be concluded that:

- TC negatively influenced the internal gap of resins at the tooth–restoration interface in Class I restorations, regardless of the material used;
- The high-viscosity, incremental-fill, resin-based composite showed better performance in terms of internal adaptation than the low-viscosity, single-fill material with similar monomer composition in Class I restorations.

Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects' oversight as per Ethics and Research Committee of Faculdade São Leopoldo Mandic. The approval code for this study is # 97266217.0.1001.5374.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this manuscript.

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Limited Etching Time Increases Self-adhesive Resin Cement Adhesion to Enamel

MÁ Saravia-Rojas • G Nima • R Geng-Vivanco • GF Abuna • LY Tay • RM Puppin-Rontani

Clinical Relevance

Enamel acid etching should precede the use of self-adhesive resin cements to obtain better adhesion and, thus, increased restoration longevity.

SUMMARY

Aim: To evaluate the influence of different enamel etching times on the bond strength of two self-adhesive resin cements (RCs) with and without thermocycling (TMC).

Methods: One hundred twenty bovine teeth were used. Blocks of enamel (8×4×2 mm) were obtained, polished, and randomly divided into two groups, according to the RC used: MaxCem Elite or RelyX U200. Groups were subdivided into four groups (n=16), according to the etching time: Control (0 seconds), 5 seconds, 10 seconds, and 20 seconds. Three RC cylinders (1-mm diameter) were built on each enamel block. The specimens were submitted to two storage conditions: 24 hours in distilled water or TMC (5000 cycles/5°C-55°C). Afterward, the specimens were submitted to the shear bond strength (SBS) test. The failure modes and adhesive interfaces were analyzed by scanning electron microscopy (SEM) and confocal laser scanning microscopy (CLSM). Data were analyzed with three-way analysis of variance (ANOVA) and Tukey test (α=0.05).

Results: Etching increased the SBS for both the RCs, especially for the groups etched for 5 and 10 seconds. TMC affected negatively the SBS of the control groups ($p<0.05$). No resin tags were observed in control groups, and the formation of tags was time dependent.

Conclusion: The 10 seconds etching time was more effective in increasing the enamel–resin bond strength. TMC negatively affected bond strength in specimens without acid etching.

[*]Miguel Ángel Saravia-Rojas, associate professor, DDS, MSc, PhD, Faculty of Stomatology, Universidad Peruana Cayetano Heredia, Lima, Perú

Gabriel Nima, DDS, MSc, PhD, Department of Restorative Dentistry, Dental Materials Division, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

Rocio Geng-Vivanco, DDS, MSc, PhD student, Department of Dental Materials and Prosthodontics, Ribeirão Preto School of Dentistry, University of São Paulo, Ribeirão Preto, SP, Brazil

Gabriel Flores Abuna, DDS, MSc, PhD, post doctoral fellow, East Carolina University, Greenville, NC, USA

Lidia Yileng Tay, DDS, MSc, PhD, assistant professor, Faculty of Stomatology, Universidad Peruana Cayetano Heredia, Lima, Perú

Regina Maria Puppin-Rontani, DDS, MSc, PhD, full professor, Department of Pediatric Dentistry, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

[*]Corresponding author: Av Honorio Delgado 430, Urb Ingeniería, Lima, Perú; e-mail: miguel.saravia@upch.pe

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INTRODUCTION

The clinical success of indirect esthetic restorations depends on many factors, including appropriate material selection and use of a proper cementation technique.[1,2] The cementation is a sensitive and complex procedure that requires conditioning of restoration and tooth surfaces followed by the use of a resin cement (RC) as a luting agent.[3] RCs have the ability to bond the restorations with the tooth structure, guaranteeing durable and reliable bonding interfaces.[4]

However, the use of RCs requires multiple steps that might compromise their bonding effectiveness.[5,6] In order to simplify the number of clinical steps involved in the cementation procedure, self-adhesive RCs have been introduced.[3,6,7] Self-adhesive RCs combine features of the resin composites, dental cements, and self-etching adhesives. According to the manufacturers, self-adhesive RCs eliminate the need for pretreatments of the dental substrates.[2,8] Self-adhesive RCs contain acidic monomers (methacrylate phosphoric acids) that promote demineralization of the enamel and modification of the smear layer on the dentin surface.[3,6,7] Simultaneously, the conditioned surfaces are infiltrated by adhesive monomers, producing micromechanical retention; in parallel, chemical bonding occurs between the acidic monomers and on the tooth hydroxyapatite.[2,3,6,7] Thus, the necessity of the acid etching step was eliminated.[9]

Despite the advantages offered by self-adhesive RCs, the bond strength achieved by them on enamel is lower than those achieved by conventional RCs.[1,10] It is known that the acidic monomers contained in the self-adhesive RCs are not sufficiently strong to promote adequate conditioning of the enamel.[7] The weak acidity of the RCs might create a shallower etching pattern in the enamel that results in lower micromechanical retention.[1]

In order to improve the bond strength between the enamel and self-adhesive RCs, an additional pretreatment of the enamel with phosphoric acid has been proposed.[3] The increase of the bond strength in the enamel may prolong the clinical longevity of indirect restorations. Several studies have already demonstrated that acid etching with 37% phosphoric acid improves the adhesion between the enamel and self-adhesive RCs.[4,5,11,12] However, the most appropriate enamel etching time for self-adhesive RCs is still not clear.

On the other hand, no long-term data exists related to the stability of the adhesion between self-adhesive RCs and enamel treated with different etching times. In this respect, it is known that the adhesive interfaces could suffer degradation resulting in bonding failure. Thermocycling (TMC) is a widely used laboratory method to accelerate the degradation of bonding interfaces, producing dimensional changes in the substrates and affecting the adhesive interface.[13-15]

Therefore, the aim of this study was to evaluate the influence of phosphoric acid etching time on the bond strength between two self-adhesive RCs and enamel immediately and after TMC. The interfacial morphology was analyzed through Scanning Electron Microscopy (SEM) and Confocal Laser Scanning Microscopy (CLSM). The null hypotheses tested were that (1) there is no difference in the bond strength to enamel and in its morphology, regardless of the etching time; and (2) the TMC does not affect the bond strength stability to enamel.

MATERIALS AND METHODS

Tooth Preparation

One hundred twenty bovine incisors, without caries, fractures, or cracks were selected and stored in deionized water at 4°C. The bovine incisors were cut at the cementoenamel junction using a diamond saw (Isomet 1000, Buehler Ltd., Lake Bluff, IL, USA) under running water. The roots were discarded, and the pulp chambers were thoroughly cleaned and washed.

Blocks of 8 × 4 × 2 mm were obtained from the buccal surfaces of the crowns. The blocks were individually embedded in acrylic resin (VipiFlash, Pirassununga, SP, Brazil) using PVC molds with 12-mm diameter. The buccal surfaces were ground flat using 180-grit silicon carbide (SiC) sandpaper on a polishing machine (Aropol-E, Arotec Diagnostics, Cotia, SP, Brazil) under water cooling to achieve a flat enamel surface and then polished with 600-, 1200-, and 2000-grit SiC sandpaper. The final polishing was performed with a 1-μm diamond solution (MetaDi Supreme; Buehler Ltd., Lake Buff, IL, USA).[16] Immediately, the specimens were cleaned (Ultrasonic Cleaner USC 750; Unique Group, São Paulo, SP, Brazil) for 5 minutes. Afterward, the specimens were examined under 20× magnification (Leica MZ6; Leica Microsystems, Wetzlar, Germany), and the specimens with any enamel surface alteration were excluded and replaced. Finally, the specimens were stored in deionized water at 4°C.

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Table 1: *Composition and Batch Number of the Materials Used in This Study*

Material	Name Shade/Batch Number Manufacturer	Composition
Self-adhesive resin cement (RC)	MaxCem Elite Clear/5365521 Kerr Corporation, Orange, CA, USA	*Bis*-GMA, UDMA, GPDM, glyceroldimethacrylate, mono-, di-, and multimethacrylate co-monomers, barium aluminum borosilicate glass, fluoraluminum silicate glass, stabilizer, CQ, others.
	RelyX U200 Translucid/562548 3M Oral Care, St. Paul, MN, USA	Base: Methacrylate monomers containing phosphoric acid groups, methacrylate monomers, initiators, stabilizers, rheological additives. Catalyst: Methacrylate monomers, alkaline fillers, silanated fillers, initiator components, stabilizers, pigments, rheological additives. Zirconia/silica fillers
Phosphoric Acid (PA)	Etch-37 630001725 Bisco Inc, Schaumburg, IL, USA	Phosphoric Acid (37%), Benzalkonium chloride (1%)

Abbreviations: Bis-GMA, 2,2-bis[4-(2-hydroxy-3-methacryloyloxypropoxy)phenyl]propane; CQ, camphorquinone; GPDM, glycerol phosphate dimethacrylate; UDMA: urethane dimethacrylate.

Bonding Procedure

The specimens were randomly divided into two groups, according to the cement used: MaxCem Elite (Kerr Dental, California, USA) or RelyX U200 (3M Oral Care, MN, USA). Both the groups were subdivided into four subgroups according to the etching times: Control (0 seconds), 5 seconds, 10 seconds, and 20 seconds. Enamel surfaces were etched with 37% phosphoric acid (Etch-37, Bisco Dental Products, Schaumburg, IL, USA) for 5 seconds, 10 seconds, or 20 seconds, followed by water rinsing for 30 seconds and air-drying for 20 seconds.

Silicone molds (Oranwash L, Zhermack, Badia Polesine, RO, Italy) containing three cylinder-shaped orifices (2-mm high and 1-mm diameter) were placed onto the enamel surfaces. The cylindrical orifices were filled with the self-adhesive RCs, following the manufacturer's instructions and light cured for 20 seconds using a light-curing LED unit (BluePhase G2, Ivoclar Vivadent, Schaan, Liechtenstein) with radiant emittance of 1200 mW/cm^2. The silicone molds were sectioned and carefully removed, and the specimens were stored in deionized water at 37°C for 24 hours. Three cylinders were built on each enamel surface, totaling 48 cylinders per group. The composition of the materials used is in Table 1.

Artificial Aging Protocols

Each subgroup of specimens was further divided into two groups (n=8) according to the aging protocol: (i) specimens were stored for 24 hours in deionized water or (ii) specimens were thermocycled (MCT-2; MM Co., São Carlos, SP, Brazil) for 5000 cycles between 5°C and 55°C, with a 30 second dwell time and a 6 second transfer time.

Shear Bond Strength (SBS)

After the artificial aging conditions, the specimens were fixed in a universal testing machine (Instron 4411; Instron Corporation, Canton, MA, USA), and the SBS was performed using a steel wire (0.009" diameter) that was looped around each RC cylinder, then a load was applied at a crosshead speed of 1 mm/min until failure.

Fractographic Analysis

The specimens were sputter-coated with gold (Bal-Tec SCD 050, USA) and analyzed under a scanning electron microscope (SEM) (JSM-5600LV, JEOL Ltd, Tokyo, Japan). Representative photomicrographs were obtained from all the specimens. The failure patterns were classified as follows: adhesive failure (failure in the bonding interface), cohesive failure within enamel, cohesive failure within the RC, and mixed failure (combination of adhesive and cohesive failure).[17]

SEM Analysis of the Enamel–cement Interface

Sixteen blocks of enamel (8×4×2 mm) were cut and wet polished, as previously described. The blocks were randomly divided into two groups according to the RC used and subdivided into four groups according to the etching time (n=2). The blocks were treated as previously described. After etching, a layer of 1 mm of RC was applied on the treated enamel and light cured. Finally, the specimens were stored in deionized water for 24 hours at 37°C.

After this period of time, the specimens were longitudinally cut in half, and all of them were embedded in epoxy resin (EpoxiCure 2, Buehler Ltd, Lake Buff, IL, USA), using PVC tubes of 24-mm diameter and 10-mm higher. After that, the surfaces

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Table 2: *Enamel Shear Bond Strength (SBS) Means and Standard Deviation (in MPa) of the Resin Cements (RC) Following Different Etching Times and Storage Conditions*

Etching time	MaxCem Elite		RelyX U200	
	24 hours	Thermocycling (TMC)	24 hours	Thermocycling (TMC)
Control	10.95 ± 3.9 Ba	0 Ca*	12.01 ± 2.3 Ba	0 Ba*
5 seconds	14.97 ± 4.1 Ab	10.55 ± 3.5 Bb*	22.58 ± 2.6 Aa	22.04 ± 3.0 Aa
10 seconds	16.76 ± 5.8 Aa	18.81 ± 3.3 Aa	19.30 ± 4.6 Aa	21.57 ± 3.5 Aa
20 seconds	10.63 ± 2.8 Bb	12.92 ± 4.6 Bb	22.61 ± 3.2 Aa	23.33 ± 5.5 Aa

Different letters indicate significant difference. Upper case letters compare etching times within the same cement and storage condition. Lower case letters compare RCs within the same etching time and storage condition. Asterisk indicates significant difference among storage conditions within the same cement and etching time. ($p<0.05$)

were polished with abrasive paper discs from 400 to 1200-grit, the final polishing was done with 1-μm diamond solution (MetaDi Supreme; Buehler Ltd, Lake Buff, IL, USA) and a polish-cloth disc. Specimens were demineralized in 20% phosphoric acid for 10 seconds and submitted to deproteinization by immersion in 10% NaOCl for 10 minutes. Specimens were dehydrated in ascending ethanol series (20%, 30%, 50%, 70%, 90%, and 100% for 20 minutes per step) and immersed in hexamethyldisilazane (Electron Microscope Sciences, Fort Washington, PA, USA) for 10 minutes. After chemical dehydration, specimens were sputter-coated with gold (Desk II, Denton Vacuum Inc, NJ, USA) and examined under SEM at 1500× magnification (JSM-5600LV; Japan Electronics Optics Laboratory, Tokyo, Japan).

CLSM Analysis of the Etching Pattern

Eight enamel samples (8×4×2 mm) were flattened and polished, as previously described, and divided in four groups (n=2) according to each etching time. After etching, the samples were rinsed for 1 minute with deionized water and then let in ethanol 100% for 5 minutes in an ultrasonic bath. Finally, the samples were stored overnight in 0.5 wt% of sodium fluorescein to reveal the etching pattern.

After immersion, the samples were assessed using CLSM (Leica TCS SP5, Leica, Mannheim, Germany) with an Argon laser of 488 nm with a band pass filter of 490-540 nm in oil immersion objective (63×, 1.4 NA). Three images of each specimen were obtained and qualitatively analyzed as the enamel etching pattern.

CLSM Analysis of the Enamel–RC Interface—Two samples of each subgroup were used for CLSM analysis and were prepared following the same protocol used for the SEM microscopy. For this analysis, 1 wt% fluorescent rhodamine B was added to the RCs, before the bonding process. After light-curing, the specimens were stored in deionized water for 24 hours at 37 °C.

The samples were then cut in slices of 1-mm thickness using a precision cutting machine (Isomet 1000, Buehler Ltd, Lake Bluff, IL, USA) with a diamond saw to obtain three slides for each sample. The slices were cleaned (Ultrasonic Cleaner USC 750; Unique Group) in deionized water for 5 minutes to remove any debris. Then, the slices were examined using CLSM (Leica TCS SP5, Leica). A mixed helium–neon (He–Ne) gas laser was used as the light source at 543 nm wavelength. The images were recorded in fluorescent mode using an oil-immersed objective (63×, 1.4 NA). A representative area of each slice was scanned (11 sections of 2.5 μm each), and the adhesive cement tags were identified.

Statistical Analysis

Specimens that failed pretest or deboned spontaneously following the storage conditions were assumed as 0 MPa. Data of SBS were tested for normality and homogeneity of variances using Shapiro–Wilk and Levene Tests ($\alpha=0.05$), which indicated that the data set were normally distributed. Then, data were analyzed using three-way analysis of variance (ANOVA) and Tukey post hoc test ($\alpha=0.05$), using SPSS 23 Statistics software (IBM Inc., Chicago, IL, USA) for Mac operating system (OS).

RESULTS

Shear Bond Strength

The shear bond strength (SBS) values obtained in this study are presented in Table 2. Three-way ANOVA showed that the bond strength values were significantly influenced by the three factors: material, storage, and etching time ($p<0.001$); the double interactions material*etching time and storage*etching time were also significant ($p<0.001$). Tukey post hoc test revealed that MaxCem Elite showed the highest bond strength values when the

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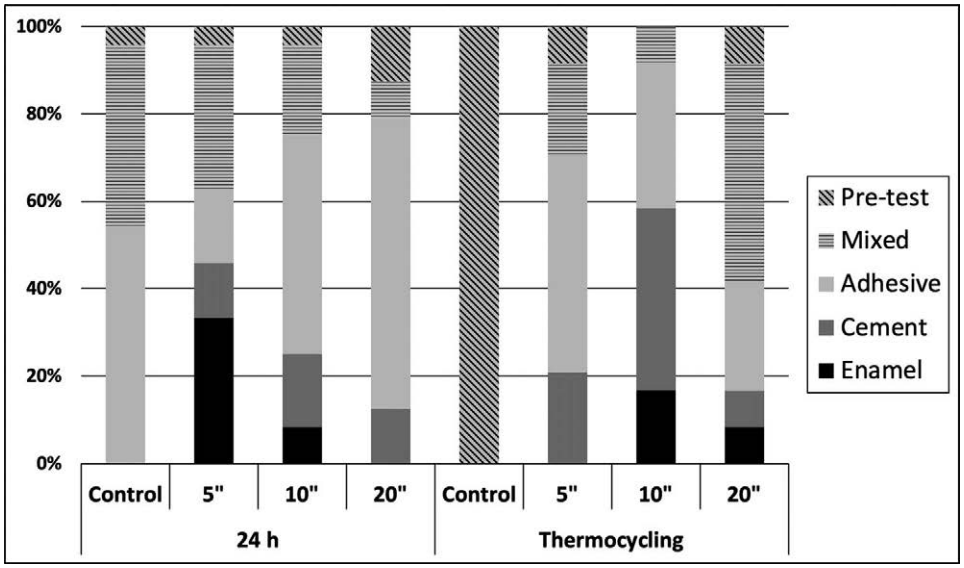

Figure 1. *Distribution of failure pattern mode for MaxCem Elite.*

enamel was etched for 10 seconds, and RelyX U200 showed the highest bond strength values when the enamel was etched regardless of the etching time used and the storage condition for both RCs. No statistically significant differences were found between storage conditions, with the exception of groups that were not treated with acid and MaxCem Elite etched for 5 seconds, in which a significant decrease in bond strength was observed after TMC compared with storage for 24 hours.

MaxCem Elite when bonded to enamel after 5-second etching time, dropped the SBS value significantly when thermocycled. However, when used with 10-second etching time, the SBS values increased even after TC. RelyX U200 SBS was not affected either by TMC or etching time. Both cements used without enamel etching were greatly affected by TMC, decreasing significantly the SBS values.

The failure mode percent distribution for the two RCs are summarized in Figures 1 and 2. Pretest failures were observed for all the groups with low incidence, with the exception of the control groups after TMC where all the specimens were lost. Specimens exhibiting pretest failure were counted as 0 MPa. Adhesive and mixed failures were observed in all groups for both the RCs, with the exception of the control groups that were submitted to TC. An increase in the cohesive failure types was observed in the groups treated with acid etching.

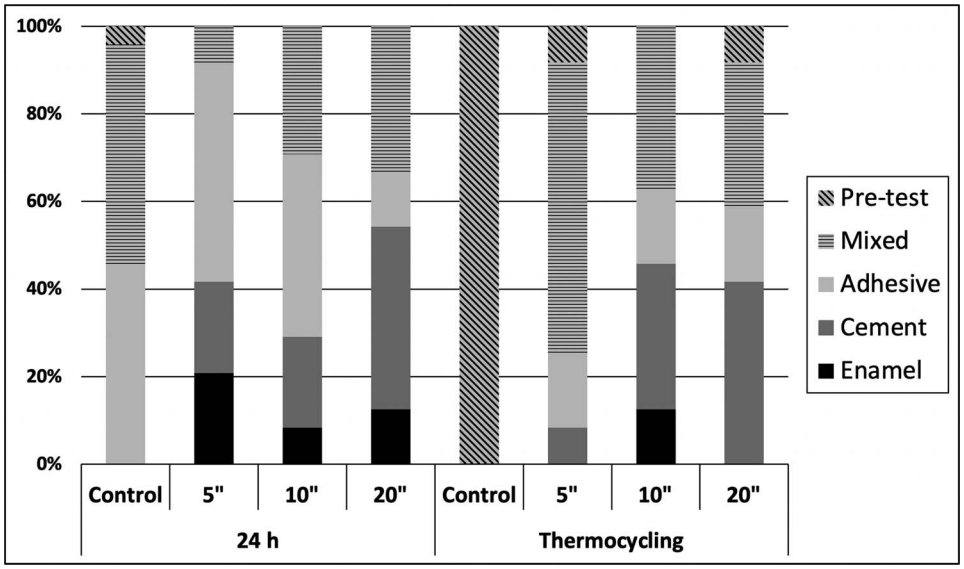

Figure 2. *Distribution of failure pattern mode for RelyX U200.*

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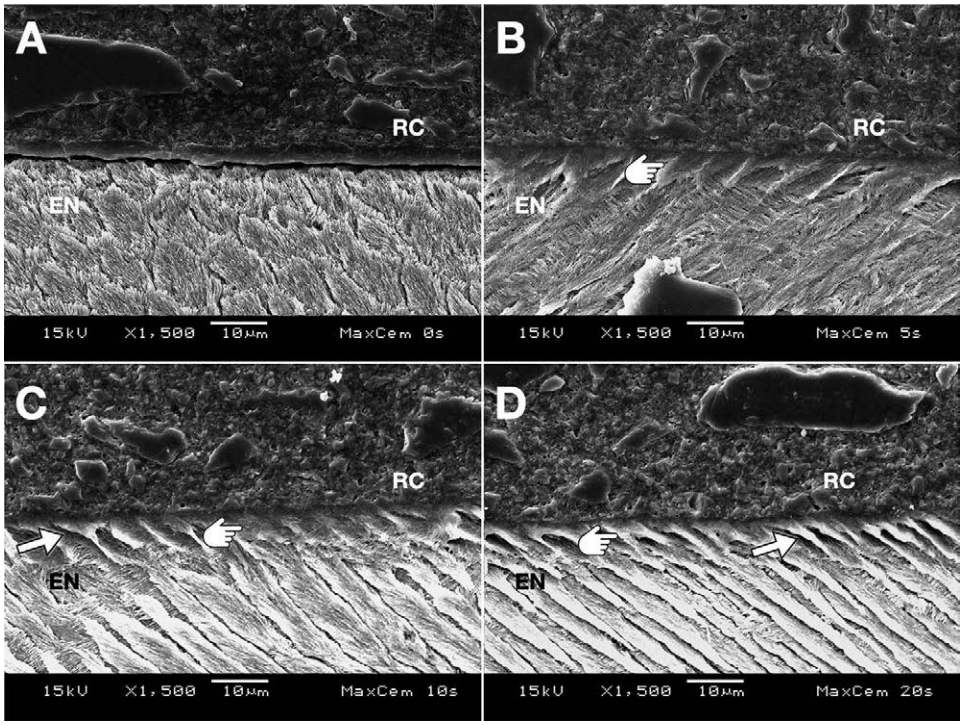

Figure 3. *Representative SEM micrographs of the RC–enamel interface with MaxCem Elite after 24 hours. Control group (A), PA for 5 seconds (B), PA for 10 seconds (C), and PA for 20 seconds (D). Resin tags are indicated with pointers. Empty spaces are indicated by white arrows. Abbreviations: RC, resin cement; EN, enamel. (1500× magnification).*

SEM Analysis of the Enamel–cement Interface

Representative images of the enamel–RC interfaces observed after 24 hours are illustrated in Figures 3 and 4. High magnification micrographs revealed that there was no interaction between the enamel and the RC, when it was treated following the manufacturer's instructions, with no enamel etching (Figure 3A and 4A). Figure 5 shows the etching acid patterns obtained on enamel, with no etching showing a smoother surface than 5- through 20-seconds enamel etching. The presence of gaps and

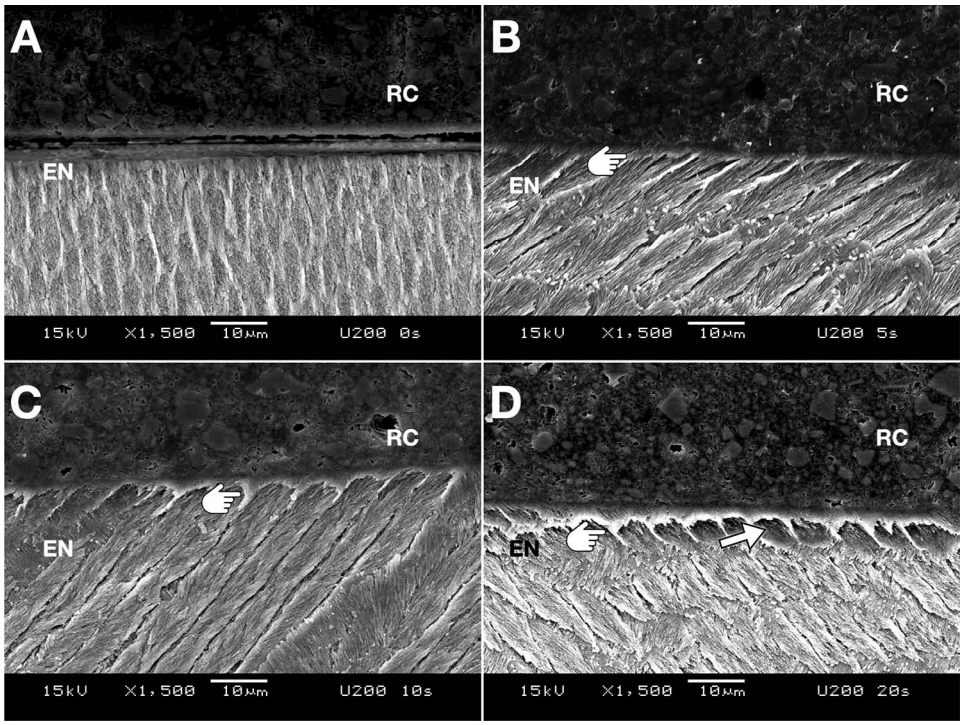

Figure 4. *Representative SEM micrographs of RCs–enamel interface with RelyX U200 after 24 hours. Control group (A), PA for 5 seconds (B), PA for 10 seconds (C), and PA for 20 seconds (D). Resin tags are indicated with pointers. Empty spaces are indicated by white arrows. Abbreviations: RC, resin cement; EN, enamel; PA, phosphoric acid. (1500× magnification).*

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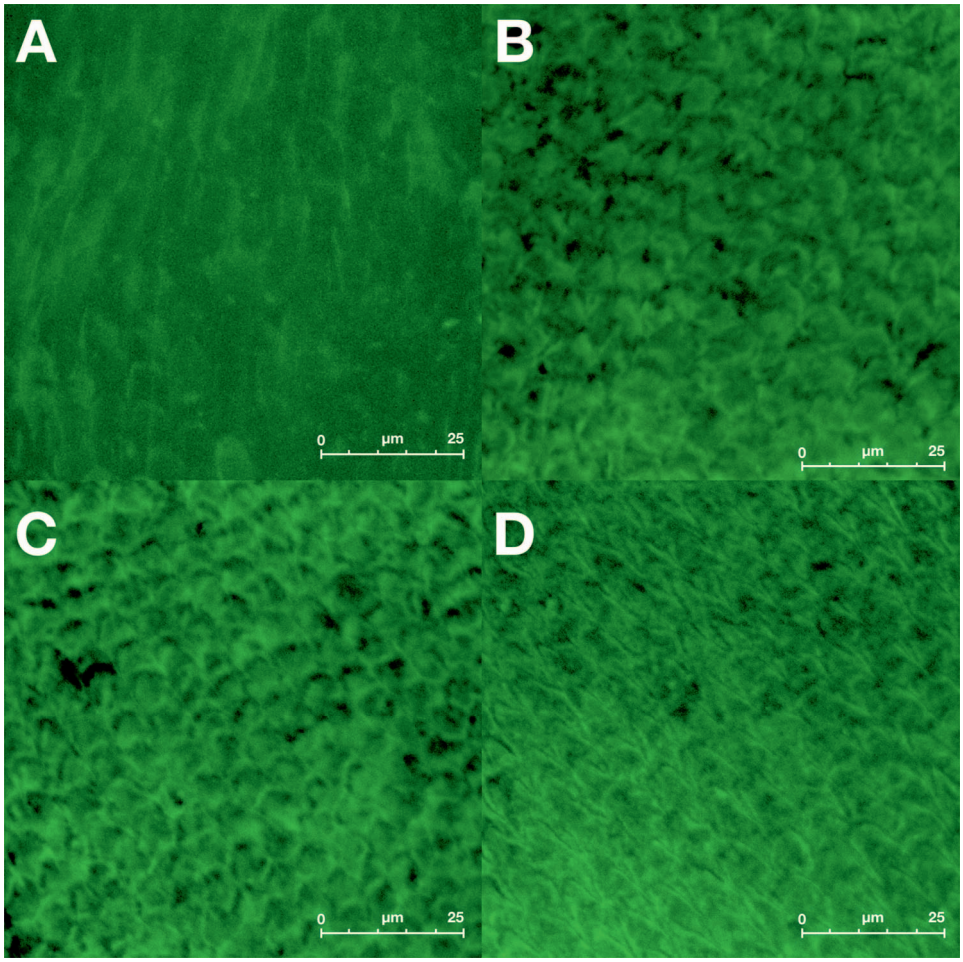

Figure 5. *Representative CLSM images of the enamel surface treated with phosphoric acid (37%) with different etching times (65× magnification). Control group (A), PA for 5 seconds (B), PA for 10 seconds (C), and PA for 20 seconds (D).*

the lack of continuity could have been the result of a very shallow interaction with the enamel (Figure 3A and 4A). When the enamel was etched with phosphoric acid, deeper resin penetration into enamel was observed with the presence of resin tags. The increase in the etching time resulted in deeper hybridization (Figures 3B-D and 4B-D). In the groups etched with phosphoric acid for 20 seconds, some spaces below the resin tags were observed (Figure 3D and 4D). Those spaces could probably be due to the lack of infiltration of the RC into the deeply demineralized enamel.

It is possible to observe differences in the filler size of the self-adhesive RCs. MaxCem Elite showed larger particles when compared with RelyX U200 (Figure 3 and 4).

CLSM Analysis

Representative images of the effects of the etching time with phosphoric acid on the enamel surface are shown in Figure 5. A smooth surface was observed in the untreated enamel (Figure 5A). When the enamel was etched with phosphoric acid, demineralized surfaces were observed (Figures 5B-D). A Type I etching pattern was observed in all the samples. The demineralization was deeper with the increase of the etching time.

Representative images of the enamel–RC interfaces after 24 hours are shown in Figures 6 and 7. No RC tags were detected in the untreated enamel (Figures 6A and 7A). When the enamel was etched with phosphoric acid, deeper resin penetration into enamel was observed, with the presence of resin tags. The increase in the etching time resulted in deeper infiltration with more resin tags (Figures 6B-D and 6B-D). Longer etching times generated greater and deeper tags.

DISCUSSION

We demonstrated the importance of time in enamel acid etching before the application of self-adhesive RC. The results show that enamel acid etching with phosphoric acid increased the bond strength of the self-adhesive RCs to the enamel. Additionally, it was

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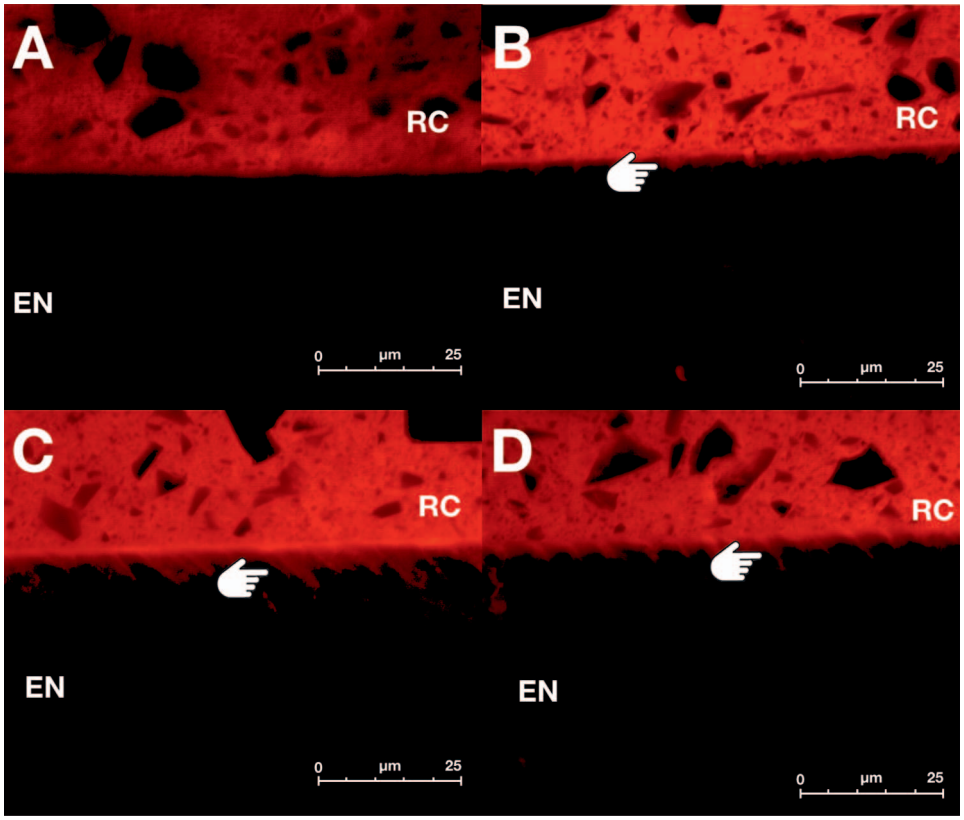

Figure 6. *Representative CLSM images of RCs–enamel interface with MaxCem Elite after 24 hours (65× magnification). Control group (A), PA for 5 seconds (B), PA for 10 seconds (C), and PA for 20 seconds (D). Resin tags are indicated with pointers.*

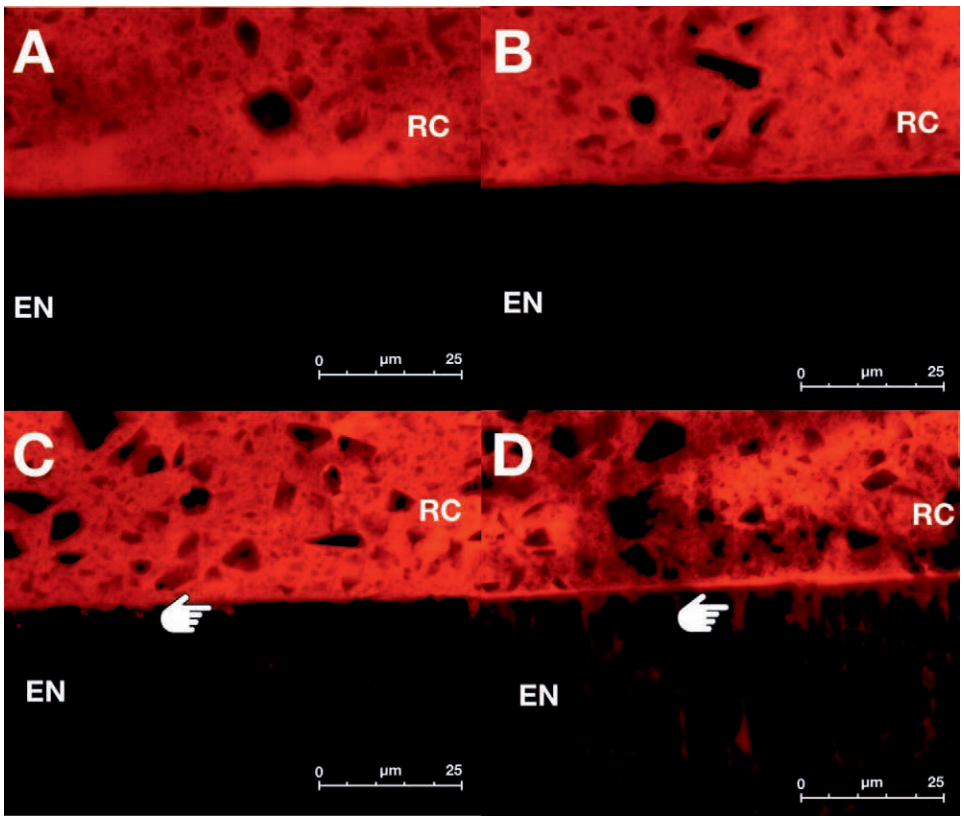

Figure 7. *Representative CLSM images of RCs–enamel interface with RelyX U200 after 24 hours (65× magnification). Control group (A), PA for 5 seconds (B), PA for 10 seconds (C), and PA for 20 seconds (D). Resin tags are indicated with pointers.*

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observed that TMC negatively affected the bond strength when the enamel was not etched.

This study used bovine enamel as a substitute of human enamel, because they have similar morphology, mineral composition, and physical properties. Bovine teeth are easy to obtain and present some advantages of having the possibility to use large flat surfaces without variable composition.[18-20]

The first null hypothesis stating there would be no difference in the bond strength to enamel and in its morphology, regardless of the etching time, was rejected. The results indicate that the use of phosphoric acid increases the bond strength values, demonstrating that the etching ability of the self-adhesive RCs is not efficient to condition the enamel surface. Several studies have reported significantly higher bond strength values between enamel and self-adhesive RCs, when the enamel was pre-etched with phosphoric acid.[1,4,5,7,10] When phosphoric acid comes into contact with the enamel, part of the hydroxyapatite crystals on the surface is dissolved. As a result, the enamel increases its wettability, facilitating the infiltration of the resin matrix.[4,21,22] The wettability is essential to enable the materials to spread across the entire surface.[22] Additionally, acid etching removes most of the contaminants from the enamel surface, exposing hydroxyl groups and turning the enamel into a hydrophilic surface,[22,23] similar to the hydrophilicity of the acidic monomers in self-adhesive RCs.[24] However, as phosphoric acid increases the wettability, the interaction among the enamel, the RCs, and the water produced during polymerization is better.[24,25]

Another effect produced by the acid etching is the increase of the surface for adhesion.[22,26] Phosphoric acid attacks the hydroxyapatite crystals, eroding them; as a consequence, a retentive and porous structure on the enamel surface is created, leading to an increase in its bonding area.[17,26,27] Since the enamel is a homogeneous substrate, this treatment creates an ideal surface for bonding, making the adhesion durable and reliable.[28] Thus, the hydrophobic monomers of the RCs may be able to penetrate into the porous structure created on the enamel, improving the micromechanical retention and the bond strength values.[7,10]

The morphology of the enamel changes as a consequence of the etching treatment. Figure 5 shows the effects on the enamel surface; the longer the acid application, the greater the demineralization produced on the enamel. Higher bond strength to the enamel was observed following by the acid etching. However, the increase in the bond strength was not proportional to the increase in the etching time. In this way, shorter etching times were more effective.[17] Similar results were found by Barkmeier and others using self-etch adhesives, where extending the etching time did not improve the performance of the adhesives.[29] Another study showed that the increase in the etching time did significantly increase the surface energy of the enamel.[23] The bond strength to enamel is related to the capacity of the monomers to penetrate into the enamel structure, rather than the length of the resin tags.[10] The longer the acid application, the greater the demineralization produced on the enamel, hindering deeper infiltration by the RC.

The demineralization produced by shorter etching times might be ideal for the viscosity of the RCs tested. It is possible to observe RCs tags throughout the cement–enamel interface for the etched enamel.[7] However, when it was etched for 20 seconds (Figures 3D and 4D), some spaces beneath the tags were observed. The high viscosity of the cement compared to the adhesive could have hampered the penetration of the cement into the microporosities created by the acid.[8] This observation could explain, in part, why shorter etching times resulted in higher bond strength. Another factor that probably favored the results was the pressure applied during the cementation process.[1,5,8] In the present study, the test design did not permit the application of pressure during the placement of the cement. The application of light-pressure might have helped the penetration of the cement into enamel.[1,8]

Regarding the composition of the self-adhesive RCs used in this study, the differences between them might have influenced the results. MaxCem Elite has glycerol phosphate dimethacrylate (GPDM) as an acidic monomer for the enamel etching,[8] and RelyX U200 has multifunctional phosphoric acid methacrylates that react with the hydroxyapatite in an aqueous solution.[30] The filler distribution and particle diameter also varied among the cements. MaxCem Elite is a cement with high filler load (72.3% by weight) with a particle diameter of 3.52 μm, different from RelyX U200 that has lower filler load (62.2% by weight) with particle diameter of 2.47 μm.[31] These differences can explain, in part, why MaxCem Elite showed lower bond strength values. Its larger particle size and lower organic content might make its penetration into the enamel porosities difficult, since these factors influence the viscosity of the self-adhesive RCs. However, viscosity

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was not measured in this study, and no information in this respect was obtained.

The second null hypothesis stating that the TMC would not affect the bond strength to enamel was also rejected. The TMC negatively affected the SBS of both RCs when applied following the manufacturer's instructions. In those groups, all the specimens had spontaneous failure after TC. The bond strength between the self-adhesive RCs and the enamel was not sufficient to resist the TMC stress. The combination of two factors might explain the results: (i) a poor infiltration of the cement into the enamel structure and (ii) the differences in the thermal conductivity and the coefficient of thermal expansion between the enamel and the self-adhesive RCs.[13,14,32] The influence of the poor penetration of the cement into the enamel has been broadly explained above, and it could be the result of the weak etching capacity of the acidic monomers contained in the self-adhesive RC and their high viscosity.

The ISO/TS 11405 considers that a TMC regimen composed of 500 cycles in water between 5°C and 55°C, with a dwell time of at least 20 seconds is an appropriate artificial aging test.[33] However, many studies demonstrated that 500 cycles were not sufficient to assay long-term bonding durability and did not influence bond strength.[15,34,35] Thus, in the present study, samples were submitted to 5000 thermal cycles.[14]

The differences in the thermal conductivity and the coefficient of thermal expansion between the enamel and the self-adhesive RCs might result in gap formation as a consequence of crack propagation along the bonded interface.[14,15] The TMC promotes the spread of gaps in the interface enamel–self-adhesive RC, resulting in a higher number of pretest failures.[14] The water and oral fluids can infiltrate through these newly formed gaps, leading to adhesive failures.[32]

Based on our results, an enamel etching time of 10 seconds is recommended prior to using self-adhesive RC. Dental practitioners should be careful to avoid extending etching to dentin. Several studies show that the dentin etching prior to cementation with self-adhesive RCs results in reduced bond strength values.[4,5,10]

The presence of other factors that were not evaluated in this study, such as variations in the enamel structure (enamel prisms and orientations), mineral content of the enamel, and buffer capacity; different acid concentrations or alternative acids,[3] water sorption and cement solubility,[36] and different composition of the RCs could also affect the adhesion between the enamel and self-adhesive RCs. Thus, further studies must focus on evaluating the influence of those factors on the bond strength to enamel.

CONCLUSION

Enamel etching improves the bond strength of the two self-adhesive RCs tested. However, there is a limit on the etching time, with 10 seconds suggested as an adequate time before the use of RCs, even after ageing. TMC negatively affected the bond strength when the enamel was not etched.

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Regulatory Statement

This study was performed after approval by the local ethics committee (Protocol: 66522) of Faculty of Stomatology, Universidad Peruana Cayetano Heredia.

Conflict of Interest

The authors of the present study certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in the present article.

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The Thickness and Opacity of Aesthetic Materials Influence the Restoration of Discolored Teeth

I Durães • A Cavalcanti • P Mathias

Clinical Relevance

Composite resin and/or ceramic veneer restorations show similar masking ability on discolored teeth, with varied opacities and thickness combinations within clinically relevant conditions.

SUMMARY

Objectives: This study aimed to evaluate the influence of thickness and opacity on the ability of composite resin and ceramic veneer restorations to mask discolored teeth.

Methods: Ninety veneers were made of lithium disilicate ceramic, shades BL1 and 0 (IPS e.max Press, Ivoclar Vivadent), and 60 were made of composite resin, shade BL-L (IPS Empress Direct, Ivoclar Vivadent). The veneers measured 4 mm in width x 4 mm in length and had a thickness of 0.7, 1.0, or 1.2 mm. One hundred and fifty human premolars were selected to obtain 150 dental fragments with the following dimensions: 4 mm x 4 mm x 3 mm (width x length x thickness). The fragments were discolored, submitted to color measurement and randomly assigned to 15 groups (n=10) according to the type and opacity of the restorative material (IPS e.max Press: high translucency [HT], low translucency [LT], and medium opacity [MO]; IPS Empress Direct: dentin and enamel) and thickness of the veneers (0.7, 1.0, and 1.2 mm). After cementation of the ceramic or composite resin veneers using a translucent resin cement (RelyX veneer, 3M), a final color measurement was taken from each specimen and the total color variation (ΔE) was calculated by subtracting the initial and the final color measurement. The final lightness (L*) of the restored dental fragments was also calculated.

Results: The highest ΔE values were observed for the LT and MO ceramic groups, followed by dentin composite resin. Regarding the different thicknesses of ceramic veneers, every 1.2-mm–thick group had higher values of ΔE, considering their respective opacities (p<0.05). The highest lightness values were found for the LT and MO ceramic veneers (thickness of 1.2 mm). Dentin-shade composite resins showed similar lightness values in all groups.

Iris Durães, MS, post-gradute student, PÓS Instituto de Ciências da Saude, Salvador, Brazil

Andrea Cavalcanti, MS, PhD, professor, Bahia School of Medicine and Public Health (EBMSP), Department of Oral Rehabilitation, Salvador, Brazil

*Paula Mathias, MS, PhD, professor, Federal University of Bahia, Department of Clinical Dentistry, Salvador, Brazil

*Corresponding author: Rua Araújo Pinha 62, Salvador, BA 40440-040, Brazil; email: pmathias@yahoo.com

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Conclusion: The best thickness/opacity combinations for masking discolored dental substrates were LT and MO ceramic veneers with 1.2-mm thickness. Dentin-shade composite resin veneers with a thickness of 0.7-1.0 mm showed good ability to mask discolored dental substrates.

INTRODUCTION

Chromatic changes in anterior teeth are frequent complaints of patients in clinical practice.[1] Depending on the etiology, discoloration may affect an individual tooth or a group of teeth, and treatment may range from bleaching of vital or non-vital teeth to more invasive procedures. When bleaching is not sufficient to change the chromatic characteristics of severely discolored teeth, dental practitioners can offer other procedures such as composite resin restorations, dental veneer restorations and all-ceramic crowns to their patients.[2-4]

In addition to the type of treatment, the characteristics of the chosen restorative material also influence its ability to mask a discolored tooth. Composite resin is a restorative material widely used for recovering an aesthetic smile. It is a versatile material whose optical characteristics permit harmonic reproduction of the tooth. Composite resins are also initially cost-effective, especially when compared to ceramics.[5] Although composite resins are widely used in clinical dental practice, studies evaluating their ability to mask discolored teeth are scarce. Another approach to vestibular surface restorations is the use of ceramic materials, such as laminate veneers. Ceramic materials are a restorative solution that balances functional and aesthetic needs of the anterior dentition with high durability and color stability.[6] However, when ceramic materials are used for masking discolored teeth, one or more of the following options may be taken into account: less translucent laminates, high-thickness restorative materials, and/or luting agents with high opacity.[7-11]

There is no consensus in the scientific literature regarding the required thickness of a restorative material to mask a discolored tooth.[12-15] Furthermore, few studies have compared the masking ability of composite resins and ceramic veneers on discolored teeth by varying thickness and opacity levels. Therefore, using the CIE L*a*b* system parameters (Commission Internationale de l'Eclairage), the present study aimed to evaluate the influence of the thickness and opacity of aesthetic restorative materials (composite resins and ceramic veneers) on restored discolored teeth.

METHODS AND MATERIALS

Layered pressed lithium disilicate ceramic was used as the ceramic system (IPS e.max Press, Ivoclar Vivadent, Schaan, Liechtenstein), BL1 shade for high translucency (HT) and low translucency (LT), and 0 shade for medium opacity (MO). The resin composite system consisted of IPS Empress Direct (Ivoclar Vivadent), BL-L shade with two levels of translucency (enamel and dentin shades). A list of the materials and their respective composition is depicted in Table 1.

One hundred and fifty laminates were prepared using the two restorative materials. The laminates measured 4 mm in width and 4 mm in length and had different thicknesses (0.7, 1, or 1.2 mm). The ceramic veneers had three different opacities (HT, LT, or MO), while the composite resin veneers had two different opacities (enamel or dentin shade), resulting in 90 ceramic and 60 composite resin restorations.

The ceramic specimens were obtained from previous wax mold samples, with a width x length of 4 mm x 4 mm and thickness of 0.7, 1, or 1.2 mm. After cooling

Table 1: *List of the Restorative Material Systems and Their Respective Composition*

Restorative Material	Composition[a]
IPS E.max Press (Ivoclar Vivadent)	Main component: SiO_2 Additional component: Li_2O, K_2O, MgO, ZnO, Al_2O_3, P_2O_5 and other oxides
IPS Empress Direct (Ivoclar Vivadent)	20-21.5% by weight of dimethacrylates 17% by weight of opalescent color 77.5-79% by weight of barium glass, ytterbium trifluoride, mixed oxides, silicon dioxide and copolymer <1% by weight of additives, catalysts, stabilizers, and pigments Inorganic particle size: 40 nm to 3000 nm (Ma = 550 nm)

Abbreviations: Al_2O_3, aluminum oxide; K_2O, potassium oxide; Li_2O, lithium oxide; P_2O_5, phosphorus pentoxide.
[a]*Manufacturers' information.*

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the refractories, the laminates were removed and finished using cleaning and glazing procedures.

The composite resin was placed into perforated stainless-steel matrices with a metal spatula. A polyester strip and a weight of 500 g were applied to the matrices for 30 seconds in order to remove excess resinous material. Next, the specimens were light cured for 40 seconds using a LED-laser source (Valo, Ultradent Products, South Jordan, UT, USA). The light intensity was 1000 mW/cm^2.

The dental specimens were obtained by selecting premolars from the Human Teeth Bank of the União Metropolitana de Educação e Cultura – UNIME (Lauro de Freitas, Bahia, Brazil), which had been stored in 0.1% thymol solution. The crowns of the teeth were separated from the roots with a double-sided diamond disc (ref 7020, KG Sorensen, São Paulo, Brazil) at low temperature and low speed. After removing the pulp tissue, the dental crowns were washed and cleaned using Robinson brushes and pumice paste under running water at low rotation. One dental fragment, from the center of respective vestibular surfaces, was removed from each premolar, for a total of 150 dental fragments with the following dimensions: 4 mm x 4 mm x 3 mm (width x length x thickness). Thereafter, the fragments were stored in distilled water for 24 hours at 37°C.

The fragments were fixed onto an acrylic device with a sticky wax (ASFER, Indústria Química Ltda, São Paulo, Brazil) and placed into an AROPOL 2V metallographic polishing machine (AROTEC, Indústria e Comércio S/A, Cotia, Brazil). During the polishing sessions, aluminum oxide papers with a grain size of P1200 and P2000 were used for 20 seconds at a constant low temperature. The dental fragments were individually submitted to an ultrasonic bath (CBU-100/1L, PLANATC, São Paulo, Brazil) in distilled water for two minutes. Next, the fragments were soaked in an aqueous solution composed of 250 mL black tea, 250 mL coffee, 250 mL red wine, 250 mL tobacco solution, 250 mL Coca-Cola and 250 mL artificial saliva, and then placed in an incubator for 96 hours at 37°C.[16] Before the initial color assessment, the dental fragments were individually coded and randomly divided into 15 experimental groups of 10 specimens each (Table 2).

The ceramic and resin laminates were cemented to the discolored fragments using 37% phosphoric acid (Condac, FGM, Santa Catarina, Brazil), an adhesive system (Scotchbond Multipurpose Plus, 3M, St Paul, MN, USA), silane (Prosil, FGM, Santa Catarina, Brazil), and a translucent resin cement (RelyX veneer, 3M). After laminate cementation following manufacturer's instructions for each material, the specimens were submitted to the final color evaluation.

Each specimen was submitted to two color measurements: 1) after discoloration of the dental fragments before adhesive cementation of the veneers, and 2) after cementation of the ceramic or resinous laminates to the discolored dental fragments. Thus, each specimen was compared to itself between time points. This method reduced *in vitro* variability, permitting a more reliable analysis of the masking ability of the restorative materials used in each experimental group. In addition, the initial color measurement enabled determination of the color homogeneity of the fragments among the experimental groups by comparing their means and standard deviations.

The color measurements were performed using a spectrophotometer (UV-2600, Shimadzu, São Paulo, Brazil), and the UVProbe software was used to obtain the spectral reflectance curves of each specimen within the visible light spectrum of 380 to 780 nm. For this purpose, the specimens were placed onto a white standard background (barium sulphate) with the aid of a template to reproduce their position. The spectra of

Table 2: *Experimental Groups Divided According to the Thickness and Opacity of the Dental Materials*

	Opacity				
	Ceramic (IPS E.max Press) Shade: BL1 (HT and LT); 0 (MO)			**Resin (IPS Empress Direct) Shade: BL-L**	
Thickness	**HT**	**LT**	**MO**	**Enamel**	**Dentin**
0.7 mm	G1 (n=10)	G4 (n=10)	G7 (n=10)	G10 (n=10)	G13 (n=10)
1.0 mm	G2 (n=10)	G5 (n=10)	G8 (n=10)	G11 (n=10)	G14 (n=10)
1.2 mm	G3 (n=10)	G6 (n=10)	G9 (n=10)	G12 (n=10)	G15 (n=10)

Abbreviations: G1 to G15, experimental group 1 to experimental group 15; HT, high translucency; LT, low translucency; MO, medium opacity.

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each specimen were analyzed using the Color Analysis software (Color Measurement Software, Shimadzu, São Paulo, Brazil), and color assessment was performed according to the parameters of the CIE L*a*b* system, with CIE illuminant D65 as reference illuminant.[17]

First, exploratory analysis of the lightness and ΔE values was performed to assess the data distribution (Shapiro-Wilk test; $p>0.05$) and other parameters of analysis of variance (ANOVA). For inferential statistical analysis, two-way ANOVA, followed by Tukey's post-hoc test, was applied for multiple comparisons between means. Data were analyzed using the SAS 9.1 software and are expressed as means and standard deviation (SD). Differences were considered statistically significant when $p\leq0.05$.

RESULTS

The results of exploratory analysis showed a normal distribution of the ΔE (color difference) values between groups. Table 3 depicts the ΔE values of each experimental group. Statistical analysis (two-way ANOVA followed by the Tukey post-hoc test) revealed a significant interaction between the factors studied (thickness versus opacity, $p<0.001$).

When thicknesses were 0.7 mm and 1.0 mm, different groups with different opacities showed similar variation. The highest ΔE values were observed for dentin resin veneers, followed by LT and MO ceramic veneers, which had the same ΔE values. In descending order, the lowest ΔE values were observed for enamel resin laminates and HT ceramic veneers.

Considering the groups with 1.2-mm thickness, the highest ΔE value was observed for LT ceramic veneers, although it did not differ significantly from the ΔE value of the MO ceramic group. In addition, statistical analysis revealed no difference in ΔE values between the MO ceramic and dentin resin groups. The ΔE values decreased in the enamel resin group, followed by the HT ceramic group. It is noteworthy that for the three different ceramic veneer opacities, significantly higher ΔE values were found for the 1.2-mm thickness groups compared to the groups with thicknesses of 0.7 and 1.0 mm under most conditions.

The ΔE values of the enamel resin groups (0.7, 1.0, and 1.2 mm) were significantly different from each other. Conversely, there was no significant difference between the dentin resin groups with 1.2 mm thickness and the 1.0 mm thickness group, and both groups exhibited higher ΔE values than the 0.7 mm thickness group.

Table 4 depicts the lightness variation in each experimental group. Statistical analysis (two-way ANOVA followed by the Tukey post-hoc test) showed a significant interaction ($p<0.001$) and a statistical relationship between the factors studied.

Comparing the experimental groups with 0.7 mm thickness, the highest lightness values were found for MO ceramic veneers and dentin resin veneers, with no significant difference between groups. Both groups differed significantly from the other 0.7 mm thickness groups. There was no significant difference in lightness levels between the HT, LT, and enamel resin groups.

In the groups with 1.0 mm thickness, statistical analysis showed similar lightness levels for the LT and MO ceramic veneer and dentin resin groups. These groups differed significantly from the remaining groups, and showed higher lightness levels than the enamel composite resin and HT ceramic groups.

At a thickness of 1.2 mm, there was no significant difference between the LT and MO ceramic groups;

Table 3: *Color Variation (ΔE) of the Experimental Groups Expressed as Means and Standard Deviation (SD)*[a]

	Thickness		
Opacity	**0.7 mm**	**1.0 mm**	**1.2 mm**
Ceramic (HT)	2.59 (0.20) Db	2.80 (0.27) Db	3.32 (0.25) Da
Ceramic (LT)	4.21 (0.14) Bb	4.49 (0.42) Bb	5.71 (0.21) Aa
Ceramic (MO)	4.28 (0.18) Bb	4.46 (0.23) Bb	5.48 (0.30) ABa
Resin (Enamel)	3.24 (0.15) Cc	3.93 (0.39) Cb	4.54 (0.52) Ca
Resin (Dentin)	4.78 (0.47) Ab	5.24 (0.17) Aa	5.22 (0.07) Ba

Abbreviations: ANOVA, analysis of variance; HT, high translucency; LT, low translucency; MO, medium opacity.

[a]*Means (SD) followed by distinct letters represent statistical significance (two-way ANOVA followed by Tukey post-hoc test; alpha level of 5%). Uppercase letters compare different levels of opacity within a settled thickness (comparison of cells in a same column). Lowercase letters compare different levels of thickness within a settled opacity (comparison of cells in a same line).*

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Table 4: *Luminosity of the Experimental Groups, Expressed as Means and Standard Deviation (SD)*[a]

	Thickness		
Opacity	**0.7 mm**	**1.0 mm**	**1.2 mm**
Ceramic (HT)	71.60 (0.83) Cb	70.92 (0.65) Cb	72.89 (0.86) Ca
Ceramic (LT)	77.53 (0.73) Bc	79.90 (0.62) Ab	83.07 (0.95) Aa
Ceramic (MO)	79.16 (0.69) Ac	80.82 (0.93) Ab	83.37 (1.01) Aa
Resin (Enamel)	72.88 (0.67) Cb	73.95 (0.30) Bb	79.47 (0.61) Ba
Resin (Dentin)	80.12 (0.70) Aa	79.77 (0.44) Aa	80.13 (0.81) Ba

Abbreviations: ANOVA, analysis of variance; HT, high translucency; LT, low translucency; MO, medium opacity.

[a]*Means (SD) followed by distinct letters represent statistical significance (two-way ANOVA followed by Tukey post-hoc test; alpha level of 5%). Uppercase letters compare different levels of opacity within a settled thickness (comparison of cells in the same column). Lowercase letters compare different levels of thickness within a settled opacity (comparison of cells in the same row).*

both groups had higher lightness levels than the composite resin groups. No significant difference was observed between the enamel and dentin resin groups, and both groups had higher lightness values than the HT ceramic group.

Analysis of specimens with the same opacity but different thicknesses showed similar lightness levels in the LT ceramic and MO ceramic groups; the highest lightness level was observed for the 1.2 mm thickness groups, while the 1.0 mm and 0.7 mm thickness groups did not differ significantly from each other. The lightness levels of the HT ceramic and enamel resin groups were significantly different, regardless of thickness; the highest lightness levels were observed for the 1.2 mm thickness groups, while the lowest levels were found for the 0.7 mm thickness groups. Finally, in the dentin resin groups, the variation in thickness did not promote any significant change in lightness values.

DISCUSSION

The color of an aesthetic restoration is the result of the interaction between the dental substrate and the restorative material.[17] The final color of dental veneer restorations is influenced by the thickness, translucency and opacity of the restorative material, the type of luting agent, and the type of substrate.[9-11,14,15,18] In the present study, color variability related to the color of the resin cement and of the substrate was minimized by the use of a translucent luting agent and by the discoloration process of the dental substrates, respectively. In addition, the color of the discolored dental fragment was used as the initial color measurement of the specimen, while the final color measurement was taken after the restoration procedures. Thus, the total color variation (ΔE) was analyzed for each specimen.

The use of a spectrophotometer enabled the measurement of color parameters based on the CIE L*a*b* scale. In the initial color assessment, a mean L* value of 69.23 and SD of 0.226 were recorded for the discolored dental fragments. This finding characterizes low variability and hence standardization of the initial color of the dental fragments. Lightness is the most used parameter in the literature to measure discoloration and bleaching of the dental structure.[15] The ΔE values were used for data description and statistical analysis; the higher the ΔE, the greater the difference between the initial and final measurements of the specimens.

At every level of thickness (0.7, 1.0, and 1.2 mm), the lowest translucent ceramic groups (LT and MO) showed the highest ΔE when compared to the HT ceramic group. Conversely, when opacity was considered, there was no statistically significant difference between the LT and MO ceramic groups at each thickness studied. These findings suggest the use of a less opaque material to change the color of a discolored dental substrate. If the lightness values are also considered, the choice of ceramic veneers with LT remains valid, except for the restorations with a thickness of 0.7 mm. In 0.7 mm thick specimens, the ceramic veneer with the highest opaqueness levels exhibited the highest lightness value. Our findings corroborate the results of Hilgert and others,[7] although these authors did not use MO ceramic veneers in their analysis.

In the present study, analysis of the thickness of ceramic veneers showed that the optical properties of laminates with 1.2 mm thickness are different from

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those of laminates with thicknesses of 0.7 mm and 1.0 mm, regardless of their translucency. The ΔE values of ceramic veneers with 0.7 mm and 1.0 mm thicknesses did not differ from each other, regardless of the type of ceramic opacity. The HT ceramic veneers had the same lightness levels. As for the LT and MO ceramic veneers, lightness increased with increasing thickness.

Our findings showed that the total ΔE values of the LT and MO ceramic veneer restorations were higher than 3.3—a clinically visible value of tooth color variation.[11] These results support clinical findings showing that an increase in the thickness of ceramic veneers benefits their optical properties when they are used to mask discolored substrates.

The findings of the present study agree with Kürklü and others.[11] According to these authors, opacity, followed by thickness, is the most relevant factor for a satisfactory result in the restoration of a discolored substrate. Therefore, when ceramic veneers are selected for masking discolored substrate restorations, more opaque materials combined with a minimum thickness should be used. In our study, the highest ΔE and lightness values were observed at the thickness of 1.2 mm for each ceramic restoration.

In the present study, when analyzing the properties of the composite resin restorations, the enamel resin (translucency of 15%) showed a significant ΔE in each group, with the highest ΔE value in 1.2 mm thick specimens. Generally, the greater the thickness of the translucent material, the greater it's masking ability, which explains our findings that increasing the thickness of the translucent material resulted in a gradual increase of ΔE. This is true until a certain thickness (known as infinite optical thickness) is reached, at which point the background no longer exerts an influence on the surface color. This assertion is supported by the Kubelka-Munk theory, which proposes that the infinite optical thickness of a restorative material varies according to its thickness and its diffusion and absorption indices for a certain wavelength of the light spectrum.[19] In addition, when lightness was analyzed separately, the value of the enamel resin did not differ from the value recorded for the dentin resin in 1.2-mm thick specimens.

Similar ΔE results (values higher than 3.3) were obtained for the dentin resin veneers (LT − 7%) with thicknesses of 1.0 and 1.2 mm. The dentin resin with 0.7 mm thickness had a mean ΔE value of 4.78, a value higher than those observed for the ceramic and enamel resin veneers. This value was even higher than the critical value, demonstrating the high masking ability of dentin resin restorations on discolored teeth.

Lightness is a measure of the amount of white light present in the specimens. Interestingly, the dentin-shade resin veneer was the restorative material with the highest lightness in specimens with 0.7 mm thickness. In the groups with 1.0 mm thickness, dentin resin as well as the LT and MO ceramic veneers provided the highest lightness values. However, increasing the thickness of these restorative materials to 1.2 mm resulted in a medium performance, which did not differ from the enamel resin lightness values at this respective thickness. Taken together, these findings show that composite resin veneers have a good masking ability when used as restorative materials of discolored teeth.

The aforementioned findings for composite resin veneers differ from the results observed by Darabi and others.[12] These authors stated that one limitation of the use of composite resins is their low ability to modify a discolored surface at a reduced thickness of 1 mm. These differences may be attributed to the different levels of translucency observed in the resinous systems.[12] Therefore, other studies that compare the masking ability of restorative materials using different resinous systems are needed.

Regarding the masking ability of the restorative materials evaluated in the present study, the LT and MO ceramic veneers showed the best ΔE values and lightness variation in 1.2-mm thick specimens. However, it is noteworthy that dentin resin veneers had superior ΔE values and lightness variation in 0.7 and 1.0 mm thick specimens. In addition, in 1.0 mm thick specimens, the lightness of dentin resin veneers was comparable to more opaque ceramic veneers (MO and LT). These findings highlight the potential use of composite resin laminates with small thicknesses as restorative materials of discolored dental substrates. This material may become an even more important approach in minimally invasive dentistry.

CONCLUSION

Based on the methodology used and the data obtained, we conclude that:

- the greater the thickness of the restorative material, the better its ability to mask discolored dental substrates;
- for indirect ceramic restorations, 0.7 and 1.0 mm thick veneers exhibit the same ability to mask discolored dental substrates;
- dentin-shade composite resin veneers with 0.7 and 1.0 mm thickness have the best ability to mask discolored dental substrates; and
- the best thickness/opacity combinations for masking discolored dental substrates were LT and MO ceramic veneers with 1.2 mm thickness.

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Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Influence of Incorporating Zirconium- and Barium-based Radiopaque Filler Into Experimental and Commercial Infiltrants

PR Pedreira • JE Damasceno • C Mathias • MAC Sinhoreti • FHB Aguiar • GM Marchi

Clinical Relevance

Important progress has been made in researching the radiopacity of resin infiltrants to determine their efficacy, since the infiltrant currently available on the market is not radiopaque. Adequate radiopacity would allow clinicians to confirm the penetration and efficacy of the infiltrant.

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SUMMARY

Objectives: To evaluate how adding different concentrations of particles (barium or zirconium oxide 25%/45% by weight) to a commercial infiltrant (Icon) and an experimental infiltrant influences cohesive strength (CS), degree of conversion (DC), water sorption (WS), solubility (SL), radiopacity, and penetration depth.

Methods and Materials: Microtensile CS (n=10) was evaluated using a universal testing machine. DC (n=5) was evaluated in a Fourier-transform infrared spectrometer. Polymerized samples were dissected, weighed, and stored to obtain the final mass for WS and SL tests (n=10). Radiopacity analysis (n=5) was performed using a digital radiography system. Penetration depth analysis (n=5) was performed by confocal laser scanning microscopy. Analyses were performed using the R program, with a significance level of 5%, except for the penetration depth analyses, which were evaluated only qualitatively.

Results: The groups with 45% zirconium showed greater CS values, regardless of the infiltrant. Among the groups with no particle addition, those of the experimental infiltrant

*Priscila Regis Pedreira, Department of Restorative Dentistry, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

Janaina Emanuela Damasceno, Department of Restorative Dentistry, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

Caroline Mathias, Department of Restorative Dentistry, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

Mário Alexandre Coelho Sinhoreti, Department of Restorative Dentistry, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

Flávio Henrique Baggio Aguiar, Department of Restorative Dentistry, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

Giselle Maria Marchi, Department of Restorative Dentistry, Piracicaba Dental School, State University of Campinas, Piracicaba, SP, Brazil

Corresponding author: Av Limeira, 901, PO Box 52 Piracicaba, SP, Brazil, CEP 13414-903; e-mail: priscilaregis1@hotmail.com

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presented higher DC than those of Icon. The experimental infiltrant presented lower WS than Icon. All groups had SL below the ISO recommended levels. Radiopacity higher than 2.24 mmAl (enamel radiopacity) was observed only in the groups with 45% zirconium. All the groups achieved similar penetration depth, but the groups containing experimental infiltrant appear to have had longer tag extensions.

Conclusions: Addition of 45% of zirconium presented good results for CS and WS, as well as SL below the ISO recommended standard, adequate radiopacity, and penetration depth similar to the other groups.

INTRODUCTION

A reduction in the incidence of dental caries has been observed in recent years, especially among children and adolescents.[1] However, the disease is still considered a public health problem, since dental caries is one of the most common diseases affecting the population.[1,2] A number of preventive measures implemented in the last decades has led to a decline in dental caries lesions.[3] However, active white spots—the first clinical observation of caries progression—are still frequent. They are caused by the high concentration of acids produced by bacteria in the biofilm and associated with poor hygiene.[4] An active white spot lesion (WSL) is an enamel subsurface demineralization that is noncavitated and that can be remineralized.[2,5]

The treatments of choice for incipient carious lesions are minimally invasive procedures adopted to avoid dental tissue removal. Noninvasive methods, topical fluoride application, and oral hygiene are resources used to promote the remineralization of incipient lesions.[2,6,7] However, these procedures require the cooperation of patients to ensure successful treatment. In addition, these methods remineralize only the surface of the lesion.[8]

Since patients are often not cooperative, other alternatives have been put into place to prevent dental caries progression in the initial phase of lesion development. The low-viscosity resin infiltration technique is one such option that has been used successfully in dentistry.[3] The principle of resin infiltration is to perfuse porous enamel by capillary action, thus interrupting the demineralization process and paralyzing the carious lesion.[9] Icon is a low-viscosity, commercially available resin infiltrant consisting of a methacrylate resin matrix, initiators, and additives.[3] It is applied mainly to initial white spots on smooth and proximal tooth surfaces.[3,4]

Given the promising studies conducted on the effectiveness of Icon infiltration and the importance of avoiding tooth wear when treating WSLs, some studies have tested infiltrant compositions according to different combinations of monomers, diluents, and solvents, seeking to improve the only commercially available infiltrant in regard to penetration depth and mechanical properties.[3,10-13] One of these formulations was studied by Mathias and others,[14] based on 25% ethoxylatedbisphenol A dimethacrylate (*Bis*-EMA), 75% triethylene glycol dimethacrylate (TEGDMA), 0.5% camphorquinone (CQ), and 1% ethyl 4-dimethylaminobenzoate (EDAB), with favorable results regarding degree of conversion (DC), sorption, and solubility (SL).

However, the disadvantage of a resin infiltrant is that it is radiolucent. According to the American Dental Association (ADA), radiopacity is an essential property of all restorative materials and one of the requirements of a dental material. Material with adequate radiopacity allows secondary caries and marginal defects to be detected, as well as missing contact points with adjacent teeth, improves restoration contours, and distinguishes caries from restorative material and surrounding tooth structure.[15-17] In addition, radiopacity is not only associated with the amount of filler present in the material but also with the type of radiopaque additives in inorganic fillers.[16] For example, most restorative resins can be visualized well in a radiographic diagnosis, albeit dependent on their composition.[16,18] The elements composing resin radiopacification have a high atomic number, such as barium oxide, lanthanum, strontium, zirconium, zinc, yttrium, and ytterbium, which vary greatly in their concentrations [18]. According to the literature researched, the most commonly used components are barium oxide and zirconium particles, which ensure the good radiographic results of radiopacity composites [17,18].

Both barium and zirconium particles consist of colorless, insoluble crystals in water, and are available in white powder form. The lower the particle size, the lower the viscosity, and the greater the penetration depth, according to Lee and others.[19] Barium oxide particles have an average size of 0.7 um, whereas zirconium oxide particles are <100 nm, on average. The composition of the only commercially available infiltrant lacks radiopacity in its composition. Consequently, penetration of the infiltrant in the lesion cannot be visualized at an

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Table 1: *Description of Experimental Group Composition*

INFILTRANT GROUP	COMPOSITION
CC (Comercial Control)	Icon
I25B	Icon, 25% Barium Oxide
I45B	Icon, 45% Barium Oxide
I25Z	Icon, 25% Zirconium Oxide
I45Z	Icon, 45% Zirconium Oxide
EC (Experimental Control)	25% *Bis*-EMA, 75% TEGDMA, 0,5% CQ, 1% EDAB
E25B	25% *Bis*-EMA, 75% TEGDMA, 0.5% CQ, 1% EDAB, 25% Barium Oxide
E45B	25% *Bis*-EMA, 75% TEGDMA, 0.5% CQ, 1% EDAB, 45% Barium Oxide
E25Z	25% *Bis*-EMA, 75% TEGDMA, 0.5% CQ, 1% EDAB, 25% Zirconium Oxide
E45Z	25% *Bis*-EMA, 75% TEGDMA, 0.5% CQ, 1% EDAB, 45% Zirconium Oxide

Description of acronyms used in the table: Bis-EMA, ethoxylatedbisphenol A dimethacrylate, ESSTECH; TEGDMA, triethylene glycol dimethacrylate, Aldrich; CQ, camphorquinone, Aldrich; EDAB, ethyl-4-dimethylamino benzoate, Aldrich.

adequate depth, and its efficacy and ability to stabilize the lesion cannot be ascertained.

In view of the scarcity of studies and the need for an infiltrant that has radiopacity, adequate physicomechanical properties, and ability to penetrate the demineralized enamel zone, this study proposed to evaluate the incorporation of barium oxide and zirconium particles into commercial and experimental infiltrants to promote radiopacity, assess resulting physical properties, and improve penetration.

METHODS AND MATERIALS

Infiltrant Preparation

The experimental infiltrant was manipulated in a laboratory with yellow light, and controlled humidity and temperature. The monomeric base used was *Bis*-EMA and TEGDMA. A CQ and a tertiary amine ethyl-4-dimethylamino benzoate (EDAB) photoinitiator system were also added. Barium oxide and zirconium particles were incorporated into the experimental infiltrant and Icon (XXX). The incorporation was performed using a magnetic stirrer for 24 hours and an ultrasonic vessel for 30 minutes, in the concentrations shown in Table 1, all in percentage by weight. The experimental infiltrants were stored individually and kept under refrigeration at 4°C.

Cohesive strength (CS)

A microtensile test was used to evaluate cohesive strength (CS). A ten bar-shaped matrix (8×1×1 mm) was used to make silicone impressions (Scan Putty, Yller) to obtain 10 specimens for each group tested. The specimens were photoactivated by an LED light source (Valo, Ultradent, xxx, power density of 1000 mW/cm^2, 395-480 nm) for 40 seconds, and stored in an incubator at 37°C for 24 hours. Each specimen was fixed with cyanoacrylate glue (Superbonder, Locitec, São Paulo, SP, Brazil) to a metal microtensile device, coupled to a universal test machine (Instron 4411, Norwood, MA, USA). The machine was operated at a speed of 1 mm/minute, until the stick ruptured. The fracture area was measured individually using a digital caliper to calculate the stress and rupture of each specimen in MPa.

Degree of Conversion (DC)

DC analyses (GC, in %, n=5) were performed by Fourier-Transform Infrared Spectroscopy (Vertex 70 Spectrometer, Bruker, Billerica, MA, USA) in transmission mode. Two readings were performed: one of the unpolymerized material and the other of the same material immediately after photoactivation with an LED light source (Valo) for 40 seconds. The conversion was obtained by recording the methacrylate absorption peak (6165/cm), before and after polymerization. The baseline technique[20] was drawn by the program itself and was used to calculate the DC.

Water sorption (WS) and Solubility (SL)

Water sorption (WS) and solubility (SL) tests were performed according to ISO 4049/2009, except on specimen size. A Teflon matrix with a cylindrical shape was used to make a silicone matrix (Scan Putty, Yller). The infiltrant was deposited in this matrix to obtain test specimens in the form of a disc (5×1 mm, n=10), which were then polymerized with an LED light source (Valo) for 40 seconds, placed in a desiccator and stored in an incubator at 37°C.

The test specimens were weighed daily on an analytical balance (Shimadzu - AUW220D, Tokyo, Japan), at 24-hour intervals until constant mass (m_1) was obtained, with a variation of less than 0.002 mg. The thickness and diameter of each specimen was measured with a digital caliper (Mitutoyo, Japan) to calculate the volume (mm^3). Afterwards, the specimens were stored at 37°C in closed Eppendorf tubes containing 1.5 mL of distilled water. After 7 days in storage, the Eppendorf tubes

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were removed from the incubator and left at room temperature for 30 minutes. The specimens were washed in running water, dried gently with absorbent paper, and reweighed on an analytical balance to obtain m_2. The samples were then dried in a desiccator containing silica gel and reweighed daily to obtain a new constant mass (m_3). The WS and SL values were calculated by two separate formulas ($S_o=m_2–m_3/V$ and $SL=m_1–m_3/V$).

Radiopacity

The radiopacity analysis was performed by making a disc-shaped specimen (5×1 mm, n=5) from a silicone matrix. The specimens were photoactivated with an LED light source (Valo) for 40 seconds and stored at 37°C for 24 hours. The Kodak Dental Systems digital radiography system (RVG 5000, Eastman Kodak Company, Rochester, NY, USA) was used to perform the analysis. This system has a sensor with electro-optical features of three juxtaposed blades: scintillator crystal, fiber optic, and filler coupled device (CCD). The blades produce an electrical signal that generates an image with a real resolution of 14 pl/mm and a real image receiver resolution of 27.03 pl/mm. The specimens were positioned together with the film at the center of the sensor, and the aluminum density scale and a tooth on the side to compare the density. The radiographic apparatus cylinder (Timex 70 E, Gnatus, Osasco, SP, Brazil), 70 kVp and 7 mA, was positioned perpendicular to the film, specimen, scale, and tooth at a distance of 5 cm, using an exposure time of 0.05 seconds.

The digital image provided optical density values in pixels at the center of each specimen, of each step of the scale, and of the points equidistant from the right and left. This allowed obtaining an average of the radiographic density value. Grayscale comparisons were made to assess and compare the radiopacity level, as evaluated by the histogram contained in the Adobe Photoshop software. The following equation was used to transform the data to mm a [21]:

$(A\times0.5)/B$+mm to immediately preceding radiographic density of the material (DRM)
A = Radiographic density of the material (DRM) – radiographic density of the aluminum increment immediately preceding DRM;
B = Radiographic density of the aluminum increment immediately after DRM–Radiographic density of the aluminum increment immediately preceding DRM;
0.5 = 0.5-mm increment of the aluminum scale.

The density of each specimen was compared with the dentin density (1.23 mmAl) and the enamel density (2.24 mmAl), represented by the thickness of the aluminum density scale of 1 mm and 2 mm, respectively. Bear in mind that this thickness had to be equivalent to or greater than these respective values, in order to determine the most adequate concentration to distinguish the material.

Penetration Depth

Preparation and Selection of Test Specimens—Sixty human molars were cleaned thoroughly with a prophylaxis brush (Microdont, São Paulo, Brazil) and pumice slurry (AAF do Brasil, Londrina, Brazil) to remove residues and then stored in a 0.1% thymol solution. Tooth roots were removed and discarded. Next, fragments (n=50) were obtained from the enamel portion of buccal and lingual/palatine faces of 60 teeth. The enamel surface of each specimen was ground flat and polished with waterproof silicon carbide papers (600-, 1200-, and 2000-grit; Sands, Norton, Guarulhos, SP, Brazil) under refrigeration, and then polished with felt disks and a diamond solution (1 μm, Buehler). The fragments were covered with two layers of resistant nail varnish (Colorama, São Paulo, Brazil), except in the polished enamel area (4×4 mm). They were stored individually in distilled water at 37°C. The resulting specimens were then tested. The initial microhardness average was obtained with a microdurometer (HMV-2000; Shimadzu Corporation, Tokyo, Japan) using three measurements 100 μm from each other, as of the center of the surface. The sample specimens with a mean value of 360 ± 28 were selected.

Simulation of the Initial Enamel Caries Lesion—The selected specimens were submitted to a caries lesion simulation in enamel. Activity in the oral cavity was simulated using a demineralizing solution (2.2 mmol $CaCl_2$, 2.2 mmol NaH_2 PO_4, and 50 mmol acetic acid, adjusted to pH 4.5 with NaOH).[22] The demineralization cycle was simulated by immersing the specimens individually into 50 ml of solution for 16 hours at 37°C, washing them with distilled water, and then keeping them in *Tris* buffer solution (0.1 M HCl, pH 7.0) at 37°C. Two other groups were made to evaluate the correct demineralization of the test specimens: one positive control and one negative control.

Penetration Depth Evaluation—After the caries lesion simulation was performed, the specimens were submitted to different commercial and experimental infiltrants. Ten study groups (n=5) of the infiltrants were used to evaluate penetration depth.

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Table 2: *Mean and standard deviation of cohesive strength (CS), degree of conversion (DC), sorption and solubility (SL), according to the infiltration and concentration of the barium and zirconium particles*

Filler concentration	0%	Barium 25%	Barium 45%	Zirconium 25%	Zirconium 45%
Cohesive Strength					
Icon (DP)	40.87 (7.76)Ab	48.18 (11.73)Ab	51.21 (9.3)Aab	46.51 (9.99)Ab	58.32 (7.30)Aa
Experimental (DP)	47.94 (8.82)Ab	44.74 (8.96)Ab	50.16 (5.60)Aab	45.20 (4.79)Ab	54.48 (10.59)Aa
Degree of Conversion					
Icon (DP)	60.50 (7.55)Bb	85.69 (1.95)Aa	85.26 (1.38)Aa	77.70 (1.95)Aa	68.63 (3.43)Ab
Experimental (DP)	77.40 (1.48)Aa	75.75 (1.24)Ba	76.92 (1.89)Ba	69.29 (12.34)Bb	68.12 (8.09)Ab
Sorption					
Icon (DP)	57.14 (3.12)Aab	59.08 (3.08)Aa	54.30 (6.73)Ab	57.11 (4.80)Aab	54.83 (3.37)Ab
Experimental (DP)	36.90 (2.77)Bb	35.03 (2.56)Bbc	33.98 (2.27)Bc	39.54 (2.78)Ba	36.55(3.72)Bb

Different uppercase letters indicate statistical difference in the same column for each test, different lowercase letters indicate statistical difference in the same line $p < 0.05$

This was performed by conditioning the enamel with 15% hydrochloric acid for 120 seconds, according to the manufacturer's recommended protocol (Icon Etch, DMG, Hamburg, Germany). The enamel was washed with a water jet for 120 seconds and then dried with air jets for 15 seconds. The teeth were washed again for 30 seconds and immersed in a 0.1% Rhodamine B ethanolic solution (Sigma–Aldrich, Steinheim, Germany) for 12 hours to fill all accessible pores with red fluorophore, as a protocol for visualization in a confocal microscope (only).

After removal of the pigment solution with a water jet, the specimens were dried with compressed air for 30 seconds, immediately before the resinous infiltration. Icon Dry (99% ethanol) was applied for 30 seconds, and the infiltrants were applied for 180 seconds, according to the manufacturer's recommendation. Afterwards, the specimens were photoactivated for 40 seconds using an LED photoactivator (Valo). The infiltrant was reapplied for 60 seconds, and photoactivation was performed for 40 seconds, as recommended by the manufacturer.

The resin-infiltrated blocks were sliced perpendicular to the surface of the enamel lesion with a diamond disc and polished (600-, 1200-, and 2000-grit; sandpaper, Norton) with water to produce approximately 1.0-mm thick fragments. Unbound red fluorophore was removed by leaving the slices in a 30% hydrogen peroxide solution for 12 hours, according to the confocal microscopy protocol. The lesion regions in which no infiltration occurred were evaluated by immersing the specimens in a 100-μM sodium fluorescein ethanolic solution (NaFl; Sigma–Aldrich, St. Louis, MI, USA) for 180 hours and subsequently washing them with deionized water for 10 seconds. After the specimens were prepared, they were evaluated by Confocal Laser Scanning (Leica, TCS NT; Leica, Heidelberg, Germany) with a 63 × 1.4 NA objective. The dual fluorescence mode was used with the oil-immersion objective, to enable fluorescence to be detected simultaneously (Rhodamine B: Ex 568-nm, 590-nm long-pass filter; fluorescein sodium: Ex 488-nm, 520/50-nm band-pass filter). Penetration depth of the images obtained was evaluated qualitatively to check for penetration.

Statistical Analysis—Initially, descriptive and exploratory analyses were performed, since the data did not meet the assumptions of a parametric analysis. Generalized linear models were then applied considering the following factors in the model: the infiltrant, the particles, and the interaction among them. All the analyses were performed using the R* program [*R Core Team (2018); R Foundation for Statistical Computing, Vienna, Austria], considering a 5% level of significance.

RESULTS

Regarding CS, the interaction between the infiltrating factors and the particles was not significant ($p>0.05$). Moreover, there was no significant difference between the Icon and experimental infiltrants ($p>0.05$), as shown in Table 2. The resistance in the 45% zirconium group was significantly higher than that of the 25% zirconium, the 25% barium, or the control groups ($p<0.05$), regardless of the infiltrant. Comparing the CC (with particle addition) and EC (without its addition) groups, EC had higher DC than CC ($p<0.05$) (Table 2). The groups with Icon presented higher DC ($p<0.05$) than the groups with the addition of 25% barium and of 25% zirconium, respectively. In the I45Z and E45Z groups, there was no significant difference between the two infiltrants ($p>0.05$). In regard to Icon, it was observed that the I45Z group did not differ from the control group, and that the other groups presented significantly higher averages ($p<0.05$) than the control group. In the

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Table 3: *Mean and Standard Deviation of Radiopacity (mm Al) Values, According to the Infiltration and Concentration of the Barium and Zirconium Particles, in Comparison with the Enamel and Dentin Radiopacity Values*

Particles	Infiltrant	
	Icon	Experimental
Control	0.47 (0.04) Ae	0.49 (0.03) Ae
25% Barium	0.88 (0.07) Ad	0.84 (0.05) Ad
45% Barium	1.15 (0.22) Ac	1.17 (0.18) Ac
25% Zirconia	1.53 (0.24) Ab	1.82 (0.40) Ab
45% Zirconia	2.77 (0.27) Aa	2.78 (0.20) Aa

Averages followed by different letters (uppercase in the same line and lowercase in the same column) differ among one another ($p \leq 0.05$). p(Infiltrant)=0.5447; p(Particles)<0.0001; p(Infiltrant×Particles)=0.4528

case of the commercial infiltrant, lower DC values were observed in the zirconium groups ($p<0.05$).

The experimental infiltrant presented lower WS than Icon, irrespective of particle concentration ($p<0.05$) (Table 2). As for Icon, the I25B group presented significantly higher WS than the I45B or zirconium ($p<0.05$) groups. As for the experimental infiltrant, the highest WS was observed in the E25Z group, whose concentration differed significantly from the other particle concentrations ($p<0.05$). As for the control groups and those with the addition of 25% barium, a higher SL was observed in the experimental group ($p<0.05$) (Table 2). Regarding Icon, greater SL was observed in the I25Z and I45Z groups, and the SL was significantly higher at the 45% concentration ($p<0.05$). Regarding the experimental infiltrant, the E45Z group presented higher SL than groups E25B and E45B, $p<0.05$.

In regards to radiopacity, Table 3 indicates that there was no significant interaction between the infiltrants and the particle concentration ($p>0.05$). Therefore, there was no significant difference in radiopacity between Icon and the experimental infiltrants, regardless of the barium oxide or zirconium particle concentrations ($p>0.05$). Greater radiopacity was observed when zirconium was added ($p<0.05$), pointing out that it was significantly higher in the 45% concentration, regardless of the infiltrant. Figure 1 shows the radiopacity of the CC, I25B, I45B, I25Z, and I45z (Figure 1a), and of EC, E25B, E45B, E35Z, and E45Z (Figure 1b) specimens, as well as a tooth fragment in relation to the aluminum scale.

The images of the degree of homogeneity of penetration of the infiltrating materials in the lesion body were evaluated qualitatively using confocal

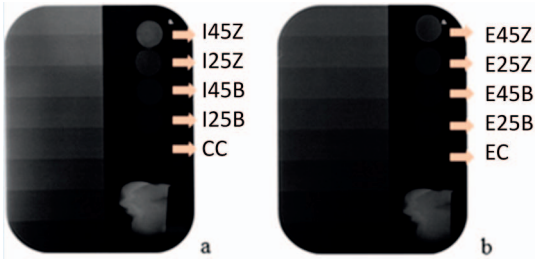

Figure 1. *a) Shows the radiopacity of specimens of the CC, I25B, I45B, I25Z, and I45z groups, compared with the tooth and aluminum scale; b) shows the radiopacity of specimens of the EC, E25B, E45B, E35Z, and E45Z groups, compared with the tooth and aluminum scale.*

microscopy (Figure 2). All the groups obtained similar depth of penetration, but the image representing the penetration depth of the experimental infiltrants suggests that the tags of the infiltrants were not only longer but also more homogeneously prolonged, thus possibly achieving better penetration depth.

DISCUSSION

The aim of this study was to evaluate how adding barium oxide and zirconium particles to experimental and commercial infiltrants would influence the physical properties of the infiltrants, to give them radiopacity. Percentage concentrations by weight of 25% and 45% barium oxide were added to the infiltrants, similar to the concentrations evaluated in the study by Askar and others.[4] These same concentrations were used for the zirconium oxide particles.[23]

The reason for using small particle sizes (0.7 μm and <100 nm) was based on the greater possibility of penetrating demineralized microporosities, since the outer layers of demineralized enamel in *in vitro* artificial lesions have microporosities with a diameter between 27 and 44 μm and a total demineralization depth ranging from 93 to 219 μm, according to Groeneveld and Arends.[24] On the other hand, Cochrane and others[25] have shown that natural lesions of enamel caries are characterized by microporosities with a smaller diameter, ranging from 35 to 130 μm.

Overall, filler particles give resinous material directly proportional resistance and viscosity properties. In other words, the higher the amount of filler particles, the greater the physical properties of the resin compound, resulting in higher resistance to material deformation and higher viscosity.[26,27] Icon presented a lower CS value without the addition of filler particles, compared to the other groups tested

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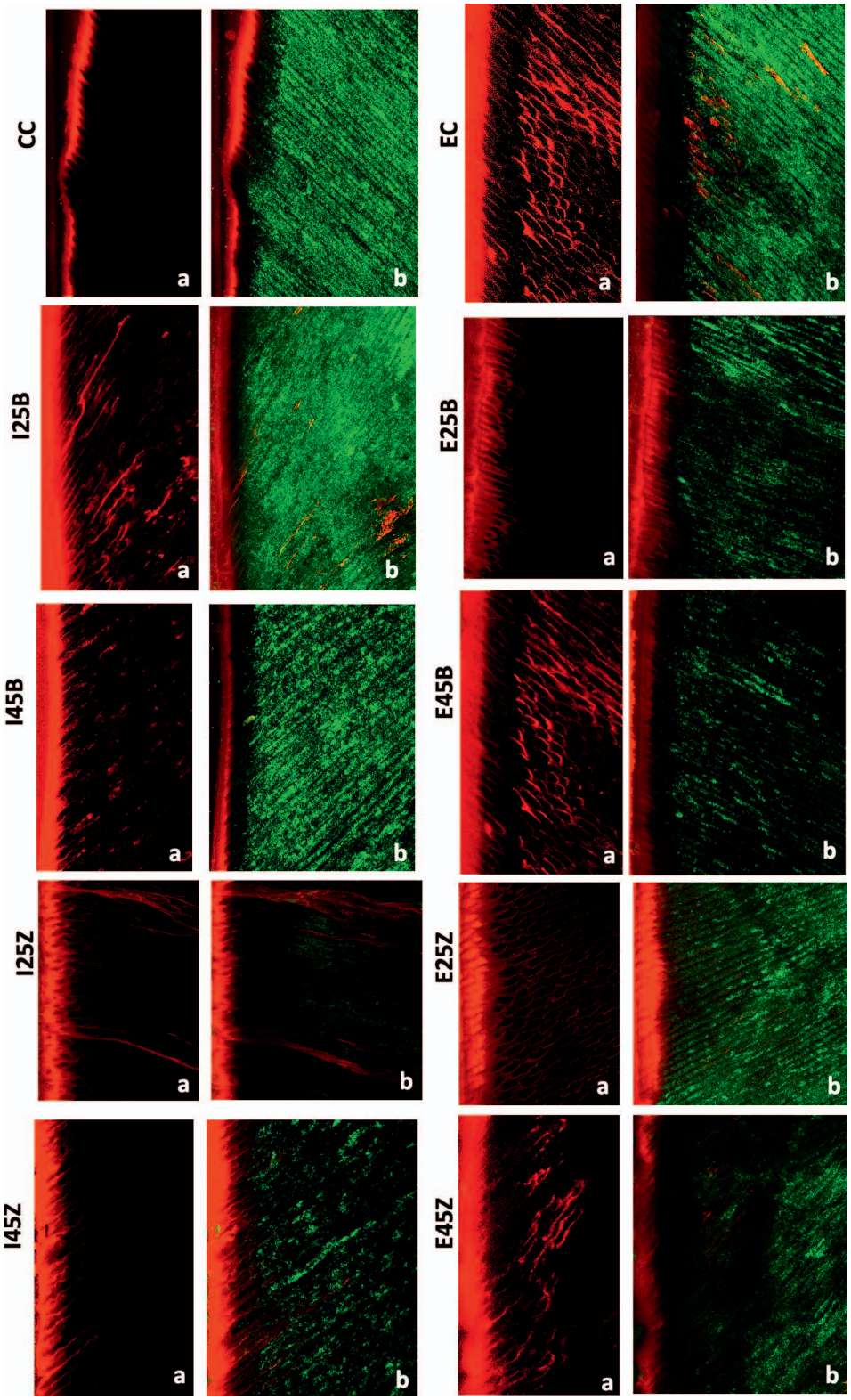

Figure 2. *Penetration depth in dual fluorescence mode of groups CC, EC, I25B, E25B, I45B, E45B, I25Z, E25Z, I45Z, E45Z. a) Colored resinous material infiltrated in red. b) Interaction between colored resin material (red) and demineralized porous structures in green. CC showed superficial penetration compared with EC. EC showed longer tags and a thicker red layer; resinous material may have been retained in that region of the lesion surface. I25B showed penetration with few extended tags. E25B showed more homogeneous tags, but not as deep. I45B showed superficial penetration with few extensions. E45B showed longer tags and a thicker red layer, resinous material may have been retained in that region of the lesion surface. I25Z showed a thicker layer of more intense red on the surface, possibly due to the presence of particles of zirconia and resin that may have been trapped in this region. E25Z showed longer and more homogeneous tags, with a thicker layer, similar to that of I25Z. I45Z showed superficial penetration with a thicker red layer; resinous material may have been retained in that region of the lesion surface. E45Z showed longer tags and a thicker red layer, also similar to I45Z.*

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in this study (Table 2). This result can be attributed to the presence of a relatively high amount of TEGDMA, as well as the absence of filler particles in its composition.[26-28] The highest values found for CS were groups with 45% addition of zirconium (Table 2); this is because a larger number of particles are needed to fill equal volumes of filler with smaller-sized particles (<100 nm). Thus, the surface area may have increased, and this may have resulted in greater interaction between the resin matrix and filler particles, and among the filler particles themselves, thus increasing the resistance.[19]

A high DC is often correlated with better mechanical properties of restorative composites, thus reducing possible risk of fractures and material wear in intraoral functions.[28] The lowest DC was found for Icon (Table 2)—a result that can be attributed to the excessive amount of TEGDMA in its composition (>90% by weight). This finding agrees with previous studies, which have shown that the DC decreases as the concentration of TEGDMA increases (>70% by weight),[29-31] TEGDMA has a high DC; however, formation of the polymer chain does not always occur. In addition, the absence of strong intermolecular secondary bonds as well as the presence of aromatic rings results in properties inferior to those of other monomers.[32] The EC group presented a higher DC value than IC (Table 2). This may have been caused by the presence of *Bis*-EMA. The molecular structure of *Bis*-EMA is similar to that of *Bis*-GMA, differing in regard to the absence of hydroxyl groups. This absence induces the nonformation of hydrogen bonds and reduces the viscosity of *Bis*-EMA compared to *Bis*-GMA. In this respect, the research literature has shown that higher DC can be achieved by using specific concentrations of monomers with lower viscosity, such as *Bis*-EMA.[28]

Addition of 45% zirconium led to a reduction in DC in both the experimental and Icon groups (Table 2). This corroborates the findings of Halvorson and others,[33] which concluded that the DC decreased when there was an increase in the number of filler particles. This can be explained by the mobility of resin monomers that can be restricted at the surface of the composite, leading to a decrease in molecular and radical motility, and resulting in lower DC. However, the influence of the filler particle on the DC may be more related to the size of the particle surface area than to the number of filler particles.[33,34] The increase in DC in groups I25B and I45B can be attributed to barium having a larger particle size than zirconium. In contrast, the addition of barium to the experimental groups had no effect (Table 2).

The mechanical properties of resinous materials can be altered due to degradation by water, and the polymerization quality of these materials may be related to the chemical characteristics of monomers.[35] Resin-based dental materials can absorb water and other fluids from the oral environment, such as WS, and may also release components into the oral environment, such as SL.[28] According to ISO 4049/2009, composites can be indicated as restorative materials only if they have WS less than or equal to 40 $\mu g/mm^3$ and SL less than or equal to 7.5 $\mu g/mm^3$ in a period of 7 days of storage. High WS and SL values can trigger chemical and physical processes that may result in detrimental effects on the structure and function of dental polymers.[28]

All groups containing Icon presented a higher than recommended WS, whereas the groups containing the experimental infiltrant presented values lower than 40 $\mu g/mm^3$ (Table 2). Thus, we may infer that the lower DC obtained with Icon may have influenced CS and WS values negatively. However, the lower values of WS obtained with the experimental infiltrants, compared to Icon, may be due to the *Bis*-EMA in their composition. This hypothesis is in agreement with an earlier study that showed low WS for *Bis*-EMA, which has a relatively higher DC value and a more hydrophobic character than *Bis*-GMA[28]. When a polymer is placed in water, hydrogen bonds are formed by water in conjunction with polymeric polar groups, such as hydroxyl and carbonyl. This condition may disrupt the intercellular interaction of the polymer.[35] Since *Bis*-EMA has no hydroxyl groups, but has ether groups instead, this effect may not occur, resulting in lower water solids.[35] In addition, TEGDMA—probably the largest component of Icon—can be homopolymer- or copolymer-free, forming a polymer chain prone to chemical degradation, especially in acidic environments.[32]

All the groups obtained lower SL values than that recommended by ISO (Table 2). This finding of the present study contradicts that of the study by Sfalcin and others,[28] who found the SL value of Icon to be 49 $\mu g/mm^3$. However, the study by Inakagi and others[35] also found lower SL values (5.76 $\mu g/mm^3$) than those recommended by ISO. However, in both studies, photopolymerization was carried out for 60 seconds, unlike the present study that used 40 seconds.

The groups that obtained higher radiopacity values than those of enamel (2.24 mmAl) were the

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I45Z and E45Z groups, whereas those that obtained higher radiopacity values than those of dentin (1.23 mmAl) were I25Z and E25Z (Figure 1). Higher radiopacity was found in the I45Z and E45Z groups, where there was a greater quantity of filler particles, since the radiopacity of a material increases as the filler particle concentration increases in higher atomic number, as has been demonstrated in other studies.[15-17] In this study, zirconium showed higher radiopacity when compared to barium in the same proportions (Figure 1), corroborating the findings of previous studies.[15,36,37] The amounts of 25% and 45% barium were not sufficient to obtain values of radiopacity above that recommended by the International Organization for Standardization (ISO 4049/2009). Studies by Watts [38] and Van Dijken and others[39] have shown that 70% of filler particles in volume by weight are required to obtain radiopacity values higher than those of enamel, whereas the percentage of high atomic number particles (radiopacifiers) may be greater than 20%. Generally, there are several particles with a high atomic number in composite resins; this may explain why barium may not have reached the required radiopacity value. However, this was the first study to test radiopacity in infiltrants. Future studies should analyze and confirm these important findings.

The ability of carious lesions to penetrate the teeth was evaluated qualitatively using confocal microscopy images (Figure 2). The addition of filler particles to the experimental and commercial infiltrant groups resulted in a similar penetration depth, but the experimental group had longer resin tags. That is to say, the addition of the particles may not have influenced the penetration of the infiltrants. The high permeability of the resin infiltrant may be attributed to the low viscosity of TEGDMA, as well as its low molecular weight, characteristics that allowed higher infiltration penetration in comparison with other materials, such as sealants and adhesives.[32]

The proposal of an infiltrant that can penetrate carious enamel lesions is promising, and the confirmation of radiographic success is of paramount importance. This study featured pioneering research into the addition of filler particles with the objective of providing infiltrant material with radiopacity, without altering its physical properties detrimentally. Further studies should expand on these findings by testing other percentages and other types of elements of high atomic number, and even by mixing two radiopacifying particles, as has been proposed in some studies.

In addition, it is important to point out that, depending on filler size, these radiopaque particles could have a negative influence due to resin staining used to mask WSLs in the vestibular region, as a result of polishing.[27] However, radiopaque particles are not as important to the vestibular as they are to the interproximal region. Therefore, there could be two types of infiltrants, which would be supplied in two different packages, considering that their application tips are different.

CONCLUSION

According to the results obtained in this study, it was possible to conclude that addition of 45% of zirconium presented good results for CS and WS, SL below the recommended standard, and adequate radiopacity, and penetration depth similar to that of the other groups.

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Regulatory Statement

This study was conducted in accordance with all the provisions of the human subjects' oversight committee guidelines and policies of Committee of Ethics in Research of Piracicaba Dental School—UNICAMP. The approval code issued for this study is 2,772,954.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this manuscript.

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Change in the Shrinkage Forces of Composite Resins According to Controlled Deflection

I-S Yoo • D Kim • K Kim • S-h Park

Clinical Relevance

Polymerization shrinkage forces and the differences in such forces between composite resins decrease with increasing cuspal deflection. When high deflection is expected, controlling composite volume with a base material or use of a layer filling technique is more practical than trying to choose a composite with low polymerization shrinkage stress.

SUMMARY

The aim of this study was to investigate how the polymerization shrinkage forces of composite resins change with change in deflection. Five composites, SDR (Dentsply Caulk, Milford, DE, USA), EcuSphere-Shape (DMG, Hamburg, Germany), Tetric N-Ceram Bulk Fill (Ivoclar Vivadent, Schaan, Liechtenstein), CLEARFIL AP-X (Kuraray Noritake Dental Inc., Sakazu, Kurashiki, Okayama, Japan), and Filtek Z350 XT (3M Dental Products, St Paul, MN, USA), were tested in this experiment. The polymerization shrinkage forces of the composites were measured using a custom-made tooth-deflection-mimicking device and software (R&B Inc, Daejon, Korea). In all measurements, six modes were tested: maximum-deflection, zero-deflection, and four deflection-controlled modes. For each deflection mode, the shrinkage forces were recorded continuously every 0.1 second for 180 seconds. Polymerization shrinkage and flexural modulus were also measured. Eight specimens of each material were allocated for each test. For each material, six groups of shrinkage force values were compared using one-way ANOVA and Tukey post hoc tests at a 95% confidence level. The polymerization shrinkage force of each material in each of the six deflection modes was analyzed with 95% confidence using one-way ANOVA and Tukey post hoc tests. The relationship between the force measured in the six deflection modes and the linear polymerization shrinkage and flexural modulus was analysed with 95% confidence using Pearson correlation analysis. For each material, the following held true: the shrinkage force was highest in zero-deflection mode, the force decreased as deflection increased, and the smallest force appeared in maximum-deflection mode ($p<0.05$). There was

Il-Sang Yoo, DDS, MS, Department of Conservative Dentistry, School of Dentistry, Yonsei University, Seoul, Republic of Korea

Dohyun Kim, DDS, MS, PhD, Department of Conservative Dentistry and Oral Science Research Center, School of Dentistry, Yonsei University, Seoul, Republic of Korea

Kwangman Kim, PhD, professor, Department of Biomaterial & Bioengineering, Yonsei University, Seoul, Republic of Korea

*Sung-ho Park, DDS, MS, PhD, Professor, Department of Conservative Dentistry, Oral Science Research Center, School of Dentistry, Yonsei University, Seoul, Republic of Korea

*Corresponding author: 50-1 Yonsei-ro, Seodaemun-gu, Seoul, Republic of Korea 03722; e-mail: sunghoopark@yuhs.ac

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a high negative correlation between allowable deflection and shrinkage force in all materials.

INTRODUCTION

As a direct restorative material, dental resin composites are widely used for anterior and posterior tooth restoration. However, one of the drawbacks of composites is that internal stress is inevitable due to the nature of vinyl polymerization, which involves reductions in intermolecular dimensions and free volume.[1] Shrinkage stress in composite restorations results from polymerization shrinkage occurring under confinement due to bonding to cavity walls;[2] confined shrinkage causes excessive residual stress that, if in tension, can cause micro-crack initiation and breakage.[3-5] Polymerization shrinkage and contraction stress can cause debonding, marginal gap formation, microleakage, secondary dental caries, post-operative hypersensitivity, and cuspal deflection.[6] More than 1% of polymerization shrinkage is unpreventable despite substantial shrinkage reduction efforts.[5]

Polymerization shrinkage stress in composite resins was first studied as a function of restoration shape by Feiltzer and others.[3] Shape was described with a configuration factor, C, representing the ratio of the restoration's bonded to unbonded (free) surfaces. In that experimental set-up, the shape of the restoration was simulated with cylindrical forms of various dimensions and shrinkage stress was continuously measured. Any axial sample contraction, which occurs due to yielding of the load cell to the shrinkage force, was immediately counteracted and the height of the cylindrical forms was maintained with a feedback mechanism. Under these stiff conditions, polymerization shrinkage stress increased as C-factor increased.

However, Watts and others[4,7] reported that teeth and their cavities display elastic and visco-elastic compliance and that stress should be measured while allowing for minimal but essential compliance. In their nonstiff system, the relationship between polymerization and C-factor is more complex than simply a ratio of bonded to unbonded surfaces. When polymerization stress was measured under nonstiff conditions, both C-factor and resin composite mass were important in the production of shrinkage stress.

Less stress was recorded in a nonstiff system than under stiff conditions due to the stress-relieving effect of allowable displacement.[4,8] In the high-compliance system, polymerization shrinkage stress decreased as C-factor increased. This tendency decreased as system compliance decreased and eventually reversed as higher C-factors increased polymerization shrinkage stress.[9]

It has been reported that placing composites in Class II cavity preparation leads to inward deformation of the cusps.[10] This has been termed cuspal deflection and is the result of the interaction between composite resin polymerization shrinkage stress and cavity wall compliance when the adhesive force between tooth and composite resin is sufficiently strong.[11]

The structural and material factors that affect cuspal deflection are cavity width and depth, thickness of residual dentin,[11,12] polymerization shrinkage of composite resin,[13] and flow and compliance of cured composite and teeth.[13,14] The clinical factors affecting cuspal deflection are use of a liner,[15] filling technique,[11,16] restoration method,[11,17] and light curing method.[18]

Cuspal deflection varies from approximately 10-45 μm depending on measurement method, tooth type, cavity preparation type, and cavity size.[10,11] Even within a prepared cavity, deflection may vary according to remaining tooth structure and location in the cavity preparation. Thus, the relationship between polymerization shrinkage and deflection could have a significant clinical effect.

The purpose of this study was to develop an *in vitro* system that exhibits constant compliance but can also exhibit various deflections, mimicking cuspal deflection of the tooth, and to evaluate the relationship between deflection and polymerization shrinkage force. In our experimental devices, the various amounts of deflection under shrinkage force can be controlled by feedback action.

The null hypotheses were:

1. Polymerization shrinkage force does not change, even if deflection changes.
2. Polymerization shrinkage force does not correlate with amount of polymerization shrinkage or flexural modulus.

METHODS AND MATERIALS

Five brands of light-cured composites were used (Table 1).

Density Measurement

Each sample had a volume of 0.063 cm^3, which was equivalent to a 3 mm (width) x 3 mm (depth) x 7 mm (length) Mesial-Occlusal-Distal (MOD) cavity. Measurements were taken, first, of the density of each material in order to apply the same volume of material, and second, of the mass equivalent to the volume. While pre-polymerization density is more accurate, post-polymerization density was used because flowable type SDR, for which pre-polymerization density is

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Table 1: *Restorative Materials Used in This Study and Density Measured*

	Manufacturer	LOT #	Density(g/cm^3)
SDR	Dentsply Caulk, Milford, DE, USA	1511000715	1.976(0.005)
EcuSphere-Shape	DMG, Hamburg, Germany	750594	2.039(0.003)
Tetric N-Ceram Bulk Fill	Ivoclar Vivadent, Schaan, Liechtenstein	S14902	2.072(0.028)
CLEARFIL AP-X	Kuraray Noritake Dental Inc., Sakazu, Kurashiki, Okayama, Japan	4J0073	2.332(0.016)
Filtek Z350 XT	3M Dental Products, St Paul, MN, USA	N678112	1.915(0.008)

Abbreviation: g/cm^2 = grams per square centimeter.

hard to measure, was included as one of the samples. The density of five specimens of each material was measured using disks 1 cm in diameter and 1 mm thick. Excellence XS Precision Balances (XS105, Mettler-Toledo International Inc, Greifensee, Switzerland) with Mettler Toledo installed Density Accessory Kits were used in a laboratory environment. Specimen weights were measured on the pan in both air and distilled water. Density, calculated according to the Archimedes principle, was recorded and average values determined. The measured density values are given in Table 1.

Polymerization Shrinkage Force Measurement and Deflection Control

The polymerization shrinkage forces of the resin composites were measured using a custom-made shrinkage force-feedback machine (Figure 1). The polymerization shrinkage force of composites and the control of the accompanying movement of the device used a feedback mechanism (R&B Inc., Daejon, Korea). The instrument was driven by a motor and was designed to move a metal bar up and down. An acrylic rod was screwed into the metal rod. A sensor (Figure 1B) was installed to control the movement of the metal and acrylic rods (Figure 1C, D) by a feedback mechanism. Before placing the composite in the device, the surface of the acrylic rod was roughened with sandpaper (180 grit), treated with adhesive resin (bonding agent, Adhese 2, Ivoclar Vivadent), and light cured. A restorative material (0.063 cm^3) was placed at the end of the acrylic rod. Its position was then adjusted with the motor connected to the metal bar until the thickness of the restorative material reached 2 mm (diameter: 6.4 mm, C-factor = 1.6). The force between the acrylic rod and the resin composite was set to zero using the software, and the resin composite was light cured (Bluephase, Ivoclar Vivadent, 800 mW/cm^2) for 20 seconds through the transparent acrylic base (Figure 1F). The polymerization shrinkage force was measured with a force cell (100 kilogram force [kgf]) connected to the bar, while the displacement of the rod was simultaneously recorded by a sensor with a resolution of 0.1 μm. Measurements were made every 0.1 second for a total time of 180 seconds. The displacement of the rod was adjusted based on feedback, using the installed software. The compliance of this system was 0.5 μm/N.

In the zero-deflection group (Group 1), when the feedback sensor (Figure 1B) detected more than 0.1 μm

Figure 1. *Device for measurement of polymerization shrinkage force and deflection control. (A): load cell; (B): feedback sensor; (C) metal rod; (D) acrylic rod; (E) space for composite specimen placement; (F) acrylic base; (G) light source.*

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of downward movement of the metal and acrylic rods (Figure 1C and 1D) during the polymerization process, the metal and acrylic rods were returned upwards to their original position via the feedback system. Thus, the system returned to its previously set position and the deflection value was 0.

In the maximum-deflection mode (Group 6), polymerization shrinkage force measurements were conducted without any feedback from the rod, and maximum deflection occurred in each composite. Deflection values of 0 and maximal deflection for each composite were measured in groups 1 and 6, respectively, and four intermediate deflection values were allocated to Groups 2, 3, 4, and 5 (Table 2). In these groups, rod deflection was controlled by the feedback system. The measurements were repeated ten times for each group of materials. A schematic of the experimental design is shown in Figure 2.

Measurement of Linear Polymerization Shrinkage

Polymerization shrinkage was measured using a custom-made Linometer (R&B Inc, Daejon, Korea) following the procedures previously described by Kim and Park.[19] Resin specimens in equal amounts were prepared by applying composite resin to a cylindrical mold with a diameter of 4.5 mm and a depth of 1.3 mm. The resin specimens were placed on the metal disk of a custom-made Linometer (R&B) and covered with a glass slide; the metal disk and the glass slide were covered with a thin coating of glycerin gel to prevent adhesion. An LED-type light-curing unit (Bluephase, Ivoclar Vivadent, 800 mW/cm^2) was placed 1 mm above the glass slide, and the material was light cured for 20 seconds. As the light irradiation progressed, the composite resin shrank in the direction of the light, and the metal disk moved together with the composite resin; the measured value of this movement was recorded by computer. Polymerization shrinkage was measured for 120 seconds from the start of light irradiation eight times.

Measurement of Flexural Modulus

This test was carried out in accordance with ISO 4049. Specimens 2 ± 0.1 × 2 ± 0.1 × 25 ± 2.0 mm in size were prepared. Each specimen was light cured along its length using a light-curing unit (Bluephase N, 800 mW/cm^2) for three 20-second exposures. If there were bubbles, voids, or other defects on the surface, a new specimen was made. The specimens were stored for 24 ± 1 hours in distilled water at 37 ± 1°C until the test. The size (width, height) of the specimen was measured with internal and external calipers, and the specimens were wet ground slightly with 320-grit silicon carbide paper on all four surfaces to reduce flash. Maximum load and maximum deflection were measured with a three-point bending test at a crosshead speed of 0.75 ± 0.25 mm/minute on a universal testing machine (Instron 3366, Norwood, MA, USA). After the measurement, flexural moduli were calculated in gigapascals (GPa) using the following equation:

$$E_{flexural} = \frac{FL^3}{4wdh^3}$$

where $E_{flexural}$ = flexural modulus, F = maximum load, L = span length, w = specimen width, h = specimen height, and d = deflection.

Statistical Analysis

For each material, shrinkage force values of the six groups were compared using one-way ANOVA and Tukey *post hoc* tests at a 95% confidence level. One-dimensional linear regression analyses were performed to explore the relationship between polymerization shrinkage force and deflection in each material. Pearson correlation analyses were done with 95% confidence to evaluate the relationship between polymerization

Table 2: *Mean (SD) of Polymerization Shrinkage Force (kgf)a*

	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6
SDR	6.5 (0.8) Cd	4.7 (0.6) BCc	4.3 (0.5) BCbc	4.1 (0.6) Cbc	3.6 (0.7) Cab	3.0 (0.3) Ba
EcuSphere-Shape	6.1 (0.5) Ce	4.9 (0.7) Cd	4.4 (0.8) Ccd	4.0 (0.6) BCbc	3.4 (0.8) BCab	2.7 (0.2) Ba
Tetric N-Ceram Bulk Fill	4.4 (0.6) ABd	3.9 (0.6) Acd	3.7 (0.6) ABc	3.2 (0.7) Abc	2.7 (0.6) ABab	2.0 (0.2) Aa
CLEAR -FIL AP-X	4.7 (0.2) Be	4.1 (0.5) ABd	3.6 (0.4) ABcd	3.3 (0.8) ABbc	2.8 (0.5) ABCb	1.9 (0.3) Aa
Filtek Z350 XT	3.9 (0.7) Aa	3.5 (0.5) Abc	3.1 (0.5) Ab	3.0 (0.4) Ab	2.2 (0.6) Aa	1.8 (0.2) Aa

[a] Groups with distinct uppercase letters exhibit statistically significant differences in each column and those with distinct lowercase letters exhibit statistically significant differences in each row ($p<0.05$).
Abbreviations: SD = standard deviation; kgf = kilogram force.

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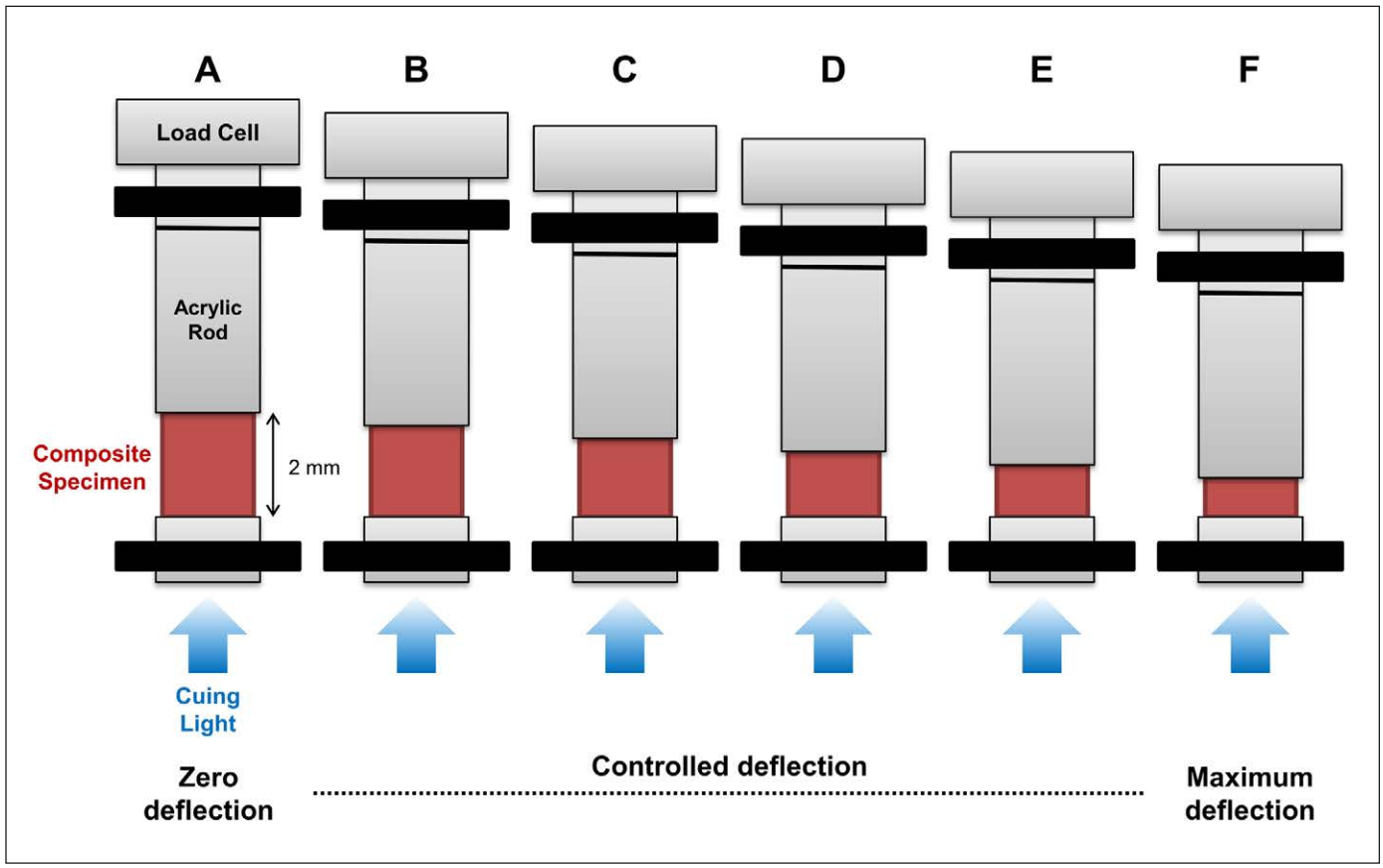

Figure 2. *Polymerization shrinkage force with various deflections. (A): zero deflection; (B-E): controlled deflection; (F): maximum deflection.*

shrinkage force and linear polymerization shrinkage of the materials in each group, between polymerization shrinkage force and flexural modulus of the materials in each group, and between linear polymerization shrinkage and flexural modulus of the materials. Statistical analyses were conducted using PASW statistics 18 software (SPSS for Windows: SPSS Inc, Chicago, IL, USA).

RESULTS

For the SDR material, when the deflection increased from 0 μm to 14.3 μm, the polymerization shrinkage force decreased from 6.5 kgf to 3.0 kgf (Figure 3A, Table 2). There were statistically significant differences in the shrinkage force value between the groups (p<0.05, Table 2). An equation of y = -0.2229x + 6.3686 (R^2=0.9082) was acquired via regression analysis to express the relationship between polymerization force and deflection value (Figure 4A).

For the EcuSphere-Shape material, when the system displacement increased from 0 μm to 14.4 μm, the polymerization shrinkage force decreased from 6.06 kgf to 2.73 kgf (Figure 3B, Table 2). There were statistically significant differences in the shrinkage force value between the groups (p<0.05, Table 2). An equation of y = -0.2435x + 6.8696 (R^2=0.8501) was acquired via regression analysis to express the relationship between polymerization force and deflection value (Figure 4B).

For the Tetric N-Ceram Bulk Fill material, when the system displacement increased from 0 μm to 10.2 μm, the polymerization shrinkage force decreased from 4.44 kgf to 2.00 kgf (Figure 3C, Table 2). There were statistically significant differences in the shrinkage force value between the groups (p<0.05, Table 2). An equation of y = -0.2116x + 4.7669 (R^2=0.7525) was acquired via regression analysis to express the relationship between polymerization force and deflection value (Figure 4C).

For the CLEARFIL AP-X material, when the system displacement increased from 0 μm to 10.2 μm, the polymerization shrinkage force decreased from 4.73 kgf to 1.94 kgf (Figure 3D, Table 2). There were statistically significant differences in the shrinkage force value between the groups (p<0.05, Table 2). An equation of y = -0.287x + 5.6857 (R^2=0.8438) was acquired via regression analysis to express the relationship between polymerization force and deflection value (Figure 4D).

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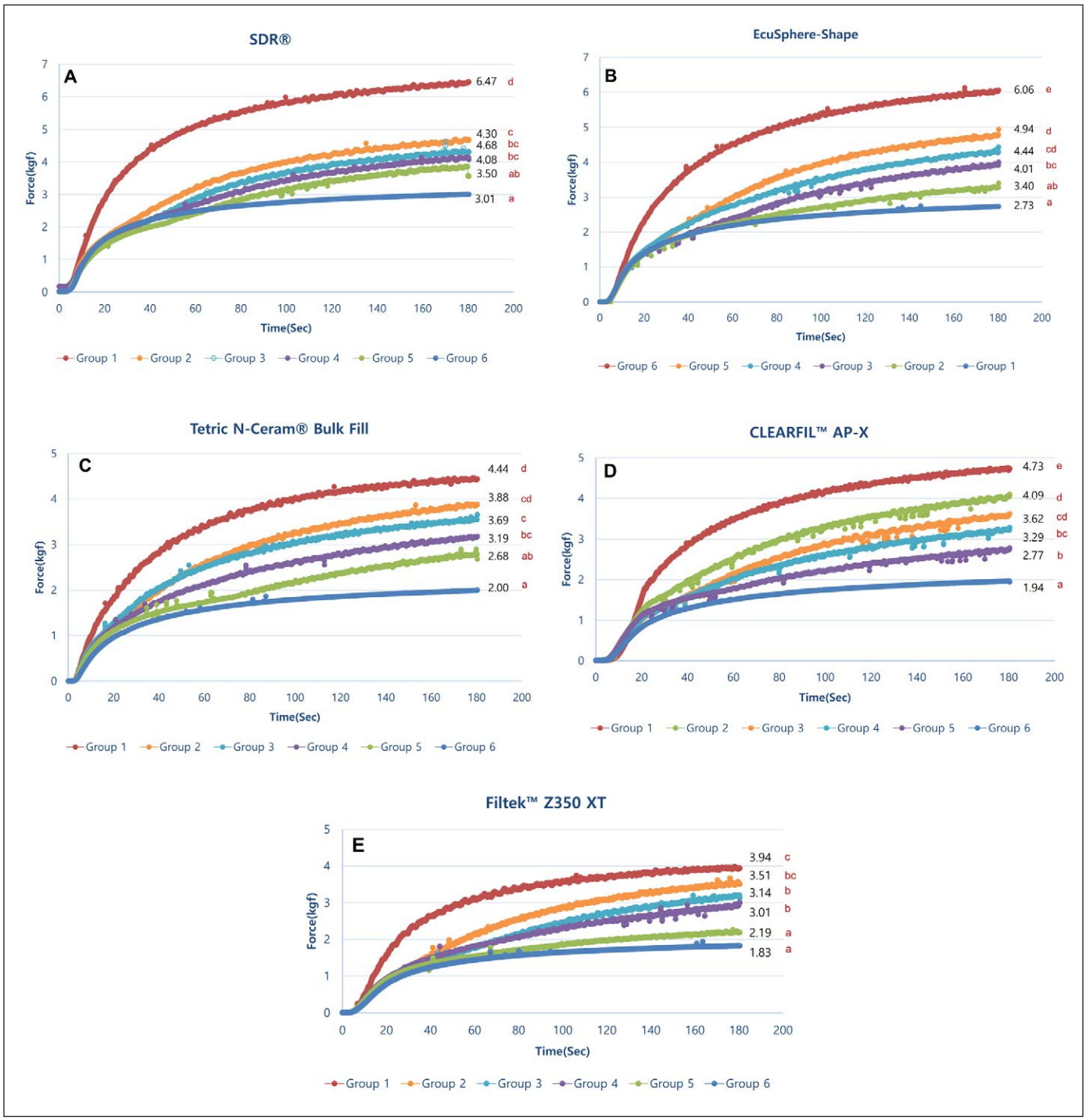

Figure 3. *Time vs force graphs for all composites. (A): SDR; (B): EcuSphere-Shape; (C): Tetric N-Ceram Bulk Fill; (D): CLEARFIL AP-X; (E): Filtek Z350 XT. a Different letters represent statistically significant differences.*

For the Filtek Z350 XT material, when the system displacement increased from 0 µm to 10 µm, the polymerization shrinkage force decreased from 3.94 kgf to 1.83 kgf (Figure 3E, Table 2). There were statistically significant differences in the shrinkage force value between the groups (p<0.05, Table 2). An equation of y = -0.1675x + 4.0691 (R^2=0.7397) was acquired via regression analysis to express the relationship between polymerization force and deflection value (Figure 4E).

There were significant differences in polymerization shrinkage forces between materials in each group (Table 2). There were also significant differences in

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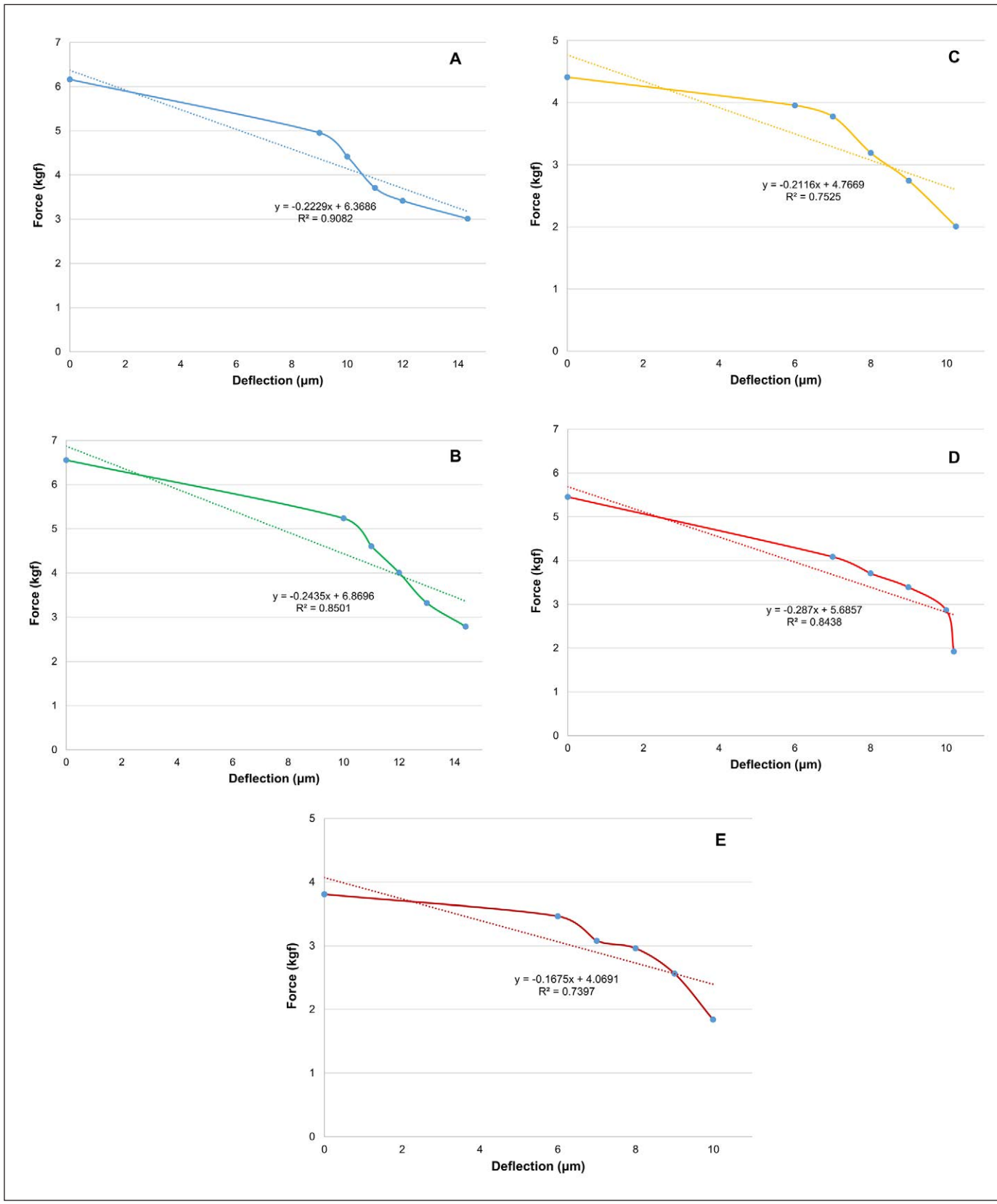

Figure 4. *Deflection vs force graphs with regression analysis. (A): SDR; (B): EcuSphere-Shape; (C): Tetric N-Ceram Bulk Fill; (D): CLEARFIL AP-X; (E): Filtek Z350 XT.*

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linear polymerization shrinkage and flexural modulus between materials ($p<0.05$) (Table 3). The Pearson product-moment correlation coefficients between the polymerization shrinkage force and the linear polymerization shrinkage in each group ranged from 0.641 (Group 4) to 0.925 (Group 6). The Pearson product-moment correlation coefficients between the polymerization shrinkage force and flexural modulus ranged from -0.444 (Group 5) to -0.776 (Group 6) (Table 4). The Pearson product-moment correlation coefficient between linear polymerization shrinkage and flexural modulus was -0.848 ($p<0.001$).

DISCUSSION

Polymerization shrinkage of composite resin causes problems such as cuspal deflection,[10,20-23] interferes with marginal and internal adaptation of composite restorations to tooth substance,[24-27] and remains as a tensile residual force on the tooth, potentially lowering tooth fatigue strength.[28,29] Initially high external and internal adaptations are exacerbated after undergoing fatiguing processes, such as simulated chewing and thermocycling, due to the residual forces on the composite resin. In addition, the degree of marginal and internal adaptations is related to the amount and degree of polymerization shrinkage.[24,26,27,30,31]

According to Watts and Satterthwaite,[7] the polymerization stress depends on both C-factor and composite mass in a compliance-allowed system. The volume of composite used in the present study was 0.063 cm^3, which was chosen to simulate Lee and Park's study[10] as much as possible. The C-factor, which was 1.6, was set to simulate that of their MOD cavity as much as possible. In their study, the cuspal deflection in the premolar MOD cavity was 14.6-22.7 μm. In the present study, deflection ranged up to 15 μm, so the two studies are consistent.

Table 3: *Mean (SD) of Polymerization Shrinkage (μm), Flexural Modulus (GPa)*

	Linear Polymerization Shrinkage	**Flexural Modulus**
SDR	31.6 (2.3) e	1.9 (0.1) a
EcuSphere-Shape	22.2 (0.7) d	3.2 (0.1) b
Tetric N-Ceram Bulk Fill	16.1 (1.5) c	5.8 (0.2) c
CLEAR -FIL AP-X	9.6 (0.8) a	13.3 (0.6) e
Filtek Z350 XT	11.6 (0.8) b	7.0 (0.3) d

Abbreviations: SD = standard deviation; μm = micrometer; GPa = gigapascal.

Table 4: *Pearson Correlations (Significance) Between the Force Measured in the Six Deflection Modes and the Linear Polymerization Shrinkage and Flexural Modulus*

Polymerization Shrinkage Force	**Linear Polymerization Shrinkage**	**Flexural Modulus**
Group 1	0.908 (0.000)	-0.642 (0.000)
Group 2	0.775 (0.000)	-0.605 (0.000)
Group 3	0.773 (0.000)	-0.514 (0.001)
Group 4	0.641 (0.000)	-0.449 (0.004)
Group 5	0.649 (0.000)	-0.444 (0.004)
Group 6	0.925 (0.000)	-0.776 (0.000)

The deflections and polymerization shrinkage forces were highly negatively correlated in all materials (Figure 4), and the first null hypothesis is rejected. With lower deflection, the system was stiffer, causing more force due to difficulties in polymerization shrinkage. On the other hand, with higher deflection, the system was more flexible, and it accommodated some of the polymerization shrinkage, thus reducing the relative force.

In this experiment, the polymerization shrinkage force and linear polymerization shrinkage were positively correlated to a moderate-to-high degree in all groups (Table 4). The Pearson correlation coefficients between the polymerization shrinkage force and the flexural modulus in each group were in a moderate range, between -0.444 and -0.776 (Table 4). Thus, the second null hypothesis is rejected.

The present study showed that deflection is highly negatively correlated with polymerization shrinkage force (Figure 4) and the polymerization shrinkage force is highly correlated with the amount of polymerization shrinkage (Table 4). This is consistent with a previous study in which the amount of polymerization shrinkage and cuspal deflection were highly correlated.[10]

The results of this study showed that linear polymerization shrinkage had a stronger effect on polymerization shrinkage force than flexural modulus in all groups (Table 4). Polymerization shrinkage itself is the fundamental cause of the polymerization shrinkage force. Flexural modulus, on the other hand, limits the proportion of the polymerization shrinkage force that is generated by polymerization shrinkage. Thus, although linear polymerization shrinkage and flexural modulus affect shrinkage force, the amount of shrinkage itself seems to be more influential in all

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groups. This is consistent with a previous study by Kim and Park,[21] in which a moderate correlation was found between flexural modulus and cuspal deflection. However, Tsujimoto and others reported that no significant relationship was found between the two.[23] The differences may be attributable to differences in the materials used. In the present study, the Pearson correlation coefficient between polymerization shrinkage and elastic modulus was -0.848. The high negative correlation between the two may have affected polymerization shrinkage force and deflection and resulted in a moderate correlation between flexural modulus and cuspal deflection.

As for the relationship between C-factor, polymerization shrinkage, and internal adaptation, Han and others[32] reported that internal adaptation in a high–C-factor cavity is inferior to that in a low–C-factor cavity for both conventional and bulk-filled composites; furthermore, polymerization stress under the compliance-allowed condition (Group 6 in the present study) was significantly correlated with internal adaptation in both high– and low–C-factor cavities. The difference in polymerization shrinkage force between materials was greater in zero-deflection mode (Group 1) and had a decreasing tendency as deflection increased (Figure 5, Table 2). The results of both the present study and the study by Han and others imply that it is important to choose composites with lower polymerization shrinkage force in clinical situations with high C-factors and/or lower deflection values, such as Class I and V cavities. On the other hand, the choice of materials is less important in higher deflection situations such as in Class II cavities. Application of a clinical technique that reduces polymerization shrinkage, such as reducing the amount of composite used with a base[33] or a proper layering technique,[21,34,35] is more important in such cases.

In a class II cavity, deflection of the tooth differs according to location and remaining tooth structure. The deflection of the cusp tip area is higher than that of the gingival or pulpal wall area. Considering the results of the present study, the polymerization shrinkage force would be lower at the cusp tip than in the pulpal or gingival wall area, and internal adaptation would differ between the areas. The study by Han and Park,[36] in which the internal adaptation of a class II cavity was

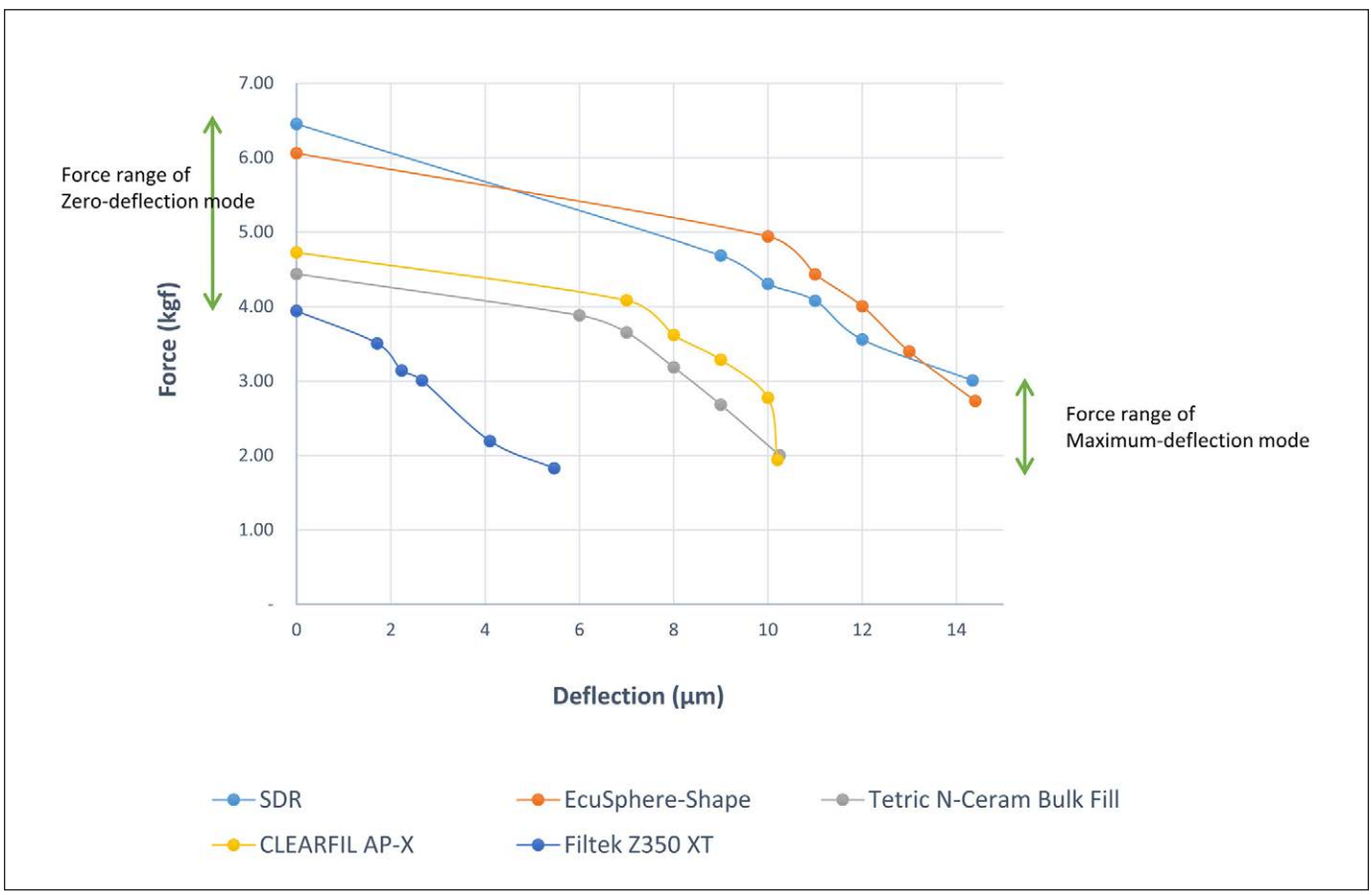

Figure 5. *Deflection vs force curves for all composites.*

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evaluated using micro-CT, supports this assumption. In that study, the gingival floor of the proximal box and the pulpal floor of the cavity preparation had higher imperfect margins than did the buccal and lingual walls of the proximal box.

Considering the results of the present study, care should be taken when composites are placed on the pulpal floor, where deflection would be limited. According to Han and others,[37] placing an intermediate layer between the pulpal floor and the composite material as a base or lining material increases the internal adaptation of a restoration by decreasing polymerization shrinkage stress. When flowable composites are considered to line a cavity floor, materials with low polymerization shrinkage stress should be chosen because of the stress's effect on internal adaptation.[37] In class II cavities, after placement of the intermediate layer, the importance of selecting materials with low polymerization shrinkage stress would be reduced; in such cases the composite is placed over the intermediate layer, which allows more deflection than the pulpal or gingival floor, and the differences in polymerization shrinkage between materials will be reduced. A proper layering technique would be more beneficial in this situation.[21,34,35]

SDR, a flowable-type bulk fill composite, showed the same or higher polymerization shrinkage force than other packable or packable-type bulk fill composites in all groups. This finding is consistent with previous studies that compared the polymerization shrinkage stress of bulk fill and packable composites.[19,34,38] However, the polymerization shrinkage stress of SDR was relatively low in previous studies when compared with that of other flowables or flowable-type bulk fill materials.[34,37,38] In this sense, SDR could be recommended as an intermediate material compared to other flowables.

CONCLUSION

For each material, the shrinkage force was the highest in zero-deflection mode, the force decreased as deflection increased, and the smallest force appeared in maximum-deflection mode. There was a high negative correlation between allowable deflection and shrinkage force in all materials.

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Acknowledgements

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Conflict of Interest

The authors have no proprietary, financial, or other personal interests of any nature or kind in any product, service, and/or company that is presented in this article.

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Evaluation of Monomer Elution and Surface Roughness of a Polymer-Infiltrated Ceramic Network CAD–CAM Material After Er,Cr:YSGG Laser-assisted Tooth Bleaching

P Mourouzis • E Diamantopoulou • ATsigarida • D Dionysopoulos A Konstantinidis • V Samanidou • K Tolidis

Bleaching treatment with Er,Cr:YSGG laser or the conventional technique is a safe procedure as regards to monomer elution and surface roughness of resin composites and resin–ceramic computer-aided design–computer-aided manufacturing materials.

http://doi.org/10.2341/20-158-L

Handling and Mechanical Properties of Low-viscosity Bulk-fill Resin Composites

E Hirokane •T Takamizawa • T Tamura • S Shibasaki A Tsujimoto • WW Barkmeier • MA Latta • M Miyazaki

Some low-viscosity bulk-fill resin composites can probably be used in stress-bearing areas, while maintaining an effective depth of cure and good handling properties.

https://doi.org/10.2341/20-253-L

Evaluation of Tooth Sensitivity of In-office Bleaching with Different Light Activation Sources: A Systematic Review and a Network Meta-analysis

BM Moran • PK Ziegelmann • SB Berger • A Burey • T de Paris Matos E Fernández • AD Loguercio • A Reis

The use of light sources for in-office bleaching does not seem to exacerbate bleaching-induced tooth sensitivity.

http://doi.org/10.2341/20-127-L

Does Addition of 10-MDP Monomer in Adhesive Systems Improve the Clinical Performance of Noncarious Cervical Lesion Restorations? A Systematic Review and Meta-analysis

RP de Oliveira • JCP Baia • TSP da Silva • MB Magno • LC Maia • SC Loeretto MH da Silva e Souza Junior

The presence of 10-MDP monomer in self-etch adhesive systems did not influence the clinical performance of noncarious cervical lesion (NCCL) restorations.

https://doi.org/10.2341/20-053-LIT

Effect of Aging on Surface Roughness and Color Stability of a Novel Alkasite in Comparison with Current Direct Restorative Materials

B Yazkan • EU Celik • D Recen

Although this novel alkasite is a promising material due to its strong mechanical properties, as reported in the literature, the material may not be as successful as composite resins in terms of meeting esthetic expectations.

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Evaluation of Monomer Elution and Surface Roughness of a Polymer-Infiltrated Ceramic Network CAD–CAM Material After Er,Cr:YSGG Laser-assisted Tooth Bleaching

P Mourouzis • E Diamantopoulou • ATsigarida • D Dionysopoulos
A Konstantinidis • V Samanidou • K Tolidis

Clinical Relevance

Bleaching treatment with Er,Cr:YSGG laser or the conventional technique is a safe procedure as regards to monomer elution and surface roughness of resin composites and resin–ceramic computer-aided design–computer-aided manufacturing materials.

SUMMARY

Purpose: The aim of this in vitro study was to examine the effect of Er,Cr:YSGG laser-assisted tooth bleaching treatment on the elution of monomers and surface roughness of a hybrid computer-aided design–computer-aided manufacturing (CAD–CAM) material, and to compare it with a resin composite for direct restorations.

*Petros Mourouzis, MSc, PhD, assitant professor, Department of Operative Dentistry, Division of Dental Tissues Pathology and Therapeutics, Faculty of Dentistry, Aristotle University of Thessaloniki, Greece

Ellisavet-Ioanna Diamantopoulou, MSc, graduate student, Department of Chemistry, Laboratory of Analytical Chemistry, Aristotle University of Thessaloniki, Greece

Alexia Tsigarida, Chemist, MSc, Department of Civil Engineering, Division of Structural Engineering, Faculty of Engineering, Aristotle University of Thessaloniki, Greece

Dimitrios Dionysopoulos, MSc, PhD, assistant professor, Department of Operative Dentistry, Division of Dental Tissues Pathology and Therapeutics, Faculty of Dentistry, Aristotle University of Thessaloniki, Greece

Avraam Konstantinidis, PhD, assistant professor, Department of Civil Engineering, Division of Structural Engineering, Faculty of Engineering, Aristotle University of Thessaloniki, Greece

Victoria Samanidou, PhD, professor, Department of Chemistry, Laboratory of Analytical Chemistry, Aristotle University of Thessaloniki, Thessaloniki, Greece

Kosmas Tolidis, PhD, professor, Department of Operative Dentistry, Division of Dental Tissues Pathology and Therapeutics, Faculty of Dentistry, Aristotle University of Thessaloniki, Greece.

*Corresponding author: 77 K Karamanli Street, GR 54246, Thessaloniki, Greece; e-mail: p.mourouzis@gmail.com

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Methods and Materials: Forty specimens of a hybrid CAD–CAM material (Enamic) and forty of a conventional resin composite (Tetric) were fabricated and randomly divided into four groups (n=10). Half of the specimens of each material were stored in distilled water and the other half in artificial saliva for 7 days. At the end of this period, the storage medium was analyzed by high-performance liquid chromatography (HPLC), and the surface roughness parameters of the specimens were evaluated by optical imaging noncontact interferometric profilometry. Afterwards, half of the specimens of each tested material received a conventional in-office tooth bleaching treatment and the other half an Er,Cr:YSGG laser-assisted bleaching treatment, and then they were again incubated in distilled water and artificial saliva for an additional 7-day time period. At the end of this period, the effect of the bleaching treatments on elution of monomers and surface roughness of the tested materials was evaluated.

Results: Bisphenol A (BPA), urethane dimethacrylate (UDMA), triethylene glycol dimethacrylate (TEGDMA), and bisphenol A-glycidyl dimethacrylate (BisGMA) were eluted from the conventional resin composite into both the solutions tested. Only TEGDMA was eluted from the hybrid CAD–CAM material. However, no statistically significant differences were found among the surface roughness parameters of both materials. Both the conventional and Er,Cr:YSGG laser-assisted tooth bleaching treatments affected the monomer elution from the composite resin. However, there were no statistically significant differences ($p<0.05$) between the treatments.

Conclusions: According to the results of this study, tooth bleaching with Er,Cr:YSGG laser or conventional technique is safe, even if the bleaching agent comes in contact with hybrid CAD–CAM restorations.

INTRODUCTION

Computer-aided design–computer-aided manufacturing (CAD–CAM) and laser technologies have increased their popularity among dental clinicians. Dental applied science continues to expand, as more dental practitioners gain access to the evolving technology and as long as there are significant developments in dental materials.[1] Often, CAD–CAM indirect restorations that have been fabricated with resin composites, or hybrid CAD–CAM materials may accidentally come in contact with a bleaching gel during tooth bleaching treatments. Tooth bleaching is a popular choice among patients due to increased aesthetic demands for whiter teeth. There are several categories of tooth bleaching treatments including: (1) over-the-counter bleaching gels, (2) hydrogen peroxide (H_2O_2) strip systems, (3) at-home bleaching, (4) power bleaching, (5) assisted or waiting room bleaching, and (6) in-office dual-activated techniques.[2] Most of the predictable tooth bleaching treatments seem to be the at-home and the in-office dual-activated technique. At-home bleaching treatment is carried out by the patient but under dental supervision, while in-office bleaching treatments are performed by the dentist at the dental office in one or more visits.[3]

The bleaching gels contain peroxide compounds like H_2O_2 and carbamide peroxide ($NH_2CONH_2{\cdot}H_2O_2$). These bleaching agents in the presence of water break down and produce oxidizing agents, which diffuse within enamel micropores. The oxidative radicals that are released degrade the extracellular matrix and oxidize the chromophores located in the enamel and dentin, causing the tooth color change.[4]

Several light sources can accelerate the bleaching procedure by heating the carbamide peroxide or the hydrogen peroxide and also by increasing the production of oxygen-free radicals.[5] Currently, the most commonly used light sources for the tooth bleaching procedure are the light-emitting diodes (LEDs) and the diode lasers. The latter produce controlled heating on the gel and exclude the risk of pulpal irritation due to their monochromatic nature.[6] Recently, erbium-family lasers such as Er:YAG (2940 nm)[5-7] and Er,Cr:YSGG (2780 nm)[8-10] take more attention in terms of laser-assisted tooth bleaching techniques. The purported advantage of the Er,Cr:YSGG laser is that it offers a fast, gentle, and effective bleaching procedure.[11,12] Moreover, the wavelength of the Er,Cr:YSGG laser (2780 nm) has a high affinity for tooth hydroxyapatite and the nearly highest absorption in water of any dental laser wavelengths, which results in the absence of additional absorbing particles in the bleaching gel – so it can be used with all water-based bleaching agents.[13] Moreover, the high absorption of the Er,Cr:YSGG laser irradiation prevents the penetration of the laser energy in the depth of hard tissues, making the bleaching procedure minimally invasive and safe.[13]

There are some concerns regarding the negative effects of the bleaching agents on the surface of the restorative materials. In particular, H_2O_2 may affect the stability of polymer networks in composite materials, since it can react with single (C–C) and double (C=C)

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carbon bonds.[14] This phenomenon may influence the physical and chemical properties of composites materials, leading to increased surface roughness[15] and increased elution of monomers and compounds.[16] The elution of monomers from restorative resin composites after tooth bleaching treatments have been adequately investigated.[17,18] On the contrary, there is a little evidence about the effect of bleaching agents on the hybrid CAD–CAM materials. The elution of residual methacrylates or other degraded monomers that leach into the oral environment can cause allergic reaction or other oral tissue pathology issues that are potentially dangerous to human health.[19-21]

Surface roughness of restorative materials is an indispensable factor in ensuring the absence of discoloration of the restorations, the lacking of periodontal inflammation, and the decrease in biofilm formation.[22] The surface roughness of ceramic restorative materials is usually lower than composite materials.[23,24] Nevertheless, the changes in surface roughness and morphology of the recently introduced hybrid ceramic materials after the influence of different tooth bleaching protocols have not sufficiently investigated.

Therefore, this *in vitro* study aimed to evaluate surface roughness changes and monomer leaching patterns of a hybrid ceramic CAD–CAM material and a nanohybrid resin composite after conventional and Er,Cr:YSGG laser-assisted tooth bleaching treatments. Three null hypotheses were set in this study: $H_0$1 was that between the two tested materials there are no differences in surface roughness change and elution of monomers after the bleaching procedures; $H_0$2 was that the bleaching procedure does not affect these two properties of the materials; and $H_0$3 was that Er,Cr:YSGG laser irradiation does not influence these two properties in comparison with the conventional bleaching technique.

METHODS AND MATERIALS

In the present study a polymer-infiltrated ceramic network (PICN) CAD–CAM material—Vita Enamic (VITA Zahnfabrik, H Rauter GmbH & Co KG) and a nanohybrid composite resin—Tetric (Ivoclar Vivadent AG, Shaan, Lichteinstein) were tested. Detailed information about the composition of the materials and the manufacturers are presented in Table 1.

Preparation of the Specimens

Each CAD–CAM block was sectioned vertically, using a 0.3-mm thick, diamond-coated, low-speed precision sectioning saw (IsoMet 1000; Buehler, Lake Blu, IL, USA) under copious water coolant resulting in 40 rectangular-shaped specimens with dimensions of 14 mm in length, 12 mm in width, and 1 mm in height. For the composite material, 40 rectangular-shaped specimens were also prepared by overfilling a customized Teflon mold with the same dimensions as the CAD–CAM specimens used in this experiment. The composite was inserted in the mold in one increment and polyester matrix strips (Polydentia SA, Messovico, Switzerland), 0.05 mm in thickness, were placed on both sides of the mold. Glass microscope slides were placed over the polyester strips and clamped to produce a standardized smooth surface, to remove excess of the material and to prevent oxygen-inhibited layer formation. Subsequently, the top and bottom surfaces of each specimen were irradiated for 20 seconds using

Table 1: *Technical Characteristics of the Tested Materials According to the Manufacturer*

Materials	Type	Composition	Manufacturer	Lot No
Enamic	PICN, CAD–CAM	Monomers: UDMA, TEGDMA (14% wt-25% v/v) Fillers: Feldspar ceramic enriched with aluminium oxide (75% v/v, 86% wt)	Vita Zahnfabrik, H Rauter GmbH & Co KG, Germany	56802
Tetric	Nanohybrid composite	Monomers: Bis-GMA, TEGDMA, UDMA(18.8 wt%) Fillers: Barium glass filler, Ytterbium trifluoride, mixed oxide (63.5 wt%), polymer (17 wt%), additive, catalysts, pigments, stabilizers (0.7 wt%) Particle size: 0.04-3 μm	Ivoclar Vivadent Schaan, Liechtenstein	V23649

Abbreviations: PICN, Polymer-infiltrated ceramic network material, CAD–CAM: Computer-aided designed–computer-aided manufactured; UDMA, Urethane dimethacrylate; TEGDMA, Triethylene glycol dimethacrylate; Bis-GMA, Bisphenol A glycidyl dimethacrylate.

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a dental LED light-curing unit (Bluephase G2, Ivoclar Vivadent AG, Schaan, Lichtenstein) at 1200 mW/cm^2, according to the manufacturer's specifications. The light intensity of the LED device was checked with a Bluephase Meter II (Ivoclar Vivadent AG, Schaan, Lichtenstein).

Both the CAD–CAM and composite specimens were wet polished, with fine (1000-grit) and superfine (3000-grit) silicon carbide abrasive papers. Immediately after the polishing of the specimens, they were immersed in 1 ml human pooled saliva for 3 days at 37°C, in order to resemble the aging of the materials intraorally. Then half of the specimens of each material were suspended individually using a silk thread in 10 ml of distilled water and the other half in 10 ml of artificial saliva for 7 days. The composition of the artificial saliva was as follows: $CaCl_2$ (0.6 g), KH_2PO_4 (0.26 g), NaCl (0.552 g), CH_4N_2 (Urea, 1.0 g), and distilled water (1000 mL), at neutral pH.

Using a thin silk thread that was passed through a hole in the middle of each specimen and with the help of a screw cap that was placed firmly on top of the glass vessel, the samples could be fully immersed and hung inside the bottles with both surfaces in direct contact with the solution.

Experimental Groups of the Study

Following this 7-day period of storage, the 40 specimens of each material were randomly divided into 4 groups (n=10). The specimens of the groups were submitted to one of two bleaching treatments.

Group A1 and A2 specimens received a conventional in-office tooth bleaching treatment using a bleaching agent (Opalescence Xtra Boost, Ultradent Products, South Jordan, UT, USA), which contained 40% H_2O_2 and also 3% potassium nitrate and 1.1% fluoride ions (10,000 ppm); pH=7. The mixing conditions of the gel and the parameters of the procedure complied with the manufacturer's instructions. More specifically, the bleaching gel was applied on the surface of the specimens in a layer approximately 1-mm thick, for 40 minutes, and then it was removed carefully with a spatula and swabbed with a cotton stick without the use of water in order to avoid washing out monomers from the specimens' surface. Subsequently, Group A1 specimens were incubated separately in 10 ml of distilled water and Group A2 specimens in 10 ml of artificial saliva, at 37°C for an additional 7-day period.

Group B1 and B2 specimens received the same in-office tooth bleaching protocol using Er,Cr:YSGG laser (solid state) irradiation to catalyze the chemical reaction of H_2O_2 breakdown. Er,Cr:YSGG (2780 nm) laser (Waterlase MD Turbo, BIOLASE, Irvine, CA, USA) had a Z-type glass tip (MZ8) with an 800-μm diameter and 6-mm length, and was used with the gold handpiece of the laser system. The laser parameters that were selected were as follows: average output power of 1.25 W, pulse duration of 700 μs (S-mode), and pulse repetition rate of 10 Hz without water- or air-flow. The laser treatment of the bleaching agent consisted of two intervals of 15 seconds for each specimen, keeping the handpiece of the laser device at a distance of 2.5 cm from the surface with the use of a custom-made spacer and positioned perpendicularly to the surfaces. The fluence of every laser pulse using the above laser parameters was 0.45 J/cm^2, which is far below the ablation threshold for enamel. To minimize the effect of operator variability, the same researcher carried out the bleaching procedures. Afterwards, Group B1 specimens were incubated in distilled water and Group B2 specimens in artificial saliva, at 37°C for an additional 7-day period.

Evaluation of Monomer Elution

At the end of the initial 7-day period, before the bleaching treatments, an aliquot of 20 μL of the storage medium was analyzed by high-performance liquid chromatography (HPLC). The technical characteristics of the chemicals used in this method are presented in Table 2. This measurement was performed in order to investigate the elution of monomers without the effect of the bleaching agent (control). A second measurement was performed after the bleaching treatments at the end of the second 7-day period.

The mobile phase was composed of acetonitrile and water (CH_3CN:H_2O, 70:30%, v/v), employing a Shimadzu (Kyoto, Japan) LC-10AD pump. The method used was previously developed and used authors' research group[25]; however, two more analytes were included. The pressure observed was 150 bar, while the flow rate was set at 1.5 mL/min. Sample injection was performed via a Rheodyne 7125 injection valve (Rheodyne, Cotati CA, USA) with a 20 μL loop. Detection was achieved by an SSI 500 UV-Vis detector (SSI, State College, PA, USA) at a wavelength of 215 nm and a sensitivity setting of 0.002 AUFS. The monomers were identified by comparison of their retention times with those of the reference compounds under the same HPLC conditions. The retention time for BPA was 5.5 minutes, for TEGDMA 9 minutes, for UDMA 21.5 minutes, and for *Bis*-GMA 22.5 minutes. Calibration curves were constructed using peak areas of eluted peaks of BPA, TEGDMA, UDMA, and *Bis*-GMA. A typical chromatogram is illustrated in Figure 1.

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Table 2: *Technical Characteristics of the Chemicals used for HPLC Method*

Chemicals	Name	Chemical Type	Molecular Weight	CAS Number	Purity	Manufacturer
BPA	Bisphenol A	$C_{15}H_{16}O_2$	228.29	80-05-7	95%	Sigma–Aldrich LLC
Bis-GMA	Bisphenol A glycidyl Dimethacrylate	$C_{29}H_{36}O_6$	513	1565-94-2; LOT: MKBR2670V	99%	Sigma–Aldrich LLC
TEGDMA	Triethylene glycol Dimethacrylate	$C_{14}H_{22}O_6$	286.32	109-16-0; LOT: 09004BC-275	99%	Sigma–Aldrich LLC
UDMA	Urethane dimethacrylate	$C_{23}H_{38}N_2O_8$	470.56	72 869-86-4; LOT:12430KC	99%	Sigma–Aldrich LLC
Acetonitrile		CH_3CN	41.05	75% v/v, ethanol; CAS:75-05-8; LOT:0001245593	HPLC grade	PanReac AppliChem
Distilled water				CAS:7732-18-5; LOT:0001118157	HPLC grade	PanReac AppliChem
Artificial Saliva		H_2O(distilled) CH_4N_2O(urea) NaCl $CaCl_2$ KH_2PO_4				Sigma–Aldrich Merck KGaA, Darmstadt, Germany

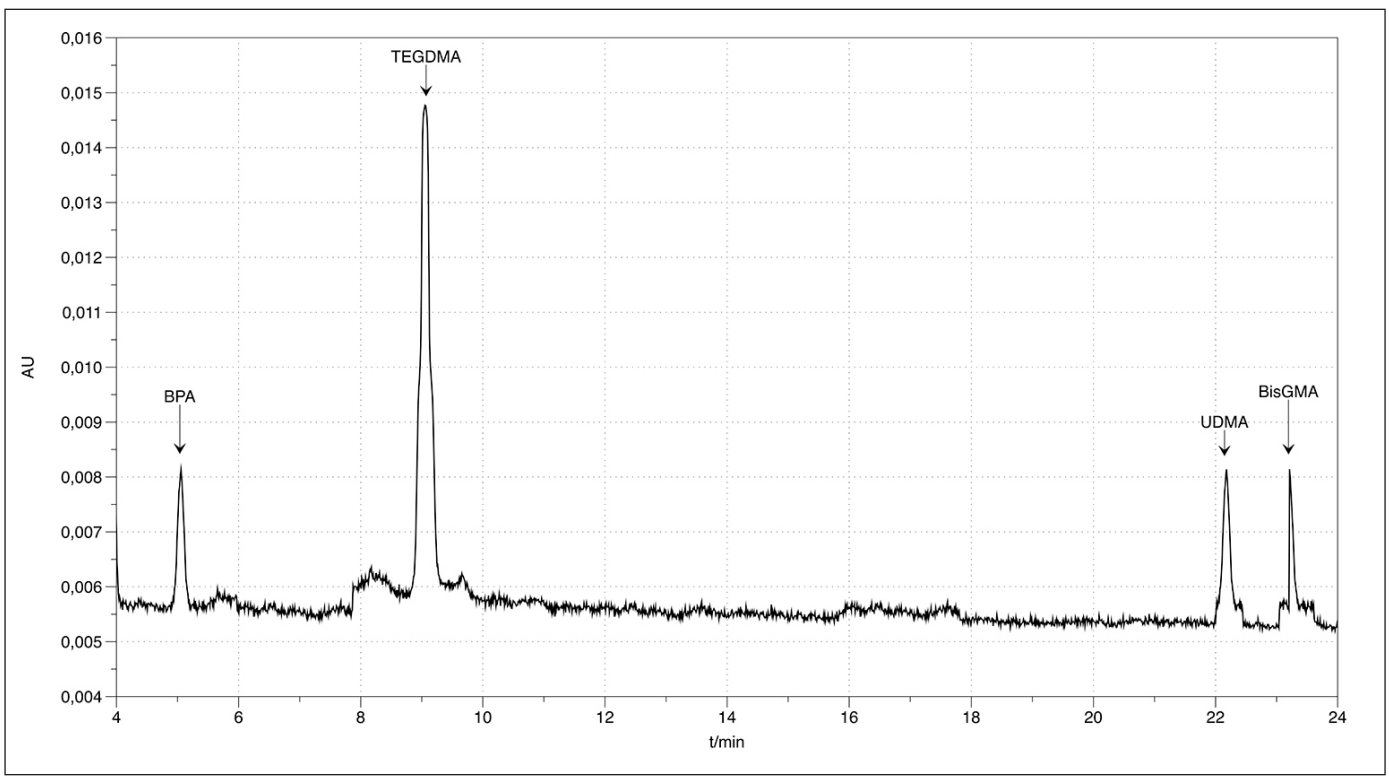

Figure 1. *Representative high-performance liquid chromatograms at 1 ng/mL standard solution of BPA, TEGDMA, UDMA, and Bis-GMA. Bis-GMA: Bisphenol A glycidyl dimethacrylate; BPA: Bisphenol A; TEGDMA: triethylene glycol dimethacrylate; UDMA: urethane dimethacrylate.*

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Analytical Procedure

The linearity of the analytical method was studied using mixtures of ethanolic standard solutions covering the entire working range. Limit of detection (LOD) values were calculated from the calibration curve according to the formula LOD=*S/N* and limit of quantification (LOQ) values according to the formula LOQ=10*S/N*, where *S*=signal and *N*=noise. The corresponding value of the LOD was 0.2 ng/μL for BPA, TEGDMA, *Bis*-GMA, and UDMA monomers. The LOQ was calculated to 0.06 ng/μL for BPA, TEGDMA, *Bis*-GMA, and UDMA monomers.

Evaluation of Surface Roughness

Surface roughness parameters of the tested materials were evaluated by optical imaging noncontact interferometric profilometry. The 3D optical profiler (3D Optical Surface Metrology System Leica DCM8, Leica Microsystems CMS GmbH, Mannheim, Germany) was used under the following conditions: vertical scanning mode, Leica lens, 20× magnifications (800×650 μm^2 analysis area), tilt correction, 5 μm Gaussian high-pass filter to remove surface waviness. The following surface roughness parameters were evaluated before and after the bleaching treatment: the absolute profile deviation versus the average over a 3D surface; S_a, the average difference between the five highest peaks and the five lowest valleys; S_z, the root mean square roughness over the entire 3D surface; S_q and the developed interfacial area ratio, expressed as the percentage of the additional surface area contributed by the texture compared to an ideal plane of the same size; S_{dr}. The surface roughness parameters S_a and S_q represented an overall measure of the texture, and S_{dr} differentiated the surface of similar amplitudes and average roughness. The surface parameter S_z defined the sum of the largest peak height value and the largest pit depth value of a defined area.

Statistical Analysis

Normality of the data distribution was checked by the Kolmogorov–Smirnov test, while the homogeneity of the variances was examined by the Levene test. The comparisons of the mean values of the leaching monomers (ng/μL) and the roughness parameters (S_a, S_q, S_z, and S_{dr}) that followed a normal distribution were evaluated with one-way analysis of variance (ANOVA) and Tukey honest significant difference (HSD) *post hoc* test. For those specimens that did not follow a normal distribution mean values were analysed with the use of nonparametric Wilcoxon test and one-way ANOVA with multiple comparisons using Dunn test or independent sample test. The statistical significance for all the tests was set at $a = 0.05$.

RESULTS

Mean values and standard deviations of each monomer released from the materials tested before and after tooth bleaching periods are presented in Tables 3 and 4 for distilled water and artificial saliva, respectively. Accordingly, in Tables 5 and 6, the mean values and standard deviations of surface roughness parameters before and after the bleaching procedures of each experimental group are shown for distilled water and artificial saliva, respectively. Mean concentrations of the monomers eluted in both the solutions from the materials tested before and after the bleaching treatment with or without the Er,Cr:YSGG laser effect are illustrated in Figure 2.

Monomer Elution

Monomer Elution from Composite Resin in Distilled Water

BPA was eluted from Tetric before and after both conventional and laser-assisted bleaching treatments. After the Er,Cr:YSGG laser bleaching treatment, BPA release was decreased significantly *(p=0.011)*. However, the conventional bleaching treatment did not affect the release of BPA *(p=0.393)*. TEGDMA was also released from the Tetric before and after both bleaching treatments. Nevertheless, the bleaching treatments had no statistically significant effect on the release of this substance (conventional: p=0.511, laser-assisted: p=0.601). UDMA and *Bis*-GMA monomers were released only before the bleaching treatments, and there were no traces of those monomers in the distilled water after the treatments.

Monomer Elution from Composite Resin in Artificial Saliva

BPA was eluted from the composite specimens in the artificial saliva before and after the bleaching treatments but in lower concentrations compared to those stored in distilled water (p<0.05), except for B2 group specimens before the bleaching treatment (p=0.823). However, there was no statistical significance of the effect of bleaching treatments on BPA elution (p>0.05). Similarly, TEGDMA was also eluted from the composite specimens in the artificial saliva before and after the bleaching treatments in lower concentrations compared to those stored in distilled water (p<0.05). Only after the laser-assisted bleaching treatment, there was an increase in the release of this monomer (p=0.009). No statistically significant differences were detected among the other experimental groups regarding TEGDMA release (p>0.05). UDMA and *Bis*-GMA were released from the composite specimens

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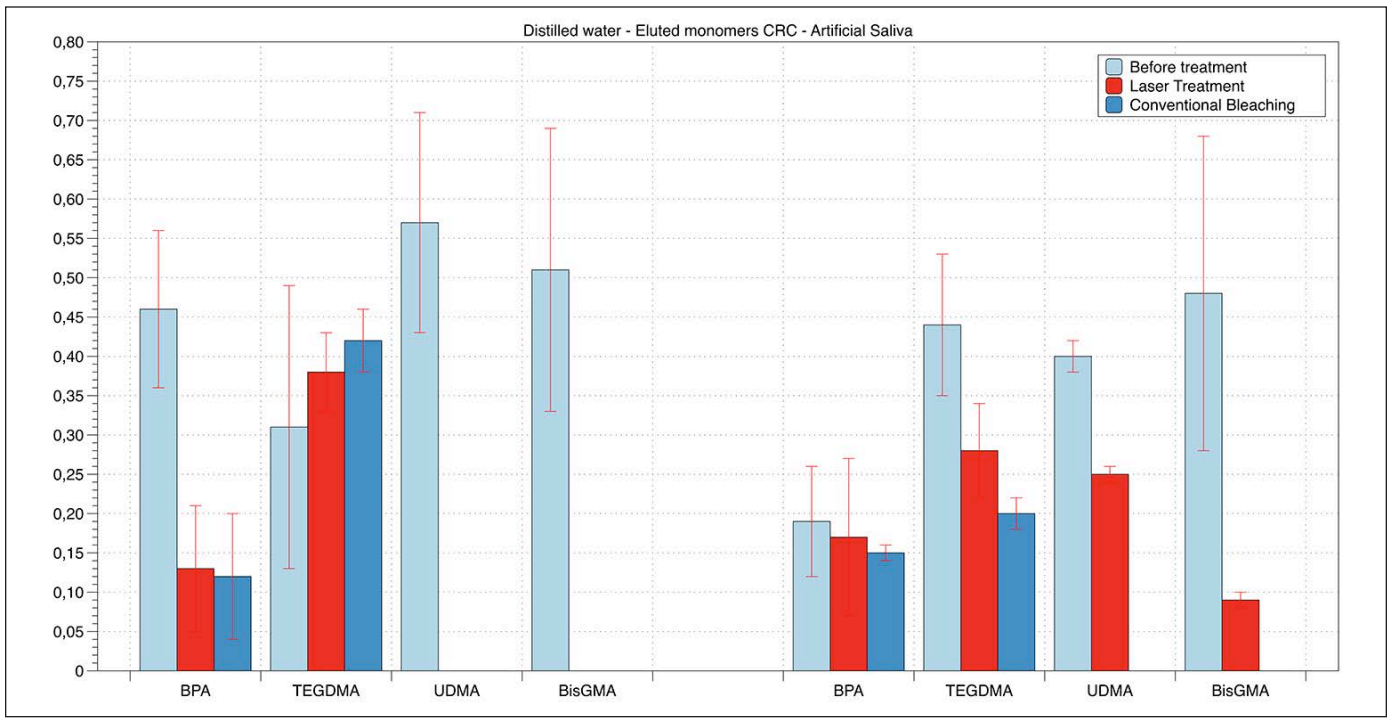

Figure 2. *Bar chart illustrating the mean values and standard deviations of the eluted monomers from the composite resin before the bleaching treatment, after the laser treatment with Er,Cr:YSGG laser, and after the conventional bleaching treatment.*

before the treatments. After the conventional bleaching technique, no traces were detected for either monomer, while after the laser-assisted bleaching treatment there was a significant decrease in UDMA and *Bis*-GMA release ($p<0.001$). UDMA and *Bis*-GMA also exhibited lower concentrations in artificial saliva than in distilled water ($p<0.05$) (Figure 3).

Monomer Elution from Hybrid CAD–CAM Material in Distilled Water and Artificial Saliva

TEGDMA was the only monomer that was released into the distilled water and artificial saliva from the specimens of Enamic before the beaching treatments. However, after the bleaching treatments no traces of TEGDMA were detected. Tooth bleaching treatments

Table 3: *Means and Standard Deviations (ng/μL) of the Eluted Monomers after Incubation in Distilled Water Before and after the Bleaching Treatments*[a]

Distilled Water	**Monomer**	**Er,Cr:YSGG Laser Bleaching Treatment**		**Conventional Bleaching Treatment**	
ng/μL		Before treatment	After treatment	Before treatment	After treatment
Enamic	BPA	ND	ND	ND	ND
Tetric	BPA	0.46 ± 0.20 a	0.13 ± 0.08 b	0.36 ± 0.05 a	0.42 ± 0.16 a
Enamic	UDMA	ND	ND	ND	ND
Tetric	UDMA	0.27 ± 0.04 a	ND	0.58 ± 0.18 a	ND
Enamic	TEGDMA	0.39 ± 0.02 a	ND	0.38 ± 0.05 a	ND
Tetric	TEGDMA	0.32 ± 0.05 a	0.39 ± 0.08 a	0.32 ± 0.02 a	0.41 ± 0.14 a
Enamic	Bis-GMA	ND	ND	ND	ND
Tetric	Bis-GMA	0.51 ± 0.28 a	ND	0.32 ± 0.10 a	ND

ND: not detected = amounts lower than method's limit of quantification (LOQ), as quantified by standard addition method.

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Table 4: *Means and Standard Deviations (ng/μL) of the Eluted Monomers after Incubation in Artificial Saliva Before and after the Bleaching Treatments*[a]

Artificial Saliva	Monomer	Er,Cr:YSGG laser Bleaching Treatment		Conventional Bleaching Treatment	
ng/μL		Before treatment	After treatment	Before treatment	After treatment
Vita Enamic	BPA	ND	ND	ND	ND
Tetric	BPA	0.19 ± 0.07 a	0.17 ± 0.10 a	0.15 ± 0.06 a	0.15 ± 0.01 a
Vita Enamic	UDMA	ND	ND	ND	ND
Tetric	UDMA	0.44 ± 0.19 a	0.25 ± 0.01 b	0.60 ± 0.12 a	ND
Vita Enamic	TEGDMA	0.58 ± 0.08	ND	ND	ND
Tetric	TEGDMA	0.26 ± 0.04 a	0.43 ± 0.02 b	0.24 ± 0.07 a	0.20 ± 0.02 a
Vita Enamic	Bis-GMA	ND	ND	ND	ND
Tetric	Bis-GMA	0.48 ± 0.20 a	0.09 ± 0.01 b	0.34 ± 0.03 a	ND

[a]*Same lowercase superscripts in rows indicate no statistically significant differences among the groups ($p>0.05$). ND: Not detected = Amounts lower than method's limit of quantification (LOQ), as quantified by standard addition method.*

did not affect elution of the other monomers from the hybrid CAD–CAM material in either storage media (Table 6).

Surface Roughness

Representative images (20× magnification) obtained from the PICN CAD–CAM material and the conventional resin composite before and after the Er,Cr:YSGG laser bleaching treatment are shown in Figure 4. No surface morphology alterations were observed after the treatments.

Surface Roughness of Composite Resin

For the composite specimens stored in distilled water, there were no statistically significant differences among the experimental groups in all the surface roughness parameters (S_a, S_q, S_z, and S_{dr}) before and after the bleaching treatments ($p>0.05$). On the other side, the specimens of Tetric stored in artificial saliva showed a statistically significant increase only in parameter S_z for the laser-assisted bleaching technique ($p=0.037$).

Surface Roughness of Hybrid CAD–CAM Material

There were no statistically significant differences in the surface roughness parameters (S_a, S_q, S_z, and S_{dr}) for the hybrid CAD–CAM material, before and after the bleaching treatments. More specifically, there was no statistical significance before and after the Er,Cr:YSGG laser bleaching treatment for the specimens of Vita Enamic either stored in distilled water ($p=0.855$ for S_a,

Table 5: *Means and Standard Deviations of Surface Roughness Parameters (S_a, S_q, S_z, and S_{dr}) of the Specimens after Incubation in Distilled Water Before and after the Bleaching Treatments*[a]

Distilled Water	Surface Parameter	Er,Cr:YSGG Laser Bleaching Treatment		Conventional Bleaching Treatment	
		Before treatment	After treatment	Before treatment	After treatment
Vita Enamic	S_a (μm)	1.14 ± 0.02 a	1.18 ± 0.01 a	1.29 ± 0.40 a	1.98 ± 0.47 a
Tetric	S_a (μm)	0.67 ± 0.09 a	0.45 ± 0.07 a	0.44 ± 0.09 a	0.51 ± 0.08 a
Vita Enamic	S_q (μm)	1.42 ± 0.02 a	1.49 ± 0.01 a	1.61 ± 0.05 a	1.89 ± 0.31 a
Tetric	S_q (μm)	0.87 ± 0.10 a	0.60 ± 0.10 a	0.59 ± 0.12 a	0.66 ± 0.10 a
Vita Enamic	S_z (μm)	8.72 ± 0.06 a	8.96 ± 0.19 a	9.55 ± 0.28 a	9.44 ± 0.22 a
Tetric	S_z (μm)	5.62 ± 0.50 a	4.04 ± 0.74 a	3.60 ± 0.70 a	4.30 ± 0.53 a
Vita Enamic	S_{dr} (%)	9.91 ± 0.43 a	10.05 ± 0.47 a	11.30 ± 0.45 a	10.97 ± 0.35 a
Tetric	S_{dr} (%)	3.00 ± 1.19 a	1.94 ± 0.74 a	1.89 ± 0.78 a	2.48 ± 0.75 a

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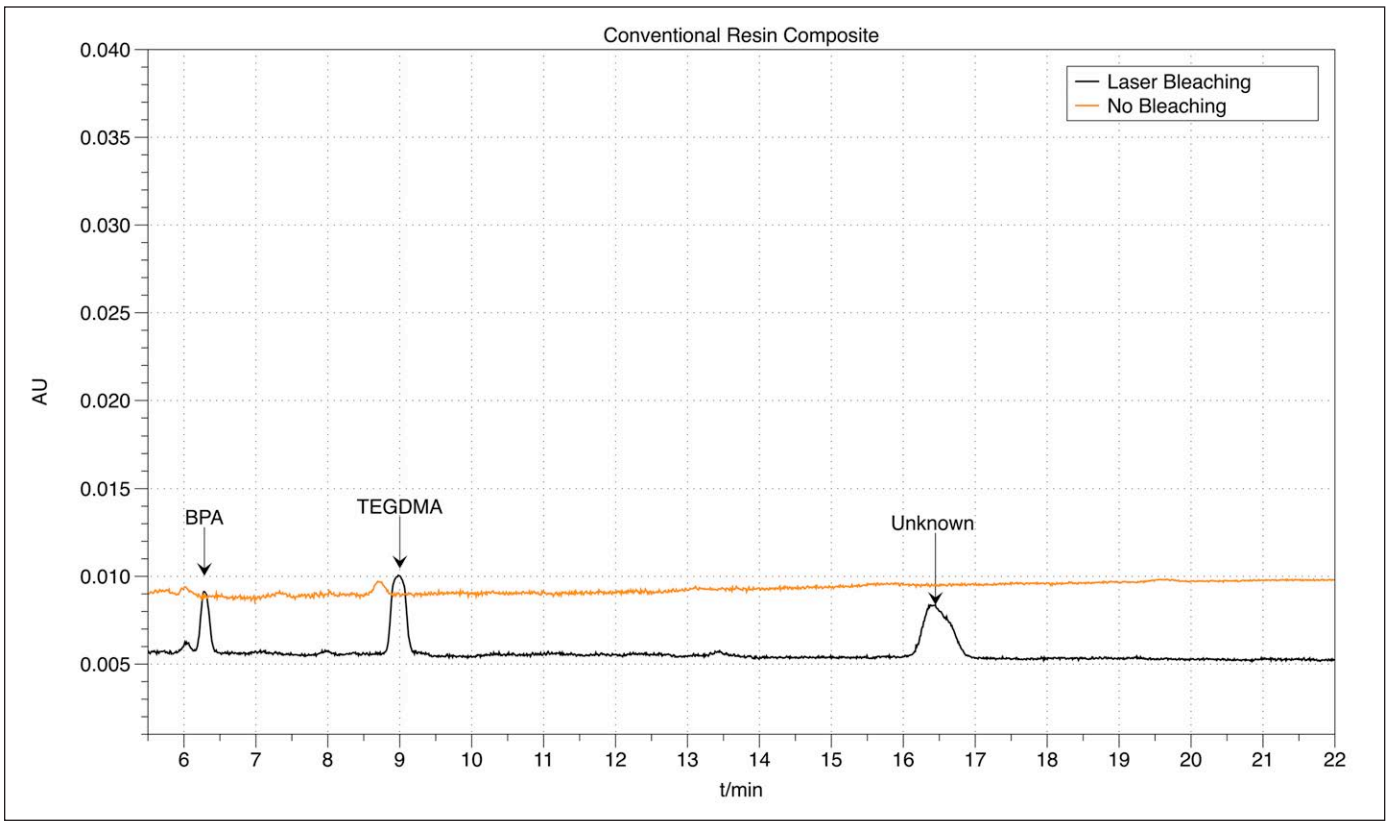

Figure 3. *Representative high-performance liquid chromatograms of a conventional composite resin specimen before and after the laser-assisted bleaching treatment. BPA: Bisphenol A; TEGDMA: triethylene glycol dimethacrylate.*

p=0.103 for S_q, p=0.237 for S_z, and p=0.591 for S_{dr}) or for those stored in artificial saliva (p=0.518 for S_a, p=0.486 for S_q, p=0.119 for S_z, and p=0.175 for S_{dr}).

DISCUSSION

According to the results of this study, $H_0$1 was rejected since more monomers were eluted into the solutions from the conventional composite resin compared to the hybrid CAD–CAM material; $H_0$2 was also rejected since both bleaching procedures influenced the elution of monomers from the materials; and $H_0$3 was accepted since Er,Cr:YSGG laser irradiation did not influence surface roughness or monomer elution in comparison with the conventional bleaching technique.

There has been thorough research concerning the elution of monomers from composite materials after storage,[26-28] or after conventional[17] or laser-assisted tooth bleaching treatments.[3,29] However, there are few studies that have evaluated the leaching pattern from CAD–CAM materials,[30-32] and, to the authors' knowledge, there are no studies that evaluated the leaching of monomers from CAD–CAM materials after an Er,Cr:YSGG laser-assisted bleaching treatment.

It has been demonstrated that tooth bleaching agents may affect the three-dimensional polymer network of resin composites.[7] The aftereffect of the above concern is the potential for release of unpolymerized monomers, additives, filler components, or degradation products and impurities of monomers in the oral environment.[33] The release of unpolymerized monomers into the oral environment causes concerns regarding toxic effects, which may irritate the surrounding soft tissues and promote allergic reactions.[34] Furthermore, some studies reported that the eluted monomers or (co)monomers and the additives released from composite materials have estrogenic and genotoxic effects.[35]

In the present study, a hybrid CAD–CAM material and a composite resin were investigated regarding the leaching of monomers after an Er,Cr:YSGG tooth bleaching treatment. The main finding of the study was that there was no monomer elution from the hybrid CAD–CAM restorative material, and that the Er,Cr:YSGG laser bleaching treatment did not have an effect on the elution of monomers from the composite resin. Studies have demonstrated that the main disadvantage of conventional resin composite materials

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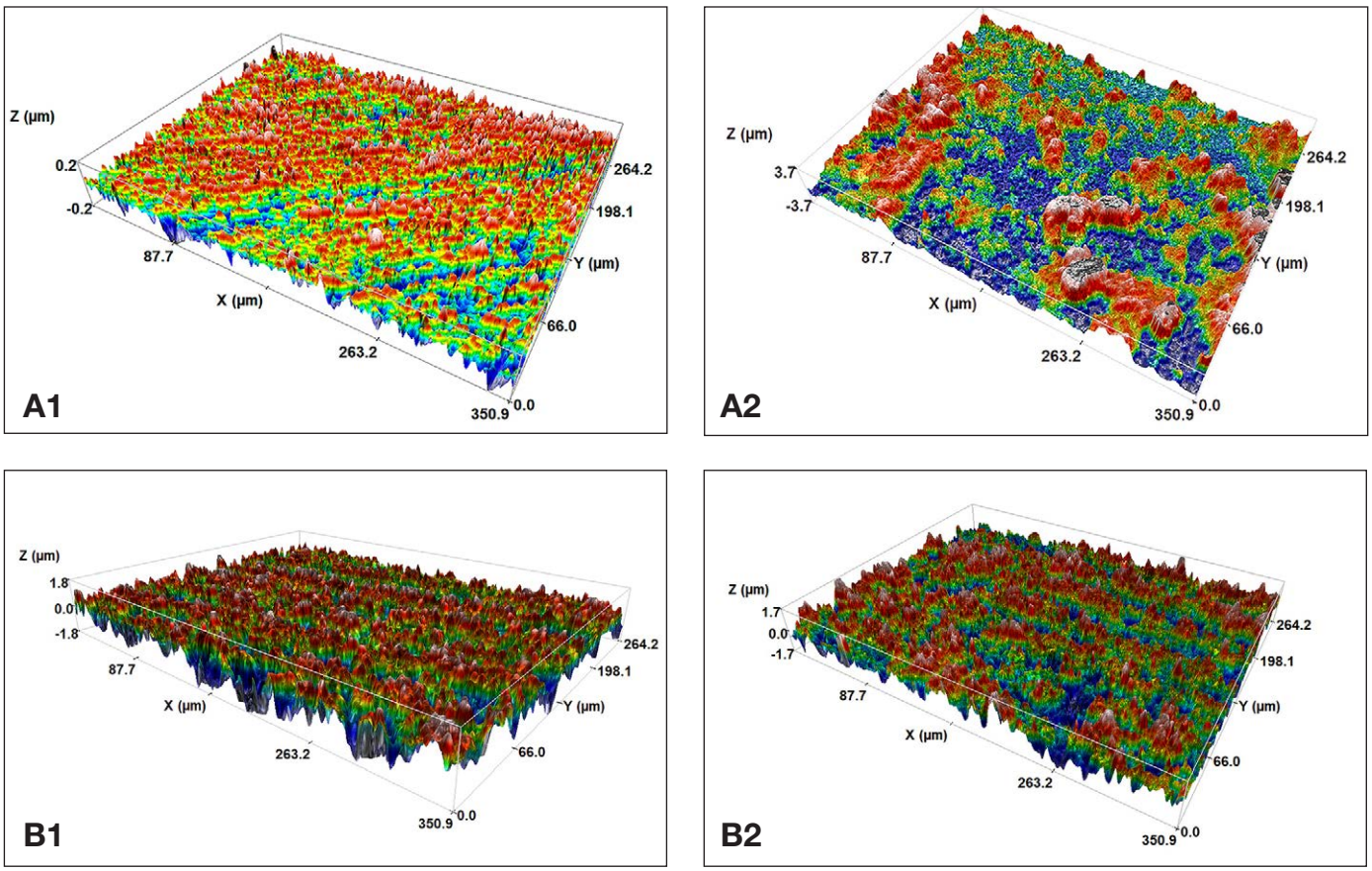

Figure 4. *Representative topographic images (20x magnification) of the surface of the specimens before (1) and after (2) the Er,Cr:YSGG laser bleaching treatment. A: Conventional resin composite and B: hybrid CAD–CAM material.*

is the incomplete polymerization.[36] In particular, the lower degree of conversion that they exhibit, results in increased release of unreacted monomers—a phenomenon that is determined by their chemical structure.[27] Furthermore, the hydrolytic degradation that follows may result in chain scission and release of polymeric breakdown products in the form of monomeric or oligomeric molecules.[37]

A previous study has reported that the amount of the eluted monomers is dependent on the medium used for extraction.[37] The solvent can penetrate the matrix of the resin composite and may enlarge the space between the polymer chains, resulting in dimensional change in the mass of the material. The latter may cause elution of unreacted monomers into the medium.[27] Most of the studies have examined the leaching of monomers in distilled water for a short time period extending between 7 and 14 days, in order to mimic the oral conditions.[37] Other studies have used organic solvents like ethanol 75%, methanol, or acetone, because, according to the Food and Drug Administration guidelines, those solutions are food simulators able to induce artificial aging of the restorations.[38] In the present study, artificial saliva was used in order to simulate the oral conditions, while distilled water was used as a control storage medium.[39] Moreover, before the experimental period, the specimens from both materials were stored in artificial saliva for 3 days to simulate the aging of the composite materials and allow for a sufficient polymerization.[17]

In the current study, the evaluation of monomer elution was implemented in artificial saliva that did not contain proteins and enzymes. As it was found in previous studies, the concentration of the eluted monomers released into the human saliva was significantly lower than the concentration released into protein-free artificial saliva. This may be because the eluted monomers are bound to proteins in both the oral cavity and in the plasma.[28]

No monomers were eluted from the hybrid CAD–CAM material after the bleaching treatments. This could be attributed to the different method

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Table 6: *Means and Standard Deviations of Surface Roughness Parameters (S_a, S_q, S_z, and S_{dr}) of the Specimens after Incubation in Artificial Saliva Before and after the Bleaching Treatments*[a]

Artificial Saliva	Surface Parameter	Er,Cr:YSGG Laser Bleaching Treatment		Conventional Bleaching Treatment	
		Before treatment	After treatment	Before treatment	After treatment
Enamic	S_a (μm)	0.93 ± 0.13 a	1.04 ± 0.17 a	1.46 ± 0.29 a	1.09 ± 0.05 a
Tetric	S_a (μm)	0.50 ± 0.22 a	0.87 ± 0.24 a	0.78 ± 0.15 a	0.65 ± 0.19 a
Enamic	S_q (μm)	1.17 ± 0.15 a	1.29 ± 0.19 a	1.81 ± 0.35 a	1.43 ± 0.03 a
Tetric	S_q (μm)	0.66 ± 0.38 a	1.14 ± 0.29 a	1.01 ± 0.20 a	0.84 ± 0.26 a
Enamic	S_z (μm)	7.30 ± 0.83 a	8.09 ± 1.05 a	8.79 ± 0.26 a	8.61 ± 0.13 a
Tetric	S_z (μm)	4.40 ± 2.59 a	7.71 ± 1.42 b	6.29 ± 0.50 a	5.46 ± 1.85 a
Enamic	S_{dr} (%)	7.30 ± 3.79 a	8.09 ± 4.02 a	10.07 ± 0.71 a	8.67 ± 0.57 a
Tetric	S_{dr} (%)	3.32 ± 1.39 a	4.34 ± 3.38 a	5.13 ± 1.96 a	3.46 ± 1.29 a
Vita Enamic	S_a (μm)	1.14 ± 0.02 a	1.18 ± 0.01 a	1.29 ± 0.40 a	1.98 ± 0.47 a
Tetric	S_a (μm)	0.67 ± 0.09 a	0.45 ± 0.07 a	0.44 ± 0.09 a	0.51 ± 0.08 a
Vita Enamic	S_q (μm)	1.42 ± 0.02 a	1.49 ± 0.01 a	1.61 ± 0.05 a	1.89 ± 0.31 a
Tetric	S_q (μm)	0.87 ± 0.10 a	0.60 ± 0.10 a	0.59 ± 0.12 a	0.66 ± 0.10 a
Vita Enamic	S_z (μm)	8.72 ± 0.06 a	8.96 ± 0.19 a	9.55 ± 0.28 a	9.44 ± 0.22 a
Tetric	S_z (μm)	5.62 ± 0.50 a	4.04 ± 0.74 a	3.60 ± 0.70 a	4.30 ± 0.53 a
Vita Enamic	S_{dr} (%)	9.91 ± 0.43 a	10.05 ± 0.47 a	11.30 ± 0.45 a	10.97 ± 0.35 a
Tetric	S_{dr} (%)	3.00 ± 1.19 a	1.94 ± 0.74 a	1.89 ± 0.78 a	2.48 ± 0.75 a

of fabrication of the hybrid CAD–CAM material (high pressure and high temperature), which provide increased polymerization. This method of fabrication is responsible for improved matrix formation of the material and the advanced interaction between fillers and matrix, contributing to a more uniform cross-linked network of monomers.[32]

Another significant finding of this study was that the Er,Cr:YSGG laser did not have an effect on the leaching of monomers from either material tested, suggesting that the bleaching treatment with a Er,Cr:YSGG laser is a safe clinical procedure to accelerate and improve in-office bleaching treatments regarding this property.

In the present investigation, a release of BPA from the conventional composite resin was detected before and after the Er,Cr:YSGG laser bleaching treatment and in both the materials tested. Pure BPA is not a component of composite resins, but derivatives of BPA are widely used as Bis-GMA. Therefore, BPA is present in composite resins as an impurity of the production process of these monomers, which can potentially be released.[40] This is one of the reasons why manufacturers prefer not to use *Bis*-GMA, and instead include UDMA and TEGDMA as the main monomers of the hybrid CAD–CAM materials or some conventional composite materials.[41]

The results of the present study coincide with those of other studies indicating that TEGDMA was the main released monomer from composite materials.[41,42] The reason of the absence of UDMA and *Bis*-GMA in the tested solutions may be the fact that bleaching agents induce a degradation procedure of those high molecular weight molecules, and thus a decrease of their concentration in the storage media. This may explain the decomposition of those monomers that possibly lead to the regeneration of other substances with other molecular weight and retention time.[17] This is in agreement with the current study, where an unknown peak appeared in the representative high-performance liquid chromatograms at 16 minutes for the laser-assisted bleaching group of the composite resin (Fig. 3). Therefore, additional research is necessary to investigate the additional substances that may be released after the Er,Cr:YSGG laser bleaching treatment that may influence the clinical behaviour of the materials.

The increased surface roughness of dental restorative materials is an important factor that may jeopardize the

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health of hard dental tissues, because it increases the risk of secondary caries formation.[43,44] Restorations that are manufactured with CAD–CAM technology are milled with rotary instruments coated with diamond abrasive particles of 64-mm grit size.[45] The above instruments produce a rather high initial surface roughness, which may lead to the increased wear of adjacent teeth and the discoloration of the restoration.[46,47] In addition, there is a constraint for the crystallization of the hybrid CAD–CAM materials, and, therefore, these materials can only be hand polished. Additionally, bleaching treatment and high-energy free radicals produced by peroxides may increase the surface roughness of resin composites and CAD–CAM restorations, since they may cause matrix softening and complete or partial detachment of the fillers and increased water uptake leading to a more porous and rougher surface of the materials.[48,49]

The ideal threshold value for the roughness of restorations in terms of bacterial retention has yet to be established.[50] However, the higher values of roughness in dental restorations, the higher the risk of plaque accumulation and caries development.47 The tested hybrid CAD–CAM material is a PICN material, and it contains a porous sintered ceramic network filled with plastic. Thus, it consists of two different interlocking networks—a ceramic and a polymer network, which is called double network hybrid. The main monomer of this material is UDMA, which, in general, achieves a lower degree of conversion and cross-link density; as a consequence, the material could wear relatively easy and leave exposed inorganic fillers on the surface.[50] However, Vita Enamic is fabricated under conditions of high temperature and high pressure during polymerization. This different approach of polymerization contributes to an improved polymeric matrix and better matrix–filler interaction, leading to a higher degree of cure and to a more homogeneously cross-linked network of monomers.[32]

There are numerous studies that have evaluated the surface roughness of resin composites after bleaching treatments,[51,52] studies that have evaluated the surface roughness of resin composites after Er,Cr:YSGG laser bleaching treatment,[3,6] or studies that have evaluated the effect of bleaching treatments on the enamel surface.[53,54] There are also studies that have evaluated the bleaching treatment on CAD–CAM materials,[49,55] but, except for the present study, there are no studies that have evaluated the surface roughness of composite resins or hybrid CAD–CAM materials after Er,Cr:YSGG laser in-office tooth bleaching.

The outcomes of the current study are in accordance with Varanda and others[56] who did not find significant alteration of surface roughness of nanofilled and microhybrid resin composites after the application of 35% bleaching agents and also in accordance with Rodrigues and others[48] where bleaching treatments did not promote alterations in the surface roughness of resin composites. Similarly, the same pattern refers to the CAD–CAM material, where the results of this study coincide with those of Karakava and others,[49] who found that bleaching application did not have any significant effect on the surface roughness and the surface topography of CAD–CAM materials. According to the results of this study, the laser irradiation did not have an effect on the surface roughness of the specimens, thus the Er,Cr:YSGG laser would not affect the bonding interface of the restorations and the resin composite does not need repolishing after the bleaching treatment.

In this study it was found that the roughness parameter S_z, for the composite resin specimens in artificial saliva, presented a statistically significant increase after the 7-day experimental period. This evidence may be attributed to the precipitation of artificial saliva ingredients on the specimen surfaces combined with the Er,Cr:YSGG laser irradiation of the surface.

CONCLUSIONS

Within the limitations of this study, it could be concluded that (1) the tested hybrid CAD–CAM material is potentially safer for tooth restoration than the tested conventional composite resin regarding the elution of residual monomers; (2) tooth bleaching treatments may influence the elution of the monomers from the tested composite resin; (3) the surface roughness of the tested materials is not affected by the tooth bleaching treatments; (4) Er,Cr:YSGG laser-assisted tooth bleaching treatment is as safe as the conventional technique in regards to changes in monomer elution and surface roughness; and (5) monomer elution was higher in distilled water compared to artificial saliva in both materials tested.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this manuscript.

Regulatory Statement

Author represents that the study was performed in compliance with author's institution's appropriate policies related to the use of animal and/or human subjects and human-derived material/s.

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Handling and Mechanical Properties of Low-viscosity Bulk-fill Resin Composites

E Hirokane • T Takamizawa • T Tamura • S Shibasaki
A Tsujimoto • WW Barkmeier • MA Latta • M Miyazaki

Clinical Relevance

Some low-viscosity bulk-fill resin composites can probably be used in stress-bearing areas, while maintaining an effective depth of cure and good handling properties.

SUMMARY

This study aimed to evaluate the filler contents (FCs), flexural properties, depth of cure (DOC), wear resistance, and handling properties of different low-viscosity bulk-fill resin composites (LVBRCs) and to determine the correlations between the tested parameters. Six LVBRCs, Beautifil-Bulk (BBF), Bulk Base Hard (BBH), Bulk Base Medium (BBM), Filtek Bulk-Fill Flowable Restorative (FBF), G-ænial Bulk Injectable (GBI), and SDR flow+ Bulk-Fill Flowable (SDR) were used. The DOC and flexural property tests were conducted according to the ISO 4049 specifications. The flexural strength, elastic modulus, and resilience were determined in 12 specimens that were obtained from each of the 6 materials. Sliding-impact-wear testing was conducted by evaluating the wear facets of the specimens using a noncontact profilometer and by confocal laser scanning microscopy. The handling properties of the LVBRC was assessed *via* extrusion force and thread formation measurements. The DOC for the majority of the LVBRCs was approximately 4 mm. Although the FCs and mechanical properties were material dependent, some LVBRCs exhibited excellent flexural properties and wear resistance. The LVBRCs demonstrated a wide range of extrusion force and thread formation. Regarding the correlations

Eizo Hirokane, DDS, Department of Operative Dentistry, Nihon University Graduate School of Dentistry, Tokyo, Japan

*Toshiki Takamizawa, DDS, PhD, Department of Operative Dentistry, Nihon University School of Dentistry, Tokyo, Japan

Tomohiko Tamura, DDS, Department of Operative Dentistry, Nihon University Graduate School of Dentistry, Tokyo, Japan

Sho Shibasaki, DDS, PhD, Department of Operative Dentistry, Nihon University School of Dentistry, Tokyo, Japan

Akimasa Tsujimoto, DDS, PhD, Department of Operative Dentistry, University of Iowa College of Dentistry, Iowa City, IA, USA

Wayne W. Barkmeier, DDS, MS, Department of General Dentistry, Creighton University School of Dentistry, Omaha, NE, USA

Mark A. Latta, DMD, MS, Department of General Dentistry, Creighton University School of Dentistry, Omaha, NE, USA

Masashi Miyazaki, DDS, PhD, Department of Operative Dentistry, Nihon University School of Dentistry, Tokyo, Japan

*Corresponding author: 1-8-13, Kanda-Surugadai, Chiyoda-ku, Tokyo, Japan; e-mail: Takamizawa.toshiki@nihon-u.ac.jp

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between the tested parameters, extremely strong negative and positive correlations were observed for the DOC versus extrusion force, flexural strength versus elastic modulus, maximum depth versus volume loss, and maximum depth versus thread formation. In addition, strong correlations between FCs and DOC, resilience, wear resistance, and extrusion force were observed.

INTRODUCTION

Over the decades, technological innovations have been mitigating the drawbacks of resin composites, such as the mechanical properties, polymerization shrinkage, color match, polishability, depth of cure (DOC), and handling properties.[1] In particular, the development of low-viscosity resin composites, namely, flowable resin composites, had a huge impact on restorative dentistry owing to their ease of handling.[2] Flowable resin composites possess high flowability and low viscosity; therefore, they can be used to restore any kind of cavity with small-gage dispensers and as a liner on the cavity floor to reduce the development of air bubbles.[3] Various improvements in flowable resin composites have been made since their introduction into the market in the early 1990s. Currently, these materials have a much broader range of applicability, and various types of flowable resin composites with different viscosities and flowabilities suitable for a variety of cavity conditions are available.[4-6]

The mechanical properties of some of the recent flowable resin composites are equal or superior to those of conventional resin composites; hence, they can be used for high-stress-bearing areas, large cavities, and class II restorations.[2,5] In our previous study, we compared the wear resistance between recent flowable and conventional resin composites, and found that four out of the six tested flowable resin composites did not exhibit any significant differences in maximum wear depth and volume loss, after slinging-impact wear testing, when compared with a nanofiller resin composite. However, the wear resistance of these materials was significantly higher than that of a hybrid-type conventional resin composite.[2] In addition to the superior mechanical properties and wear resistance, "injectable" flowable resin composites have good handling properties when used to create anatomical features, marginal ridges, and molar cusps.

Bulk-fill resin composites (BRCs) were developed to reduce the contraction stress and the number of filling steps.[7-9] They can be used as a single layer (up to 4 mm in thickness) with adequate C=C double bond conversion and short activation times owing to their increased translucency properties and the presence of modified photoinitiators and resin monomers.[10-13] This new type of resin composite is promising for use not only in deep cavities but also as a direct core foundation material. BRCs can be classified into two types: low-viscosity type similar to flowable resin composites and high-viscosity type resembling conventional resin composites.[14] Moreover, they can be classified based on the mode of use as base composites or final filling restoratives, which do not need an additional resin paste.[8,14]

Low-viscosity BRCs (LVBRCs) are used more frequently for base materials, owing to their inferior mechanical properties and their ability to conform to the cavity floor more easily, as compared with high-viscosity materials.[8,14,15] However, some LVBRCs are thought to have mechanical properties similar to those of high-viscosity BRCs, along with good handling properties, due to recent advances in flowable resin composite technology.[16] Therefore, it is likely that LVBRCs will be used as final filling restoratives, as for high-viscosity BRCs or flowable resin composites with advanced properties. However, information on the mechanical properties, wear resistance, or handling properties of LVBRCs is scarce.

The purpose of this study was to investigate some of the mechanical properties of LVBRCs, including the filler content, DOC, flexural properties, wear resistance, and handling properties. The null hypotheses to be tested were as follows: (1) the mechanical properties, wear, and handling properties of the tested LVBRCs would not be affected by the type of LVBRC used, (2) no correlations between the tested parameters would be observed.

METHODS AND MATERIALS

Study Materials

The six LVBRCs used in this study were as follows (Table 1): Beautifil-Bulk (BBF; Shofu, Kyoto, Japan), Bulk Base Hard (BBH, Sun Medical, Shiga, Japan), Bulk Base Medium (BBM, Sun Medical), Filtek Bulk-Fill Flowable Restorative (FBF, 3M Oral Care, St. Paul, MN, USA), G-ænial Bulk Injectable (GBI, GC, Tokyo, Japan), and SDR flow+ Bulk-Fill Flowable (SDR, Dentsply Sirona, Charlotte, NC, USA).

A halogen–quartz–tungsten curing unit (Optilux 501; SDS Kerr, Danbury, CT, USA) was used,[17] and the light irradiance (600 mW/cm^2) of the curing unit

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Table 1: *Materials Used in This Study*[a]

Code	Resin Composite (Shade; Lot No.)	Main Components	Manufacturer
		Low-viscosity bulk-fill resin composite	
BBF	Beautifil Bulk Flowable (Universal; 071934)	*bis*-GMA, UDMA, *bis*-MPEPP, TEGDMA, fluoroalminosilicate glass, reaction initiator, others	Shofu, Kyoto, Japan
BBH	Bulk Base Hard (Universal; TK12)	*bis*-MPEPP, urethane acrylate, barium glass filler, strontium aluminosilicate glass, initiator, aromatic amine, others	Sun Medical, Shiga, Japan
BBM	Bulk Base Medium Flow (Universal; TL12)	*bis*-MPEPP, urethane acrylate, barium glass filler, strontium aluminosilicate glass, aromatic amine	Sun Medical, Shiga, Japan
FBF	Filtek Bulk Fill Flowable restorative (Universal; NA10949)	*bis*-GMA, UDMA, bis-EMA, procrylat resins, TEGDMA, zirconia/silica filler, ytterbium trifluoride filler	3M Oral Care, St. Paul, MN, USA
GBI	G-ænial Bulk Injectable (Universal; 1906292)	*bis*-EMA, dimethacrylate, bismethacrylate, dimethacrylate component, UDMA, UV-light absorber, silane, silica, barium glass filler, photoinitiator, stabilizers, pigments	GC, Tokyo, Japan
SDR	SDR flow+ Bulk Fill Flowable (Universal; 17339)	modified urethane dimethacrylate resin, TEGDMA, polymerizable dimethacrylate resin, BHT, polymerizable trimethacrylate resin, ethyl-4(dimethylamino)benzoate photoaccelerator silanated barium-alumino-fluoroborosilicate glass silanated strontium alumino-fluorosilicate glass, surface treated fume silicas, ytterbium fluoride, pigments	Dentsply Sirona, Charlotte, NC, USA

[a] *Light irradiation time was followed manufacturer's instructions (20 seconds) for a halogen curing light unit.*
Abbreviations: bis-GMA, 2, 2-bis[4-(2-hydroxy-3-methacryloyloxypropoxy)phenyl] propane; UDMA, urethane dimethacrylate; bis-MPEPP, 2, 2′-bis(4-methacryloxy polyethoxyphenyl) propane; TEGDMA, triethylene glycol dimethacrylate; bis-EMA, bisphenol A ethoxylate dimethacrylate; BHT, butylated hydroxy toluene.

was checked using a dental radiometer (Model 100, Kerr). In order to standardize light irradiation conditions for each test and material, the guide tip of the curing unit was attached on the transparent matrix tape directly, and irradiation was performed for 20 seconds. Light irradiation time was followed as per the manufacturer's instructions.

Inorganic Filler Content (FC)

The inorganic filler contents (FCs) of the tested LVBRCs were measured using a dental laboratory furnace. Approximately 50 mg of resin paste from each LVBRC was placed in a crucible, a cylindroid of pure platinum that was 7 mm in diameter and 10 mm in depth, and heated in the electric furnace from 25°C to 700°C until the organic components were completely incinerated. The weight of the residual resin paste was measured using an electronic balance (AE163; Mettler-Toledo, Greifensee, Zürich, Switzerland) with an accuracy of ±0.1 mg, and the FC (wt%) was calculated. Five measurements were obtained for each resin, and the average FC (wt%) was determined.

Depth of Cure (DOC)

Measurements of the depth of cure (DOC) for the LVBRCs were conducted in a 4-mm-diameter and 10-mm-high plastic cylinder in accordance with the international standard, ISO 4049.[18] The mold was placed on a glass slide covered with a matrix tape (Matrix Tape and Dispenser; 3M Oral Care). Then, it was filled in bulk with one of the tested composites. The topside of the mold was covered with a transparent matrix tape, and the resin paste was pressed flush with the mold using a second glass slide. Ten specimens were irradiated from the top of the cylinder mold with 600 mW/cm^2 light irradiance for 20 seconds. As soon as the curing was over, the material was pressed out of the mold, and the unpolymerized part was removed using a plastic spatula and cotton dipped in alcohol. The remaining cured part was measured using a digital caliper (CPM15-25DM; Mitutoyo, Tokyo, Japan) with an accuracy of ±0.1 mm, and the measured value was divided by two, as specified by ISO 4049. This value was recorded as the DOC for each specimen.

Flexural Strength Test

The flexural properties of the LVBRCs were tested according to ISO 4049.[18] A stainless steel split mold (dimensions 25×2×2 mm) was set on a glass slide covered with a matrix strip. Each resin composite paste was filled into the mold, and the topside of the mold was covered with a transparent matrix tape. The resin paste was pressed with a second glass slide under a 5 N load. The middle-third of the specimen

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was irradiated for 20 seconds, followed by the remaining thirds for 20 seconds each. The opposite side was irradiated in the same manner. After removing the hardened specimen from the mold, all the six sides were wet polished with #1200-grit SiC paper (Fuji Star Type DDC; Sankyo Rikagaku, Saitama, Japan). Baseline specimens were stored in distilled water at 37°C under dark conditions for 24 hours before the flexural strength test was conducted. The other prepared specimens were similarly stored in distilled water at 37°C for 24 hours under dark conditions before being subjected to 30,000 thermal cycles (TC) between 5°C and 55°C, with a dwell time of 30 seconds.

After the storage period, 12 specimens per test group were subjected to the three-point bending test using a universal testing machine (model 5500R; Instron, Canton, MA, USA) at a crosshead speed of 1.0 mm/minute until the breaking of the specimen. The specimens were set on the three-point bending apparatus with a span length of 20.0 mm. The flexural strength (σ_F) in MPa was calculated as follows:

$$\sigma_F = 3P \bullet D/2W \bullet H^2,$$

where P=peak load, D=distance between the supports (20 mm), W=width, and H=height.

The elastic modulus (E) in GPa was determined from the stress–strain curve using a computer software program (Bluehill version 2.5; Instron) linked to the testing device. The modulus of resilience (R) was calculated using the following equation[19]:

$$R = \sigma_F^2/2E$$

Sliding-Impact Simulated Wear Test

The wear properties of the 12 specimens from each group were determined using a sliding-impact-wear testing machine (K655-06; Tokyo Giken, Tokyo, Japan). A polytetrafluoroethylene cylindrical mold (6 mm in diameter and 2 mm in height) was set on a glass slide covered with a matrix strip. Each LVBRC paste was condensed into the mold, and the top side was covered with a transparent matrix tape. The resin paste was pressed through a glass slide under a 5 N load and light irradiated for 20 seconds. One flat surface of each specimen was polished using a sequence of SiC papers up to 2000 grit. Subsequently, they were stored under dark conditions in distilled water at 37°C for 24 hours.

The specimens were attached to the center of a custom fixture made of cold-cured acrylic resin (Tray Resin II, Shofu, Kyoto, Japan) with a small amount of repair glue before wear testing. A stainless steel ball bearing (radius 2.4 mm) set inside a collet assembly was used as an antagonist for the wear-simulation test. The simulator contained a plastic water bath with a constant provision of distilled water at 37°C. Four custom fixtures were positioned inside the bath. During the wear-simulation test, the antagonists directly impacted the specimens from above with a maximum force of 50 N at a rate of 0.5 Hz and slid horizontally for 2 mm. Each specimen was subjected to 50,000 cycles of the sliding-impact motion.

Sliding-Impact Wear Measurements

After the wear-simulation test, the specimens were ultrasonically cleaned with distilled water for 1 minute. The wear facets were evaluated using a confocal laser scanning microscope (CLSM, VK-9710; Keyence, Osaka, Japan) and its built-in software (VK-Analyzer, Keyence). The maximum facet depth (MD in μm) and volume loss (VL in mm^3) of each wear facet were measured.

Extrusion Force Measurement

The extrusion force and thread formation (stickiness) were determined, as described previously.[2] A universal testing machine (model 5500R; Instron) was used to determine the extrusion force of the tested materials. A special jig was prepared to fix a syringe containing unused fresh LVBRC at the flange, and the plunger was subjected to perpendicular load stress at a crosshead speed of 10 mm/minute. The load stress was automatically monitored during the test, which ended when the resin paste was completely discharged from the syringe. The extrusion force of the resin composite was measured by the peak load stress (MPa) over the course of the testing. Six measurements were performed for each LVBRC.

Thread Formation Property (Stickiness)

A creepmeter (Rheoner II, model RE 2-3305C; Yamaden, Tokyo, Japan) was used to measure the thread formation of the tested LVBRCs. The test resin pastes were filled into a cylindrical mold (diameter, 10 mm; height, 2 mm) made of polytetrafluoroethylene and left for 3 minutes to relieve the internal stresses. A cylindrical rod (diameter 5 mm) was inserted up to 1 mm into the resin paste and pulled up at a crosshead speed of 10 mm/second.

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Thread formation was continuously monitored using a video camera (HDR-CX680; Sony, Tokyo, Japan). The vertical distance from the bottom of the rod to the top of the mold (mm) was measured at the point at which the thread broke. Six measurements were performed for each LVBRC.

Scanning Electron Microscope (SEM) Observations

Each cured specimen was polished with abrasive disks (Fuji Star Type DDC), followed by a series of diamond pastes down to a particle size of 0.25 μm (DP-Paste; Struers, Ballerup, Denmark). The polished surfaces were subjected to argon ion beam etching (IIS-200ER, Elionix, Tokyo, Japan) for 45 seconds, with the ion beam directed perpendicular to the polished surface (accelerating voltage, 1 kV; ion current density, 0.4 mA/cm^2). The surfaces were then coated with a thin film of gold in a Quick Coater vacuum evaporator (Type SC-701; Sanyu Denchi, Tokyo, Japan). Observations were conducted via scanning electron microscopy (SEM; FE-8000; Elionix) at an operating voltage of 10 kV and under magnifications of 5000× and 20000×.

SEM examinations were conducted at the center of the wear facets on the tested LVBRCs. The specimens were randomly selected after the wear measurements; the coating of samples was performed as described for the polished specimens. The coated surfaces were visualized using SEM with an operating voltage of 10 kV (magnification 2500×).

Statistical Analysis

To determine the appropriate sample size for each test, a statistical power analysis was conducted. The tests were initially performed with sample sizes of 5 for inorganic filler content measurement; 12 for flexural strength, DOC tests, and simulated wear measurements; and 6 for extrusion force and thread formation measurements. After gathering the data, post hoc power tests were conducted using two statistical software systems (G Power calculator and SigmaPlot version 13.0, Systat Software, Chicago, IL, USA) with an f value of 0.75, α value of 0.05, and power of 0.95. The tests indicated that the sample size for each test was adequate.

Owing to the homogeneity of variance (Bartlett test) and normal distribution (Kolmogorov–Smirnov test), the data for each material were subjected to the one-way analysis of variance test followed by Tukey honest significant difference test at a significance level of 0.05. The Pearson product-moment correlation coefficient was employed for pairwise comparisons to evaluate the interrelationships between the tested parameters. All statistical analyses were conducted using a software system (Sigma Plot).

Table 2: *Inorganic Filler Contents (FCs) and Depth of Cure (DOC) of the LVBRCs*[a]

	Inorganic Filler Content wt%	DOC mm
BBF	69.4 (0.6) a	3.87 (0.06) c
BBH	69.6 (0.7) a	3.10 (0.05) d
BBM	69.5 (0.3) a	3.18 (0.13) d
FBF	61.4 (0.6) c	4.36 (0.06) a
GBI	67.7 (0.5) b	3.93 (0.03) c
SDR	69.0 (0.4) a	4.13 (0.12) b

[a] *Values in parentheses indicate standard deviation. Same lowercase letter indicates no difference at 5% significance level.*

RESULTS

Inorganic Filler Content

The average inorganic FC in the tested LVBRCs ranged from 61.4 to 69.6 wt% (Table 2). The tested materials listed in descending order of the inorganic filler content were BBH, BBM, BBF, SDR, GBI, and FBF. FBF exhibited a significantly lower inorganic filler content than the other bulk-fill composites.

Depth of Cure

The results of the DOCs are presented in Table 2. The average values in the tested LVBRCs ranged from 3.10 to 4.36 mm. The tested materials listed in descending order based on the DOCs were FBF, SDR, GBI, BBF, BBM, and BBH. FBF exhibited a significantly higher DOC than the other BRC. No significant difference in DOC was observed between BBH and BBM; however, the values of these two materials were significantly lower than those of the remaining four materials (Table 2).

Flexural Properties

The flexural strengths (σ_F) of the LVBRCs are presented in Table 3. At baseline (24-hours water storage group), the mean σ_F values of the LVBRCs ranged from 102.0 to 143.9 MPa. BBH and GBI exhibited significantly higher σ_F values than the other LVBRCs. BBM presented with the lowest σ_F value ($p<0.05$) among the materials tested. In the TC group, the mean σ_F value of the LVBRCs ranged from 93.1 to 134.0 MPa, and the changing rates were −4.8% to −14.3%, when the σ_F value of baseline is defined as 100%. BBH and GBI exhibited signifi-

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Table 3: *Influence of Thermal Cycling on Flexural Strength of the LVBRCs*[a]

	Baseline MPa	TC 30,000 MPa	Changes %
BBF	122.5 (6.9) bA	105.0 (7.5) bcB	−14.3
BBH	140.7 (6.1) aA	134.0 (5.6) aB	−4.8
BBM	102.0 (6.9) cA	93.1 (4.5) dB	−8.9
FBF	117.4 (8.5) bA	103.0 (4.9) cB	−12.3
GBI	143.9 (7.1) aA	129.4 (6.6) aB	−10.0
SDR	122.0 (6.8) bA	111.0 (5.5) bB	−9.1

[a] *Values in parentheses indicate standard deviation.*
Same lowercase letter in vertical columns indicates no difference at 5% significance level.
Same uppercase letter in horizontal rows indicates no difference at 5% significance level.

cantly higher σ_F values than the other LVBRCs ($p<0.05$), whereas BBM had the lowest σ_F value when compared with the other LVBRCs. A statistically significant reduction in σ_F after TC was observed in each material, when compared with the baseline values.

The elastic moduli (E) of the LVBRCs are presented in Table 4. The mean value of E ranged from 4.1 to 8.4 GPa in the baseline group. BBH and BBM presented with significantly higher and lower E values, respectively, than the other LVBRCs. In the TC group, the mean E values of LVBRCs ranged from 4.4 to 9.5 GPa, and the changing rates were +6.0% to +18.1%. Although no significant difference was observed among BBF, BBH, and GBI, they presented with significantly higher E values than the other LVBRCs. In most of the cases, the E values of the LVBRCs were significantly higher in the TC group than in the baseline group.

The resilience (R) values of the BRCs are presented in Table 5. The mean R in the baseline group ranged from 1.0 to 1.3 MJ/mm^3. BBF exhibited a significantly lower R than the other LVBRCs. For all the materials, statistically significant reductions in R were observed after TC when compared with the baseline, and the changing rates were −17.7% to −40%.

Table 4: *Influence of Thermal Cycling on Elastic Modulus of the LVBRCs*[a]

	Baseline GPa	TC 30,000 GPa	Changes %
BBF	7.2 (0.3) bA	8.5 (1.3) aB	+18.1
BBH	8.4 (0.4) aA	8.9 (0.7) aA	+6.0
BBM	4.1 (0.2) eA	4.4 (0.3) cB	+7.3
FBF	5.5 (0.4) dA	6.3 (0.3) bB	+14.5
GBI	7.7 (0.6) bA	8.8 (1.2) aB	+14.3
SDR	6.4 (0.7) cA	7.0 (0.5) bB	+9.3

[a] *Values in parentheses indicate standard deviation.*
Same lowercase letter in vertical columns indicates no difference at 5% significance level.
Same uppercase letter in horizontal rows indicates no difference at 5% significance level.

Table 5: *Influence of Thermal Cycling on Resilience of the LVBRCs*[a]

	Baseline MJ/mm^3	TC 30,000 MJ/mm^3	Changes %
BBF	1.0 (0.1) bA	0.6 (0.1) cB	−40.0
BBH	1.2 (0.1) aA	1.0 (0.1) aB	−17.7
BBM	1.2 (0.2) aA	1.0 (0.1) aB	−17.7
FBF	1.3 (0.1) aA	0.8 (0.1) bB	−38.5
GBI	1.3 (0.1) aA	1.0 (0.2) aB	−23.1
SDR	1.2 (0.1) aA	0.9 (0.1) aB	−25.0

[a] *Values in parentheses indicate standard deviation.*
Same lowercase letter in vertical columns indicates no difference at 5% significance level.
Same uppercase letter in horizontal rows indicates no difference at 5% significance level.

Sliding-Impact Simulated Wear Test

The MD and VL of the LVBRCs after the sliding-impact-wear test are presented in Table 6. The mean value of the MD and VL ranged from 44.0 to 208.6 μm and from 0.022 and 0.443 mm^3, respectively. The LVBRCs were classified into high- and low-wear resistance groups based on the wear behavior. BBH, FBF, and GBI exhibited a significantly higher wear resistance than BBF, BBM, and SDR.

Handling Properties

The flowability (extrusion force and thread formation) relating to the handling of the LVBRCs are presented in Table 7. The mean extrusion force value ranged from 0.10 to 0.37 MPa. SDR demonstrated a significantly lower extrusion force than the other LVBRCs; conversely, BBH and BBM exhibited

Table 6: *Maximum Facet Depth (MD) and Volume Loss (VL) after Sliding-impact Wear Test*[a]

	MD μm	VL mm^3
BBF	174.5 (32.1) a	0.414 (0.08) a
BBH	49.2 (6.5) b	0.025 (0.0002) b
BBM	208.6 (33.4) a	0.443 (0.07) a
FBF	51.2 (6.9) b	0.034 (0.004) b
GBI	44.0 (9.7) b	0.022 (0.006) b
SDR	208.1 (47.9) a	0.390 (0.09) a

[a] *Values in parentheses indicate standard deviation.*
Same lowercase letter in vertical columns indicates no difference at 5% significance level.

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Table 7: *Handling Properties of the LVBRCs*[a]

	Extrusion force MPa	Thread formation mm
BBF	0.27 (0.026) b	36.6 (3.3) c
BBH	0.37 (0.024) a	36.9 (3.6) c
BBM	0.36 (0.025) a	55.6 (2.8) b
FBF	0.10 (0.006) c	37.6 (1.0) c
GBI	0.13 (0.013) c	11.9 (1.0) d
SDR	0.06 (0.005) d	68.6 (6.4) a

[a] *Values in parentheses indicate standard deviation. Same small case letter in vertical columns indicates no difference at 5% significance level.*

significantly higher extrusion forces than the other materials. The extrusion forces of BBH and BBM were approximately six times higher than that of SDR, and three to four times higher than those of FBF and GBI.

For thread formation, the mean value ranged from 11.9 to 68.6 mm. GBI exhibited a significantly lower value than the other LVBRCs. SDR presented with significantly higher thread formation than the other materials, more than six times as high as GBI.

SEM Observations

Representative SEM images of the highly polished LVBRC specimens after argon ion etching are presented in Figure 1. Although each LVBRC showed differences in filler shape, size, and distribution, BBF, BBH, BBM, and SDR exhibited similar morphological features. They exhibited a wide range in size with irregular filler particles—from 0.1 to 10 μm (Figures 1A, 1B, 1C, and 1F). Conversely, GBI employed densely packed nanosized irregular filler particles (Figure 1E). FBF consisted of nanosized spherical particles with aggregates of filler particles ranging from 0.5 to 3 μm in size (Figure 1D)

Representative CLSM images of the wear facets and SEM images at the center of the facets are presented in Figure 2. The depth and width of the wear facet were material dependent. The wear facets in the BBF, BBM, and SDR specimens (Figures 2A, 2C, and 2F) were deeper and wider than those in the BBH, FBF, and GBI specimens. SEM revealed plucking of the large irregular filler particles in BBF, BBM, and SDR (indicated by white arrows), whereas BBH and GBI exhibited a similar wear pattern with a somewhat smooth surface (Figures 2B and 2E). While some cracks were observed (indicated by yellow arrows), detecting the plucking of fillers in the GBI specimens (Figures 2E) was difficult. The surface of FBF was smooth, with some evidence of the plucking of the nanofillers (Figures 2D).

Correlation between the Tested Parameters in the LVBRCs

The Pearson product-moment correlation coefficients (r) and p values for the correlations between the tested parameters in the LVBRCs are presented in Table 8. Extremely strong negative and positive correlations were observed for the DOC versus EF, σ_F versus E, MD versus VL, and MD versus TF. All the correlations were statistically significant ($p<0.05$), except for MD versus TF ($p=0.067$). Strong negative correlations were observed for FC versus DOC, FC versus R, σ_F versus MD, σ_F versus VL, σ_F versus TF, E versus MD, E versus VL, E versus TF, R versus MD, R versus VL, and R versus EF, statistical significance notwithstanding ($p>0.05$). Likewise, strong positive correlations were observed between FC and MD, FC and VL, FC and EF, and VL and TF, although they were not statistically significant ($p>0.05$).

DISCUSSION

LVBRCs are thought to be suitable for base materials in deep cavities or for the restoration of narrow and deep cavities in nonstress-bearing areas.[14,15] In recent years, the wear resistance of this resin composite has been improved to broaden the range of applicability.[16] However, the available information on the use of LVBRCs in stress-bearing areas while maintaining the good handling properties and DOC is scarce.

The first and second null hypotheses were rejected, based on the results of this study. Although the LVBRCs showed different mechanical and handling properties depending on the type, some tested parameters showed strong correlations. Further, some LVBRCs showed excellent flexural strength and wear resistance while maintaining handling properties and DOC. In this study, the average DOC ranged from 3.10 to 4.36 mm. Although this value is influenced by light curing conditions, it has been shown that achieving an acceptable value (at 4 mm) is dependent on the material used.[15] The three main strategies used to increase the curing depths of resin composites include the development of a more translucent resin composite, reduction in filler concentrations, and adoption of more efficient photoactivation systems.[10-13] Matching the refractive indices of fillers and the resin matrix is considered as the best way to increase the DOC.[10] Therefore, most of the LVBRCs are highly transparent when com-

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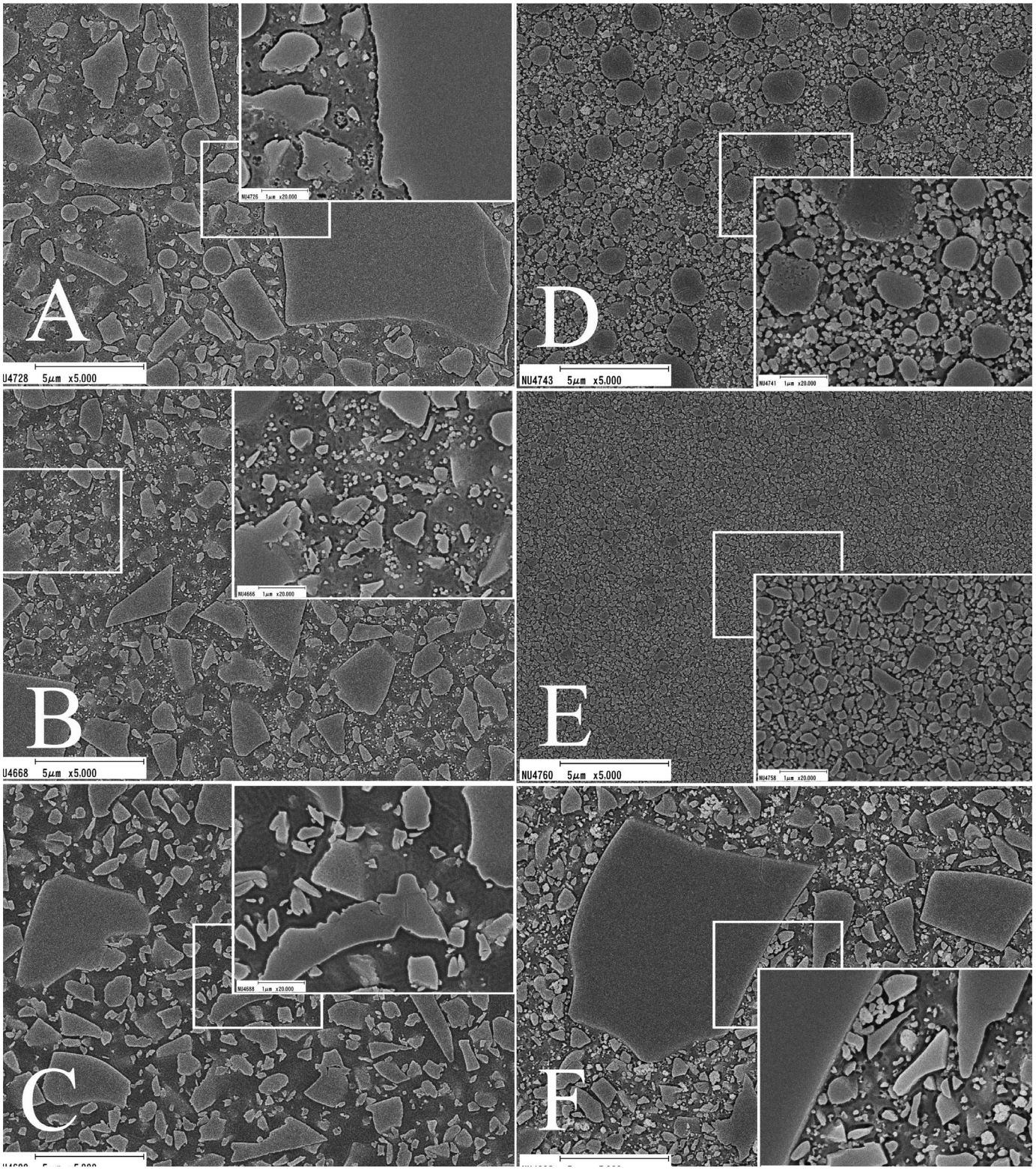

Figure 1. *Scanning electron microscope (SEM) images of the argon-ion-etched surfaces of the low-viscosity bulk-fill resin composites* (*LVBRCs*). *SEM images at magnifications 5000× and 20,000×.*
A. BBF
B. BBH
C. BBM
D. FBF
E. GBI
F. SDR

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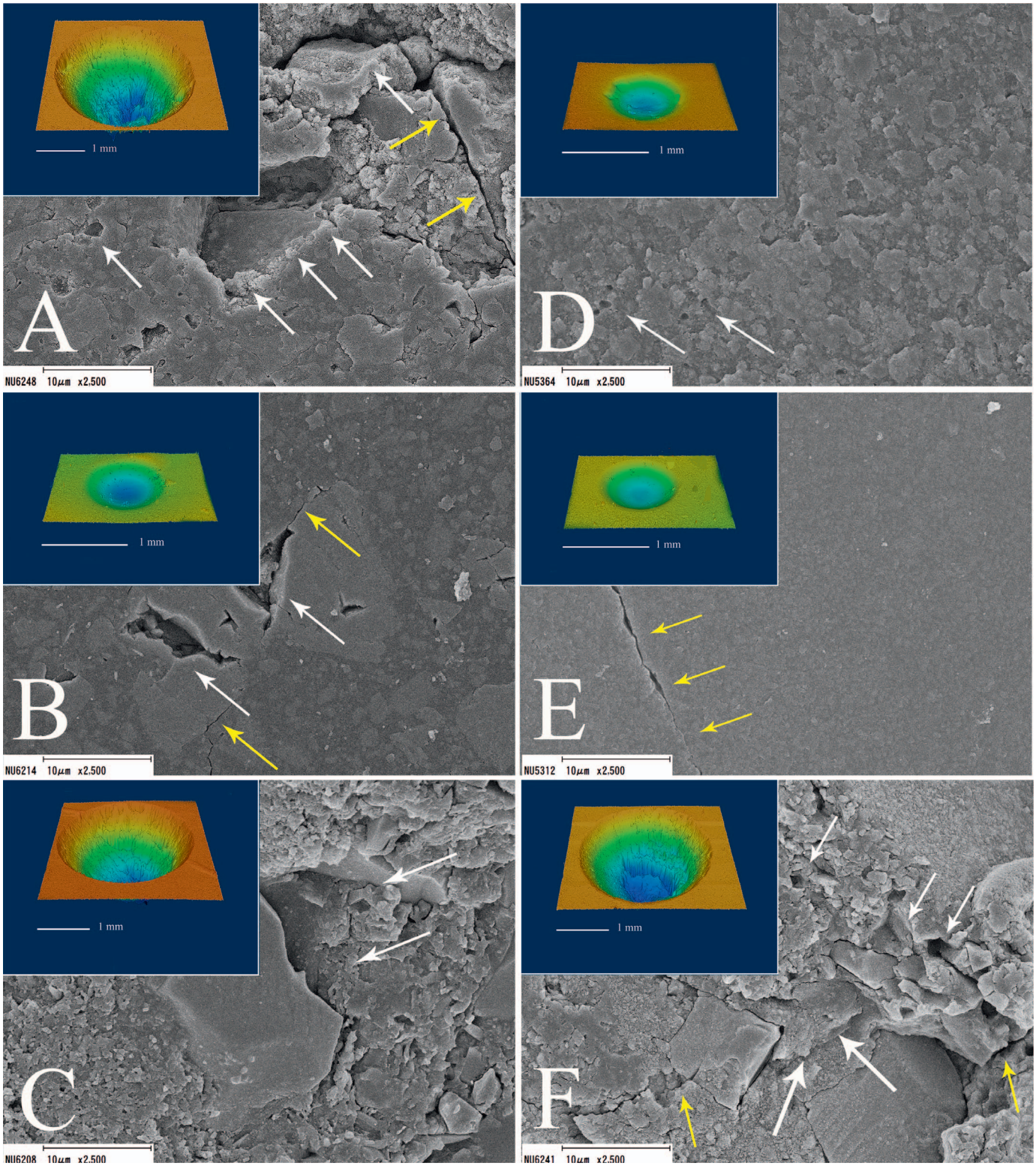

Figure 2. *Representative wear facets of low-viscosity bulk-fill resin composites (LVBRCs) after the sliding impact wear test.*
Confocal laser scanning microscopy images of wear facet and scanning electron microscope (SEM) image of the center of the facet (2500×).
A. BBF
B. BBH
C. BBM
D. FBF
E. GBI
F. SDR
White arrows indicate evidence of the plucking of inorganic filler particles.
Yellow arrows indicate cracks.

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Table 8: *Correlation Between the Tested Parameters in the LVBRCs*

		DOC	σ_F	*E*	*R*	*MD*	*VL*	*EF*	*TF*
FC	*r*	−0.661	0.114	0.265	−0.554	0.504	0.514	0.540	0.221
	P value	0.153	0.830	0.612	0.254	0.308	0.297	0.268	0.674
DOC	*r*	0.006	−0.054	0.196	−0.096	−0.113	−0.923	−0.061	
	P value		0.991	0.918	0.709	0.856	0.831	0.009	0.908
σ_F	*r*		0.963	0.192	−0.696	−0.694	−0.124	−0.663	
	P value		0.006	0.716	0.125	0.126	0.815	0.151	
E	*r*			−0.140	−0.527	−0.501	0.013	−0.529	
	P value			0.792	0.283	0.311	0.981	0.280	
R	*r*				−0.561	−0.660	−0.417	−0.224	
	P value				0.246	0.154	0.411	0.670	
MD	*r*				0.986	0.101	0.779		
	P value				0.0003	0.849	0.067		
VL	*r*					0.171	0.692		
	P value					0.746	0.128		
EF	*r*						−0.011		
	P value						0.983		

Abbreviations: FC, Inorganic filler content; DOC, depth of cure; σ_F, Flexural strength; E, Elastic modulus; R, Resilience; MD, Maximum depth; VL, Volume loss; EF, Extrusion force; TF, Thread formation; r, correlation coefficient.

pared with conventional flowable and universal resin composites. Although the present study confirmed a strong negative correlation between FC and the DOC, the reduction in filler content leads to reduced mechanical properties. Hence, the two strategies make it difficult to restore a cavity using only LVBRC in stress-bearing and esthetic areas. The filler details are different; for example, irregular fillers are believed to reduce light transmission owing to their higher levels of reflection.[20]

Among the tested materials in this study, most resin composites exhibit a DOC of approximately 4 mm, except for BBH and BBM. The different DOCs in the different materials may be attributed to their composition. FBF had the lowest filler content, and consisted of nanosized spherical fillers and aggregated fillers (Figure 1D). Conversely, although SDR consisted of irregular fillers, the filler size was larger than those of the other materials (Figure 1F). Therefore, it can be hypothesized that filler properties play a significant role in light transmission and the DOC.[10,21,22]

BBH and GBI exhibited significantly higher σ_F values than the other materials at both baseline and after TC. Conversely, BBM demonstrated a significantly lower σ_F value compared with the other LVBRCs. Although BBH and BBM were obtained from the same manufacturer, the instructions indicated that BBH can be used either as a veneer or base material, whereas BBM can only be used as a base (or lining) material. These two resins consisted of the same resin monomers and filler types. Although the filler size, shape, and distribution were similar in BBH and BBM, several nanosized filler particles were observed between somewhat larger irregularly shaped fillers in BBH (Figures 1B and 1C). A possible explanation for the significant increase in σ_F value in BBH when compared with that in BBM is the presence of nanofillers that might inhibit crack propagation from external stress. However, the mixing ratios of the resin monomers might be different. GBI presented with a high σ_F value (>140 MPa), which was equal or superior to those of conventional flowable resin composites measured in a previous study.[2] The high σ_F value in the GBI specimen might be attributed to the densely packed, nanosized, irregular filler particles (Figure 1E) and the surface treatment of the inorganic fillers.

A statistically significant reduction in σ_F after TC when compared with the baseline was observed with all the materials. However, different reduction rates were observed among the materials (ranging from −4.8% to −14.3%). BBF and FBF exhibited higher reduction percentages than the other materials. The degradation process during TC is thought to be caused by thermal stress and water absorption.[23,15] Although water susceptibility may be different in different resin monomers, the hydrophilic ether linkage in TEGDMA (*triethylene glycol dimethacrylate*), hydroxyl groups in *bis*-GMA (2, 2-bis[4-(2-hydroxy-3-methacryloyloxypropoxy)phenyl] pro-

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pane), and urethane linkage in UDMA (*urethane dimethacrylate*) act as scaffolds for hydrolytic degradation.[24] A previous study reported the water sorption in three homopolymers in descending order as follows: TEGDMA>*bis*-GMA>UDMA.[24] Among the resin composites used in the current study, BBF and FBF employ *bis*-GMA and TEGDMA. Therefore, these resin monomer components might influence resin matrix degradation.

As for the σ_F, BBH demonstrated a significantly higher E value, and BBM presented with a significantly lower E value than the other LVBRCs. In general, resin composites tend to have increased E and σ_F values.[25] In the present study, an extremely strong positive correlation between σ_F and E was observed. Izabela and others[26] determined the E of three typical homopolymers and revealed that UDMA had a lower E than *bis*-GMA and TEGDMA, indicating that the resin monomer components may also affect the E of a resin composite. Most LVBRCs showed significantly higher E values in the TC group than in the baseline group. This may be due to the increase in the brittleness of the material as a result of the curing during TC.[27] Although resin composites with low E are more flexible and deform elastically under external stress, those with high E are stiff with a limited capacity to absorb the occlusal forces. Therefore, functional stresses might be transferred to the cavity walls if the E values of the materials increase over time.[28]

R is considered as the material's ability to absorb energy when deformed elastically under external stress without failing.[27] Most LVBRCs demonstrated similar R values at baseline, and a statistically significant reduction in the R values was noted after TC in all the materials tested in this study. The temperature rise due to TC might increase the rigidity of the material due to postcure strengthening, and water immersion might change the material's properties due to plasticization by water absorption.[27]

Based on the results of the wear test, the LVBRCs were classified into two groups: high- and low-wear resistance. Ujiie and others[16] compared the wear resistance of flowable resin composites and LVBRCs using the Leinfelder–Suzuki (Alabama) localized wear test and reported that although LVBRCs exhibited a wide range of wear properties, some demonstrated similar wear behaviors to those of flowable resin composites. Although the wear method and apparatus used were different, the materials tested in that study included the three materials that were examined in the present study; additionally, the outcome of the aforementioned study was in line with that of the current study. In both the studies, GBI exhibited the highest wear resistance when compared with the other LVBRCs. GBI employs densely packed ultrafine 150-nm barium fillers, and the interparticle space is obviously smaller than those in the other LVBRCs (Figure 1E). It is thought that the filler size influences the friction coefficient and surface roughness, which are the determining factors for the wear resistance of resin-based materials.[28] Smaller filler particles are related to lower friction coefficients and lead to lower internal shear stress in the resin matrix.[28] A lower wear rate was observed in FBF, which might be explained by a wear mechanism similar to that of GBI. Although FBF contains some large aggregated fillers consisting of nanosized zirconia/silica fillers, the interparticle spaces are filled with dispersed nanosized zirconia/silica fillers and small ytterbium trifluoride fillers. A previous investigation of the wear behavior of flowable resin composites using the same method as that in this study reported wear ranging from 49.4 to 110.7 μm for MD and 0.021 to 0.109 mm^3 for VL^2; the levels of wear resistance of GBI, BBH, and FBF in the present study were similar to those of the flowable resin composites reported in their study. Therefore, in the results of mechanical properties and wear resistance, GBI and BBH can probably be used in stress-bearing areas while maintaining the DOC.

Conversely, BBF, BBM, and SDR exhibited approximately 15-20 times higher volumes of the VL for GBI, BBH, and FBF. BBF, BBM, and SDR have somewhat larger irregular particles and large interparticle space, resulting in lower wear resistance. In this study, the flexural properties (σ_F, E, and R) and wear properties (MD and VL) exhibited strong negative correlations, indicating that the low-wear resistance group showed low flexural properties. Hence, they are designed for use as base or lining materials owing to their lower mechanical properties.

In clinical situations, the force required to extrude the resin paste from a syringe is directly related to the ease of use. When the resin paste needs a stronger force to be extruded, it is more difficult to control the speed of the syringe plunger and the position of the tip. If the extrusion force is less, an excessive amount of resin paste might be pushed out from the syringe plunger. Moreover, if the resin paste forms threads, it might be difficult to control the amount of paste used and to create optimal anatomical forms when the syringe is withdrawn.

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Table 9: *The Definition of Abbreviations in This Study*
LVBRC: Low-viscosity bulk-fill resin composite
BBF: Beautifil-Bulk
BBH: Bulk Base Hard
BBM: Bulk Base Medium
FBF: Bulk-Fill Flowable Restorative
GBI: G-ænial Bulk Injectable
SDR: SDR flow+
σ_F: Flexural strength
E: Elastic modulus
R: Resilience
TC: Thermal cycles
BRC: Bulk-fill resin composites
FC: Inorganic filler content
DOC: Depth of cure
MD: Maximum depth
VL: Volume loss
CLSM: Confocal laser scanning microscope
EF: Extrusion force
TF: Thread formation
r: Correlation coefficient
SEM: Scanning electron microscope
bis-GMA: 2, 2-bis[4-(2-hydroxy-3-methacryloyloxypropoxy)phenyl] propane
UDMA: Urethane dimethacrylate
TEGDMA: Triethylene glycol dimethacrylate
bis-MPEPP: 2, 2′-bis (4-methacryloxy polyethoxyphenyl) propane

The mean extrusion force values ranged from 0.10 to 0.37 MPa in the present study, and might have been affected by the types of resin monomers and their combinations. Aromatic dimethacrylates, such as *bis*-GMA and *bis*-MPEPP (*2, 2′-bis(4-methacryloxy polyethoxyphenyl) propane*), are frequently used as base monomers for resin-based materials.[29] These resin monomers include a hard segment containing a bisphenol backbone.[29] Although the viscosity of *bis*-MPEPP is considerably lower than those of *bis*-GMA and UDMA, it is higher than that of TEGDMA.[30,31] BBH and BBM use the relatively low-viscosity *bis*-MPEPP, but do not contain TEGDMA, which may have resulted in the higher extrusion forces in these materials.

The mean value of thread formation was material dependent. Although the extrusion force of SDR was significantly lower than those of the other materials, it had a significantly higher thread formation, more than six times as high as GBI. Features such as the type of resin monomer, mixing ratio, and content, size, shape, and surface treatment of the filler may have influenced this phenomenon. However, regarding the handling properties of LVBRCs in clinical situations, there is no doubt that a low extrusion force with less thread formation is preferable.

CONCLUSION

The present study revealed that the DOC, flexural properties, and wear resistance of LVBRCs are material dependent. The LVBRCs were classified into high- and low-wear resistance groups based on the wear behavior. BBH, FBF, and GBI exhibited higher wear properties than the other LBRCs and similar to those of recent flowable resin composites. The LVBRCs also showed a wide range of extrusion force and thread formation. The handling properties of this study can be helpful to select the preferable materials with objective indices. Extremely strong negative and positive correlations were observed for the DOC versus extrusion force, flexural strength versus elastic modulus, maximum depth versus volume loss, and maximum depth versus thread formation. Strong correlations between filler content and DOC, resilience, wear resistance, and extrusion force were observed. Likewise, the correlations between the DOC and extrusion force, flexural properties parameters and wear resistance, flexural properties parameters and thread formation, and wear parameters and thread formation were robust.

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Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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Evaluation of Tooth Sensitivity of In-office Bleaching with Different Light Activation Sources: A Systematic Review and a Network Meta-analysis

BM Moran • PK Ziegelmann • SB Berger • A Burey
T de Paris Matos • E Fernández • AD Loguercio • A Reis

Clinical Relevance

The use of light sources for in-office bleaching does not seem to exacerbate bleaching-induced tooth sensitivity.

SUMMARY

Objectives: A systematic review and network meta-analysis were performed to answer the following research question: Are there differences in the risk and the intensity of tooth sensitivity (TS) among eight light activation systems for in-office bleaching in adults?

Methods: Randomized controlled trials (RCTs) that compared at least two different in-office bleaching

*Bianca M Maran, DDS, MS, PhD, professor, Department of Restorative Dentistry, School of Dentistry, State University of Western Paraná, Cascavel, Paraná, Brazil; Postgraduate Program in Dentistry, School of Dentistry, University of North Paraná, Londrina, Paraná, Brazil

Patrícia K Ziegelmann, DDS, MS, PhD, associate professor, Statistics Department and Post-Graduation Program in Epidemiology, Federal University of Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil

Sandrine Bittencourt Berger DDS, MS, PhD, professor, Department of Restorative Dentistry, School of Dentistry, University of North Paraná, Londrina, Paraná,

Adrieli Burey, DDS, MS, PhD student, Department of Restorative Dentistry, School of Dentistry, State University of Ponta Grossa, Ponta Grossa, Paraná, Brazil

Thalita de Paris Matos, DDS, MS, PhD student, Department of Restorative Dentistry, School of Dentistry, State University of Ponta Grossa, Ponta Grossa, Paraná, Brazil

Eduardo Fernández, DDS, MS, PhD, professor, Department Restorative Dentistry, University of Chile, Santiago de Chile, Chile; Professor, Universidad Autónoma de Chile, Instituto de Investigaciones Biomédicas, Santiago de Chile Chile

Alessandro D Loguercio, DDS, MS, PhD, adjunct professor, Department of Restorative Dentistry, State University of Ponta Grossa, Ponta Grossa, PR, Brazil

Alessandra Reis, DDS, MS, PhD, adjunctive professor, Department of Restorative Dentistry, State University of Ponta Grossa, Ponta Grossa, PR, Brazil

*Corresponding author: Rua Engenharia, 464 – Universitário, Cascavel, Paraná, Brazil - 85819-190; e-mail: medeiros.bianca@hotmail.com

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light activations were included. The risk of bias (RoB) was evaluated with the RoB tool version 1.0 from the Cochrane Collaboration tool. A random-effects Bayesian mixed treatment comparison (MTC) model was used independently for high- and low-concentration hydrogen peroxide. The certainty of the evidence was evaluated using the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) approach. A comprehensive search was performed in PubMed, Bridge Base Online (BBO), Latin American and Caribbean Health Sciences Literature database (LILACS), Cochrane Library, Scopus, Web of Science, and grey literature without date and language restrictions on April 23, 2017 (updated on September 26, 2019). Dissertations and theses, unpublished and ongoing trials registries, and IADR (International Association for Dental Research) abstracts (2001–2019) were also searched.

Results: After title and abstract screening and the removal of duplicates, 32 studies remained. Six were considered to be at low RoB, three had high RoB, and the remaining had an unclear RoB. The MTC analysis showed no significant differences among the treatments in each network. In general, the certainty of the evidence was graded as low due to unclear RoB and imprecision.

Conclusion: There is no evidence that the risk and intensity of TS are affected by light activation during in-office bleaching.

INTRODUCTION

A Brazilian study[1] that evaluated patients' desire to undergo dental bleaching reported that 85.9% of the patients wanted to undertake the treatment, and this desire was 2.31 times higher in patients who visited the dentist in the last year, compared to those who visited the dentist more than a year ago. Another cross-sectional study conducted in Iran[2] reported that approximately 62% of patients preferred dental bleaching for cosmetic treatment. In Israel,[3] a study showed that 56.2% of patients were not happy with the color of their teeth and that dental bleaching was the treatment most desired by patients. Therefore, dental bleaching has become the treatment of choice to improve patients' smiles and self-esteem[4] because it is a simple and non-invasive technique for the treatment of discolored teeth.

Currently, there are three types of dentist-supervised bleaching techniques: at-home bleaching, in-office bleaching, and combined bleaching technique.[5,6] Regardless of the bleaching technique, the mechanism of action seems to be the oxidization of organic components of the dental substrate by unstable free radicals produced by the dissociation of hydrogen peroxide (HP), an oxidizing agent capable of diffusing into the dental structure.[7]

Although at-home bleaching is widely used by patients,[8] in-office bleaching is usually chosen by patients who do not like wearing trays and who wish for more immediate results.[9] There are various bleaching agent brands that vary in concentration,[10] pH,[11] application method,[12] and duration of application,[13] factors which may play a role in the degree of whitening. Additionally, bleaching agents can be used with light sources,[14] with the aim of accelerating the bleaching effect. Light-emitting diodes (LEDs), lasers, halogen lamps, and plasma arc lamps (PACs) are some of the devices used for light activation of the bleaching gel.

It is known that different light activation systems vary in type of lamp, energy outcome, energy delivery, and generated heat. For instance, the heat produced by a PAC is much higher than that produced by a halogen lamp,[15] which, in turn, is higher than that produced by an LED.[16] Although we have shown in previous network analysis that these differences had no impact on the whitening outcome,[17] they may affect patient experiences of tooth sensitivity (TS).

The systematic review of the literature with network meta-analysis performed in this work allows the comparison of different treatments in a single model and provides clinicians with scientific evidence on the effectiveness of multiple interventions.[18] Mixed treatment comparison (MTC) models combine two sources of evidence: the indirect one that comes from different trials with a common comparator (such as bleaching without light) and direct comparisons of light activation (that is, head-to-head trials).[19]

Thus, the purpose of this systematic review was to compare the risk and intensity of bleaching-induced TS associated with different light sources: light-free and seven types of light-activated bleaching (halogen lamp, laser, LED/laser, LED, metal halide light, violet light, and PAC) for high- or low-concentration HP.

METHODS AND MATERIALS

Protocol and Registration

This study protocol was registered at the International Prospective Register of Systematic Reviews (PROSPERO) under number CRD42018095806 and followed the recommendations of the Preferred

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Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement for reports.[20]

Eligibility Criteria

The following participant-intervention-comparator-outcome (PICO) framework research question was investigated in this study: Are there differences in the risk and intensity of tooth sensitivity associated with in-office bleaching performed in adults with eight different light activation systems (light-free, halogen lamp, LED/laser, LED, metal halide light, violet light, laser, and PAC)?

We included parallel and split-mouth RCTs that compared at least two of these different light activation systems. RCTs were excluded if they compared in-office dental bleaching with combined bleaching. To minimize publication bias, no year or language restrictions were applied.

Information Sources and Search Strategy

Controlled vocabulary (MeSH terms) and free keywords, defined based on the concepts of the PICO question, were used for the search strategy. The search strategy was first performed in MEDLINE (Table 1) via PubMed and then adapted to other databases (Cochrane Library, Brazilian Library in Dentistry, LILACS, and the citation databases Scopus and Web of Science) (Table 1). The reference lists of all primary studies were hand-searched for additional relevant publications. We also searched the first page of related article links of each primary study in the PubMed database to increase the sensitivity of the search.

Additionally, grey literature was investigated by searching dissertations and theses from the ProQuest Dissertations and Theses full-text database, Periódicos Capes Theses database, the abstracts of the annual conference of the International Association for Dental Research and its regional divisions (2001-2019), and the database System for Information on Grey Literature in Europe. The following clinical trial registries were also inspected to locate unpublished and ongoing trials: Current Controlled Trials, International Clinical Trials Registry Platform, ClinicalTrials.gov, ReBEC, and EU Clinical Trials Register.

Study Selection and Data Collection Process

Articles that appeared in more than one database were considered only once. After removal of duplicates, three review authors (BMM, AB, and TPM) screened the articles by title and then by abstract. When the title and abstract presented insufficient information, full-text articles were obtained to make a clear decision. Subsequently, the three reviewers classified those that met the inclusion criteria.

Each eligible article received a study ID combining the first author's name and the year of publication. Relevant information about the study design, participants, interventions, and outcomes was extracted independently, using customized extraction forms. In the case of disagreements between the review authors, a fourth author was consulted (AR). Studies usually assess TS at different points in time, which is a source of variation among them; to deal with that problem, we collected the worst mean/score value from the numeric rating scale (NRS) or visual analog scale (VAS) for the risk and intensity of TS reported for the study group.

In studies with more than two experimental groups (ie, three- or four-arm studies), different pairwise comparisons were included in the network meta-analysis. However, to avoid double counts of the "shared group," the number of events and participants was divided approximately evenly between comparisons for dichotomous outcomes. For continuous outcomes, the means and standard deviations were kept constant, and the number of patients divided among the comparisons.

Risk of Bias in Individual Studies

The risk of bias (RoB) of the eligible trials was determined by three independent reviewers using the RoB tool from the Cochrane Collaboration for RCTs.[21] The assessment criteria are composed of six domains: selection bias (adequate sequence generation and allocation concealment), performance bias (blinding of participants and patients), detection bias (blinding of evaluators), attrition bias (incomplete outcome data), reporting bias (selective reporting), and other sources of bias. The last domain was not assessed in this systematic review. Disagreements between the reviewers were solved through discussion and, if needed, by consulting a fourth reviewer (AR).

Each domain level was judged as low, high, or unclear RoB. At the study level, the study was considered to have low RoB if all domains of each outcome had low RoB. If one or two key domains were judged as having unclear RoB, the study was classified as unclear RoB; if at least one key domain had high RoB, the study was considered to have high RoB.

Summary Measures and Statistical Analyses

Independent analyses were performed for two outcomes (intensity of TS with pain scales, risk of TS) and considered both high- and low-concentration bleaching gels. Products with HP concentrations higher than 25% were classified as high-concentration

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Table 1: *Electronic Database and Search Strategy Conducted Initially on April 23, 2017 (updated on September 26, 2019)*

PUBMED (#1 and #2 and #3)		
#1 ((((((((((((((((((tooth discoloration[MeSH Terms]) OR dentition, permanent[MeSH Terms]) OR color[MeSH Terms]) OR color[Title/Abstract]) OR colour[Title/Abstract]) OR "tooth discoloration"[Title/Abstract]) OR "tooth discolouration"[Title/Abstract]) OR "teeth discoloration"[Title/Abstract]) OR "teeth discolouration"[Title/Abstract]) OR "discolored tooth"[Title/Abstract]) OR "discolored teeth"[Title/Abstract]) OR "discoloured tooth"[Title/Abstract]) OR "discoloured teeth"[Title/Abstract]) OR "tooth staining"[Title/Abstract]) OR "teeth staining"[Title/Abstract]) OR "dental discoloration"[Title/Abstract]) OR "dental discolouration"[Title/Abstract]) OR "stained teeth"[Title/Abstract]) OR "stained tooth"[Title/Abstract]) OR "dental staining"[Title/Abstract]	#2 ((((((((((((((((((tooth bleaching[MeSH Terms]) OR peroxides[MeSH Terms]) OR tooth bleaching agents[MeSH Terms]) OR hydrogen peroxide[MeSH Terms]) OR carbamide peroxide[Supplementary Concept]) OR light[MeSH Terms]) OR lasers[MeSH Terms]) OR bleaching[Title/Abstract]) OR whitening[Title/Abstract]) OR "hydrogen peroxide"[Title/Abstract]) OR "carbamide peroxide"[Title/Abstract]) OR "in office"[Title/Abstract]) OR "light activation"[Title/Abstract]) OR heat[Title/Abstract]) OR ultraviolet[Title/Abstract]) OR lamp[Title/Abstract]) OR "light activated"[Title/Abstract]) OR LED[Title/Abstract]	#3 (randomized controlled trial[pt] OR controlled clinical trial[pt] OR randomized controlled trials[mh] OR random allocation[mh] OR double-blind method[mh] OR single-blind method[mh] OR clinical trial[pt] OR clinical trials[mh] OR ("clinical trial"[tw]) OR ((singl*[tw] OR doubl*[tw] OR trebl*[tw] OR tripl*[tw]) AND (mask*[tw] OR blind*[tw])) OR (placebos[mh] OR placebo*[tw] OR random*[tw] OR research design[mh:noexp] OR comparative study[pt] OR evaluation studies as topic[mh] OR follow-up studies[mh] OR prospective studies[mh] OR control*[tw] OR prospective*[tw] OR volunteer*[tw]) NOT (animals[mh] NOT humans[mh])
COCHRANE (#8 and #15)		
#1 MeSH descriptor: [Tooth Discoloration] explode all trees #2 MeSH descriptor: [Dentition, Permanent] explode all trees #3 MeSH descriptor: [Color] explode all trees #4 t*th next discoloration:ti,ab,kw or discolored next t*th:ti,ab,kw or t*th next staining:ti,ab,kw or dental next discoloration:ti,ab,kw or stained next t*th:ti,ab,kw (Word variations have been searched) #5 dental next staining:ti,ab,kw or color:ti,ab,kw (Word variations have been searched) #6 #1 or #2 or #3 or #4 or #5 #7 MeSH descriptor: [Tooth Bleaching] explode all trees #8 MeSH descriptor: [Peroxides] explode all trees	#9 MeSH descriptor: [Tooth Bleaching Agents] explode all trees #10 MeSH descriptor: [Hydrogen Peroxide] explode all trees #11 MeSH descriptor: [Light] explode all trees #12 MeSH descriptor: [Lasers] explode all trees #13 "carbamide peroxide":ti,ab,kw or bleaching:ti,ab,kw or whitening:ti,ab,kw or "hydrogen peroxide":ti,ab,kw or "in office":ti,ab,kw (Word variations have been searched) #14 light next activat*:ti,ab,kw or heat:ti,ab,kw or ultraviolet:ti,ab,kw or lamp:ti,ab,kw or LED:ti,ab,kw (Word variations have been searched) #15 #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14	

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Table 1: *Electronic Database and Search Strategy Conducted Initially on April 23, 2017 (updated on September 26, 2019) (Continued)*

LILACS/BBO (#1 and #2)	
#1 (MH:"tooth discoloration" OR MH:"dentition permanent" OR MH:color OR color OR cor OR colour OR "tooth discolouration" OR "descoloração de dente" OR "decoloración de lo diente" OR "teeth discoloration" OR "decoloración de los dientes" OR "descoloração dos dentes" OR "teeth discolouration" OR "discolored tooth" OR "diente descolorido" OR "dente descolorido" OR "discolored teeth" OR "dientes descoloridos" OR "dentes descoloridos" OR "discoloured tooth" OR "discoloured teeth" OR "tooth staining" OR "manchas en los dientes" OR "manchamento dental" OR "dental discoloration" OR "decoloración dental" OR "descoloração dental" OR "dental discolouration" OR "stained teeth" OR "dientes manchados" OR "dentes manchados" OR "stained tooth" OR "diente manchado" OR "dente manchado" OR "dental staining" OR "mancha en los dientes" OR "mancha nos dentes")	#2 (MH:"tooth bleaching" OR MH:peroxides OR MH:"tooth bleaching agents" OR MH:"hydrogen peroxide" OR MH:light OR MH:lasers OR "peroxide carbamide" OR "peróxido de carbamida" OR bleaching OR blanqueo OR branqueamento OR whitening OR blanqueamiento OR "in office" OR "en el consultorio" OR "em consultório" OR "light activation" OR "activación de la luz" OR fotoativação OR heat OR calor OR ultraviolet OR ultravioleta OR lamp OR lámpara OR lâmpada OR "light activated" OR "activado por la luz" OR "ativado por luz" OR LED)
SCOPUS (#1 and #2)	
#1 (TITLE-ABS-KEY ("permanent dentition") OR TITLE-ABS-KEY ("t??th discoloration") OR TITLE-ABS-KEY (colo*r) OR TITLE-ABS-KEY ("t??th discolouration") OR TITLE-ABS-KEY ("discoloured t??th") OR TITLE-ABS-KEY ("discolored t??th") OR TITLE-ABS-KEY ("t??th staining") OR TITLE-ABS-KEY ("dental discolo*ration") OR TITLE-ABS-KEY ("stained t??th") OR TITLE-ABS-KEY ("dental staining"))	#2 TITLE-ABS-KEY ("t??th bleaching") OR TITLE-ABS-KEY (peroxides) OR TITLE-ABS-KEY ("t??th bleaching agents") OR TITLE-ABS-KEY ("hydrogen peroxide") OR TITLE-ABS-KEY (light) OR TITLE-ABS-KEY (lasers) OR TITLE-ABS-KEY (bleaching) OR TITLE-ABS-KEY (whitening) OR TITLE-ABS-KEY ("carbamide peroxide") OR TITLE-ABS-KEY ("in office") OR TITLE-ABS-KEY ("light activat*") OR TITLE-ABS-KEY (heat) OR TITLE-ABS-KEY (ultraviolet) OR TITLE-ABS-KEY (lamp) OR TITLE-ABS-KEY (led)
WEB OF SCIENCE (#1 and #2)	
#1 Tópico: ("permanent dentition") OR Tópico: ("t*th discolo*ration") OR Tópico: (colo$r) OR Tópico: ("discolo*red t*th") OR Tópico: ("t*th staining") OR Tópico: ("dental discolo*ration") OR Tópico: ("stained t*th") OR Tópico: ("dental staining")	#2 Tópico: ("t*th bleaching") OR Tópico: (peroxides) OR Tópico: ("tooth bleaching agents") OR Tópico: ("hydrogen peroxide") OR Tópico: (light) OR Tópico: (lasers) OR Tópico: (bleaching) OR Tópico: (whitening) OR Tópico: ("carbamide peroxide") OR Tópico: ("in office") OR Tópico: ("light activat*") OR Tópico: (heat) OR Tópico: (ultraviolet) OR Tópico: (lamp) OR Tópico: (LED)

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products, and those with concentrations equal to or lower than 25% were considered low-concentration products. This classification was done based on the previous knowledge of the different HP concentrations available in the international dental market. Although this arbitrary classification may have implications in the study results, lack of classification would merge a wide variety of HP concentrations into a single group, providing unrealistic findings.

Traditional and network meta-analyses were conducted using mean difference (MD) or standardized mean difference (SMD) for the intensity of TS and risk ratio (RR) for risk of TS. The choice of the effect measure for continuous outcomes depended on whether or not studies used different instruments/scales for measurement of the outcome. For the intensity of TS, we included in the meta-analyses studies that used VAS or NRS scales, and SMD was chosen as the effect measure.

Traditional meta-analysis was performed for all pairwise comparisons where evidence was available from one or more head-to-head studies. Random effect models with the DerSimonian and Laird variance estimator were used since high heterogeneity among studies was expected. The Mantel-Haenzel method was used for the risk of TS (dichotomous), and the inverse of the variance method was used for the intensity of TS (continuous). The I^2 statistic and the Cochran Q test were used to measure heterogeneity among studies.

MTC is a Bayesian hierarchy model supported by Markov Chain Monte Carlo (MCMC) methods. Its versatility allows the simultaneous comparison of all eight treatments and the incorporation of trials with three or more arms. The evidence of each possible pairwise comparison was evaluated exclusively from direct evidence (head-to-head trials), exclusively from indirect evidence (trials with a common comparator), or from a combination of both, depending on what evidence was available for each pair. Both fixed and random effects with homogeneity of variances were adjusted, and the one with the better performance following the Deviance Information Criterion (DIC) was chosen. The consistency assumption was checked for all pairwise comparisons that had both direct and indirect evidence, using the Bayesian *p*-values produced by the node-splitting method proposed by Dias and others.[22] The evidence of a pair was considered inconsistent if the *p*-value was lower than the significance level (α=0.05) adjusted for multiple comparisons. The results were displayed in point estimates and 95% credible intervals (CrIs, [CrIs are the Bayesian equivalent of frequentist confidence intervals]). Surface under the cumulative ranking curve (SUCRA) values (higher values indicate smaller risk or intensity of TS) were also calculated if at least one comparison of the network was found to have a significant difference. All analyses were implemented using the meta (multi-environment trail analysis) and GeMTC packages of the R statistical program (R Foundation).

Assessment of the Certainty of the Evidence Using Grading of Recommendations: Assessment, Development, and Evaluation

We followed the GRADE approach to appraise the confidence in estimates derived from network meta-analysis. Direct evidence from RCTs starts at high confidence and can be rated down based on RoB, indirectness, imprecision, or inconsistency (heterogeneity); publication bias can be rated to levels of moderate, low, and very low confidence. The rating of indirect estimates starts at the lowest rating of the pairwise estimates that contribute as first-order loops to the indirect estimate but can be rated down further due to imprecision or intransitivity (dissimilarity between studies in terms of clinical or methodological characteristics). If direct and indirect estimates are similar (ie, coherent), then the higher of their ratings can be assigned to the network meta-analysis estimates.

RESULTS

Study Selection

The database screening returned a total of 9442 studies, which was reduced to 5541 following the removal of duplicates. After title screening, 227 studies remained, and this number was reduced to 32 full texts that were assessed for eligibility (Figure 1).

Characteristics of Included Articles

Study Design and Method of Tooth Sensitivity Evaluation—

The characteristics of the 32 eligible primary studies are listed in Table 2. The study design was balanced: nineteen studies used parallel design[14,23-41] and thirteen studies used the split-mouth design.[42-54]

Twenty studies evaluated the intensity of TS; of these, fourteen employed the VAS for pain evaluation,[a] five employed the NRS,[24,27,29,42,45] and only one[36] employed both the VAS and NRS.

The risk of TS was evaluated in twelve studies.[b]

[a] Ref. 23,25,26,30,34,35,38,40,43,46,48-50,54,55.

[b] Ref. 14,23,25-29,31-33,36,39,41,42,44,45,47,48,52,53.

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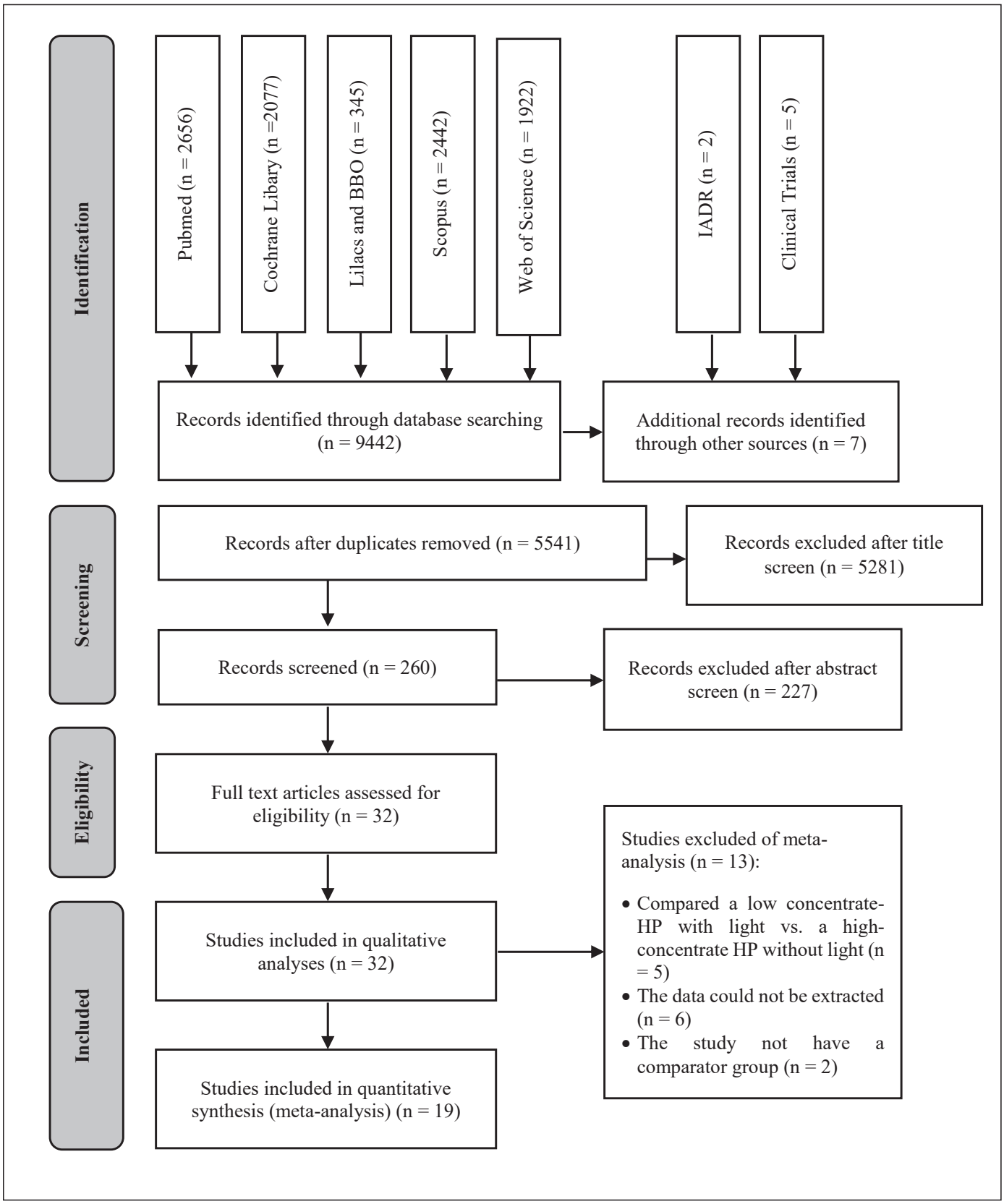

Figure 1. *Flow diagram of study identification.*

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Table 2: *Summary of the Primary Studies Included in this Systematic Review*

Study ID	Study Design [setting]	Subjects' Age, Mean ± SD [range] (y)	Number of Subjects [%] (male)	Baseline Color/ Evaluated Tooth	Groups and Materials/Number of Patients per Group
Almeida, 2012[23]†	Parallel [n.r.]	n.r. ± n.r. [18-28]	n.r. [n.r.]	n.r./n.r.	I: AH 10% CP[a]/10 II: IO 35% HP[bLF]/10 III: IO 35% HP[b] + light[HL]/10 IV: IO 35% HP[b] + light[LL]/10
Almeida Farhat, 2014[42]	Split-mouth [n.r.]	n.r ± n.r. [18-30]	n.r. [n.r.]	C_2/Anterior teeth	I: IO 35% HP[c] + light[LED]/16 II: IO 35% HP[c] + light[LL]/16
Alomari, 2010[24]†	Parallel [n.r.]	27.8 ± n.r. [18-40]	12 [30.0]	A_3/Anterior teeth	I: IO 35% HP[dLF]/10 II: IO 35% HP[d] + light[HL]/10 III: IO 35% HP[d] + light[LED]/10 IV: IO 35% HP[d] + light[MHL]/10
Bernardon, 2010[43]	Split-mouth [n.r.]	n.r. ± n.r. [n.r.-n.r.]	n.r. [n.r.]	A_2/Anterior teeth	I: AH 10% CP[a] vs. IO 35% HP[b] + light[LL]/30 II: IO 35% HP[bLF] vs. IO 35% HP[b] + light[LL]/30 III: AH 10% CP[a] vs. IO 35% HP[b] + light[LL] [1 session] and AH 10% CP[a]/30
Bortolatto, 2013[25]	Parallel [n.r.]	n.r. ± n.r. [18-25]	n.r. [n.r.]	n.r./n.r.	I: IO 35% HP[cLF]/20 II: IO 35% HP[c] + light[LL]/20
Bortolatto, 2014[26]	Parallel [University]	21.1 ± 2.26 [18-25]	n.r. [n.r.]	n.r./Anterior teeth	I: IO 15% HP[e] + light[LL]/20 II: IO 35% HP[cLF]/20
Bortolatto, 2016[27]	Parallel [University]	24.15 ± 3.92 [18-25]	24 [50]	n.r./n.r.	I: IO 6% HP[e] + light[LL]/24 II: IO 35% HP[f] + light[LL]/24
Brugnera 2019[28]	Parallel [University]	27.6 ± 4.70 [20-35]	11 [22.0]	A_2/Canine	I: IO 35% CP[gLF]/25 II: IO 35% CP[g] + light[VL]/25

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Table 2: *Summary of the Primary Studies Included in this Systematic Review (Extended)*

Bleaching Protocol	**Light Source**			
Applications x min [sessions] – interval (days)	**Light Protocol: Applications x time (interval)**	**Spectrum (nm) / Intensity, (mW/cm²) / Power output (W)**	**Tooth Sensitivity Scale [outcome]**	**Follow-up [Drop-outs]**
I: 4h/daily (21 days) II-IV: 3 x 10 [3] – 7	III: 3 x 20 sec (n.r.) IV: 3 x 3 min (n.r.)	III: 450-500 / 400 / n.r. IV: 470 and 808 / 120 and n.r. / n.r. and 0.2	VAS 0-10 [Risk and Intensity of TS]	During [0] Immediately [0] 7 d [0] 30 d [0] 180 d [0]
I-II: 3 x 10 [2] – 7	I-II: 3 x 1 min (2-min)	I: n.r. / n.r. / n.r. II: 425-480 and 810 / 300 and 300 / 0.3 and 0.2	NRS 0-4 [Risk and Intensity of TS]	During Immediately [0] 12 h [0] 1 d [0] 2 d [0] 30 d [0] 180 d [0]
I-IV: 3 x 20 [1]	II-IV: 3 x 20 min (0-min)	II-IV: n.r./ n.r. / n.r.	NRS 0-3 [Intensity of TS]	Immediately [n.r.] 30 d [n.r.]
AH: 8h/daily (14 days) IO: 3 x 15 [2] – 15	I-III: 1 x 4 min (n.r.)	I-III: n.r. and n.r. / n.r. / n.r. and n.r.	VAS 0-10 [Intensity of TS]	Daily [n.r.]
I: 3 x 15 [3] – 7 II: 3 x 8 [3] – 7	I-II: 4 x 1 min (n.r.)	II: 425-480 and 810 / 300 and 300 / 1.8 and 0.6	VAS 0-100 [Risk and Intensity of TS]	Immediately [8]
I: 3 x 16 [3] – 7 II: 3 x 15 [3] – 7	I: 4 x 1 min (2-min)	I: 455-485 and 808 / 300 and 300 / 1.8 and 0.6	VAS 0-100 [Risk and Intensity of TS]	7 d [15] 14 d [15] 21 d [15]
I-II: 2 x 12 [2] – 7	I-II: 6 x 1 min (1-min)	I-II: 455-485 and 810 / 300 and 300 / 1.8 and 0.6	NRS 0-3 [Risk and Intensity of TS]	Immediately [0] 7 d [0] 14 d[0]
I-II: 1 x 30 [2] – 7	II: 20 x 1 min (30-sec)	II: 405-410 / 300 / 1.2	VAS 0-100 [Risk of TS]	Immediately [0] 7 d [0] 14 d [0]

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Table 2: *Summary of the Primary Studies Included in this Systematic Review (Continued)*

Study ID	Study Design [setting]	Subjects' Age, Mean ± SD [range] (y)	Number of Subjects [%] (male)	Baseline Color/ Evaluated Tooth	Groups and Materials/Number of Patients per Group
Ferraz 2018[29]	Parallel [University]	26.4 ± n.r. [18-40]	21 [38.9]	A_1/n.r.	I: 6% HP^e + $light^{LL}$/27 II: 15% HP^e + $light^{LL}$/27
Freitas, 2016[44]	Split-mouth [University]	20.5 ± n.r. [18-25]	10 [45.4]	A_2/Anterior teeth	I: IO 35% HP^{cLF}/22 II: IO 35% HP^c + $light^{LL}$/22
Gomes, 2008[45]	Split-mouth [n.r.]	n.r. ± n.r. [20-30]	n.r. [n.r.]	n.r./n.r.	I: IO 35% HP^b + $light^{LED}$ vs. IO 35% HP^b + $light^{HL}$/12 II: IO 35% HP^b + $light^{LL}$ vs. IO 35% HP^{bLF}/12
Gurgan, 2010[30]†	Parallel [n.r.]	27.3 ± n.r. [18-30]	11 [27.5]	A_3/Anterior teeth	I: IO 38% HP^{dLF}/10 II: IO 37% HP^h + $light^{LA}$/10 III: IO 35% HP^i + $light^{PAC}$/10 IV: IO 38% HP^j + $light^{LED}$/10
Henry, 2013[46]	Split-mouth [n.r.]	38.4 ± 13.64 [n.r.-n.r.]	24 [49.0]	A_3/Anterior teeth	I: IO 25% HP^k + $light^{MHL}$/49 II: IO 25% HP^{kLF}/49
Kossatz, 2011[31]	Parallel [University]	n.r. ± n.r. [n.r-n.r.]	n.r. [n.r.]	C_2/Upper central incisors	I: IO 35% HP^b + $light^{LL}$/15 II: IO 35% HP^{bLF}/15
Kugel, 2006[47]	Split-mouth [n.r.]	n.r. ± n.r. [n.r.-n.r.]	n.r. [n.r.]	A_3/Anterior teeth	I: IO 15% HP^l + $light^{MHL}$/10 II: IO 38% HP^{dLF}/10
Kugel, 2009[32]	Parallel [University]	30.9 ± n.r. [22-48]	n.r. [n.r.]	A_2/n.r.	I: IO 25% HP^m + $light^{MHL}$/11 II: IO 25% HP^{mLF}/11 III: $Light^{MHL}$/11
Marson, 2008[33]†	Parallel [n.r.]	n.r. ± n.r. [18-28]	n.r. [n.r.]	n.r./Anterior teeth	I: IO 35% HP^{bLF}/10 II: IO 35% HP^b + $light^{HL}$/10 III: IO 35% HP^b + $light^{LED}$/10 IV: IO 35% HP^b + $light^{LL}$/10

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Table 2: *Summary of the Primary Studies Included in this Systematic Review (Extended)*

Bleaching Protocol	**Light Source**			
Applications x min [sessions] – interval (days)	**Light Protocol: Applications x time (interval)**	**Spectrum (nm) / Intensity, (mW/cm²) / Power output (W)**	**Tooth Sensitivity Scale [outcome]**	**Follow-up [Drop-outs]**
I-II: 3 x 10 [3] – 7	I-II: 5 x 1 min (n.r.)	I-II: 470 and 808/ 300 and 300 / 1.8 and 0.6	NRS 0-3 [Risk and Intensity of TS]	7 d [2] 14 d [2] 30 d [2]
I: 3 x 15 [1] II: 3 x 8 [1]	II: 3 x 1 min (n.r.)	470 and 810 / 350-400 and n.r. / n.r. and 0.2	VAS 0-10 [Risk of TS]	Immediately [0] 1 d [0]
I-II: 3 x 15 [2] – 7	I: 3 x 30 sec (n.r.) II: 3 x 3 min (n.r.)	I: 440-480 vs. n.r. / 1400 vs. n.r. / n.r. vs. n.r. II: 470 and 830 / 500 and 5036 / n.r. and n.r.	NRS 0-3 [Risk and Intensity of TS]	During [0] Immediately [0]
I: 2 x 15 [1] II: 3 x 8 [1] III: 3 x 20 [1] IV: 2 x 20 [1]	II: 8 x 15 sec (1-min) III: 3 x 10 min (30-sec) IV: 2 x 20 min (0-min)	II: 815 / n.r. / 10 III: 400-490 / 2800 / n.r IV: 400-500 / n.r. / n.r.	VAS 0-10 [Intensity of TS]	Immediately [0]
I-II: 3 x 15 [1]	I: 3 x 15 min (0-min)	I: n.r. / n.r. / n.r.	VAS 0-100 [Intensity of TS]	Immediately [0] 7 d [0] 14 d [0]
I-II: 3 x 15 [2] – 7	I: 5 x 1 min (2-min)	I: 470 and 830 / 200 and n.r. / n.r. and n.r.	NRS 0-4 [Risk of TS]	Immediately [0] 1 d [0] 2 d [0]
I-II: 3 x 20 [1]	I: 3 x 20 min (0-min)	n.r. / n.r. / n.r.	Questionnaire [Risk of TS]	14 d [0]
I-III: 3 x 20 [1]	I and III: 3 x 20 min (0-min)	n.r. / n.r. / n.r.	NRS 0-3 [Risk of TS]	Immediately [0] 7 d [0] 30 d [3]
I-IV: 3 x 15 [2] – 7	II-IV: 3 x 15 min (0-min)	II: 400-500 / n.r./ n.r. III: 450-500 / n.r. / n.r. IV: 470 and n.r. / n.r. and n.r. / n.r. and n.r.	NRS 1-4 [Risk of TS]	During [0]

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Table 2: *Summary of the Primary Studies Included in this Systematic Review (Continued)*

Study ID	Study Design [setting]	Subjects' Age, Mean ± SD [range] (y)	Number of Subjects [%] (male)	Baseline Color/ Evaluated Tooth	Groups and Materials/Number of Patients per Group
Martin, 2013[34]; Moncada, 2013[38]	Parallel [University]	23.0 ± 3.77 [18-37]	23 [26.1]	n.r./n.r.	I: IO 15% HP^{e} + light^{LL}/25 II: IO 35% HP^{c} + light^{LL}/27 III: IO 35% HP^{nLF}/36
Martin, 2015[35]	Parallel [University]	23.6 ± 4.00 [18-37]	n.r. [n.r.]	n.r./n.r.	I: IO 15% HP^{e} + light^{LL}/35 II: IO 35% HP^{c} + light^{LL}/35
Martín, 2015[48]	Split-mouth [n.r.]	24.5 ± 6.33 [18-44]	19 [63.3]	A_2/Central incisors	I: IO 35% HP^{c} + light^{LL}/30 II: IO 6% HP^{c} + light^{LL}/30
Mena Serrano, 2016[36]	Parallel [University]	22.5 ± 3.81 [18-27]	27 [35.1]	A_3/Upper Canine	I: IO 20% HP^{bLF}/19 II: IO 20% HP^{b} + light^{LL}/19 III: IO 35% HP^{bLF}/20 IV: IO 35% HP^{b} + light^{LL}/19
Michielin 2015[37]	Parallel [n.r.]	n.r. ± n.r. [n.r.-n.r.]	n.r. [n.r.]	n.r./n.r.	I: IO 10% HP$^{n.r.}$ + light^{VL}/12 II: IO 15% HP^{e} + light^{LL}/12 III: IO 35% HP^{f} + light$^{n.r.}$/12 IV: 35% HP^{fLF}/12
Mondelli, 2012[49]	Split-mouth [n.r.]	n.r. ± n.r. [n.r.-n.r.]	n.r. [n.r.]	A_3/Anterior teeth	I: IO 35% HP^{c} + light^{LL} vs. II: IO 35% HP^{cLF}/16 III: IO 38% HP^{d} + light^{LL} vs. IV: IO 38% HP^{dLF}/16 IV: AH 15% CP^{o}/16
Mondelli 2018[50]	Split-mouth [n.r.]	n.r. ± n.r. [n.r.-n.r.]	n.r. [n.r.]	A_3/Anterior teeth	I: IO 35% HP^{c} + light^{LL} vs. II: IO 35% HP^{cLF}/10 III: IO 35% HP^{b} + light^{LL} vs. IV: IO 25% HP^{cLF}/10
Ontiveros, 2009[51]	Split-mouth [n.r.]	n.r. ± n.r. [n.r.-n.r.]	n.r. [n.r.]	A_2/Anterior teeth	I: IO 25% HP^{k} + light^{MHL}/20 II: IO 25% HP^{kLF}/20

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Table 2: *Summary of the Primary Studies Included in this Systematic Review (Extended)*

Bleaching Protocol	**Light Source**			
Applications x min [sessions] – interval (days)	**Light Protocol: Applications x time (interval)**	**Spectrum (nm) / Intensity, (mW/cm²) / Power output (W)**	**Tooth Sensitivity Scale [outcome]**	**Follow-up [Drop-outs]**
I: 3 x 15 [1] II: 3 x 10 [1] III: 1 x 45 [1]	I: 5 x 1 and 30 sec (n.r.) II: 5 x 1 min (1-min)	I-II: 450 and 830 / 400 and 100 / 1.8 and 0.4	VAS 0-100 [Intensity of TS]	Immediately [0] 7 d [27] 30 d [46]
I: 3 x 15 [1] II: 3 x 12 [1]	I: 3 x 15 min (0-min) II: 3 x 12 min (0-min)	I-II: 450 and 808 / 400 and 100 / n.r. and n.r.	VAS 0-100 [Intensity of TS]	Immediately [0] 7 d [16] 30 d [20]
I-II: 2 x 12 [3] – 7	I-II: 2 x 12 min (0-min)	I-II: n.r and n.r. / n.r. and n.r. / n.r. and 1.5	VAS 0-100 [Risk and Intensity of TS]	Immediately [0] 7 d [1] 14 d [1]
I-IV: 3 x 15 [2] – 7	5 x 1 min (2-min)	II and IV: 470 and 830 / 200 and 200 / n.r. and n.r.	VAS 0-10 NRS 0-4 [Risk and Intensity of TS]	During [0] Immediately [0] 2 d [0]
I-II: 5 x 7,5 [n.r.] – 7 III: 3 x 7,5 [n.r.] – 7 IV: 3 x 15 [n.r.] – 7	I-III: 3 x 2 (30-sec)	I: n.r. II: n.r. III: n.r.	VAS n.r.-n.r. [n.r.]	Immediately [n.r.] 1 d [n.r.] 7 d [n.r.]
I and III: 3 x 11 [1] II and IV: 3 x 15 [1] V: 2h/daily (10)	3 x 3 min (1-min)	I and III: 470 and 810 / 350 and 200 / n.r. and n.r.	VAS 0-10 [Intensity of TS]	Immediately [0] 1 d [0] 2 d [0] 7 d [4]
I and III: 3 x 7,5 [1] II and IV: 3 x 15 [1]	I and III: 3 x 2 (30-sec)	I and III: 470 and 810 / 350 and 200 / n.r. and n.r.	VAS 0-10 [Intensity of TS]	Immediately [0] 1 d [0] 7 d [0]
I-II: 3 x 15 min [1]	I: 3 x 15 min (0-min)	I: 350-600 / n.r. / 0.2	VAS 0-10 [Intensity of TS]	Immediately [n.r.] 1 d [n.r.] 7 d [n.r.]

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Table 2: *Summary of the Primary Studies Included in this Systematic Review (Continued)*

Study ID	Study Design [setting]	Subjects' Age, Mean ± SD [range] (y)	Number of Subjects [%] (male)	Baseline Color/ Evaluated Tooth	Groups and Materials/Number of Patients per Group
Papathanasiou, 2002[52]	Split-mouth [University]	n.r. ± n.r. [n.r.-n.r.]	n.r. [n.r.]	A_3/Anterior teeth	I: IO 35% HP^{d} + $light^{HL}$/20 II: IO 35% HP^{dLF}/20
Polydorou, 2013[14]†	Parallel [n.r.]	27.6 ± 5.00 [18-70]	n.r. [n.r.]	C_1/Upper Canines	I: IO 38% HP^{dLF}/20 II: IO 38% HP^{d} + $light^{HL}$/20 III: IO 38% HP^{d} + $light^{LA}$/20
Santos 2018[41]	Parallel [University]	n.r. ± n.r. [18-40]	n.r. [n.r.]	n.r./n.r.	I: $Light^{VL}$/20 II: IO 35% CP^{g} + $light^{VL}$/20 III: IO 35% HP^{bLF}/20 IV: $Light^{VL}$ + gingivoplasty/20
Strobl, 2010[53]	Split-mouth [n.r.]	n.r. ± n.r. [n.r-n.r.]	7 [35.0]	A_1/n.r.	I: IO 35% HP^{p} + $light^{LA}$/20 II: IO 35% HP^{pLF}/20
Tavares, 2003[39]	Parallel [n.r.]	44.0 ± n.r. [17-64]	38 [43.7]	D_4/Upper Incisors	I: IO 15% $HP^{n.r.}$ + $light^{PAC}$/29 II: IO 15% $HP^{n.r.LF}$/29 III: IO Placebo gel + $light^{PAC}$/29
Ward, 2012[54]	Split-mouth [n.r.]	37.0 ± n.r. [18-78]	12 [80]	A_3/Anterior teeth	I: 15% HP^{m} + $light^{MHL}$/15 II: 25% HP^{m} + $light^{MHL}$/15
Ziemba, 2005[40]	Parallel [Clinical]	n.r. ± n.r. [18-70]	[n.r.]	A_3/Anterior teeth	I: IO 25% HP^{k} + $light^{MHL}$/25 II IO 25% HP^{kLF}/25

Abbreviations: ID–identification; SD–standard deviation; y–year n.r.–not reported in the study; AH–At-Home bleaching; CP–Carbamide Peroxide; IO–In-Office bleaching; HP–Hydrogen Peroxide; VAS–Visual Analog Scale; TS–Tooth Sensitivity; NRS: Numeric Rating Scale; LF-light-free; HL-Halogen Lamp; LL-LED/Laser; LED-light-emitting diodes; MHL-Metal halide light; VL-Violet light; LA-Laser; PAC-Plasma arc lamp.

†The study entered in the meta-analysis twice, once in each subgroup.

[a] *Whiteness Perfect (FGM, Joinville, Santa Catarina, Brazil).*

[b] *Whiteness HP Maxx (FGM, Joinville, Santa Catarina, Brazil).*

[c] *Lase Peroxide Sensy (DMC, São Carlos, São Paulo, Brazil).*

[d] *Opalescence Xtra Boost (Ultradent Inc., South Jordan, Utah, United States).*

[e] *Lase Peroxide Lite (DMC, São Carlos, São Paulo, Brazil).*

[f] *Total Blanc (Nova DFL, Rio de Janeiro, Rio de Janeiro, Brazil).*

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Table 2: *Summary of the Primary Studies Included in this Systematic Review (Extended)*

Bleaching Protocol	**Light Source**			
Applications x min [sessions] – interval (days)	**Light Protocol: Applications x time (interval)**	**Spectrum (nm) / Intensity, (mW/cm²) / Power output (W)**	**Tooth Sensitivity Scale [outcome]**	**Follow-up [Drop-outs]**
I-II: 1 x 20 min [1]	I: 1 x 20 min (0-min)	I: n.r. / n.r. / n.r.	Questionnaire [Risk of TS]	1 d [0]
I-III: 4 x 15 min [1]	II: 4 x 8 min (7-min) III: 4 x 30 sec (14,5-min)	II: 480-520 / n.r. / 150 III: 980 / n.r. / 6	Questionnaire [Risk of TS]	Immediatelly [0]
II-IV: 3 x 10 [4] – 7	I-II and IV: 20 x 1 min (30-sec)	I and II and IV: 390-410 / 112 / 1.2	VAS 0-100 [Risk of TS]	Immediatelly [n.r.] 7 d [n.r.] 14 d [n.r.] 21 d[n.r.] 30 d [n.r] 42 d [n.r.] 180 d [n.r.]
I-II: 2 x 1 min and 45 sec [2] – 7	I: 3 x 10 sec (n.r.)	I: 1064 µm / 1.4 J/cm² / 4	Questionnaire [Risk of TS]	Immediately [0]
I-III: 3 x 20 min [1]	I and III: 3 x 20 min (0-min)	I and III: 400-505 / 130-160 / n.r.	NRS 0-3 [Risk of TS]	Immediately [0] 7 d [0] 60 d [0] 180 d [0]
I-II: 3 x 20 min [1]	I-II: 3 x 20 min (0-min)	I-II: 400-505 / n.r. / n.r.	VAS 0-10 [Intensity of TS]	Immediately [0] 1 d [0] 7 d [0]
I-II: 3 x 15 min [1]	I: 3 x 15 min (0-min)	I: 365-500 / n.r. / n.r.	VAS 0-10 [Intensity of TS]	Immediately [0] 7 d [0] 30 d [1]

[g] Whiteform (Fórmula e Ação, São Paulo, São Paulo, Brazil).
[h] LaserWhite 10 (Biolase Technology Inc., San Clemente, California, United States).
[i] Remewhite (Remedent, Deurle, Belgium).
[j] By White (Biowhite, Ensodent, Italy).
[k] Zoom 2 (Discus Dental, Inc., Culver City, California, United States).
[l] BriteSmile (BriteSmile, Walnut Creek, California, United States).
[m] ZOOM Chairside Whitening System (Discus Dental, Inc., Culver City, Calilfornia, United States).
[n] White Gold Office (Dentsply, 38West Clarke Ave., Milford, United States).
[o] Opalescence PF (Ultradent, South Jordan, Utah, United States).
[p] Fotona (Fotona d.d., Ljubljana, Slovenia).

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Age and Gender of The Patients in the Primary RCTs—

The patients ranged from 18 to 78 years old; ten studies did not report participant age.[31,37,43,46,47,49-53] The mean age of all participants included in the RCTs that reported this information was approximately 27.9 years, showing a predominance of young adults (Table 2). Females were predominant in most studies that reported this characteristic.[c]

Bleaching Protocols—

High-concentration HP. Twenty-four studies used high-concentration HP.[d] The concentration of the products employed were: 35%, 37%, 38% (varying from 35% to 38%) (Table 2).

Low-concentration HP. Seventeen studies used low-concentration HP.[e] The concentrations of the products employed were: 6%, 15%, 20%, 25% (varying from 6% to 25%); when 35% CP was used, the study was included in the low-concentration HP subgroup as 35% CP corresponds to approximately 12% active HP[58] (Table 2).

The application protocol of the in-office bleaching was quite varied. Several studies applied the product in three 15-minute applications in each clinical session.[f] However, variations with one to five applications per clinical session were also observed.

Most studies involved only a single clinical session,[g] but two to four clinical sessions with intervals between seven and 15 days were also observed (Table 2).

Different types of light activation were used. Six studies used halogen lamps,[14,24,33,45,52,57] eighteen used LEDs/lasers,[h] five used only LEDs,[24,30,33,42,45] seven used metal-halide light,[24,32,40,46,47,51,54] three used a violet light,[28,37,41] three used only a laser source,[14,30,53] and two used PACs[30,39] with various protocols.

Assessment of the RoB

The RoB of the eligible studies is presented in Figure 2. Six studies were classified as having low RoB,[27,36,39,44,48,50] and three were considered to have high RoB.[32,34,35,38] A few full-text studies reported the method of randomization and allocation concealment and therefore were classified as having unclear RoB.

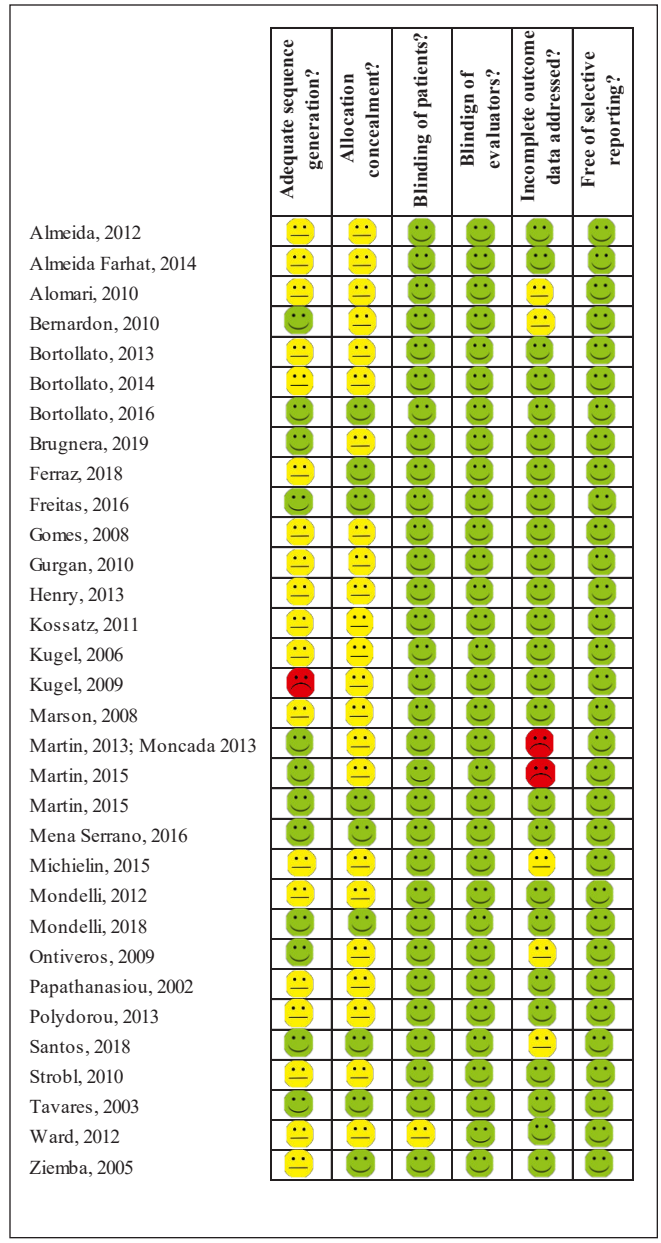

Figure 2. *Summary of the risk of bias assessment, according to the Cochrane Collaboration tool.*

Traditional and Network Meta-analysis

In this phase, thirteen eligible studies could not be meta-analyzed. The studies by Bortolatto (2014),[26] Bortolatto (2016),[27] Kugel (2006),[47] Martin (2015),[48] and Martin (2015)[35] were removed because the authors compared a low-concentration HP with a high-concentration HP. The studies by Henry (2013),[46] Michielin (2015),[37] Mondelli (2012),[49] Papathanasiou (2002),[52] Santos (2018),[41] and Strobl (2010)[53] were removed because the data could not be extracted. The studies by Ferraz (2018)[29] and Ward (2012)[54] were

[c] Ref. 24,28-30,34,36,38,39,46,53,56.
[d] Ref. 14,24-27,30,31,33-38,41-45,47-50,52,53,57.
[e] Ref. 26-29,32,34-41,46-48,51,54.
[f] Ref. 25,26,31,33-38,40,43-46,49-51.
[g] Ref. 14,24,30,32,34,35,38-40,46,47,49,50,52,54-56.
[h] Ref. 25-27,29,31,33-38,42-45,48-50,57.

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removed because the authors did not have a common comparator group. In summary, nineteen studies were included in the meta-analysis. Thirteen studies had only two arms,[i] two studies had three arms,[14,57] and four studies had four arms.[24,30,33,45] The geometry of the evidence is presented in Figure 3. In the network figures, each node represents a treatment, and the line thickness represents the number of studies included in the comparison.

Risk of Tooth Sensitivity

Regarding the risk of TS, a total of five treatments with high-concentration products were compared in the network (Figure 3A), totaling ten pairs of comparisons with 351 patients. Direct evidence was available for eight pairs (Figure S1A) and no significant differences in risk among treatments were found. The results from the network meta-analysis are described in Figure 4 (lower diagonal). This network of evidence has some pairwise comparisons with only indirect evidence (LED vs. laser, for example) and six comparisons with both direct and indirect evidence, for which no inconsistency was found (Figure 5). Network results also show no difference among the five treatments.

In the consideration of products with low concentration, five treatments were compared (Figure 3B), totaling ten pairs of comparisons with 168 patients. Direct evidence was available for four pairs

[i] Ref. 25,28,31,32,34,36,38-40,42-44,50,51.

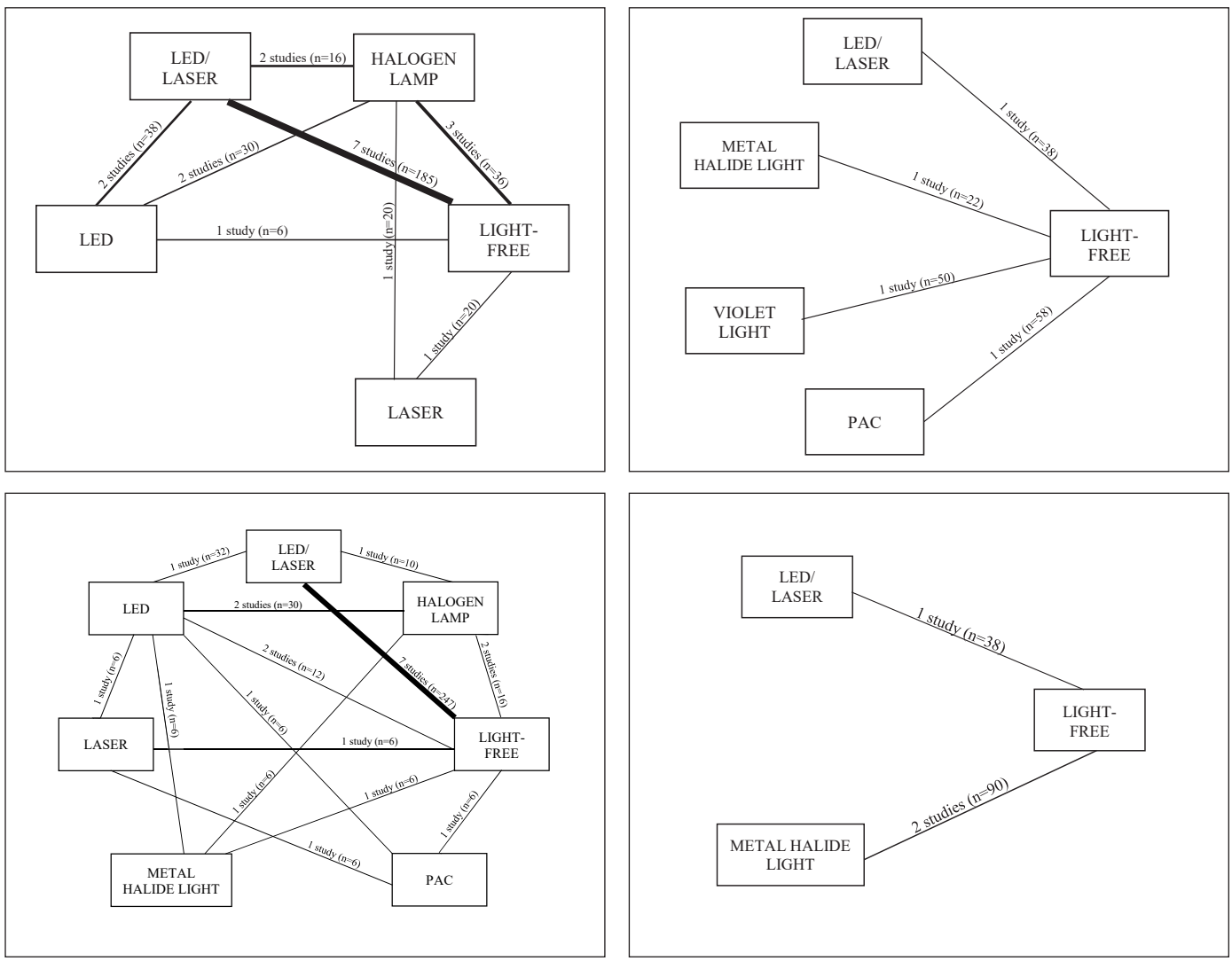

Figure 3. *Network of eligible comparisons. Risk of tooth sensitivity (TS) for: (A): High-concentration hydrogen peroxide (HP) and (B): Low-concentration HP. Intensity of TS for (C): High-concentration HP and (D): low-concentration HP.*
n = number of patients in the pair comparison.

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PAC	--	0.47 (0.01, 13.6) VERY LOW[1,2,3]	0.77 (0.23, 2.40) VERY LOW[1,2,3]	--	1.10 (0.36, 3.20) VERY LOW[1,2,3]	--	1.20 (0.54, 2.60) LOW[1,2]
--	**Laser**	--	--	--	--	--	--
--	--	**Violet light**	1.60 (0.04, 11.0) VERY LOW[1,2,3]	--	2.20 (0.06, 14.9) VERY LOW[1,2,3]	--	2.50 (0.11, 10.6) LOW[1,2]
--	--	--	**Metal halide light**	--	1.40 (0.49, 4.40) VERY LOW[1,2,3]	--	1.60 (0.72, 3.80) LOW[1,2]
--	9.56 (0.98, 328.59) VERY LOW[1,2,3]	--	--	**LED**	--	--	--
--	9.98 (1.08, 339.94) VERY LOW[1,2,3]	--	--	1.10 (0.61, 1.90) LOW[1,2]	**LED/Laser**	--	1.10 (0.55, 2.40) LOW[1,2]
--	10.93 (1.23, 372.21) LOW[1,2]	--	--	1.10 (0.58, 2.20) LOW[1,2]	1.10 (0.56, 1.90) LOW[1,2]	**Halogen lamp**	--
--	9.48 (1.03, 323.79) LOW[1,2]	--	--	1.00 (0.50, 1.70) LOW[1,2]	0.96 (0.59, 1.30) MODERATE[1]	0.88 (0.44, 1.50) MODERATE[1]	**Light-free**

On the upper diagonal, the results are for the low-concentrate HP and RR are between the row-defining treatment and the column-defining treatment, RR<1 favors the row-defining treatment. The results on the lower diagonal are for high-concentrate HP and RR are between the column-defining treatment and the row-defining treatment, RR<1 favors the column-defining treatment. The 95% CrI that crosses the null value of 1 indicates that we do not have evidence to state significant difference between the two treatments compared.
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect
Explanations: 1. Risk of bias: most eligible studies are at unclear risk of bias; 2. Imprecision: Wide confidence interval that includes the null effect; 3. Indirectness: Information provided only by indirect evidence

Figure 4. *Mixed treatment comparison (MTC) results (risk ratio [RR] with 95% credible intervals [CrI]) and quality of evidence (gradings of recommendations assessment [GRADE]) for risk of tooth sensitivity (TS).*

(Figure S1B) and no significant differences in risk were found. As we can see from the geometry of the network (Figure 3B), the four pairs of comparisons have only direct evidence, with the light-free condition as the common comparator. The results from this network meta-analysis are described in Figure 4 (upper diagonal), which also shows that there was no evidence of difference among the five treatments.

Intensity of Tooth Sensitivity

Regarding the intensity of TS, a total of seven treatments with high concentration products were compared in the network (Figure 3C), totaling 21 pairs of comparisons with 395 patients. Direct evidence was available for 14 pairs (Figure S2A), and no significant differences in intensity were found. The results from the network meta-analysis are described in Figure 6 (lower diagonal). This network of evidence has some pairwise comparisons with only indirect evidence (PAC vs. metal halide light, for example) and six comparisons with both, direct and indirect evidence, for which no statistical inconsistency was found (Figure 7). When all treatments were analyzed together, no evidence of difference was found.

Considering products with low concentration, three treatments were compared (Figure 3D), totaling three pairs of comparisons with 128 patients. Direct evidence was available for two pairs (Figure S2B), and no significant differences in intensity were found. As we can see from the geometry of the network (Figure 3D), the pair comparing metal halide light to LED/laser has only direct evidence, with the light-free condition as the common comparator. The results from this

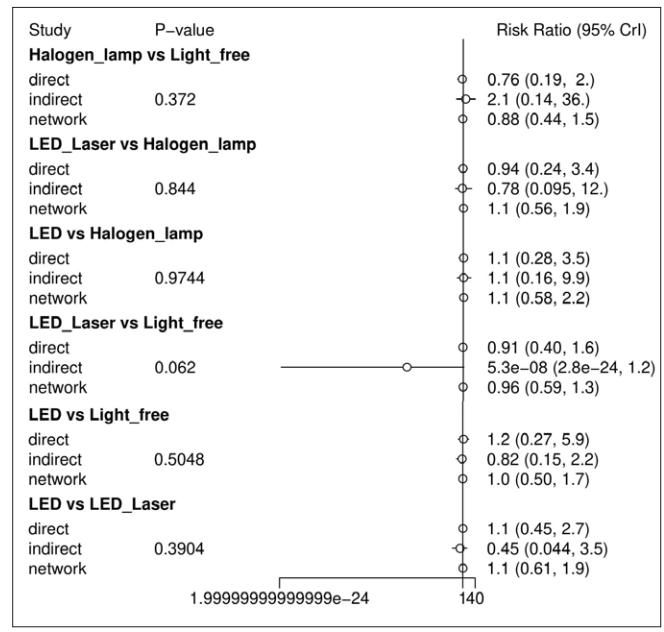

Figure 5. *Forest plot of the evaluation of the inconsistency assumption between direct and indirect evidence used in the network meta-analysis of the risk of tooth sensitivity (TS) for bleaching with high-concentrate hydrogen peroxide (HP) with different light activation methods (p<0.05 indicates inconsistency of the pairs).*

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PAC	--	--	--	--	--	--	--
2.00 (-2.15, 6.14) LOW[1,2]	**Laser**	--	--	--	--	--	--
--	--	**Violet light**	--	--	--	--	--
0.24 (-4.67, 5.29) VERY LOW[1,2,3]	-1.75 (-6.79, 3.22) VERY LOW[1,2,3]	--	**Metal halide light**	--	0.35 (−2.60, 3.10) VERY LOW[1,2,3]	--	0.62 (−0.64, 2.10) LOW[1,2]
0.72 (-2.97, 4.50) LOW[1,2]	-1.27 (-5.05, 2.48) LOW[1,2]	--	-0.47 (-4.14, 3.10) LOW[1,2]	**LED**	--	--	--
0.67 (-3.24, 4.61) VERY LOW[1,2,3]	-1.34 (-5.23, 2.67) VERY LOW[1,2,3]	--	-0.41 (-4.20, 3.34) VERY LOW[1,2,3]	-0.05 (-2.40, 2.30) LOW[1,2]	**LED/Laser**	--	0.98 (−1.40, 3.50) LOW[1,2]
0.24 (-3.91, 4.46) VERY LOW[1,2,3]	-1.76 (-5.92, 2.46) VERY LOW[1,2,3]	--	0.01 (-3.66, 3.64) LOW[1,2]	0.49 (-2.00, 3.00) LOW[1,2]	0.44 (-2.10, 3.00) LOW[1,2]	**Halogen lamp**	--
0.05 (-3.7, 3.77) LOW[1,2]	-1.95 (-5.7, 1.83) LOW[1,2]	--	0.21 (-3.38, 3.80) LOW[1,2]	0.68 (-1.60, 2.90) LOW[1,2]	-0.62 (-2.10, 0.84) MODERATE[1]	0.19 (-2.20, 2.60) LOW[1,2]	**Light-free**

On the upper diagonal, the results are for the low-concentrate HP and MD are between the row-defining treatment and the column-defining treatment, MD positive favors the column-defining treatment. The results on the lower diagonal are for high-concentrate HP and SMD are between the column-defining treatment and the row-defining treatment, SMD positive favors the row-defining treatment. The 95% CrI that crosses the null value of 0 indicates that we do not have evidence to state significant difference between the two treatments compared.
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect
Explanations: 1. Risk of bias: most eligible studies are at unclear risk of bias; 2. Imprecision: Wide confidence interval that includes the null effect; 3. Indirectness: Information provided only by indirect evidence

Figure 6. *Mixed treatment comparison (MTC) results (mean difference [MD] with 95% credible intervals [CrI]) and quality of evidence (gradings of recommendations assessment [GRADE]) for intensity of tooth sensitivity (TS).*

network meta-analysis are described in Figure 6 (upper diagonal), which also shows no evidence of difference among the three treatments.

Sensitivity Analysis

In two studies that did not report the standard deviation (SD),[43,45,50] we imputed an SD based on the average of the coefficients of variation of the other studies that reported the same finding.[59] More extreme imputations (such as a value corresponding to the lowest coefficient of variation of the primary studies and a value that was as high as the reported mean) were evaluated in a sensitivity analysis, and no differences in the results reported here could be detected.

The studies by Almeida Farhat (2014),[42] Alomari (2010),[24] and Gomes (2008)[45] used NRS pain scale to measure the intensity of TS, so SMD was used to summarize the effect of high-concentration products on intensity of TS. We also performed a sensitivity analysis by removing these three studies and using MD. The same conclusions in MTC analysis were observed whether the MTC was run with MD or SMD effect measures.

Assessment of the Certainty of the Evidence

In general, the quality of evidence was graded as low, due to unclear RoB and imprecision (Figures 4 and 6). Some comparisons were graded as very low, due to an unclear RoB in the vast majority of the studies, as well as imprecision and indirectness.

DISCUSSION

Although network meta-analyses are very common in health areas such as medicine and pharmacy,[60-64] there are only a few available studies in the dental field.[17,65,66]

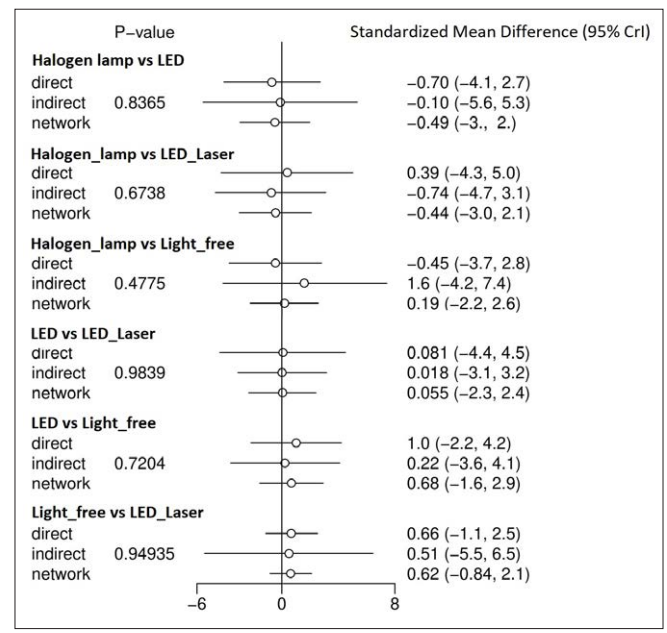

Figure 7. *Forest plot of the evaluation of the inconsistency assumption between direct and indirect evidence used in the network meta-analysis of the intensity of tooth sensitivity (TS) for bleaching with high-concentrate hydrogen peroxide (HP) with different light activation methods (p<0.05 indicates inconsistency of the pairs).*

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Perhaps this low number of network meta-analyses reflects the small number of potential treatment options compared to the innumerable drugs available in medicine and pharmacy. Nevertheless, it is a valid method for making comparisons between treatments, because it allows for the aggregation of a larger amount of evidence, either direct or indirect, which comes from large or small clinical trials.[67-69] It allows the researcher to determine, among all available treatment options, which is the best[18] in terms of efficacy and safety.

This systematic review and network meta-analysis was conducted to evaluate the risk and intensity of TS for different types of light activation used for bleaching. TS is the most common adverse effect reported by patients during bleaching[70] and sometimes leads to treatment discontinuation.[32,71] Many studies have evaluated clinical alternatives to minimize this undesirable side effect. Administration of different types of medications (non-steroidal analgesics, anti-inflammatories, corticoids, opioids), application of topical desensitizers (based on potassium nitrate or fluoride), reduction of product concentration, and use of different bleaching protocols[23,50,71-74] have already been investigated.

Although in Europe the Scientific Committee on Cosmetic Products and Non-Food Products[75] recommends that tooth-bleaching products should contain between 0.1% and 6.0% hydrogen peroxide, this is not a rule worldwide. Such low-concentration products can be used in-office, but they are most commonly used in at-home protocols in countries where in-office bleaching with high-concentration HP is allowed.

While some researchers focus on the investigation of alternatives to reduce bleaching-induced TS, others focus on the investigation of protocols to improve bleaching efficacy, light activation being among the possible alternatives studied so far. It is widespread knowledge that light, *per se*, can catalyze the decomposition of HP into free radicals, the reason this product is usually sold in dark vials. However, the increased number of free radicals is not associated with improved bleaching efficacy, as stated in previous systematic reviews of the literature,[76-78] including one network meta-analysis.[17]

In addition to efficacy, the safety of alternative bleaching protocols requires investigation. It is desirable to know whether a bleaching protocol performed with any type of light can cause additional harm to the pulp. Theoretically, the higher quantity of free radicals produced by light activation could easily reach the pulp chamber and cause pulp inflammation[79,80] and chemical irritation, which may trigger pain transmission through sensory nerves.[25] Another issue that must be addressed in this discussion is that some light sources are no longer used in dentistry, such as PAC and halogen lamps. They were included in the present systematic review, however, as some clinicians may still have them in their offices. Additionally, they are important to provide improved network connectivity. Some *in vitro* studies have reported other disadvantages in using these light sources, such as the increase in pulp temperature, which is an additional source of damage to pulp tissue and TS.[81,82]

Few comparisons performed in this network meta-analysis found evidence that any type of light source was more harmful than others in terms of risk and intensity of TS, either for low- or high-concentration HP products. Network meta-analysis involves the pooling of individual study results, but the total number of trials in a network, the number of trials with more than two comparison arms, and heterogeneity may influence effect estimates.[83] For more significant evidence, the nodes of a network must be well connected, because the lack of specific comparisons creates uncertainty in the results.[84] This RCT highlights that there are many comparisons that lack either direct or indirect evidence, and this may serve as a research question for authors of RCTs.

Although all previous systematic reviews on this topic[17,76-78] have reported that light activation does not add any benefit to the whitening outcome, they have differed in their conclusions about high-concentration HP products. He and others (2012)[76] showed that light activation increases the intensity and the risk of TS during in-office bleaching, but this finding may be simply due to random bias, as few studies were eligible to be included by the time the study was conducted. Maran and others (2018)[77] only observed higher levels of TS when light activation was associated with low-concentration HP. In this study, Maran and others (2018)[85] compared light-activation bleaching to bleaching without light activation, thus increasing the power of the comparison and allowing the identification of a difference in the subgroup of low-concentration HP. SoutoMaior and others (2018)[78] observed lower levels of TS when light activation was used, but their meta-analysis presented some methodological flaws that made their conclusions unreliable; examples include inclusion of studies with more than one effect size without accounting for the fact that the same control group was employed in both estimates, and the choice of a fixed-effect rather than random-effects model.

In the present study, different light sources were evaluated individually, while in the previous systematic

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review, data from different light sources were merged, increasing statistical power. However statistically significant results do not necessarily mean important clinical significance. Any small, clinically insignificant difference in effect size may be statistically significant if the sample size is large enough. Thus, care should be taken in evaluating statistically significant findings, and focus should be placed on the effect size and its precision.

The results of the present systematic review suggest that TS is neither exacerbated nor minimized by light activation with any type of light source. The amount of free radicals that reach the pulp with high- and low-concentration in-office bleaching products is already enough to reach the pulp chamber, causing cellular damage[86] and TS.[77] Because the quality of evidence was graded as low or very low for most of the comparisons, our confidence in the effect estimates generated is limited, because the true effect may be substantially different from what is reported here.

The reasons for downgrading the certainty of evidence are related to the unclear RoB of eligible studies and imprecision. Lack of description of how the random sequence was generated and how allocation concealment was guaranteed were the main reasons studies were considered to have an unclear RoB. The report of RCTs in accordance with the CONSORT statement[87] is deficient in bleaching studies,[j] preventing review authors from evaluating the method of random sequence and allocation concealment. This deficiency highlights the need to conduct more rigorous studies to answer this specific research question. By using appropriate methods of randomization, allocation concealment, and examiner blinding, RCTs with low RoB may be published, producing more reliable conclusions.

Another critical topic to be evaluated in meta-analysis is the size of the statistical heterogeneity. Differences in methods, study design, study populations, the composition of materials, definitions, and measurements of outcome, follow-up, or other features make trials different,[84] and therefore trials usually estimate effect sizes specific to the population they represent. If the heterogeneity is substantial, the point estimate produced by the meta-analysis may not serve as a good estimator of the effect size in different populations. Unfortunately, due to the low number of studies included in this network meta-analysis, heterogeneity in each pairwise comparison was difficult to assess, because the low number of studies produced imprecise estimates of heterogeneity.

[j] Ref. 13,14,23-26,30,31,37,42,45-47,49,52-54.

CONCLUSIONS

We did not find evidence that the use of any type of light source causes increased risk and intensity of TS. However, for the majority of comparisons, the quality of evidence was graded as low or very low, limiting our confidence in the conclusions.

Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

Supplemental Data

Figures S1 and S2 are available online at https://meridian.allenpress.com/operative-dentistry.

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Does Addition of 10-MDP Monomer in Self-etch Adhesive Systems Improve the Clinical Performance of Noncarious Cervical Lesion Restorations? A Systematic Review and Meta-analysis

RP de Oliveira • JCP Baia • TSP da Silva • MB Magno
LC Maia • SC Loretto • MH da Silva e Souza Junior

Clinical Relevance

The presence of 10-MDP monomer in self-etch adhesive systems did not influence the clinical performance of noncarious cervical lesion (NCCL) restorations.

SUMMARY

Background: Functional acidic monomers are able to chemically interact with hydroxyapatite, and this bond appears to be very stable. Therefore, this aspect of the 10-MDP molecule made it attractive and added to self-etch adhesives. Objectives: The objective of this Systematic Review (SR) and Meta-analysis (MA) was to determine whether systems with the 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) functional monomer in their formula showed better clinical performance in restorations placed in noncarious cervical lesions (NCCL) when compared to systems without it.

*Roberta Pimentel de Oliveira, Master, Federal University of Pará, Belem, Pará, Brazil

Juliana Costa Pereira Baia, Master, Federal University of Pará, Belem, Pará, Brazil

Taise Sousa Pamplona da Silva, Master, Federal University of Pará, Belem, Pará, Brazil

Marcela Baraúna Magno, Doctor, Federal University of Rio de Janeiro, Brazil

Lucianne Cople Maia de Faria, Doctor, Federal University of Rio de Janeiro, Brazil

Sandro Cordeiro Loretto, Doctor, Federal University of Pará, Belem, Pará, Brazil

Mário Honorato da Silva e Souza Junior, Doctor, Federal University of Pará, Belem, Pará, Brazil

*Corresponding author: 495 Tiradentes St, Reduto, 66053-330 Belém, Pará, Brazil; email: betapimentel@hotmail.com

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The PROSPERO registration number of the MA is CRD42016050538.

Data and sources: An e-search was conducted through MEDLINE via PubMed, Cochrane Library, Scopus, Web of Science, OpenGrey, Clinical Trials, Current Controlled Trials, and EU Clinical Trials Register, and a search through the references of included studies was also performed. Randomized Controlled Clinical Trials, in which the effectiveness of self-etch adhesive systems, with or without the 10-MDP functional monomer for NCCL, was discussed, were included. Risk of bias was performed according to the Cochrane Collaboration tool, and the certainty of evidence was evaluated through GRADE.

Study selection: The data were grouped, heterogeneity (I^2) was tested, and after duplicate removal, 4208 manuscripts were retrieved. From these, 11 studies were included in the qualitative analysis (risk of bias), with nine classified as low risk and two unclear. GRADE analysis detected moderate-to-high certainty of evidence, so the quantitative synthesis [Meta-analysis (MA)] was performed including the 11 studies.

Results and Conclusion: There were no statistical differences in the clinical performance of restorations conducted using "with or without 10-MDP" adhesive types, for all evaluated criteria (p=0.05), with heterogeneity ranging from 0% to 53%. Thus, the presence of 10-MDP functional monomer did not influence the clinical performance of restorations placed in NCCL.

INTRODUCTION

Due to its organic–inorganic nature, dentin still remains a challenging substrate when a stable and long-lasting bond is desired. Self-etch systems bond composite resin materials to dental substrates; however, some drawbacks still need to overcome,[1-4] so, to improve their effectiveness, different functional monomers have been included in adhesive system formulae, and their effectiveness has been studied over the past decades.[5,6]

In a recent systematic review (SR) and meta-analysis (MA),[7] 2-hydroxyethyl methacrylate (HEMA)-free adhesive was compared to HEMA-containing systems, and similar clinical behaviour was found. HEMA is a monomer present in a great number of systems and plays an important role, due to its hydrophilicity, wettability, and miscibility.[8,9] However, some other monomers that have different functions are also found in adhesive systems, especially in self-etch systems.

Functional acidic monomers, for instance, present in self-etch mode, are able to chemically interact with hydroxyapatite (HAp) and are composed by specific carboxylic, phosphonic, or phosphate groups, such as: Phenyl-P, 10-methacryloyloxydecyl dihydrogen phosphate (10-MDP) and 4-methacryloyloxyethyl trimellitic acid (4-MET).[10]

Depending upon the acid dissociation constants (pKa values), etching aggressiveness in self-etch adhesive systems can be classified into "strong" (pH$<$1), "intermediately strong" (pH$\approx$1.5), "mild" (pH$\approx$2), and "ultramild" (pH$\geq$2.5).[11] The more aggressive the system, the deeper demineralization of the tooth substrate occurs, resembling that of phosphoric acid-etching treatment.[12]

Mild self-etch adhesives bond to tooth tissue through a twofold micromechanical and chemical bonding mechanism. They only partially demineralize dentin, with some HAp remaining around the collagen within a submicron, hybrid layer.[13,14] Thus, functional acidic monomers, such as 10-MDP, that are able to react with calcium, would certainly bond electrostatically to HAp, forming calcium salt around the partially demineralized collagen fibers. This possibility has been proved by X-ray photoelectron spectroscopy (XPS).[5]

After patent expiration of the 10-MDP molecule from Kuraray, this monomer quickly became present in the compositions of several brands of so-called multimode or universal adhesives. Several aspects of the 10-MDP molecule made it attractive: firstly, it readily adhered to HAp, and this bond appeared to be very stable, as confirmed by the low dissolution rate of its calcium salt in water.[15] Secondly, 10-MDP bonding versatility has allowed its use beyond dental substrates, to several others, such as zirconia, lithium-disilicate, and metals, which has been very interesting from a clinical viewpoint.[16,17] Therefore, 10-MDP was introduced very quickly into multimode adhesive system compositions (the so-called universal adhesives) globally.

It is important to mention that 10-MDP is not the only constituent in adhesive system compositions, but is present amongst a blend of monomers, solvents, initiators and, nowadays, nanoparticles, which combine to complete the adhesive process.[10] However, due to the great interest in the addition of 10-MDP to adhesive systems, and the good results

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presented in laboratory studies,[18-23] the aim of this paper was to present a review of the clinical performance of noncarious cervical lesion (NCCL) resin restorations made with adhesives that either did, or did not, contain the 10-MDP monomer, through SR and MA.

METHODS

Protocol and Registration

This study protocol was registered at the Prospective Register of Systematic Reviews (PROSPERO - CRD42016050538), and it followed the recommendations in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement on the reporting of SR.[24]

Information Sources, Eligibility criteria and Search Strategy

The Medical Subject Heading (MeSH) terms, synonyms, and free terms (keywords) in the search strategy were defined using the PICOS[25] guidelines:

1. Population (P): Adult patients with NCCLs
2. Intervention (I): Composite resin restorations placed in NCCLs in a self-etch mode, with 10-MDP-containing adhesive systems
3. Comparison (C): Composite resin restorations placed in NCCLs in a self-etch mode without 10-MDP in the adhesive system formulae
4. Outcome (O): Clinical performance of restorations (note that no outcome was used in the search strategy to maximize its results)
5. Study design (S): Randomised controlled clinical trials (RCTs) and controlled clinical trials (CCTs).

In this sense, only RCTs comparing the clinical effectiveness of self-etch adhesive systems with and without the functional monomer 10-MDP for NCCL direct resin composite restorations in the permanent dentition of adult patients (male and female) of any age group were included. Editorial letters, historical reviews, pilot studies, *in vitro* studies, and cohort, observational, and descriptive studies, such as case reports and case series, were excluded.

To identify articles for inclusion in this review, an electronic search of the literature was conducted up to 21 March 2019, plus an alert for recently published articles was requested from the following databases: MEDLINE via PubMed, Web of Science, Scopus, Cochrane Library, OpenGrey, Clinical Trials, Current Controlled Trials, and EU Clinical Controlled Trials. No restrictions were applied on either publication date or language, except that the study must have included a follow-up of at least 1 year.

The search strategies were defined appropriately for each database (Table 1), and searches were performed by two independent reviewers (RPO and JCPB) to identify eligible studies. Full-text versions of all articles that appeared to meet the inclusion criteria were obtained for subsequent evaluation and data extraction. Next, a hand search was performed in the reference lists of included articles to identify any additional relevant studies that had not been found during database searches.

Study Selection and Data Collection Process

According to the described search strategy, article selection was first performed by title and abstract. If articles appeared in more than one database, they were included only once; and, in cases with different follow-up periods for the same study, only the last version was accepted. Full-text articles were obtained when there was not sufficient information in the title and abstract, and for cases lacking data within the full text, the authors were contacted weekly, for up to five weeks, to clarify the data. Subsequently, the two reviewers classified the articles that met the inclusion criteria. Each eligible study received an ID combining the first author and year of publication.

Relevant details about the study design, participants, interventions, and outcome were extracted, using customized extraction forms. If there were reports of the same study with different follow-ups, data extraction was performed using data from the largest follow-up period.

Risk of Bias in Individual Studies

The Cochrane Collaboration's tool for assessing risk of bias in RCTs was used by two independent reviewers (RPO and JCPB) to perform quality assessments of the trials. The assessment criteria contained six items: sequence generation, allocation concealment, blinding of the outcome assessor, incomplete outcome data, selective outcome reporting, and other possible sources of bias. Any disagreement between the reviewers during data selection and quality assessment had to be discussed until an agreement was reached. If necessary, a third reviewer was involved as referee (TSPS).

The risk of bias for each domain of each quality assessment was scored following recommendations described in the Cochrane Handbook for Systematic

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Table 1: *Search Strategies for Databases*

Pubmed #1 AND #2 AND #3 (21/03/2019)
#1 (tooth erosion[MeSH Terms]) OR "tooth erosion"[Title/Abstract]) OR "tooth erosions"[Title/Abstract]) OR "teeth erosion"[Title/Abstract]) OR "teeth erosions"[Title/Abstract]) OR tooth abrasion[MeSH Terms]) OR "tooth abrasion"[Title/Abstract]) OR "tooth abrasions"[Title/Abstract]) OR "teeth abrasion"[Title/Abstract]) OR "teeth abrasions"[Title/Abstract]) OR "dental abrasion"[Title/Abstract]) OR tooth wear[MeSH Terms]) OR "tooth wear"[Title/Abstract]) OR "teeth wear"[Title/Abstract]) OR "dental wear"[Title/Abstract]) OR "tooth abfraction"[Title/Abstract]) OR "teeth abfraction"[Title/Abstract]) OR permanent dental restorations[MeSH Terms]) OR "permanent dental restorations"[Title/Abstract]) OR "permanent dental restoration"[Title/Abstract]) OR "permanent dental fillings"[Title/Abstract]) OR "permanent dental filling"[Title/Abstract]) OR dental restoration, permanent[MeSH Terms]) OR "NCCL"[Title/Abstract]) OR NCCLs[Title/Abstract]) OR "noncarious cervical lesion"[Title/Abstract]) OR "noncarious cervical lesion"[Title/Abstract]) OR "noncarious cervical lesion"[Title/Abstract]) OR "cervical lesion"[Title/Abstract]) OR "cervical lesions"[Title/Abstract]) OR "class V lesion"[Title/Abstract]) OR "cervical restorations"[Title/Abstract]) OR "cervical restoration"[Title/Abstract]) OR "class v restoration"[Title/Abstract]) OR "class v"[Title/Abstract]) OR "class 5"[Title/Abstract]
#2 (monomer*[Title/Abstract]) OR "functional monomer"[Title/Abstract]) OR "10 MDP"[Title/Abstract]) OR 10-MDP[Title/Abstract]) OR MDP[Title/Abstract]) OR "phosphatic monomer"[Title/Abstract]) OR "methacryloyloxi-decyl-dihydrogen-phosphate"[Title/Abstract]) OR 10-methacryloyloxydecyldihydrogenphosphate[Title/Abstract]) OR "10-methacryloyloxydecyl dihydrogen phosphate"[Title/Abstract]) OR adhesives[MeSH Terms]) OR adhesives[Title/Abstract]) OR adhesive[Title/Abstract]) OR "adhesive material"[Title/Abstract]) OR dentin-bonding agents[MeSH Terms]) OR "dentin-bonding agents"[Title/Abstract]) OR dental-bonding agents[MeSH Terms]) OR "dental-bonding agents"[Title/Abstract]) OR dental bonding[MeSH Terms]) OR "dental bonding"[Title/Abstract]) OR bonding[Title/Abstract]) OR "dentin bonding"[Title/Abstract]) OR "dental adhesive"[Title/Abstract]) OR "dental adhesion"[Title/Abstract]) OR "agents, dentin bonding"[Title/Abstract]) OR "bonding agents, dentin"[Title/Abstract]) OR "dentin-bonding agents"[Title/Abstract]) OR "dentin bonding agents"[Title/Abstract]) OR "bonding, dental"[Title/Abstract]) OR "etch-and-rinse adhesive"[Title/Abstract]) OR "total-etch adhesive"[Title/Abstract]) OR "self-etch adhesive"[Title/Abstract]) OR "self-etching adhesive"[Title/Abstract]) OR "all-in-one adhesive"[Title/Abstract]) OR "one-bottle adhesive"[Title/Abstract]) OR "etching adhesive"[Title/Abstract]
#3 (clinical trial[MeSH Terms]) OR clinical trial*[Title/Abstract]) OR clinical*[Title/Abstract]) OR trial*[Title/Abstract]) OR clinical study[MeSH Terms]) OR clinical stud*[Title/Abstract]) OR prospective studies[MeSH Terms]) OR prospective stud*[Title/Abstract]) OR prospective evaluation*[Title/Abstract]) OR longitudinal studies[MeSH Terms]) OR longitudinal stud*[Title/Abstract]) OR longitudinal survey*[Title/Abstract]) OR controlled clinical trial[MeSH Terms]) OR controlled clinical trial*[Title/Abstract]) OR randomized controlled trial[MeSH Terms]) OR randomized controlled trial*[Title/Abstract]) OR random allocation[MeSH Terms]) OR "random allocation"[Title/Abstract]) OR observational study[MeSH Terms]) OR double-blind method[MeSH Terms]) OR "double-blind method"[Title/Abstract]) OR "double blind method"[Title/Abstract]) OR "double-blind study"[Title/Abstract]) OR "double blind study"[Title/Abstract]) OR single-blind method[MeSH Terms]) OR "single-blind method"[Title/Abstract]) OR "single blind method"[Title/Abstract]) OR "single-blind study"[Title/Abstract]) OR "single blind study"[Title/Abstract]) OR "comparative study"[Title/Abstract]) OR follow-up studies[MeSH Terms]) OR "follow-up studies"[Title/Abstract]) OR "follow-up study"[Title/Abstract]) OR "follow up study"[Title/Abstract]) OR "follow-up study"[Title/Abstract]) OR randomization*[Title/Abstract]) OR "double-masked method"[Title/Abstract]) OR "double masked method"[Title/Abstract]) OR "double-masked study"[Title/Abstract]) OR "double masked study"[Title/Abstract]) OR controlled clinical stud*[Title/Abstract]
Web of Science #1 AND #2 (21/03/2019)
#1 "tooth erosion" *OR* "teeth erosion" *OR* "tooth abrasion" *OR* "teeth abrasion" *OR* "dental abrasion" *OR* "tooth wear" *OR* "teeth wear" *OR* "dental wear" *OR* "tooth abfraction" *OR* "teeth abfraction" *OR* permanent dental restoration* *OR* "permanent dental filling" *OR* NCCL *OR* cervical lesion* *OR* non carious cervical lesion* *OR* non* carious cervical lesion* *OR* class V lesion* *OR* cervical restoration* *OR* class V restoration*
#2 monomer* *OR* "functional monomer" *OR* "10 MDP" *OR* 10-MDP *OR* MDP *OR* "phosphatic monomer" *OR* "methacryloyloxi-decyl-dihydrogen-phosphate" *OR* 10-methacryloyloxydecyldihydrogenphosphate *OR* "10-methacryloyloxydecyl dihydrogen phosphate" *OR* adhesive* *OR* "adhesive material" *OR* dentin-bonding agent* *OR* dentin bonding agent* *OR* dental-bonding agent* *OR* dental bonding agent* *OR* "dental bonding" *OR* "dentin bonding" *OR* bonding *OR* "dental adhesive" *OR* "dental adhesion"
Scopus #1 AND #2 AND #3 (21/03/2019)
#1 (TITLE-ABS-KEY ("tooth erosion") OR TITLE-ABS-KEY ("tooth erosions") OR TITLE-ABS-KEY ("teeth erosion") OR TITLE-ABS-KEY ("teeth erosions") OR TITLE-ABS-KEY ("tooth abrasion") OR TITLE-ABS-KEY ("tooth abrasions") OR TITLE-ABS-KEY ("teeth abrasion") OR TITLE-ABS-KEY ("teeth abrasions") OR TITLE-ABS-KEY ("dental abrasion") OR TITLE-ABS-KEY ("tooth wear") OR TITLE-ABS-KEY ("teeth wear") OR TITLE-ABS-KEY ("dental wear") OR TITLE-ABS-KEY ("tooth abfraction") OR TITLE-ABS-KEY ("teeth abfraction") OR TITLE-ABS-KEY ("permanent dental restoration") OR TITLE-ABS-KEY ("permanent dental fillings") OR TITLE-ABS-KEY ("permanent dental filling") OR TITLE-ABS-KEY ("dental restoration, permanent") OR TITLE-ABS-KEY ("NCCL") OR TITLE-ABS-KEY ("NCCLs") OR TITLE-ABS-KEY ("noncarious cervical lesion") OR TITLE-ABS-KEY ("noncarious cervical lesion") OR TITLE-ABS-KEY ("non carious cervical lesion") OR TITLE-ABS-KEY ("cervical lesion") OR TITLE-ABS-KEY ("cervical lesions") OR TITLE-ABS-KEY ("class V lesion") OR TITLE-ABS-KEY ("cervical restoration") OR TITLE-ABS-KEY ("cervical restorations") OR TITLE-ABS-KEY ("class V restoration") OR ("class V") OR TITLE-ABS-KEY ("class 5"))
#2 (TITLE-ABS-KEY (monomer*) OR TITLE-ABS-KEY ("functional monomer") OR TITLE-ABS-KEY ("10 MDP") OR TITLE-ABS-KEY (10-mdp) OR TITLE-ABS-KEY (mdp) OR TITLE-ABS-KEY ("phosphatic monomer") OR TITLE-ABS-KEY ("methacryloyloxi-decyl-dihydrogen-phosphate") OR TITLE-ABS-KEY ("10-methacryloyloxidecyl dihydrogen phosphate") OR TITLE-ABS-KEY (adhesives) OR TITLE-ABS-KEY (adhesive) OR TITLE-ABS-KEY ("adhesive material") OR TITLE-ABS-KEY ("dentin-bonding agents") OR TITLE-ABS-KEY ("dental-bonding agents") OR TITLE-ABS-KEY

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Table 2: *Dichotomy of Results According to the Studies Evaluation Criteria*

Parameters	Modified USPHS Criteria I [26, 27, 31, 32, 36]		Modified USPHS Criteria II [29]		Slightly Modified USPHS Criteria [35]		Modified FDI Criteria [28]		Modified Ryge Criteria [33, 34]		Vanherle and others 1986 Criteria [30]
Unacceptable	Acceptable	Unacceptable	Acceptable	Unacceptable	Acceptable	Unacceptable	Acceptable	Unacceptable	Acceptable	Unacceptable	Acceptable
Marginal 3, 4 Adaptation	Alpha Bravo	Charlie	Alpha Bravo	Charlie	0, 1, 2	3, 4	5, 4, 3	2, 1	Alpha Bravo	Charlie	1, 2
Marginal 3, 4 Discoloration	Alpha Bravo	Charlie	Alpha Bravo	Charlie	0, 1, 2	3	5, 4, 3	2, 1	Alpha Bravo	Charlie	1, 2
Loss (necessary 3, 4 repair or replacement)	Alpha	Bravo Charlie	Alpha Bravo	Charlie	0	1	5, 4, 3	2, 1	Alpha Bravo	Charlie	1, 2
Secondary 2 Caries	Alpha	Bravo Charlie	Alpha	Charlie	0	1	5, 4, 3	2, 1	Alpha	Bravo	1
Postoperative 2 Hypersensitivity	Alpha	Bravo Charlie	Alpha	Charlie	0	1	5, 4, 3	2, 1	Alpha	Bravo	1

Reviews of Interventions 5.1.0 (http://handbook.cochrane.org). For each entry, the judgement involved recording "Yes" indicating minimal risk of bias, "No" indicating elevated risk of bias, and "Unclear" indicating either lack of information or uncertainty over the potential for bias.

The following domains were considered as key for the bias risk assessment: sequence generation, allocation concealment, blinding of participants and personnel, blinding of the outcome assessment, incomplete outcome data, selective reporting, and other bias. To be considered to embody a low bias risk, studies had to present low bias risk in all the key domains. If the study was considered unclear in any key domains, authors were contacted to obtain information sufficient to allow a definitive judgement. When one or more of these criteria were classified as either unclear or as high bias risk, the whole study was considered either unclear or high bias risk, respectively.

Summary Measures and Results Synthesis

The extracted data were analysed using RevMan software (Review Manager v. 5.3, The Cochrane Collaboration, Copenhagen, Denmark). Five meta-analyses were performed according to the main parameters analysed: retention (RE), marginal adaptation (MA), marginal discoloration (MD), caries (CA), and postoperative sensitivity (POS). Each parameter and the overall effect (clinical performance) were analysed.

The outcomes were divided into acceptable or unacceptable (Table 2), according to the classification criteria used by each study. The prevalence of unacceptable (failures/events), and the total number of restorations for each group, were used to calculate the risk difference with a 95% confidence interval (CI). Random effects models were employed, and heterogeneity was tested using the I^2 index.

If some of the information needed for the MA was missing from any of the selected studies, the authors were contacted to see if the missing data could be provided. Where contact was necessary, up to five attempts at contact were made; and, if after these contact attempts no response was received from the authors, or the authors did not provide the data, the study was not included in the MA.

Assessing the Certainty of Evidence

The certainty of evidence was determined for each outcome using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) approach. Randomized clinical studies started as high evidence, and the quality of evidence could decrease to moderate, low, or very low if serious or very serious issues related to risk of bias, inconsistency, indirectness, imprecision, or publication bias were present. In addition, the quality of the evidence designation could be upgraded if the magnitude of effect was large or very large, or if the effect of all plausible confounding factors was to reduce the effect or suggest spurious effects. In this way, the quality of the evidence varied from very low to high.

RESULTS

Study Selection

The selection methodology has been summarised in Figure 1. A total of 7927 citations was obtained from the database searches. Following the exclusion of duplicates, 4208 articles were identified, and then, after title screening, 215 studies re-

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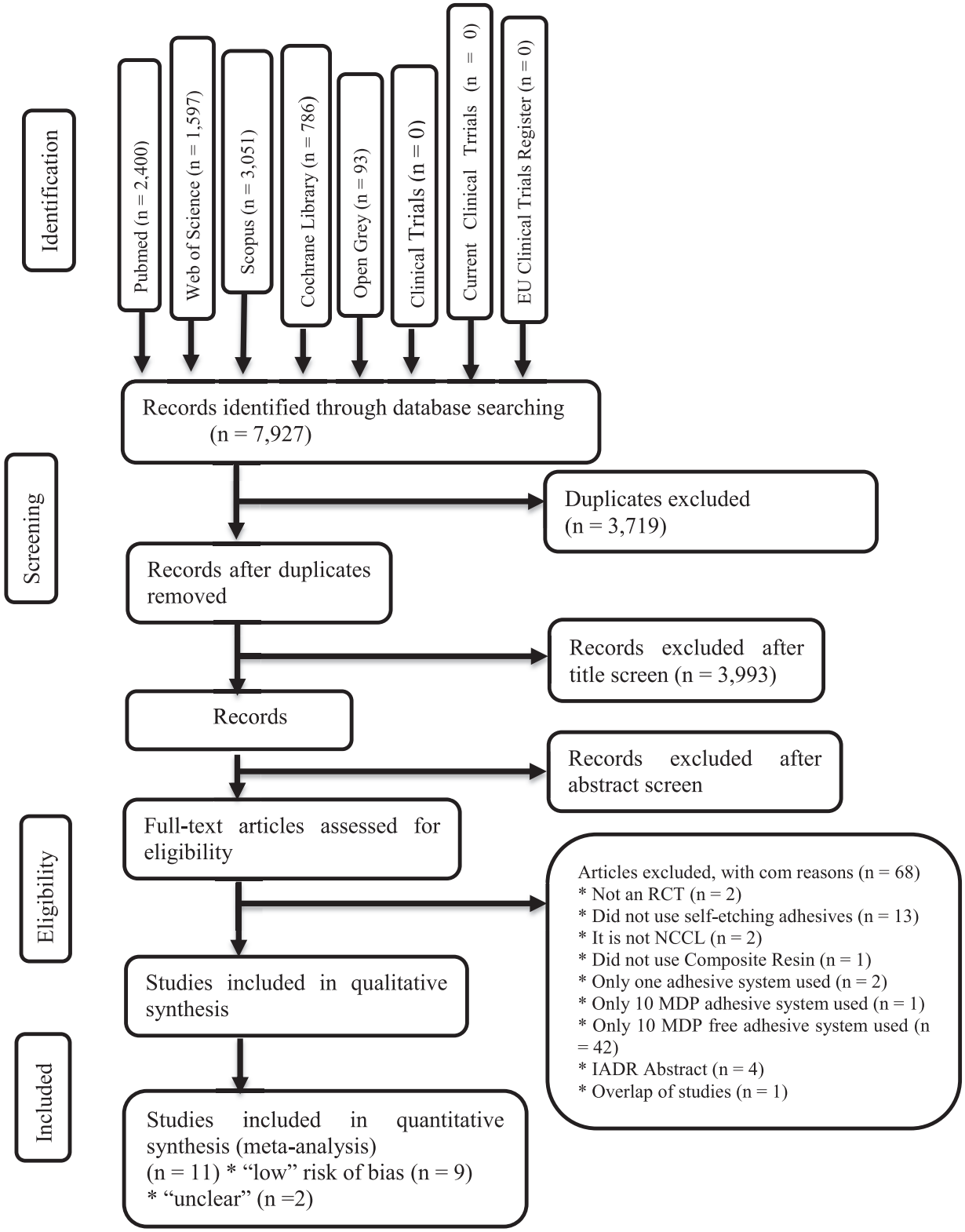

Figure 1. *Flow chart.*

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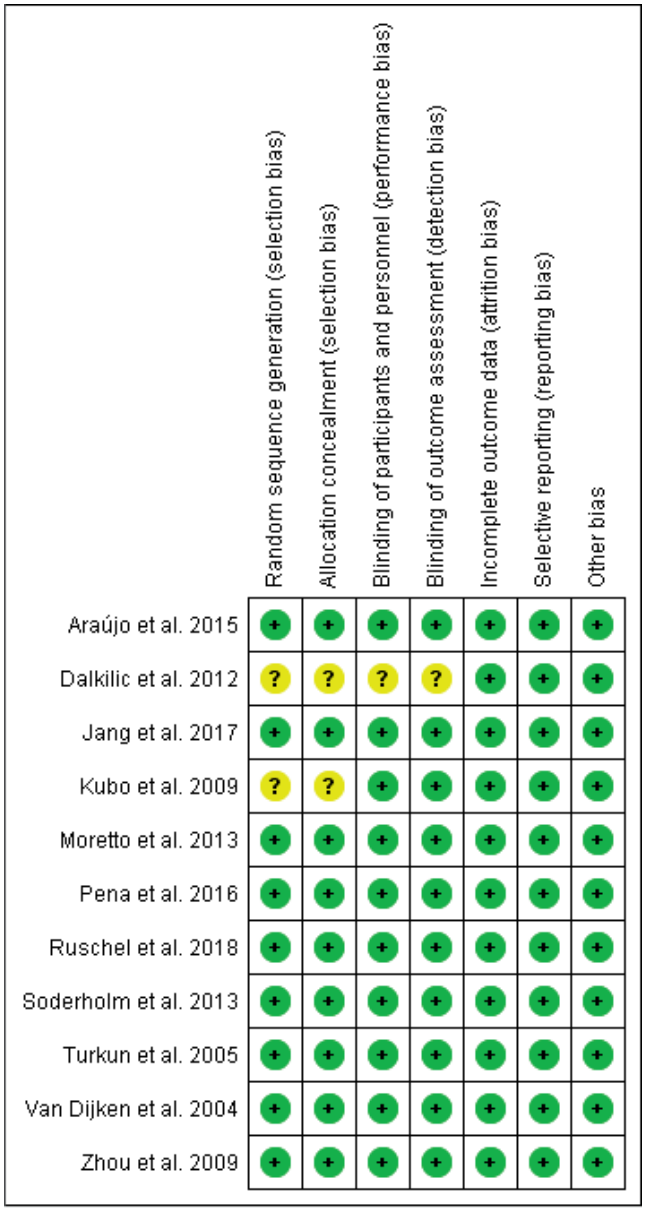

Figure 2. *Risk of bias.*

mained, with this number then further reduced to 79, through careful review of the abstracts. The full texts of the remaining 79 articles were examined for eligibility, leading to an additional 68 exclusions, with the remaining 11[26-36] admitted into our SR and MA.

Characteristics of the Included Articles

The characteristics of the 11 included studies, which varied in length from 1 to 4 years, have been listed in Table 3. The numbers of patients involved in these randomized clinical trials varied from 21 to 124, and their ages spanned 20–84 years. During the restoration procedure, there was generally just one operator involved, although the number of operators did range up to two. The incremental technique was the most commonly used filling method, and the most common isolation technique involved use of cotton rolls and saliva aspirators. In two studies,[32,35] exposed dentin was superficially prepared by bur roughening, and the enamel was bevelled in one study,[31] while both the procedures (roughening and bevelling) were performed in four studies.[29,30,33,36] No preparation procedures were performed in another four studies.[26-28,34]

In total, 11 different adhesives were tested in the included studies. The most tested adhesive without 10-MDP was GC bond, and the most tested system with 10-MDP was Clearfil SE Bond. With regard to the adhesive approach, all studies used one- or two-step, self-etch techniques. Among systems without 10-MDP, six used the one-step, self-etch approach and two used the two-step, self-etch method. Among those with 10-MDP, two used one-step, self-etch and three used the two-step, self-etch approach.

For restoration evaluation, the majority (seven) of the studies used the modified United States Public Health Service (USPHS) criteria,[26,27,29,31,32,35,36] one used the Federation Dentaire Internationale (FDI) criteria,[28] two used the Modified Ryge criteria,[33,34] and one used the Vanherle and others criteria[30] (Table 2).

Assessment of Bias Risk

An assessment of bias risk was performed for the included articles, and the results have been presented in Figure 2. E-mails were sent to all authors, requesting further information, and nine responded.[26,28,30-36] Among the 11 selected studies therefore, two full-text articles[27,29] were classified as having an "unclear risk of bias", in the key domains of the Cochrane bias tool, and nine studies—those listed above whose authors responded to our request for additional information—were considered as having a low risk of bias.

Meta-analysis

The meta-analysis (MA) was conducted with the data available in the "low and unclear risk of bias" studies included in this SR. Only two studies did not provide sufficient data for POS—Kubo and others[29] and Ruschel and others.[32] The group data that had the highest prevalence of failures (events) was used for studies that included more than one group of 10-MDP-containing Zhou and others[36] or 10-MDP-free adhesive systems Van Dijken and others.[35]

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Table 3: *Summary of the Studies Selected for this Systematic Review*

Study ID/ Country	Study Design	Subject's Age Mean [Range] (Years)	Adhesive System	Outcomes Evaluated	Evaluation Criteria	
Without 10-MDP (nbaseline)/(nfollow-up)						
Araújo 2015 Brazil	RCT Split-mouth	n.r. [37-53]	AdheSE Rest: (32)/(23)	Clearfil SE Rest: (32)/(30)	Retention; marginal discoloration; marginal adaptation; secondary caries; postoperative sensitivity	Modified USPHS
Dalkilic 2012 Turkey	RCT Split-mouth	n.r. [30-70]	Single Bond (total etch) (30) / (17) Xeno III (30) / (20)	Clearfil SE (41) / (32)	Retention; marginal discoloration; marginal adaptation; secondary caries; postoperative sensitivity.	Modified USPHS
Jang 2017 Korea	RCT Split-mouth	55[30-73]	Xeno V (81)/(68)	Clearfil SE Bond (83)/(72)	Retention; marginal discoloration; marginal adaptation; secondary caries; postoperative sensitivity.	Modified FDI
Kubo 2009 Japan	RCT Split-mouth	61,8 [30-79]	G-Bond (55)/(54)	Clearfil S3 Bond (53)/(52)	retention; marginal discoloration; marginal adaptation; secondary caries;	Modified USPHS
Moretto 2013 Brazil	RCT Split-mouth	n.r. [20-69]	G-Bond (88)/(82)	Clearfil S3 Bond (87)/(75)	Retention; marginal discoloration; marginal adaptation; secondary caries; postoperative sensitivity	A set of criteria introduced by Vanherle et al. (1986)
Pena 2016 Brazil	RCT Split-mouth	n.r.	Xeno V (56) / (52)	Clearfil SE Bond (56) / (52)	Retention; marginal discoloration; marginal adaptation; secondary caries; postoperative sensitivity	Modified USPHS
Ruschel 2018 Brazil	RCT Parallel	n.r. [21-67]	Prime & Bond Elect (51)/(41)	Scotchbond Universal 50/37	Retention; marginal discoloration; marginal adaptation; secondary caries;	Modified USPHS
Soderholm 2013 USA	RCT Split-mouth	54 [43-77] Female 52 [44-70] Male	iBond SE (42)/(31)	Clearfil SE (42)/(33)	Retention; marginal discoloration; marginal adaptation; secondary caries; postoperative sensitivity.	Modified Ryge protocol
Turkun 2005 Turkey	RCT Split-mouth	44 [26-59]	Xeno III (78) / (75)	Clearfil Protect Bond (85) / (85)	Retention; marginal discoloration; marginal adaptation; secondary caries; postoperative sensitivity.	Modified Ryge
Van Dijken 2004 Sweden	RCT Parallel	58 [46-72]	One Coat Bond (46) / (?) Prompt-L Pop (52) / (?)	Clearfil Liner Bond2 (46) / (?)	Retention; marginal discoloration; marginal adaptation; secondary caries;	Modified USPHS

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Table 3: *Summary of the Studies Selected for this Systematic Review (ext.)*

Study ID/ Country	Recall Period (Years)	Rubber Dam	Dentin Prepare	Enamel Bevel	Results	Conclusion
With 10-MDP (nbaseline)/(nfollow-up)						
Araújo 2015 Brazil	02	No	No	No	No significant difference was observed between baseline and 2-year for any criteria when adhesives with and without the addition of CHX were compared ($p > 0.05$)	The inclusion of CHX into the primer of both self-etch systems did not add clinical advantages over the 2-year period. Clearfil SE Bond resulted in better retention rate than AdheSE
Dalkilic 2012 Turkey	2	No	No	No	After 2 years: - No significant difference was found between the retention rates of the groups ($p > 0.05$) - Although groups CL and SI showed significantly better marginal adaptation than group XE ($p < 0.05$), no significant difference was found between the marginal adaptation of the groups CL-B, SI-B and XE-B ($p > 0.05$) - No significant difference was observed among the marginal staining results of all groups ($p > 0.05$)	Although all adhesive systems showed similar retention rates, Clearfil SE and Single Bond showed better marginal adaptation than Xeno III after 2 years of follow-up
Jang 2017 Korea	2	No	No	No	Three restorations were dislodged: two in CS / Sof and one in CS / EP. None of the restorations required any repair or retreatment, except those showing retention loss. CS and XE did not show differences in any criteria (p.0.05)	XE, one-step self-etch adhesives showed clinically equivalent performance to CS, two-step self-etch adhesives
Kubo 2009 Japan	2	No	Yes	Yes	One restoration of each adhesive group was lost during two years. Only the marginal integrity at enamel was a minor clinical problem. 11 restorations of both S3 and GB showed slight marginal staining. There was no significant difference in the clinical performance between S3 and GB for each variable	Both adhesive systems showed an acceptable clinical performance up to two years
Moretto 2013 Brazil	3	No	Yes	Yes	Retention rates: CS3 (93.8%) and GB (98.8%). There were no significant differences between the two adhesive systems for all the parameters evaluated. CS3 and GB showed an increased percentage of clinically acceptable marginal discoloration (CS3: 32.9% and GB: 26.8%) and marginal defects (CS3: 35.8% and GB: 26.5%). A severe marginal defect was presented by only one dentin margin of a GB restoration. One CS3 restoration showed caries	Both adhesive materials showed an equally good clinical performance at three years
Pena 2016 Brazil	2	Yes	No	Yes	Significant differences were detected only after 18 months for marginal staining in the groups Clearfil SE non-etch ($p = 0.009$) and Xeno V+ etch ($p = 0.004$). One restoration was lost during the trial (Xeno V+ etch; $p > 0.05$). No sensitivity in any recall period was observed ($p > 0.05$). Secondary caries were not observed in any group ($p > 0.05$)	Overall clinical success of the two self-etching adhesive systems tested in this study was not affected by selective enamel etching in the 24-month evaluation. There was no significant difference between groups tested for retention rate, marginal integrity, secondary caries, and postoperative sensitivity
Ruschel 2018 Brazil	1,5	No	No	No	A statistically significant difference was reached only for the comparison Scotchbond Universal / selfetch (SU_SE) and Prime & Bond Elect / etch and rinse (PBE_E&R) groups ($p = 0.01$), where a restoration with SU_SE was 66% less likely to maintain a score of Alpha for marginal discoloration than a restoration performed with PBE_E&R	Scotchbond Universal and Prime & Bond Elect presented acceptable clinical performance after 18 months of clinical service. However, Scotchbond Universal, when applied with a self-etch approach, did demonstrate a relatively high level of marginal discoloration when compared to the other groups
Soderholm 2013 USA	4	No	Yes	Yes	In relation to retention, marginal integrity and marginal discoloration, there were no significant differences between the two adhesive systems	The performance of the two adhesive systems tested did not differ significantly during four years. The most pronounced problem with these two materials was the development of marginal defects/staining – which may be related to operator problems or to the soluble precipitates formed by the self-etching adhesives at the adhesive interface
Turkun 2005 Turkey	1	No	No	No	At one year, the retention rates for the restorations in the two-step group were 100%. They were 96 percent for the restorations in the one-step group. Of the retained 75 restorations from the one-step group, two had marginal discoloration and slight anatomical form problems. In both groups, color matching ability and postoperative sensitivity remained excellent	The performance of both self-etching adhesive systems was excellent during this one-year clinical trial. However, the two-step system exhibited slightly better retention than the one-step system
Van Dijken 2004 Sweden	2	No	Yes	No	All except three restorations were evaluated over 2 years. No differences were seen between the groups for the acceptable restorations. None of the participants reported postoperative sensitivity	The three systems provide acceptable initial clinical retention, but that the increasing loss rate observed during the 2-year follow-up indicated that the simplification of adhesive systems seems to restrict

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For this MA, the overall heterogeneity was not important (I^2=0%). For each parameter, the heterogeneity ranged from 0-53% (53% for RE, 47% for MA, 12% for MD, 0% for CA, and 0% for POS), or from "absent" to "substantial."[38] The 10-MDP-free adhesive group showed 35 failures out of 546 restorations evaluated for the RE parameter, 39 failures out of 511 restorations that were evaluated for MA, 13 failures from 511 restorations that were evaluated for MD, 1 failure out of 511 restorations that were evaluated for CA, and 6 failures from 418 restorations evaluated for POS.

The 10-MDP-containing adhesive group showed 24 failures from a total of 573 restorations evaluated for the RE parameter, 33 failures out of 549 restorations evaluated for MA, 19 failures from 549 restorations evaluated as MD, 1 failure from 549 restorations evaluated as CA, and 5 failures from 461 restorations evaluated for POS. The overall risk difference was −0.00 [−0.01, 0.00] (p=0.77), and was −0.01 [−0.05, 0.02] (p=0.46) for RE, −0.01 [−0.03, 0.02] (p=0.46) for MA, 0.00 [−0.01, 0.01] (p=0.90) for MD, 0.00 [−0.01, 0.01] (p=0.92) for CA, and 0.00 [−0.01, 0.01] (p=0.94) for POS (Figure 3).

This meant that 10-MDP-free and 10-MDP-containing adhesive systems showed statistically similar clinical performance (overall effect) for all isolated parameters, with moderate certainty of evidence for retention and high certainty of evidence for other parameters (MA, MD, CA, POS, and for pooled results). Table 4 lists the detailed GRADE classifications for each parameter.

DISCUSSION

Modern adhesive systems have exhibited good short-term bond ability; however, interface stability is still challenging where long-term behaviour is concerned.[37] Adequate restorative material stability, in terms of its adhesion to the dental substrate, is only possible when high-quality and long-lasting micromechanical and chemical interactions take place between the adhesive system and dental substrate[38,39] in a hybrid layer, as described by Nakabayashi.[40,41] The evidence for this adhesive interaction was based on deep impregnation of dental substrates, especially dentin, by the adhesive system, after strong acid conditioning.[42,43]

Lately, some studies have been published that identified, *inter alia*, problems related to clinical performance. These issues were found as part of middle- and long-terms follow-ups, and were mostly related to inability on the part of the adhesive systems to totally fill the spaces provided by the acid etching. This was seen to have left collagen deprived of mineral protection, leaving it degradation prone, mainly by some enzymes (matrix metalloproteinases) activated during the acid etching.[31,44-47]

Self-etching systems were developed not only to simplify the entire adhesive process but also to allow complete monomer infiltration, allowing tissue conditioning and resin infiltration to take place at the same time.[46,48] In these systems, acidic monomers were added to play this role, and several modifications have been made over time to self-etching adhesive systems. Changes in the number of steps (one or two) and aggressiveness (strong, middle, mild, and ultra-mild) were the principle modifications,[42-44] and, as for etch-and-rinse adhesives, strong self-etch adhesives completely remove hydroxyapatite (HAp) from dentin, resulting in relatively deep dentin hybridization that is several micrometers thick. However, part of the HAp remains in the hybrid layer, where it may negatively influence bond strength. On the other hand, mild self-etch adhesives, due to their less aggressiveness, form only submicron-thick hybrid layers, and the HAp is not attacked as observed for the strong self-etch adhesives, which allows better mechanical and chemical interactions between functional monomers and HAp. [5,49,50]

Conceptually, mild self-etch adhesives bond to tooth tissue through a twofold (micro-mechanical and chemical bonding) mechanism. Partial dentin conditioning occurs, leaving some HAp around collagen fibers within a submicron hybrid layer.[13,42] In the 80's, Kuraray developed and patented 10-MDP, a mild functional monomer, with a hydrophobic methacrylate group at one end, capable of reacting with methacrylate-based restorative materials, and a hydrophilic polar phosphate group at the other end, which was able to react with metals, zirconium, and dental mineralized tissues.[20,21] This monomer also exhibited the interesting property of low hydrophilicity, due to its long molecular chain.[5,51]

Based on the adhesion–decalcification (AD) concept, functional monomers like 10-MDP bond electrostatically to HAp, forming an insoluble MDP-calcium salt CaMHP2,[10,52,53] thereby contributing to the long-term stability of the bond.[50,54] Primary chemical bonding to HAp was first demonstrated using XPS,[5] and later confirmed using X-ray diffraction (XRD) and nuclear magnetic resonance spectroscopy (NMR).[44,45,55] The XRD examination also

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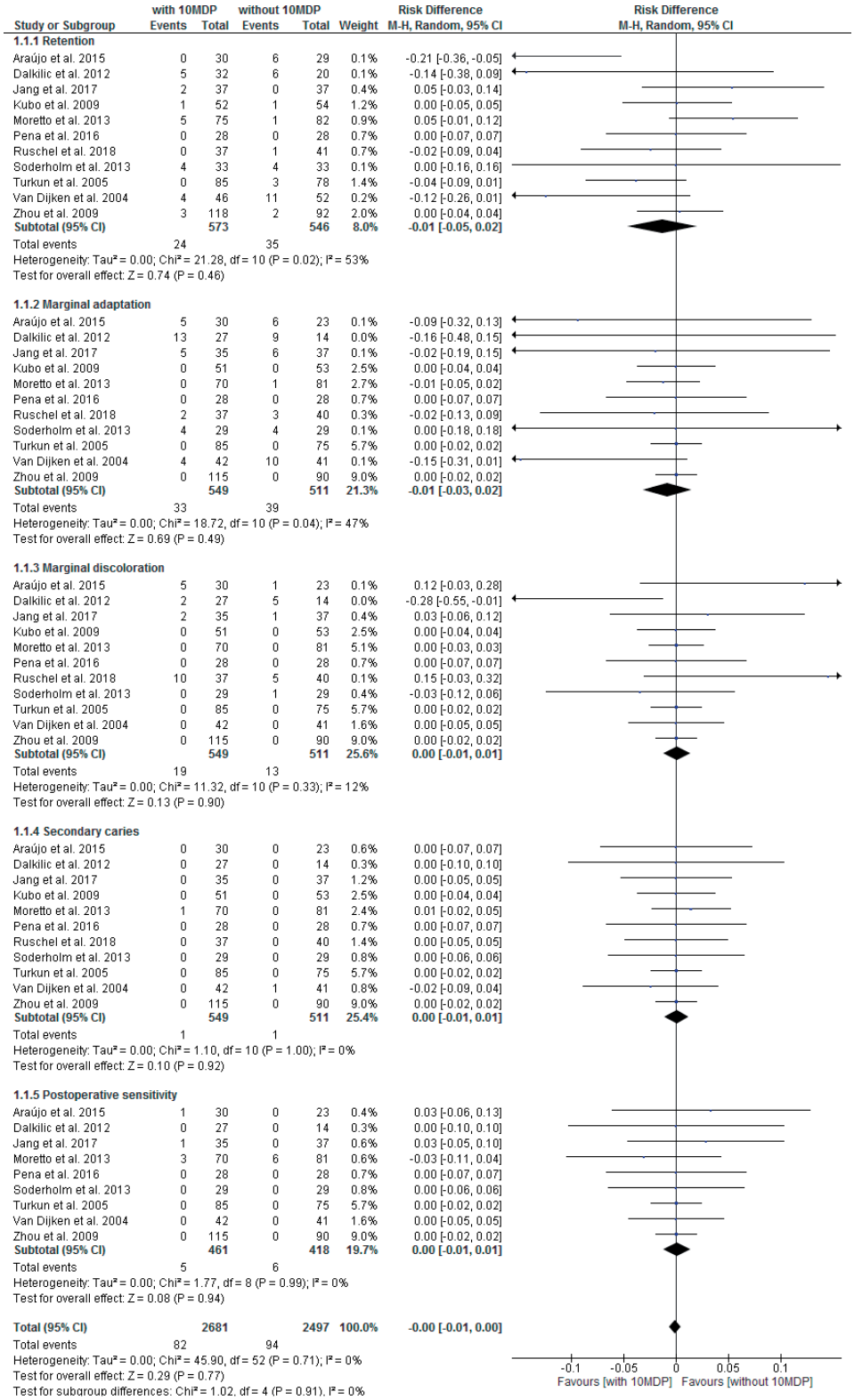

Figure 3. *Meta-analysis (MA).*

showed that 10-MDP bonding to calcium formed a Ca–HAp compound, characterized by a nanolayered structure.[22,42,55] This salt protects the interface against hydrolysis, due to its hydrolytic stability.[48]

The immediate and widespread interest by several manufacturers—including the makers of Clearfil SE Bond, Clearfil S3 Bond, and Clearfil Protect—in adding 10-MDP to adhesive systems was probably

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Table 4: *Certainty of Evidence*

Certainty Assessment						Summary of Findings				
Number of participants (studies) Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Overall certainty of evidence	Study event rates (%)	Relative effect (95% CI)	Anticipated absolute effects	
With control			With 10-MDP				Risk with control			
Retention										
1119 (11 RCTs)	Not serious	Very serious a, b	Not serious	Serious c	Very strong association	⊕⊕⊕○ MODERATE	35/546 (6.4%)	24/573 (4.2%)	**RD −0.01** (−0.05 to 0.02)	62 per 1000
Marginal adaptation										
1060 (11 RCTs)	Not serious	Serious b	Not serious	Serious c	Very strong association	⊕⊕⊕⊕ HIGH	39/497 (7.8%)	33/525 (6.3%)	**RD -0.01** (−0.03 to 0.02)	76 per 1000
Marginal discoloration										
1060 (11 RCTs)	Not serious	Not serious	Not serious	Serious c	Very strong association	⊕⊕⊕⊕ HIGH	13/511 (2.5%)	19/549 (3.5%)	**RD 0.00** (−0.01 to 0.02)	25 per 1000
Secondary caries										
1060 (11 RCTs)	Not serious	Not serious	Not serious	Serious c	Very strong association	⊕⊕⊕⊕ HIGH	1 / 511 (0.2%)	1/549 (0.2%)	**RD 0.00** (−0.01 to 0.01)	2 per 1000
Postoperative sensitivity										
879 (9 RCTs)	Not serious	Not serious	Not serious	Serious c	Very strong association	⊕⊕⊕⊕ HIGH	6/418 (1.4%)	5/461 (1.1%)	**RD 0.00** (−0.01 to 0.01)	14 per 1000
Pooled results—Clinical performance										
1119 (11 RCTs)	Not serious	Not serious	Not serious	Serious c	Very strong association	⊕⊕⊕⊕ HIGH	79/546 (14.5%)	82/573 (14.3%)	**RD 0.00** (−0.01 to 0.00)	145 per 1000

due to the good results observed when Kuraray systems were tested.[20,21,46] Some laboratory studies demonstrated good performance when bond strength and sealing ability were important.[20-23,39,46] In one of them the adhesive systems were evaluated using mechanical and physical parameters, and the results showed that only systems containing 10-MDP[43,45] were able to protect the bond interface against nanoleakage, and that these systems presented a higher elastic modulus after 1 year.[10,39,45]

Some clinical studies showed favourable short- and mid-term performance when using systems with formulae that included 10-MDP. It is of interest to mention here that, among the 11 RCTs included in this SR, 10 used Kuraray's system (containing 10-MDP in their formulae), compared to other self-etching systems without this functional monomer. Only one study, published in 2018,[32] used different systems, applying Scotchbond Universal (3M) and Prime & Bond Elect (Dentsply Sirona). The RCTs selected normally used retention, marginal degradation and staining, postoperative sensitivity and secondary caries as clinical criteria.

As the MA only accepted paired comparisons, two systems from each RCT were selected—one containing 10-MDP and the other not. In this study, only the adhesion of self-etching systems to dentin was considered. Dentin is a vital substrate, is very dynamic, and has a high water content,[56] and it has also been noted that some pathological changes may occur over time, which make the adhesion process very challenging.[1,57] In this particular SR, neither clinical studies that involved adhesion to enamel nor the total etch technique were included, due to the number of variables that should be considered and discussed, such as self-etch or selective approaches.

Retention is normally used as the primary outcome, and for definition purposes in this study, partial or total loss of restorations was taken as implied by their replacement.[58] The results for this clinical criterion in seven studies[27,28,30,31,33,34,36] did not present significant differences between the two compared groups. On the other hand, statistical differences for retention criteria were reported in two studies.[26,35] When these results were subjected to the MA, however, they did not show any differences when adhesives containing 10-MDP or not were compared. Better clinical performance (retention) had been expected, when 10-MDP was present in the adhesive formulation, once this functional monomer reacted with HAp-forming Ca-MDP salt, which has a hydrolysis protective effect.[54,57-59]

In the present SR, all of the 10-MDP systems included were in commercially available products

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with the HEMA monomer in their composition; perhaps this association could explain the MA results in which no significant difference in retention among the adhesive systems were detected. Despite the important role, in a recent SR and MA, the adhesive containing HEMA was compared to HEMA-free adhesives, and a similar clinical behaviour was found.[7] Over time, the high hydrophilicity of this monomer promotes an increase in water acceptance that results in a hydrolytic degradation of the adhesive interface.[60,61]

The presence of HEMA may also interfere with the MDP-Ca nanolayer formation, so thus the retention rate for the 10-MDP-containing systems were not significantly higher, as had been expected.[54,57-59] In a study by Tian and others,[62] several commercial adhesive systems showed little nanolayer formation behaviour at the resin–dentin interface, while more uniform CA-MDP nanolayering was detected for the one system (G-Premio Bond/GC) that did not use HEMA in its formulations. The demineralization rate of HAp by 10-MDP is reduced by HEMA presence, and 10-MDP remains adsorbed onto the HAp surface. Using XRD and NMR to better understand the nanolayering structure in the presence of functional monomer HEMA, Yoshida and others[54] confirmed the chemical interaction between Ca dissociated from HAp and MDP to form the MDP-Ca salt-layered structure. However, when HEMA was added, MDP-Ca salt formation was remarkably decreased and part of the crystalline phase compromised. As XRD analysis can only detect the presence crystalline structures, NMR was used to investigate the chemical interaction of MDP with HAp in HEMA-containing formulations and to unravel the mechanism of how HEMA inhibits nanolayering formations. The NMR analysis showed that when HEMA concentration was increased, the interaction of MDP and HAp decreased. Assessing HEMA-free MDP formulations, shoulder peaks that indicate more consolidated crystalline structures were observed. On the other hand, when HEMA was present in the formulation, weak shoulder peaks were detected that may explain the reduction in the nanolayering formation, probably due to the affinity of HEMA molecules to the HAp, which may compete with the MDP-Ca salt formation. Therefore, one can speculate that this phenomenon could interfere in the retention rates and also in the bond durability.[54]

10-MDP benefits could be demonstrated in laboratory studies, in which the adhesives were synthetized with a high degree of purity and were applied using controlled concentrations. Some studies[21,42,63] have evaluated different 10-MDP concentrations (1%, 3%, 5%, and 15%) with high purity, in terms of Ca-MDP nanolayer formation, and the 15% 10-MDP formulated adhesive exhibited more intense nanolayer deposition. Unfortunately, neither the degree of purity nor the concentration are clearly presented for commercial adhesive systems. On the other hand, Carrilho and others[59] in an SR of 73 laboratory studies stated that commercial adhesives containing 10-MDP had a proven capacity to interact to HAp; however, some clinical steps relating to application of this bonding system must be conducted with due care and attention, because of their influence on the quality of the resulting bond interface. These steps include the selective enamel etching and scrubbing technique used to apply the adhesive systems to dental substrates. The authors also emphasized the importance of allowing sufficient time for the solution to infiltrate, to hybridize, and to form the MDP-Ca salt, protecting collagen fibrils and improving adhesive stability. Perhaps these techniques have not been followed in some clinical studies as precisely as they would have been in laboratory studies, which could also have influenced the results.

Follow-up time is another point to be considered, when reviewing the equity of the various retention rate results described in the RCTs. The longest clinical tracking time was 4 years (Table 3), which may not have been sufficient to detect significant differences.

Secondary outcomes considered in this SR included marginal staining and degradation, and here again, the MA did not detect significant differences when the presence of 10-MDP was considered. Formation of CA-MDP nano layering is more closely related to retention aspects, and so plausible explanations of differences may only show over time, which in some cases may not have been sufficient to detect differences, or to differentiate between variations in the mechanical and physical properties of the restorative materials. Clearly, longer evaluation periods will need to be considered for future studies.

Secondary caries and postoperative sensitivity were also considered as secondary outcomes, and, again, no significant differences were detected in the MA for these effects. The ease with which the restored areas can be kept free of biofilm, and the favourable C-Factors of the NCCLs, may also explain why the different restorative systems showed no significant variations with respect to these characteristics.[7]

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Several other aspects may affect the clinical behaviour of dental restorations over time, including the patient, the type of tooth and cavity, the operator, and the restorative system used.[28,56] When the integrity of the adhesive interface is a concern, the type of tooth, cavity, and restorative system may have more impact.[64,65] In this SR, only clinical trials that involved NCCL restorations were included, although for this type of cavity, variation in size and in the amount of exposed dentin would probably not lead to different results. However, we could not affirm the same in cases with different C-factors, or types of occlusion, or with the morphological and/or pathological dentin changes normally present in class II cavities, for instance. The NCCLs that were the subjects of these controlled clinical studies reported little variation in these aspects.[7,31]

Noting that two studies considered for inclusion were regarded as unclear in some review domains, the strength of the data in those studies that were included in this SR was an important aspect that needed to be addressed; and the GRADE approach indicated that the evidence was of high quality for all evaluation criteria, except for retention, which was classified as moderate. This confirmation suggested that it would be unlikely that future studies would arrive at conclusions different from those of the present SR.

CONCLUSION

According to results from this SR and MA, strengthened by application of the GRADE approach to the evidence of selected articles, and considering the follow-up time presented in selected RCTs, the authors were able to conclude that the presence of 10-MDP monomer in self-etch adhesive systems did not influence the clinical performance of NCCL restorations.

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Regulatory Statement

This study protocol was registered at the Prospective Register of Systematic Reviews (PROSPERO - CRD42016050538), and it followed the recommendations in the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) statement on the reporting of systematic review.
The approval code issued for this study is PROSPERO CRD42016050538.

Conflict of Interest

The authors of the present study certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in the present article.

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Effect of Aging on Surface Roughness and Color Stability of a Novel Alkasite in Comparison with Current Direct Restorative Materials

B Yazkan • EU Celik • D Recen

Clinical Significance

Although this novel alkasite is a promising material due to its strong mechanical properties, as reported in the literature, the material may not be as successful as composite resins in terms of meeting esthetic expectations.

SUMMARY

Aim: To compare the surface roughness and color stability of a novel alkasite with current direct restorative materials with and without an aging step.

Methods and Materials: Twenty-six specimens of each of the following materials were prepared: alkasite, ormocer, giomer, high-viscosity glass ionomer, glass carbomer, and nanohybrid composite (control). Half of the specimens in each group were stained, the other half of the specimens were aged and then stained. Color and surface roughness evaluations were conducted at baseline, after aging and after staining, using a dental spectrophotometer, and a three-dimentional (3D) noncontact optical profilometer, respectively. Statistical analyses were completed using one-way analysis of variance, post hoc Tukey test, and paired samples *t*-test.

Results: At baseline and after aging, the surface of alkasite was found to be rougher than nanohybrid composite and ormocer surfaces ($p<0.05$). However, in terms of roughness increase caused by aging, ormocer, nanohybrid composite, and alkasite were affected in a similar way ($p>0.05$). In terms of color stability, alkasite was more colored than nanohybrid composite and ormocer ($p<0.05$), and performed similar to giomer ($p>0.05$).

Conclusions: The surface roughness and color stability characteristics of alkasite material was between composite resins and glass ionomer-based materials after aging.

[*]Basak Yazkan, PhD, Pamukkale University, Faculty of Dentistry, Department of Restorative Dentistry, Kınıklı, Denizli, Turkey

Esra Uzer Çelík

Duygu Recen

[*]Corresponding author: Pamukkale University, Faculty of Dentistry, Department of Restorative Dentistry, Kınıklı, Denizli, Turkey; e-mail: basakyazkan@hotmail.com

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INTRODUCTION

Although composite resin restorations have almost completely replaced amalgam restorations due to the alleged mercury toxicity and dark color of the latter, they do have disadvantages, including technique-

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sensitive adhesive application steps, a susceptibility to polymerization shrinkage leading to microleakage, their high wear rate, and their propensity for discoloration and cytotoxicity, which are all unresolved concerns for clinicians. These concerns have motivated the search for a new esthetic material with the ability to withstand occlusal and masticatory forces in the posterior teeth, a low marginal leakage, high color stability, and longevity.

In an attempt to overcome the drawbacks of composite resin restorations described above, different alternative materials have been developed such as high-viscosity glass ionomer, giomers, glass carbomers, and ormocers.[1] Although some of these materials have specific advantages, such as acceptable physical properties, wear resistance, and the self-adherable bonding ability to dentin of high viscosity bulk replacement glass ionomers[2] and glass carbomers,[3] satisfying optical properties, antibacterial effects, durability, potential for fast treatment of giomers,[4] and high abrasion resistance and biocompatibility of ormocers,[5] composite resins have not been completely replaced by these alternative restorative materials due to their lower mechanical, esthetic, or color stability properties.

As a result, researchers have long sought a real alternative to the current direct restorative materials. This sought-after material should be cheap, easy to use without the need for complicated equipment, strong, high in compressive strength, and esthetically pleasing.[6] Recently, Cention N (Ivoclar Vivadent, Liechtenstein) has been introduced as an innovative material with these sought-after features. This novel category alkasite restorative material consists of a separately packaged powder and liquid.[7] The liquid contains dimethacrylates and initiators, while the powder contains various initiators, pigments, and alkaline glass fillers, which release acid neutralizing fluoride, calcium, and hydroxide ions when the pH of the oral cavity decreases.[8] It is a self-curing material with optional light-curing, leading to increased strength and longevity of the restoration.[7]

In previous studies evaluating this novel alkasite material, its shear bond strength,[9] microtensile bond strength,[10] compressive strength,[11] and fracture resistance[12] was found similar to composite resins and higher than glass ionomer-based materials. In addition, the microleakage of the material in the enamel–restoration junction was found lower than composite resins.[8,13] However, since the demand for esthetic restorations is increasing, materials with similar or better surface roughness and color stability compared to composite resins are required in restorative dentistry.

There are only three studies in the literature analyzing the novel alkasite material in terms of surface roughness and color stability. In one of these studies, the color stability of the alkasite material was compared only with a high-viscosity glass ionomer material[14], and in the others, the surface roughness of the alkasite was compared with a composite resin[9,15] and a glass ionomer-based material.[9] Aging is of great importance in this respect, and it should be investigated in the literature. However, it is seen that the effects of aging have not been evaluated in these studies. Therefore, the aim of this laboratory study was to compare the effect of aging on the surface roughness and color stability properties of this novel alkasite material with all the current direct restorative alternatives including composite resin, orcmocer, high-viscosity glass ionomer, glass carbomer, and giomer. The tested null hypotheses were that (1) aging would not affect the surface roughness of alkasite more than the other tested direct restorative materials, (2) aging would not affect the color of alkasite more than the other tested direct restorative materials, and (3) staining would not affect the color of alkasite more than the other tested direct restorative materials, whether aging was performed or not.

METHODS AND MATERIALS

Specimen preparation

A total of 156 disc-shaped specimens (10 mm in diameter and 2 mm in thickness) were prepared using a Teflon mold following the manufacturer's application instructions, as described in Table 1. All the materials selected were of the same shade (A2) (n=26). The materials were placed into the molds with a slight overflow and covered with a transparent band (Mylar, DuPont, Wilmington, DE, USA). The excess material was removed by applying pressure with a glass lamina measuring 1 mm in thickness. The chemically activated materials were allowed to set for a period of time according to the manufacturer's instructions, and the resin-based materials were polymerized using a LED lamp at a distance of 1 mm (1000 mW/cm^2) using the standard power curing mode of a VALO Cordless (Ultradent Products, South Jordan, UT, USA).

The prepared specimens were stored in distilled water for 24 hours at 37°C to allow for polymerization completion. This rehydration simulated the first

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Table 1: *Materials Used for Each Group, Their Composition, and Application Procedure*

Groups	Material/Manufacturer/ Batch Number	Material Composition	Application Procedure
Alkasite (CN)	Cention N/Ivoclar Vivadent AG, Bendererstrasse, Schaan, Liechtenstein/W96066	**Filler:** Barium aluminium silicate glass, ytterbium trifluoride, isofiller (Tetric N-Ceram technology), Calcium barium aluminium fluorosilicate glass, Calcium fluoro silicate glass. **Liquid:** UDMA, DCP, Tetramethyl-xylylen-diurethane dimethacrylate, PEG-400 DMA	-Manually mix 2 measuring spoons of powder and 2 drops of resin till a smooth consistency. -The mixing time should not exceed 60 seconds. -Leave the material for 10 minutes from the start of mixing (no light curing).
Ormocer (AF)	Admira Fusion x-tra/VOCO GmbH, Cuxhaven, Germany/1807658	**Resin matrix:** Aromatic and aliphatic dimethacrylates, methacrylate-functionalized polysiloxane **Inorganic filler:** Barium , aluminum, glass, silicon dioxide, **Photoinitiator:** Camphorquinone	-Apply the material in layers that are a maximum of 4-mm thick, -Adapt with an instrument and light cure (20 seconds for shade A2)
Giomer (BF)	Beautifil Flow Plus/Shofu Inc, Kyoto, Japan/PN2002	***Base resin*:** Bis-GMA (15 wt%)/ TEGDMA (13wt%) resin ***Filler*:** Multi functional glass filler and S-PRG filler based on fluroboroaluminosilicate glass. **Photoinitiator:** Camphorquinone	-Apply the material in layers that are a maximum of 2-mm thick, -Adapt with an instrument and light cure (20 seconds for shade A2)
High-viscosity glass ionomer (EF)	EQUIA Forte/GC Corp, Tokyo, Japan/1804061	**Liquid:** Polyacrylic acid, distilled water, polybasic carboxylic acid **Powder:** Fluoro-alumino-silicate glass, polyacrylic acid powder, pigment	-Activate the capsule and mix in a high-frequency mixer. -Apply EQUIA Forte® directly into the cavity preparation after mix for 10 seconds on a mixing device. -Remove excess material.
Glass Carbomer (GC)	GCP Glass Seal/GCP Dental, Boelewerf, Ridderkerk, The Netherlands/71712907	**Powder:** Fluoroaluminosilicate glass, apatite **Liquid:** Polyacids.	-Activate the capsule and mix in a high-frequency mixer (GCP CarboMix, GCP Dental) for 15 seconds. -Light-cure the material with a high output light device (GCP CarboLED, GCP Dental) for 90 seconds. -Coat the surfaces with GCP gloss (GCP Dental) and light-cure for 90 seconds.
Nanohybrid Composite (GS)	GrandioSo/ VOCO GmbH, Cuxhaven, Niedersachsen, Germany / 1806497	**Inorganic fillers:** glass ceramic filler (particle size 1 μm), silicon dioxide nanoparticles (20-40 nm), Bis-GMA, Bis-EMA, TEGDMA, initiators, inorganic pigments, BHT	-Apply the composite resin material in one increment and light cure for 20 seconds.

Abbreviations: *Bis-GMA: bisphenol-A-diglycidyl methacrylate; TEGDMA: triethyleneglycol dimethacrylate; S-PRG filler, surface pre-reacted glass-ionomer filler; UDMA, urethane dimethacrylate; DCP, tricyclodecan-dimethanol dimethacrylate; PEG-400 DMA, polyethylene glycol 400 dimethacrylate; DMA, dimethacrylate;* GIC, glass ionomer cement; Bis-EMA, *ethoxylated bisphenol-A dimethacrylate*; BHT, *butylhydroxytoluene*.

day of service for materials in the oral conditions. After 24 hours, the specimens were removed from distilled water and dried. Next, the upper surfaces of all the specimens were polished with medium (15 seconds), fine (15 seconds), and superfine (15 seconds) aluminum oxide-impregnated discs (Sof-Lex, 3M Oral Care, St. Paul, MN, USA), respectively, with a 10,000 rpm micromotor set to low speed and moved with a one-way rotation under light hand pressure and dry conditions. A new disk was used for each sample. For the chemically activated materials, surface coatings were applied as recommended by the manufacturers. The unpolished lower surfaces of each specimen were marked with a code name to identify each sample.

The prepared specimens were randomly divided into two subgroups (n=13). Half of the specimens in each group were stained after the baseline measurements. The other half were aged immediately after the baseline evaluations. The flow diagram of the study is shown in Figure 1.

Aging of the specimens

Half of the specimens in each group were thermal loaded (n=13, Figure 1). The specimens were

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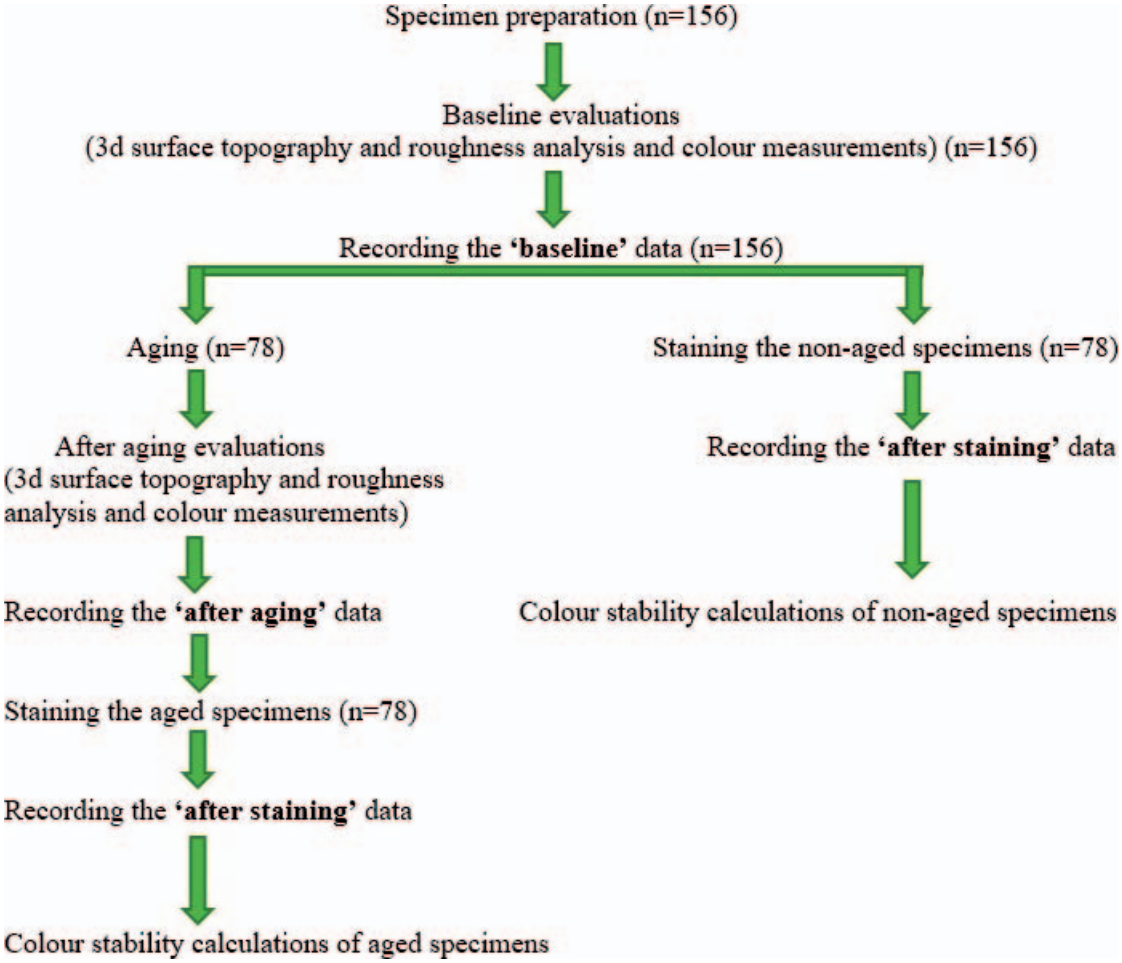

Figure 1. *The flow diagram of the study.*

subjected to 20,000 thermal cycles between 5°C and 55°C with a 60-second dwell time using a thermal cycler device (ModDental, Esetron Smart Robotechnologies, Ankara, Turkey).

Staining of the specimens

Coffee solution was selected for staining. The solution was prepared by adding a spoonful of soluble coffee (Nescafe Classic, Nestle, Vevey, Switzerland) to 250 ml of boiling water, which was then stirred and cooled to room temperature. The staining process was conducted at room temperature with daily 3-hour coffee immersion periods, followed by daily storage in distilled water for 28 days (Figure 1).[1] The specimens from each group were placed in separate containers, and the coffee solution in each container was changed daily. The stained specimens were removed from the solution and washed for 10 seconds with distilled water, then dried with paper for 10 seconds before the color measurements.

Surface roughness measurement

To determine the surface roughness, a three-dimentional (3D) noncontact optical profilometer (PS50, Nanovea, Irvine, CA, USA) was used. An area of 1 × 1 square millimeter was used for the roughness analysis. The scanning process was conducted in steps of 5 μm for both X and Y directions with a 5 mm/s velocity. The evaluations of 3D surface roughness were completed using Mountains Software Version 6.2.7487 (Digital Surf, Besançon, France). Profile roughness lines were taken from the 3D scanned surfaces.

A surface roughness recording was made after specimen preparation (baseline) and after aging (Figure 1).

Color evaluation

Color measurements were performed with a dental spectrophotometer (VITA EasyShade Advance 4.0, VITA Zahnfabrik, Bad Säckingen, Germany). The device was calibrated before starting and after com-

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Table 2: *The Surface Roughness Values (R_a) For Each Group at Each Evaluation Point, Intergroup and Intragroup Comparisons p-Values, and Significant Pairs*

Groups		Surface Roughness Values: Baseline R_a Values (After Polishing)	Surface Roughness Values: After Aging R_a Values	Intergroup Comparisons *p*-Values
Alkasite (CN)	Mean ± SD	0.087 ± 0.006	0.139 ± 0.005	0.0001*
	Med (min-max)	0.085 (0.080-0.094)	0.137 (0.130-0.148)	
Ormocer (AF)	Mean ± SD	0.065 ± 0.004	0.120 ± 0.005	0.0001*
	Med (min-max)	0.064 (0.058-0.072)	0.121 (0.112-0.131)	
Giomer (BF)	Mean ± SD	0.084 ± 0.005	0.135 ± 0.004	0.0001*
	Med (min-max)	0.083 (0.077-0.091)	0.136 (0.127-0.142)	
High Viscosity Glass Ionomer (EF)	Mean ± SD	0.128 ± 0.005	0.203 ± 0.005	0.0001*
	Med (min-max)	0.128 (0.121-0.135)	0.203 (0.195-0.211)	
Glass Carbomer (GF)	Mean ± SD	0.230 ± 0.004	0.682 ± 0.004	0.001*
	Med (min-max)	0.229 (0.225-0.236)	0.681 (0.676-0.689)	
Nanohybrid Composite (GS)	Mean ± SD	0.077 ± 0.005	0.129 ± 0.007	0.0001*
	Med (min-max)	0.075 (0.072-0.087)	0.129 (0.116-0.139)	
Intragroup comparisons p values		0.0001**	0.0001**	
Significant pairs		AF & GS, AF & BF, **AF & CN**, AF & EF, AF & GF, GS & BF, **GS & CN**, GS & EF, GS & GF, BF & EF, BF & GF, **CN & EF**, **CN & GF**, EF & GF	AF & GS, AF & BF, **AF & CN**, AF & EF, AF & GF, GS & BF, **GS & CN**, GS & EF, GS & GF, BF & EF, BF & GF, **CN & EF**, **CN & GF**, EF & GF	

*Paired samples t-test and repeated-measures ANOVA, $p<0.05$.
**One-way Analysis of Variance (ANOVA), the post hoc Tukey test, $p<0.05$.

pleting the measurements of every five specimens. The specimens were placed on a standardized flat white floor (Leneta Company, Mahwah, NJ, USA) inside of a black box. Doing so ensured that the spectrophotometer was the only source of illumination. The tip of the spectrophotometer was placed perpendicular to the specimen surface. Color recordings were taken after specimen preparation (baseline), after aging, and after the staining of both the nonaged and aged specimens (Figure 1). All color measurements were conducted by the same operator (BY).

Three measurements were taken from each specimen, and the averages of the obtained L^*, a^*, and b^* values were recorded. The total color difference (ΔE) for each specimen was calculated using the following equation:

$$\Delta E^* = [(\Delta L*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{1/2}$$

where $\Delta L^* = L(\text{Final}) - L(\text{Initial})$, $\Delta a^* = a(\text{Final}) - a(\text{Initial})$, and $\Delta b^* = b(\text{Final}) - b(\text{Initial})$.

Statistical analysis

Shapiro-Wilk tests were used for testing normality. A one-way analysis of variance (ANOVA) was used for comparisons among the groups. The post hoc Tukey test was used when the ANOVA determined a significant difference. For pairwise comparisons, a paired samples *t*-test and repeated measures ANOVA were used. All statistical analyses were conducted with the IBM SPSS Statistics 25.0. A *p*-value of <0.05 was considered significant.

RESULTS

Surface roughness results

Table 2 presents the surface roughness values (R_a) for each group at each evaluation point, the *p*-values of surface roughness for intragroup comparisons (between evaluation points), and intergroup comparisons in each evaluation point and significant pairs. Table 3 presents the values of increased surface roughness (ΔR_a) after aging for each group and *p*-values of ΔR_a for intragroup comparisons and significant pairs.

At both evaluation points (baseline and after aging), the surface roughness of alkasite was significantly higher than ormocer and nanohybrid composite and significantly lower than high viscosity glass ionomer and glass carbomer ($p<0.05$, Table 2).

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Table 3: *The Surface Roughness Increase Values (ΔR_a) after Aging for Each Group and Intragroup Comparisons p-Values and Significant Pairs*

Groups		Roughness Increase Values After Aging ΔRa values ($R_{aAfter\ aging\ -Baseline}$)
Alkasite (CN)	Mean ± SD	0.052 ± 0.007
	Med (min-max)	0.056 (0.041-0.063)
Ormocer (AF)	Mean ± SD	0.056 ± 0.006
	Med (min-max)	0.057 (0.04-0.062)
Giomer (BF)	Mean ± SD	0.051 ± 0.008
	Med (min-max)	0.055 (0.037-0.064)
High Viscosity Glass Ionomer (EF)	Mean ± SD	0.075 ± 0.008
	Med (min-max)	0.057 (0.04-0.062)
Glass Carbomer (GF)	Mean ± SD	0.452 ± 0.007
	Med (min-max)	0.450 (0.443-0.463)
Nanohybrid Composite (GS)	Mean ± SD	0.053 ± 0.001
	Med (min-max)	0.053 (0.029-0.064)
Intragroup comparisons *p*-values		0.0001*
Significant pairs		AF & EF, AF & GF, GS & EF, GS & GF, BF & EF, BF & GF, **CN & EF**, **CN & GF**, EF & GF

*One-way analysis of variance (ANOVA), the post hoc Tukey test, $p<0.05$.

Furthermore, at baseline and after aging, alkasite and giomer presented similar roughness values ($p>0.05$, Table 2).

The aging led to a statistically significant increase in roughness values of all groups ($p<0.05$, Table 2). The amount of increase (ΔR_a) in the roughness of alkasite was the lowest and was statistically similar to the ΔR_a values of giomer, ormocer, and nanohybrid composite ($p>0.05$, Table 3), followed by the ΔR_a values of high viscosity glass ionomer and ΔR_a values of glass carbomer ($p<0.05$, Table 3).

Figure 2 presents the surface topography images of the alkasite material at baseline (2a) and after aging (2b). Additionally, Figure 3 presents the surface topography images of the glass carbomer material at baseline (3a) and after aging (3b). The surface topography of all the specimens was observed to be rougher after aging. Similar topographic images were obtained in the other groups, except glass carbomer. The glass carbomer group showed higher surface deterioration, and, in some areas, cleavages were observed.

Color stability results

Table 4 shows the values of color change after aging ($\Delta E_{\text{AFTER AGING-BASELINE}}$), after staining of nonaged specimens ($\Delta E_{\text{AFTER STAINING-BASELINE}}$), and after staining of aged specimens ($\Delta E_{\text{AFTER STAINING-AFTER AGING}}$) for each group, and the p values of color change values for intragroup comparisons and significant pairs.

After aging and staining of both nonaged and aged specimens, the color change of alkasite was found to be higher than ormocer and nanohybrid composite ($p<0.05$, Table 4), similar to the color change of giomer ($p>0.05$, Table 4), and lower than the color change of high-viscosity glass ionomer and glass carbomer ($p<0.05$, Table 4).

Staining with coffee caused more color differences than aging ($p<0.05$).

DISCUSSION

Surface roughness

Based on the results of the present study, our first null hypothesis was rejected, since the surface roughness increased in all of the groups after aging.

The current study used a 3D noncontact optical profilometer, which had a higher resolution than a mechanical stylus and eliminated the possibility of surface damage from contact with a mechanical sensor that could cause errors in the results.[16] In our study, the R_a values measured after polishing (at baseline) ranged from 0.065 μm to 0.230 μm. Although a threshold for unacceptable surface roughness has not yet been agreed on, it has been reported that an R_a above 0.2 μm results in an increase of plaque accumulation and a higher risk for caries.[17] Other reports found that when the R_a was lower than 0.3 μm, the surfaces were visibly smooth.[18]

Studies have used various methods to simulate the aging of materials, such as cyclic loading, water storage, and thermal cycling. The recommended thermal cycle time ranges from 3000 to 100,000 cycles.[19] It has been reported that 10,000 cycles may represent a 1-year usage period.[20] In our study, 20,000 cycles, which are clinically equivalent to about 2 years of wear, were used for the aging process.

During thermal cycling, the resin matrix absorbs water.[21] The hygroscopic expansion caused by this water absorption accelerates the weakening of the matrix–filler interface. Then, the thermal cycles cause repeated shrinkages and expansions due to

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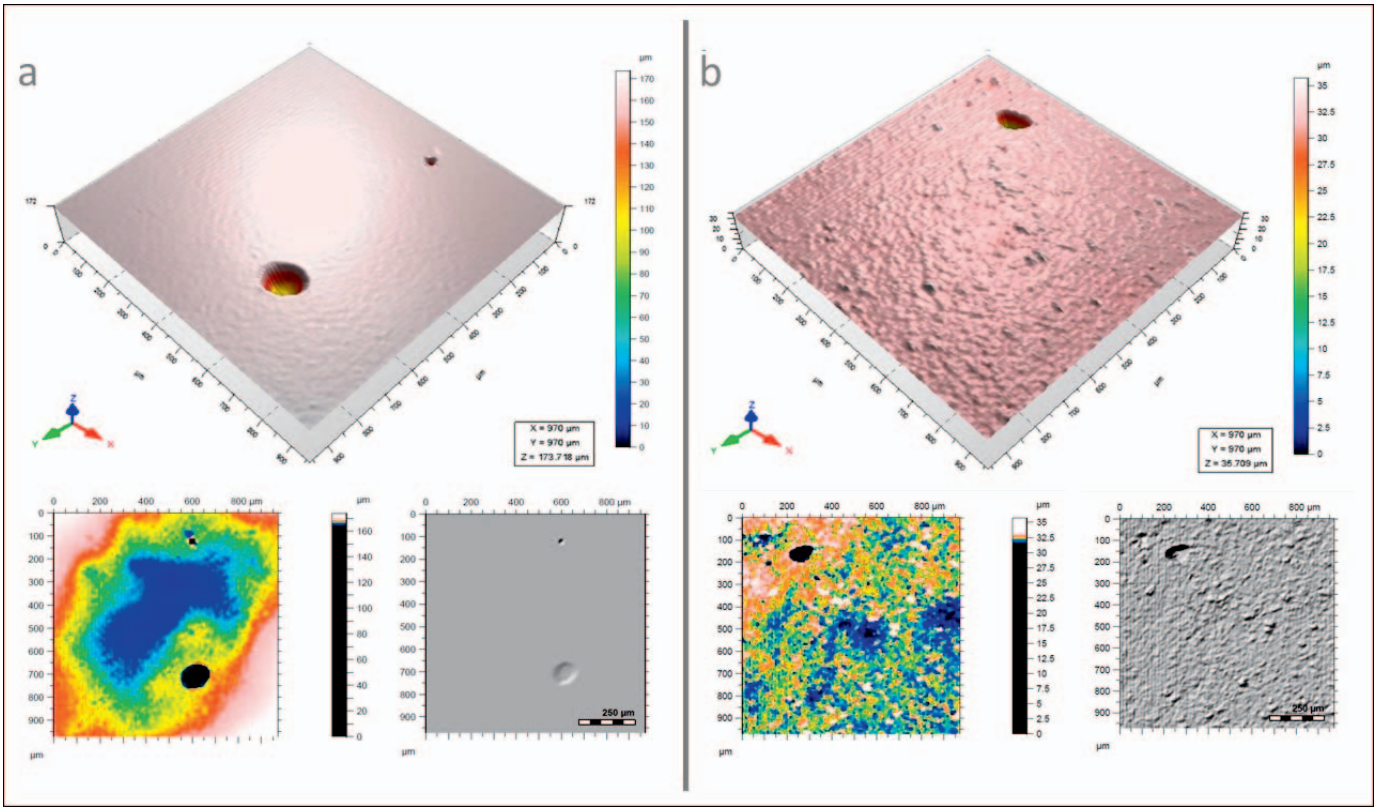

Figure 2. *Three-dimensional (3D) Optical Profilometery images: a) Surface topography of an alkasite at baseline, b) surface topography of an alkasite after aging.*

differences in the thermal expansion coefficient or thermal conductivity coefficient between the resin matrix and filler particles. As a result, the filler particles become disjoined.[22]

In this study, the alkasite material exhibited a smoother surface than glass ionomer-based materials and a rougher surface than composite resins at baseline and after aging. According to the studies evaluating the surface roughness of the alkasite material, similar to the results of our study, the surface roughness of the alkasite was higher than that of nanohybrid composite at baseline (after polishing).[9] The greater roughness of the alkasite material compared to the nanohybrid composite at baseline (after polishing) might be the result of greater average particle sizes of the Cention N fillers (0.1-35 µm)[23] than composite fillers (0.1-1.0 µm).[24]

However, different from the results of the present study, the mechanical aging (50,000 cycles in chewing simulator) was reported to affect the surface roughness of nanohybrid composite more than the alkasite.[9] In our study, the samples were aged with a thermal cycle. The rougher surface of the alkasite material than nanohybrid composite after thermal cycling may be due to the high ion release property of the material. Water diffusion capacity caused by the ion release property of the material may cause a chemical degradation and de-bonding of the matrix.

According to our results, the surface roughness and surface characteristic of alkasite was between the composite resins and glass ionomer-based materials after aging. The smoother surface of alkasite when compared with the glass ionomer-based materials may be explained by the dissolution of the matrix surrounding the glass particles in the glass ionomers [1,25]. Also, the relatively higher ΔR_a values of the glass ionomer-based materials when compared to alkasite and composite resins may be due to their water absorption capacity.

In the present study, the alkasite material was affected by the aging process as were nanohybrid composite, ormocer, and giomer in terms of surface roughness, which clinically approximated 2 years of aging. However, the aging process affected the surface characteristics of glass ionomer-based materials more than alkasite and composite resins. This result can be interpreted as the alkasite material presenting some structural properties similar to

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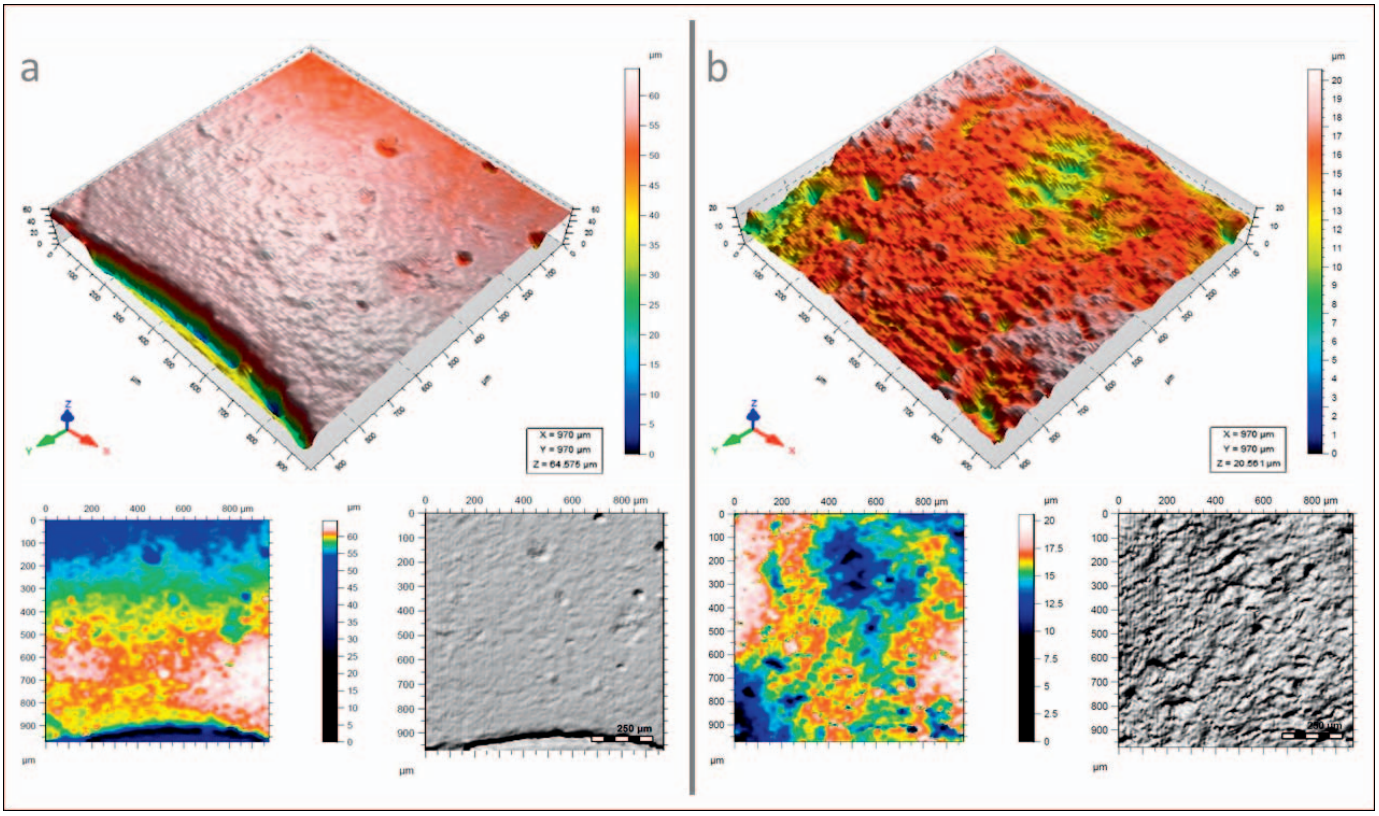

Figure 3. *Three-dimensional (3D) Optical Profilometery images: a) Surface topography of glass carbomer at baseline, b) surface topography of glass carbomer after aging.*

composite resins depending on its composition. Cention N is a dual-cure restorative material that contains urethane dimethacrylate (UDMA) in the liquid. UDMA creates rigid networks, and its stronger mechanical properties may be attributed to its higher viscosity and lack of hydroxyl side groups, which are hydrophobic in nature and consequently exhibit lower water absorption rates.[26] This restorative material includes a patented filling, which is partially silanized, reducing the contraction stress to a minimum.[27] When attached to the filler particles, silanes improve the connection between the inorganic filler (the particles of glass and quartz) and the matrix, since they can establish a chemical bond between the surface of the glass and the matrix.[28]

Color stability

Within an oral environment, restorative materials are constantly exposed to staining by food and beverage colorants as well as changes in temperature and pH.[29] This exposure results in a series of extrinsic and intrinsic changes in the materials, ultimately affecting the materials' physical, mechanical, and esthetic properties.[30]

Our second hypothesis and our third hypothesis were rejected, since not all of the materials reacted in the same way. After aging and staining, whether aging was performed or not, the color change of the alkasite material was higher than that of ormocer and nanohybrid composite, similar to the color change of giomer and lower than the color change of glass ionomer-based restorative materials.

It is currently accepted that a color difference of $\Delta E<1.0$ is imperceptible to human eye, while values of $\Delta E>3.3$ are regarded as clinically unacceptable.[29] In our study, only ormocer and nanohybrid composite presented clinically acceptable ΔE values after thermocycling (20,000 cycles), and the novel alkasite material showed clinically unacceptable color changes after aging. Although there are no other studies in the literature to support the results, alkasite was found to be less successful in this study in terms of color stability than composite resin and ormocer. This result may be associated with the absorption of large amounts of water that may cause a chemical degradation of the material, a de-bonding of the matrix, and the release of residual monomers. The ion release from a restorative material is known to be mediated by its capacity for water diffusion.

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Table 4: *The Color Change (ΔE) Values for Each Group, Intragroup Comparisons p-Values, and Significant Pairs*

Groups		ΔE Values		
		$\Delta E_{\text{AFTER AGING-BASELINE}}$	$\Delta E_{\text{AFTER STAINING-BASELINE}}$	$\Delta E_{\text{AFTER STAINING-AFTER AGING}}$
Alkasite (CN)	Mean ± SD	4.44 ± 0.158	9.01 ± 0.169	7.97 ± 0.23
	Med (min-max)	4.33 (4.26-4.66)	9.06 (8.76-9.28)	8.05 (7.64-8.28)
Ormocer (AF)	Mean ± SD	2.34 ± 0.077	6.25 ± 0.129	5.86 ± 0.144
	Med (min-max)	2.31 (2.25-2.48)	6.22 (6.12-6.54)	5.92 (5.58-6.01)
Giomer (BF)	Mean ± SD	3.83 ± 0.154	8.81 ± 0.134	7.32 ± 0.223
	Med (min-max)	3.87 (3.64-4.15)	8.84 (8.56-8.98)	7.32 (6.93-7.64)
High-Viscosity Glass Ionomer (EF)	Mean ± SD	6.19 ± 0.089	11.41 ± 0.175	9.40 ± 0.114
	Med (min-max)	4.33 (4.26-4.66)	9.06 (8.76-9.28)	8.05 (7.64-8.28)
Glass Carbomer (GF)	Mean ± SD	8.26 ± 0.132	14.99 ± 0.104	12.03 ± 0.172
	Med (min-max)	8.25 (8.05-8.46)	14.99 (14.75-15.19)	12.04 (11.75-12.24)
Nanohybrid Composite (GS)	Mean ± SD	2.57 ± 0.097	6.41 ± 0.281	4.74 ± 0.19
	Med (min-max)	2.57 (2.39-2.76)	6.32 (6.12-7.25)	4.81 (4.42-5.01)
Intragroup comparisons p values		0.0001*	0.0001*	0.0001*
Significant pairs		AF & BF, **AF & CN**, AF & EF, AF & GF, GS & BF, **GS & CN**, GS & EF, GS & GF, BF & EF, BF & GF, **CN & EF**, **CN & GF**, EF & GF	AF & BF, **AF & CN**, AF & EF, AF & GF, GS & BF, **GS & CN**, GS & EF, GS & GF, BF & EF, BF & GF, **CN & EF**, **CN & GF**, EF & GF	AF & BF, **AF & CN**, AF & EF, AF & GF, GS & BF, **GS & CN**, GS & EF, GS & GF, BF & EF, BF & GF, **CN & EF**, **CN & GF**, EF & GF

*One-way analysis of variance (ANOVA), the post hoc Tukey test, $p<0.05$.
*$\Delta E_{\text{AFTER AGING-BASELINE}}$: Colour change after aging.
*$\Delta E_{\text{AFTER STAINING-BASELINE}}$: Colour stability of nonaged specimens.
*$\Delta E_{\text{AFTER STAINING-AFTER AGING}}$: Colour stability of aged specimens.

On the other hand, although alkasite is an ion-releasing material, in this study it was found to be more successful than glass ionomer-based materials in terms of color stability. In another laboratory study, parallel with the results of this study, Cention N showed a higher color stability than glass ionomers.[14] It is thought that the results obtained may be due to the differences of the setting reaction of the alkasite material from the setting reaction of glass ionomers. In addition, alkasite does not contain polyacrylic acid. Also, satisfying color stability in alkasite can be attributed to the presence of resin components in its composition.

In the present study, coffee was used for staining due to its high capacity. According to Guler and others,[31] the average time for consumption of 1 cup of coffee is 15 min, and, among coffee drinkers, the average consumption is 3.2 cups per day. Therefore, 15 days of storage was approximately equal to 1 year of coffee consumption.

The present study was a laboratory study. Therefore, one of the limitations was that it did not precisely simulate clinical conditions. Moreover, the aging was only performed with thermal cycling. The responses of these materials to mechanical loads were not evaluated. Consequently, further clinical studies are needed to expand the clinical applications of the tested materials.

CONCLUSIONS

Within the limitations of this study, the following conclusions were reached:

- The alkasite material performed better than glass ionomer-based materials, in terms of surface roughness and color stability after aging.
- At baseline (after polishing) and after aging, the surface of the alkasite material was found to be rougher than nanohybrid composite and ormocer surfaces. However, in terms of increased roughness caused by aging, the ormocer, nanohybrid composite, and the alkasite material were affected in a similar way.
- In terms of color stability, the alkasite material was more colored than nanohybrid composite and ormocer, and performed similar to giomer.

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Conflicts of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this manuscript.

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