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Sealing of Minimally Invasive Class II Fillings (slot) Using an Adhesive Patch: Sealant Margin Extension for Prevention

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Clinical Relevance

The sealing of minimally invasive restorations using a prefabricated adhesive patch significantly reduces leakage and caries formation.

SUMMARY

A laboratory study was performed to assess the potential of an adhesive patch to seal small, unbeveled, Class II, box-only (slot) composite fillings.

After minimal access cavity preparation with an 80 µm diamond bur, 40 box-only Class II cavities were prepared mesially and distally in 20 extracted human molars using a u-shaped PCS insert (EMS). One cavity per tooth was adhesively filled with a hybrid composite material in one increment. A patch, acting as an adhesive matrice, was applied to the other cavity of each tooth to seal the restoration. The margin of the patch was located in areas easily accessible to oral hygiene measures and self-cleaning. All the teeth were subjected to thermo-mechanical stress in a computer-controlled masticator device. In 10 teeth, caries was induced in a microbial-based artificial mouth model and quantitatively determined by confocal laser scanning microscopy. Microleakage was assessed in the other 10 teeth in two planar sections after immersion in 0.5% basic fuchsin solution.

The results showed no demineralization at the filling margins protected with the patch. Microleakage was observed in one sample only and was limited to the enamel. In contrast, the margins of fillings without the patch application showed a mean demineralization depth of 146 ± 42 µm and dye penetration into the dentin in five sections.

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This innovative approach to sealing restorative margins with an adhesive patch results in less leakage and filling margin demineralization and merits further investigation.

INTRODUCTION

The treatment of primary approximal caries has been challenged in recent years, and more conservative forms of treatment, which focus on both tooth preservation and restoration longevity, have been recommended.[1] The challenges of minimally invasive preparations due to limited access include the difficulties that control excavation, finish the margins and fill the cavity.[2-3] A further problem is polymerization shrinkage, which may initiate failure of the composite–tooth interface and result in interfacial gaps. This can lead to microleakage, marginal discoloration and secondary caries.[4] Several minimally invasive restoration forms and placement techniques have been introduced. The preparation of a bevel at the margins has been suggested to improve the bonding surface and reduce gap formation and microleakage.[5-6] Oscillating preparation systems that avoid damage to the adjacent teeth have also been proposed.[7-8] Nevertheless, it must be acknowledged that, despite beveling, a remarkable loss of marginal integrity can be observed in small, box-only Class II (slot) fillings.[9] Incremental placement of light-activated resin composite has been recommended to decrease overall contraction. In small cavities, however, the adaptation of multiple layers is difficult and may lead to trapped air, which is an additional weak link.

An adhesive patch (prototype patch, Ivoclar Vivadent, Schaan, Liechtenstein), especially designed to seal smooth enamel surfaces, has recently been developed.[10] It is a methacrylic, elastic, cross-linked, urethane-based polymer material approximately 80-100 µm thick. Upon light exposure in the wavelength of 400 to 500 nm (blue light), full polymerization of the methacrylic groups occurs, rendering the patch hard and solid. As a result, it can copolymerize with other resin-based dental materials. The same prototype patch has already proved to be an excellent sealant with caries-protective properties and abrasion resistance when used for smooth surface sealing.[11-12]

This study assessed the marginal quality of sealed, small, box-only Class II composite restorations without marginal beveling when placed in combination with this adhesive patch. The authors hypothesized that, by using this prefabricated polyurethane foil acting as an adhesive matrice, the filling could be sealed, and caries formation and leakage at the primary filling margins could be effectively eliminated. This leads to a conceptual "sealant margin extension for prevention" approach, which creates secondary margins on areas of the tooth that are more accessible to self-cleaning.

METHODS AND MATERIALS

Tooth Selection, Cavity Preparation and Filling Procedure

Twenty human molars from the department's collection of extracted teeth were mounted centrally to roughened SEM mounts (Baltec AG, Balzers, Liechtenstein) with super glue (Renfert Sekundenkleber Nr 1733, Dentex AG, Zurich, Switzerland) and fixed with chemically cured acrylic resin (Paladur, Heraeus Kulzer GmbH, Wehrheim, Germany) (Figure 1A). The occlusal aspects of the teeth were ground flat to ensure a standardized approximal cavity size. Dentin fluid pressure was stimulated according to Krejci and others.[13] Undersized Class II access cavities with cervical margins located in enamel were prepared mesially and distally with water-cooled coarse diamond burs (80 µm, FG8614, Intensiv SA, Viganello, Switzerland). The cavity margins were then finished using a selective diamond-coated u-shaped ultrasonic tip to prepare non-beveled cavities (PCS, EMS, Nyon, Switzerland) applied by an ultrasonic device (Master Piezon, EMS, Nyon, Switzerland) at medium energy (Figures 1B and 1C). All preparations were made with low application pressure and water-cooling (2 x 3 x 1.6 mm).

The enamel was etched with 35% phosphoric acid (Ultraetch, Ultradent, South Jordan, UT, USA) for 30 seconds, then rinsed with water spray for 20 seconds (Figure 1D). After careful drying of the cavities with air, self-conditioning maleic acid containing Primer (Syntac Primer, Ivoclar-Vivadent AG, Schaan, Liechtenstein) was applied for 15 seconds and gently air-dried before the application of a second primer (Syntac Adhesive) for 20 seconds. After gentle air application, an unfilled bonding resin (Heliobond, Ivoclar Vivadent) was applied for 20 seconds and light-cured for 40 seconds (Optilux 500, Demetron Kerr Inc, Danbury, CT, USA). Before filling placement, one cavity per tooth was randomly allocated to the filling technique with or without patch application. In one cavity per tooth, the filling (Tetric A2, Ivoclar Vivadent) was placed in one increment against a metal matrice that was light-cured for 60 seconds. The patch (6 x 4 mm) was firmly adapted to the enamel of the other cavity (Figures 1E and 1F) and was also light-cured for 60 seconds. The resin composite material was then placed in bulk, while the patch acted like a matrix (Figure 1G) and again was light-cured for 60 seconds.

Contouring, finishing and polishing of the fillings was performed under a stereomicroscope (Stemi 1000, Carl Zeiss AG, Oberkochen, Germany) at 12x magnification. Flexible abrasive discs (Sof-Lex, 3M ESPE, Seefeld, Germany) and abrasive polishing brushes (Occlubrush, Hawe Neos) were used under water-cooling. In the patch group, great care was taken not to abrade the patch, but rather to smooth and remove any excess material.

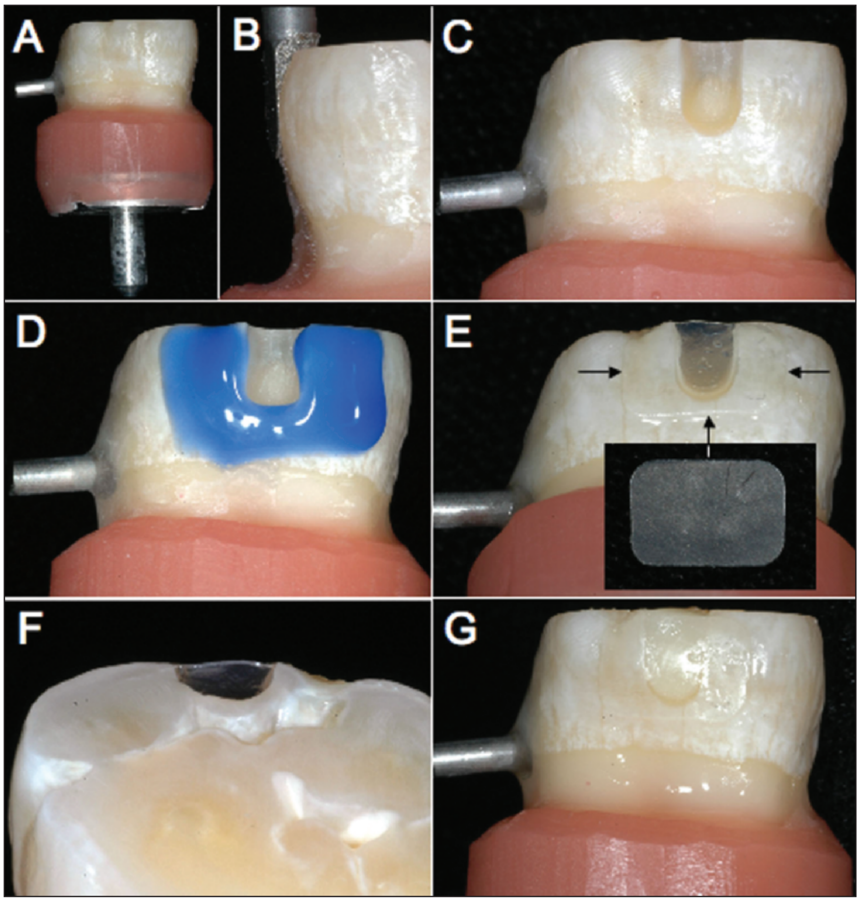

Figure 1. *Illustration depicting the patch application: The teeth were fixed in SEM mounts (A) and a standardized box-only Class II slot was prepared (B,C). After application of phosphoric acid to enamel (D) and conditioning of the dentin with a three-step adhesive system, the patch was firmly adapted to the cavity margins (E), acting as a matrix (F): view of the occlusal surface. The resin composite was applied in one increment (G).*

Thermomechanical Loading

Caries-free palatal cusps were used as antagonists. The test specimens were loaded in the center of the occlusal surface of a computer-controlled masticator device (CoCoM 2, PPK) with 49 N at 1.7 Hz and simultaneous thermal stress with temperature changes of 5°C and 50°C for five equivalent years (1,200,000 cycles).[14] After this thermomechanical loading phase, 10 specimens were transferred into an *in vitro* bacterial-based caries model, while the remaining 10 samples were used for microleakage evaluation.

In Vitro Caries Formation and Evaluation

The bacterial-based *in vitro* caries model consisted of a custom-made reaction chamber in which the test specimens were mounted on the outer rim of a specimen turntable for incubation. A biofilm formed from *Streptococcus mutans* medium ensured the development of caries-like enamel lesions (for details see Seemann & others).[15]

The specimens were separated from the SEM mounts, cut in half bucco-orally and mounted on the specimen turntable of the device to expose the approximal surface. A stainless steel pin was fixed in the pulp chamber with resin composite (Tetric, Ivoclar Vivadent). A custom-made positioning device assured the central position of the pin, thus positioning the approximal filling surfaces of all teeth on the same level. Before entering the *in vitro* caries model, the teeth were sterilized using ethylene oxide.[15]

Over a period of 21 days, the specimens received a continuous treatment regime of trypticase soy broth (TSB) (Becton Dickinson, Sparks, MD, USA) for five minutes, followed by 15 minutes of artificial saliva. A 10% sucrose solution was applied for five minutes every hour instead of TSB solution. All fluids were applied by dripping, with a perfusion rate of 0.4 mL/minute. Operation of the peristaltic pumps (Alitea, model XV; Watson Marlow Alitea, Stockholm, Sweden) was regulated with a custom-made computer-controlled switch. After seven days, the teeth were infected by dripping 30 mL of *S mutans* (ATCC 25175) inoculum through an additional inlet pipe in a manner similar to transfer of the other media (0.4 mL/minute). To prepare the inocula, *S mutans* was first grown on blood agar plates for three days. Single colonies were transferred to 30 mL of TSB and incubated anaerobically at 37°C overnight (approximately 10^9 cells/ml). During the inoculation procedure, the addition of all other media was stopped.

This procedure was repeated after one week. Plaque was removed from the specimens with a soft-bristle toothbrush and buffered saline, and the teeth were transferred to 50 mL Falcon tubes filled with sterile buffered saline until they were examined for caries.

During the experiment, samples of waste fluid were taken each week for bacterial analysis in order to confirm the purity of the *S mutans* cultures. The samples were plated on Columbia blood agar (Sifin GmbH, Berlin, Germany) and mitis–salivarius bacitracin agar (20% sucrose and 200 IU/L bacitracin, BD Difco) and were incubated anaerobically at 37°C for three days. If necessary, media bottles and waste containers were exchanged.

All the teeth were then imbedded in PMMA resin (PalaXpress, clear; Heraeus Kulzer). After the resin had set, the specimens were cut horizontally using a 100-

µm-thick diamond saw (Zeitz 1600; Ernst Zeitz, Wetzlar, Germany). Two sections 0.5 mm thick were polished with silicon carbide paper (4000 grit). Based on the method described by Fontana and others,[16] sections were analyzed using a confocal laser scanning microscope (Zeiss LSM 510; Carl Zeiss, Jena, Germany) without staining in order to measure autofluorescence of the demineralization.[20] Using the measuring tool of the Zeiss LSM 510 image browser software (Carl Zeiss), demineralization depth was measured at the margins of the patch and filling. Undermining caries formation under the patch was also evaluated (Figure 2).

Microleakage Assessment

The apices of the embedded teeth were sealed with sticky wax, and the samples were coated with two consecutive layers of nail varnish up to 1 mm from the filling/patch margins. The samples were then immersed in 0.5% fuchsin solution (Fluka, Buchs, Switzerland) for 20 hours. After rinsing thoroughly with distilled water, the samples were air-dried and embedded in epoxy resin (Struers, Copenhagen, Denmark). Two parallel longitudinal sections were made parallel to the occlusal plane by using a kerosene-cooled low-speed diamond saw (Isomet, Buehler, Lake Bluff, IL, USA). Digital photographs of each section were obtained at 20x (1280x1024 resolution) under a stereomicroscope (Olympus, Tokyo, Japan). Photographs were taken at 3.2x and 6.4x (Leica Dialux 20 and ProgRes C14, Jenoptik, Jena, Germany) and electronically captured and evaluated (Image Access, Imagic, Glattbrugg, Switzerland). The degree of leakage at the filling margin was determined based on an ordinal ranking system (0-3) as follows:

0) no leakage
1) leakage limited to the enamel
2) leakage reaching the dentin, but limited to the lateral axial wall
3) leakage along the full length of the lateral axial wall, reaching the pulpo-axial surface

Two readings were taken per slice (at both lateral axial walls) but only the higher leakage score was used for further analyses.

Data Presentation and Analysis

Statistical analysis was performed with StatView (Version 5, Abacus Concepts Inc, Berkeley, CA, USA). Results of the confocal scanning laser microscope (CLSM) were illustrated with box plots. The mean values and standard deviations were calculated and the Student's paired *t*-test was used for statistical analysis. The normal distribution was analyzed using the Kolmogorov–Smirnov test.

For microleakage evaluation, an additional score frequency table was presented. The results were grouped for statistical analysis using the Kruskal-Wallis nonparametric tests. A Wilcoxon signed rank test was used to compare leakage for the two restoration groups.

For all statistical analyses, the level of significance was set at 95%.

RESULTS

Caries Formation

Results of the caries formation are depicted in Figures 2 and 3.

In all samples, demineralization could be visualized as a green fluorescent line within the unprotected enamel and at the tooth-restoration or tooth-patch interfaces (Figure 2). In two samples with the patch, inadequate sealing was evident as aliform elevation of the patch (Figure 2 B-C). Whereas delamination was unilateral in one sample, both axial aspects were affected in the other sample. The maximal undermining demineralization length observed was 255 µm but did not reach the filling margin. The other eight samples with the patch showed good adaptation and no undermining caries formation. The demineralization depth at filling margins without additional patch application had a mean demineralization depth of 146 ± 42 µm (Figure 3). When a patch was used, no demineralization was observed. The demineralization depth at the patch margins was 96 ± 23 µm.

Microleakage

The median microleakage score at the filling margins was 1 for the filling only and 0 for the filling/patch group (Figure 4). The two groups showed a statistically significant difference (p=0.0042). Seven sections in the filling-only group showed no leakage, eight sections had a score of 1. Noteworthy is that five sections showed complete dye penetration. In the filling/patch group, only two sections had a microleakage score of 1; whereas all other sections exhibited no signs of dye penetration.

DISCUSSION

This investigation clearly demonstrated that the use of an adhesive patch to seal filling margins is a promising approach to avoid or at least markedly reduce microleakage and caries formation in small Class II box-only (slot) fillings. The idea of adhesively occluding restorative margins is not new. The techniques of bonding and re-bonding have been recommended to increase marginal integrity.[15-16] Applying filled and unfilled low-viscosity resins to the restoration material surface and surrounding tooth structures has been proposed as a means to infiltrate possible interfacial gaps and promote sealing, thereby reducing the risk of microleakage and caries formation. The use of pit and fissure sealant materials has also been investigated. Their limited suc-

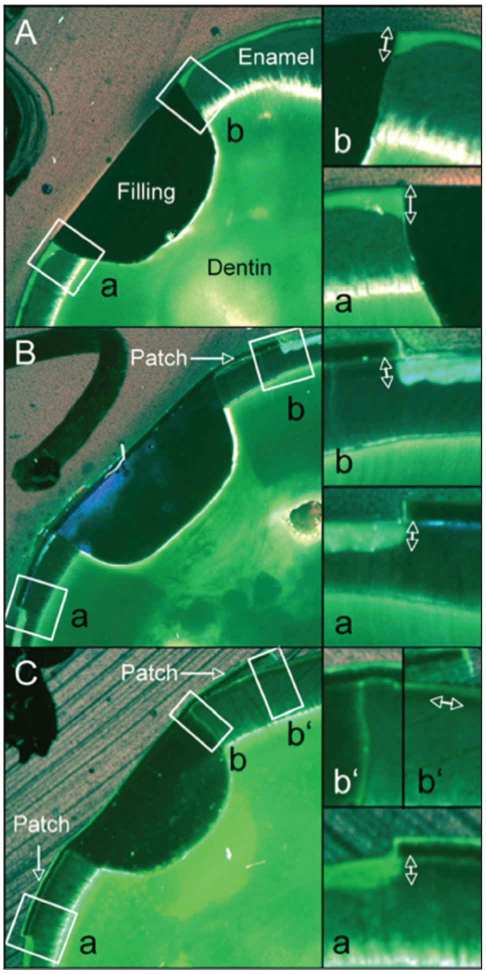

Figure 2: *Representative CLSM images visualizing demineralization as a green fluorescent line within the enamel (dark green; the dentin appears light green). Demineralization depth was measured perpendicular to the surface (two-way arrow) or parallel to the surface in case of undermining caries formation under the patch. (A) Small box-only Class II slot filling in a horizontal section. Caries formation is evident with an increasing demineralization depth pattern towards the exposed filling margin. (B) Filling protected with an adhesive patch. The demineralization front stops at the margin of the patch. No caries is evident at the filling. (C) The same technique as in B, but with unilateral inadequate sealing. However, no caries formation was evident at the filling-enamel interface.*

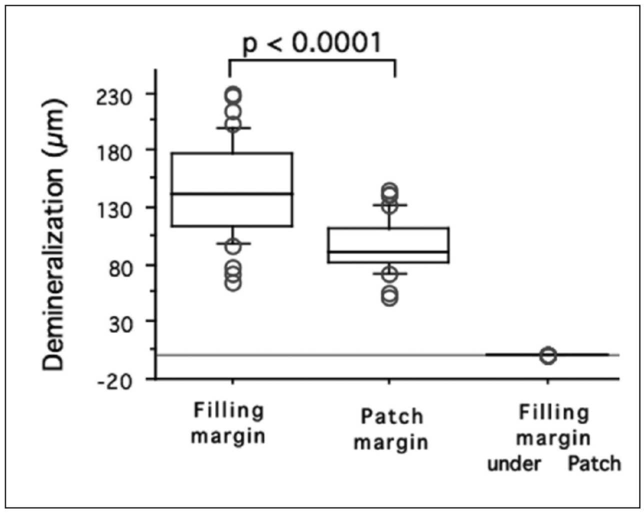

Figure 3: *Box plots depicting the demineralization depth in μm (horizontal bars: medians; boxes: inter-quartile areas; error bars: 10th and 90th percentiles; dots: extreme values). Significant differences are indicated with bar (paired* t*-test).*

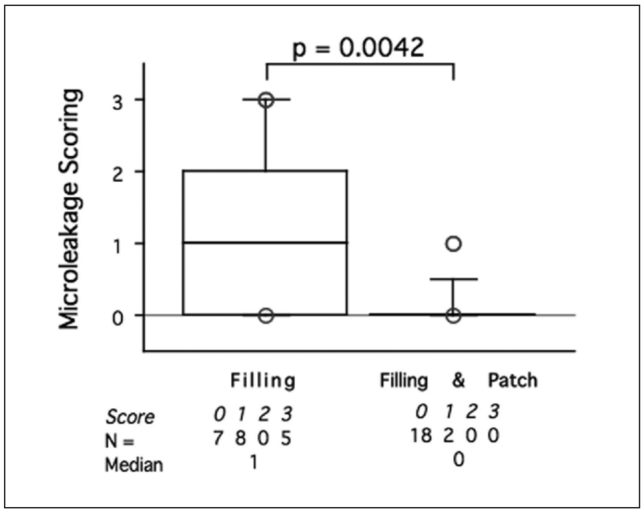

Figure 4: *Box plots depicting the microleakage score at the filling margins with and without an additional patch application. Significant differences are indicated with bar (Wilcoxon signed rank test). In addition, a score frequency table is presented to show the results in detail.*

cess has been related to polymerization contraction stress.[17-18] In a recent laboratory study, the effect of seven surface sealants on the marginal seal of mixed Class V hybrid resin composite restorations was assessed.[16] Although the results showed a significant reduction in microleakage scores and a potential for improving marginal integrity, a remarkable degree of microleakage was still noticeable. None of the tested materials was completely resistant to dye penetration. In the current investigation, only two patch samples showed signs of leakage and demineralization. In this context, it is noteworthy that no demineralization was shown at the filling margin and dye penetration was only limited to enamel. The two samples with quality loss showed macroscopically visible partial patch detachment. In all other samples, no demineralization or dye penetration was observed.

The concept of sealing smooth enamel has proven to be effective in previous laboratory studies.[10-12] Within the limitations of this evaluation, the protective potential of the adhesive patch was again confirmed.

CONCLUSIONS

Within the limitations of this laboratory proof-of-principle study, the sealing of minimally invasive cavities using a prefabricated adhesive patch can significantly reduce secondary caries formation and microleakage at filling margins. The idea presented that, sealing restorative margins with a patch whose margins are easily accessible for oral hygiene and self-cleaning, a new interpretation of "extension for prevention," is an innovative approach that merits further investigation.

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