©Operative Dentistry, 2010, **35-2**, 156-164

Clinical Evaluation of Indirect Composite Restorations at Baseline and 36 Months After Placement

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Clinical Relevance

Indirect resin composite restorations represent a good choice for the therapy of severely damaged teeth. There is no clinical difference between Ormocer and nano-hybrid resin composite after 36 months.

SUMMARY

This study determined the differences in clinical performance between materials for indirect composite restorations based on Ormocer (Admira) and nano-hybrid resin composite (Grandio), both at baseline and 36 months after placement. Modified USPHS criteria were used to analyze the degree of quality.

Marginal integrity was assessed 36 months after placement, whereupon, the restorations fabricated from Grandio achieved an Alpha 1 score of 70.7% and an Alpha 2 score of 29.3%. The Wilcoxon test revealed a statistically significant difference in the evaluation of marginal integrity (p=0.003), anatomic form of the marginal step (p=0.025) and discoloration of the margins (p=0.014) at baseline and after 36 months. For Admira, the Wilcoxon test showed statistically significant differences in the evaluation of surface texture (p=0.025), anatomic form of the complete surface (p=0.034), anatomic form of the marginal step (p=0.008), marginal integrity (p=0.002) and discoloration of the margins (p=0.008) at baseline and after 36 months.

According to the number of restorations awarded the Alpha 1 score (excellent), the over-

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DOI: 10.2341/09-133-C

all success rates for marginal integrity were 70.7% for Grandio and 71.8% for Admira; both were evaluated 36 months after placement. The results have shown that the indirect restorations were acceptable after 36 months, which indicates a 100% success rate. Over 36 months, no statistically significant differences were noted between the two materials. Indirect resin composite restorations represent a good therapy choice for severely damaged teeth.

INTRODUCTION

Current trends in esthetic dentistry necessitate tooth-colored materials that comply with the patient's desired appearance and with the postulates of contemporary dentistry. The concept of bonding a material directly onto the enamel or dentin was explained some 50 years ago,[1-2] although the first application of esthetic inlays dates back to the end of the 19th century.[3]

According to the definition, inlays are single-tooth restorations that compensate a proximal-occlusal or gingival lesion with minimal or moderate extensions, whereas onlays cover the occlusal surface with a wide mesio-occluso-distal restoration.[4]

Despite the popularity of using resin composite materials, their polymerization shrinkage during curing presents a serious problem that contributes to marginal defects, cuspal distortion, crack formation and propagation within the tooth's structures, resulting in postoperative sensitivity.[5] In an attempt to find a solution to these problems, an indirect inlay technique has been developed.[6] Polymerization shrinkage takes place outside the mouth, thus limiting the shrinkage to an acceptable level—the thickness of the luting cement layer. Also, post-curing at a high temperature results in higher stress relaxation and degree of conversion compared to the directly placed light-cured composite restoration.[7-11]

Many *in vitro* tests have been conducted to explore the durability of composite inlays and ceramic inlays under *in vitro* conditions; however, they are unable to substitute *in vivo* testing of the material.[12-14] Long-term clinical use of composite and ceramic inlays as restorative materials in the posterior region has been researched through studies.[15-33] A study by Manhart relays a 100% success rate for ceramic inlays and a 90% success rate for composite inlays two years after placement.[33] Scheibenbogen quotes success rates of 100% and 94%, respectively, for ceramic and composite inlays evaluated one year from placement, and 93% and 90%, respectively, when tested two years after placement;[22-23] while long-term research investigating such restorations at 5 and 11 years after placement showed a low rate of restoration failure.[21,28] However, there are differences in the criteria applied in the clinical evaluation of these restorations.

Therefore, clinical trials require objective, reliable and relevant criteria to assess the performance of restorations.[34-35] A method commonly used for the analysis of the clinical success of restorations is the US Public Health Service (USPHS) evaluation system,[35] originally designed to reflect differences in acceptability (yes/no) rather than differences in the degrees of success.[36]

Admira (Voco GmbH, Cuxhaven, Germany) is an Ormocer-based material introduced to dentistry in 1999. It contains three-dimensional polymerizable inorganic-organic polymer chains and aliphatic and aromatic dimethylacrylates.[37]

Ormocers are organically modified ceramic materials formed in the following way: alkoxy silane is functionalized with a polymerizable group and is subjected to hydrolysis and condensation, which brings forth an oligomeric Si-O-Si nanostructure.[38]

The manufacturer claims that the main advantages of the Ormocer material are reduced polymerization shrinkage, high wear resistance and long-lasting stability of the polymer matrix.

The current study determined whether there are differences in various aspects of clinical performance between the two materials tested—Ormocer (Admira) and nano-hybrid resin composite (Grandio) at baseline and 36 months after placement.

METHODS AND MATERIALS

A total of 71 indirect resin composite restorations were placed on permanent molars by one experienced dental professional. The sample population selected for this study consisted of 51 consenting adults, 32 male and 19 female, whose ages ranged between 16 and 23 years. The patients were selected from routine patients in the dental clinic and volunteer patients, as well as dental staff and their family members. The indications for placement of the indirect composite restorations were large, multi-surfaced cavities on permanent molars involving at least one cusp.

The patients agreed to keep their recall appointments and keep in touch with the investigators, which kept the sample size stable. Teeth with hypersensitive pulp reactions, direct pulp capping and root canal therapy were excluded from the current study.

A total of 35 restorations fabricated from Voco Admira were placed, representing the Ormocer test group. Thirty-six composite restorations fabricated from Voco Grandio were also placed and these restorations represented the composite test group. The restorations were cemented with Voco Bifix QM com-

posite cement with thixotropic properties using the ultrasonic insertion technique.

Indirect Composite Restoration Preparation

One dentist, proficient in both materials, prepared, manufactured and placed all the restorations. They were prepared according to the principles of indirect composite restoration preparation, whereby the cavity walls diverged 8-10°, which was achieved with Inlay Preparation Set #4261 (Komet Gebr, Brasseler, Lemgo, Germany). The pulp was protected with Dycal–a calcium hydroxide material (Dentsply, York, PA, USA). A glass-ionomer-based material, Fuji 9 (GC Dental Products, Tokyo, Japan), was used to replace lost dentin. The finishing lines of all cavity preparations were entirely within the enamel.

After the initial preparation with rough inlay burs, the cavity floor and walls were finished using Set #4331 fine grit inlay burs (red and yellow ring) to remove the irregularities and undercuts and make the walls divergent by 8-10°, but the enamel margins were not beveled. A bevel placed on an occlusal margin may result in thin composite on the occlusal surface in areas of potentially heavy contact. This could result in fracture or wear of the composite material in these areas. Beveled composite margins may also be more difficult to finish.[39] It was important to have a flat surface on the cavity floor and have all the walls diverge 8-10°.

Full arch impressions were taken with vinyl-polysiloxane Express putty (3M ESPE, St Paul, MN, USA) and Express regular body (3M ESPE) using a one-step impression technique in accordance with the manufacturer's instructions. Bite registration was taken with Virtual Bite registration material (Vivadent, Schaan, Liechtenstein). Temporary resorations were placed in the prepared cavities and cemented with the temporary cement Voco Provicol (Voco GmbH).

Tooth-colored composite restorations were made with Voco Admira Ormocer-based composite or Voco Grandio nano-hybrid resin composite. The restorations were made by a single operator using the horizontal incremental placement technique, where the layers are maximally 2 mm thick. Each increment was light-cured with the 3M ESPE Elipar Freelight LED for 40 seconds according to the manufacturer's instructions.

After approximately seven days, the restorations were inserted. The temporary material was removed, each cavity was cleaned with a bristle brush mounted on a handpiece and dry working conditions were secured with a saliva ejector and rubber dam. The fabricated composite restorations were cleaned with 70% ethyl alcohol and air dried. The restorations were roughened using a bur, then pre-treated with Voco Monobond S silane coupling agent. Hawe Supermat steel matrices 0.05-mm thick (KerrHawe, Bioggio, Switzerland) were placed to prevent cement leakage. The cavity walls were etched with 35% phosphoric acid Vococid gel for 30 seconds, then rinsed. The (Voco GmbH) Solobond Plus adhesive system was placed according to the manufacturer's instructions. The dual-cured composite luting material used for luting the restorations was Voco Bifix QM in the universal shade. The ultrasonic insertion technique with vibrating probe was used for five seconds. With the help of an external force (a vibrating probe), this technique brings about a change in the viscosity of the composite cement for a short period of time, so that its viscosity decreases, which allows for better adaptation to cavity walls and fills small defects that may exist within the cavity itself or within the restoration material.[40] Each restoration was light-cured with the 3M ESPE Elipar Freelight LED curing unit at 400mW/cm^2 for 40 seconds. No glycerine gel was used to prevent the oxygen-inhibited layer.

Indirect composite restorations were initially treated with fine (30 µ grit size) and extra fine (15 µ grit size) pointed and egg-shaped Komet burs with water-spray cooling, followed with medium and fine grit 3M ESPE Sof-Lex polishing discs. Occlusion control was performed with micro thin 80 micron and 40 micron articulation papers (Dr Jean Bausch KG, Köln, Germany) and additional corrections were made, where necessary. Final polishing was done using Komet composite polishers and Vivadent Proyxt RDA8 polishing paste.

The restorations were evaluated after seven days (baseline) and 36 months after placement by another researcher who did not participate in the clinical procedure and who did not know which materials were used on the teeth that he was evaluating. Of the 51 total patients, 45 (88.23%) came to their recall appointment within the agreed 36 months, whereas six (11.76%) arrived roughly one month after the recall appointment.

Modified USPHS criteria were used to analyze the degree of quality, according to the description in a study by Kramer and Frankenberger[27] (Tables 1 and 2 and Figures 1 and 2).

Statistical evaluation was performed with program solution SPSS 13 (SPSS Inc, Chicago, IL, USA). Since this is ordinal data structure, non-parametrical tests were used.

The Mann-Whitney test was used to examine statistical differences between the two materials, according to the modified USPHS criteria. The Wilcoxon signed-rank test was used to individually examine the difference between the results of the baseline and 36-month evaluation for each criterion.

Table 1: *Modified USPHS Criteria for Evaluation*

Modified Criteria Criteria	Description	USPHS
Alpha 1 (excellent)	Perfect, without fault, no need for correction or intervention	Alpha
Alpha 2 (good)	Slight deviations from ideal performance, correction possible without damage of tooth or restoration	
Bravo (sufficient)	Few defects, correction impossible without damage of tooth or restoration. No negative effects expected	Bravo
Charlie (insufficient)	Severe defects, prophylactic removal for prevention of severe failures	Charlie
Delta (poor)	Immediate replacement necessary	Delta

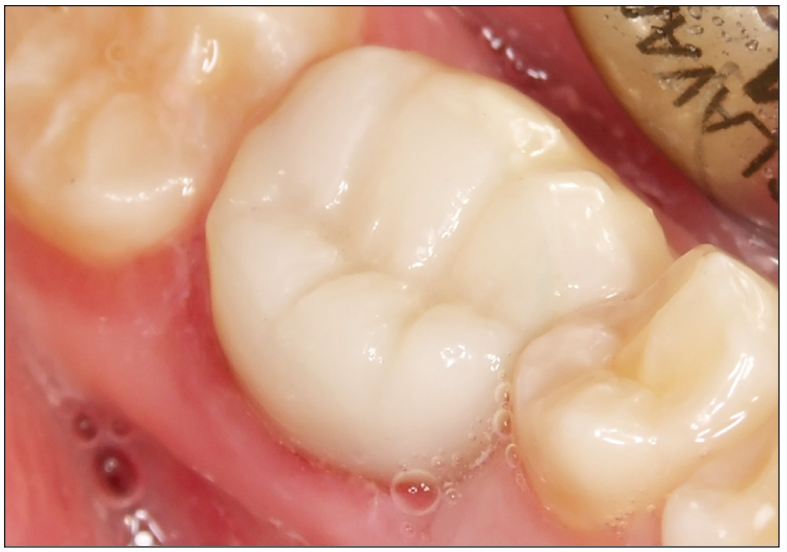

Figure 1: *Clinical condition at the baseline.*

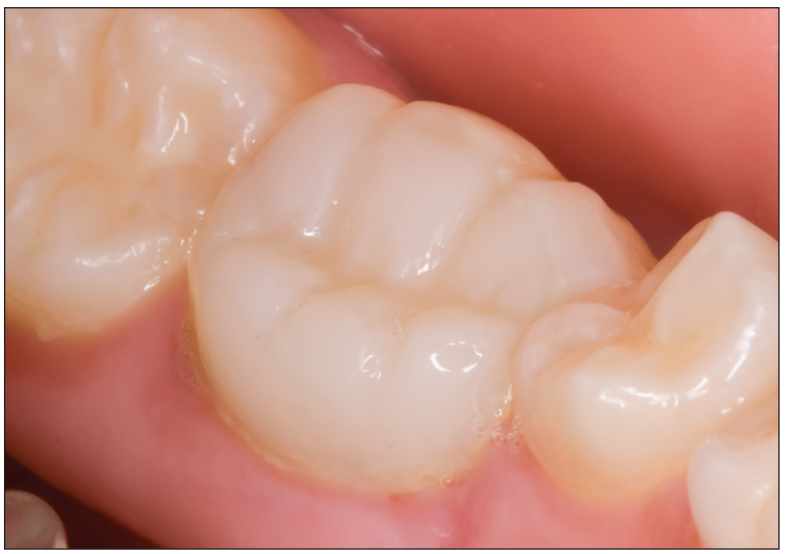

Figure 2: *Clinical condition at 36 months.*

RESULTS

The results of the clinical evaluation of indirect composite restorations for the materials Voco Grandio and Voco Admira are shown in Tables 3 and 4.

When tested 36 months after placement, the Voco Grandio restorations achieved excellent results (Alpha 1) for the following criteria: sensitivity test, postoperative symptoms and patient compliance. The Wilcoxon test proved a statistically significant difference in the evaluation of marginal integrity (p=0.03), anatomic form of the marginal step (p=0.025) and discoloration of the margins (p=0.014) at baseline and after 36 months. As for Admira, it achieved excellent results (Alpha 1) in the following criteria: sensitivity test, postoperative symptoms and patient compliance after 36 months, which is equal to the results of Grandio. The Wilcoxon test showed statistically significant differences in the evaluation of surface texture (p=0.025), anatomic form of the complete surface (p=0.034), anatomic form of the marginal step (p=0.008), marginal integrity (p=0.002) and discoloration of the margins (p=0.008) at baseline and after 36 months.

The Mann-Whitney test did not reveal any statistically significant differences between the two materials—at the baseline evaluation or after 36 months (p>0.05), according to the modified USPHS criteria. In some categories, the Admira material achieved Bravo results, which the Grandio material did not, but these differences were not statistically significant.

DISCUSSION

USPHS criteria were used to evaluate the different dental restorations, including indirect composite restorations. The USPHS criteria has four degrees and is very useful for showing absolute differences (acceptable/not acceptable) and, therefore, the criteria have direct clinical implications.[35] This evaluation procedure is the method of choice for large-scale research and pilot studies due to its simplicity and built-in definition for the clinical acceptability of restorations.[36]

Very strict standards were used; for example, only excellent restorations were graded Alpha 1, whereas a large number of restorations were graded Alpha 2. Restorations awarded the Alpha 2 score also belong to the group of clinically acceptable restorations, along with those graded

Table 2: *Descriptive Criteria Used for Scoring Restoration Quality*

	Alpha 1	Alpha 2	Bravo	Charlie	Delta
Surface texture	Smooth surface	Small pits or slightly rough	Moderate pits, loss of gloss	Deeply pitted, irregular grooves	Pits and grooves throughout the material
Color match	Excellent match of color and translucency compared to neighboring tooth tissue, restoration almost invisible	Slight mismatch only visible by close examination	Moderate mismatch in color, shade or translucency	Extensive color mismatch, outside the limits of acceptable appearance	Gross mismatch
Anatomic form of the complete surface	The restoration is contiguous with tooth anatomy, ideal	Minor defects that can be removed, slightly affected	Slightly under- or over-contoured restoration, marginal ridges slightly under-contoured contact slightly open, (may be self-correcting), height reduced locally	Restoration is under-contoured, dentin or base exposed contact is faulty, not correcting, occlusal height reduced, occlusion affected, intervention (correction) necessary	Parts of restoration missing form is completely unsatisfactory
Anatomic form of the marginal step	Marginal step is perfect, no under- or overfilling, contiguous with tooth anatomy	Minor defects that can be removed	Slightly under- or over-contoured restoration at marginal step, can be rounded by time	Extensive underfillings or overfilling, dentin or base exposed, extensive plaque accumulation	Severe periodontal problems due to the poor marginal step
Marginal integrity	No visible gap, probe does not catch	Slight catching of probe	Slight penetration of probe	Visible gap or extensive probe penetration between cavity wall and restoration	Loose restoration, secondary caries
Proximal contact	Waxed dental floss meets resistance, similar to healthy teeth	Dental floss meets less resistance than when used between healthy teeth	Contact is not visibly open, but dental floss meets no resistance	Contact is visibly open, probe tip can pass through proximally	Contact is visibly open, whole probe can pass through proximally
Discoloration of the margin	No discoloration	Minor staining, can be polished	Moderate surface staining, not aesthetically unacceptable	Surface staining present on the restoration, intervention necessary	Severe staining and/or subsurface staining
Integrity of the tooth	No enamel defects	Minor defects, enamel chipping, hairline cracks in the enamel	Enamel split	Major enamel split with dentin or base exposed, probe penetrates	Cusp or tooth fracture
Integrity of the restoration	No defects in material, no cracks or fractures	Small hairline cracks	Two or more larger hairline cracks and/or chipping, but not affecting the marginal integrity or proximal contact	Chipping fractures which damage marginal quality or proximal contact	Partial or complete loss of restoration
Occlusion	Contacts on all cusps, similar to adjacent teeth	Less number of contacts than adjacent teeth	Contact only on one side of the occlusal surface	Contact only on one cusp	No contact, does not occlude
Sensitivity test	Normal reaction to cold spray compared to non-restored teeth	Normal reaction to cold spray; sporadic increased sensitivity	Increased cold sensitivity	Spontaneous pain	Non-vital

Table 2: *Descriptive Criteria Used for Scoring Restoration Quality (cont.)*

	Alpha 1	Alpha 2	Bravo	Charlie	Delta
Postoperative symptoms	Asymptomatic, normal vitality	Low hypersensitivity for a limited period of time, normal vitality	Slighly more intense, delayed/weak sensitivity; no subjective complaints,no treatment needed	Premature/very intense, extremely delayed/weak with subjective complaints, negative sensitivity	Very intense, acute pulpitis or non-vital
Patient compliance	Entirely satisfied	Satisfied	Minor criticism of aesthetics	Desire for improvement	Completely dissatisfied

Table 3: *Clinical Results for Grandio Material*

Grandio	**Baseline**		**36 Months**		
	A1	**A2**	**A1**	**A2**	**B**
	%	%	%	%	%
Surface texture	90.2	9.8	87.8	12.2	
Color match	78.0	22.0	75.6	24.4	
Af of the complete surface	92.7	7.3	82.9	14.6	2.4
Af of the marginal step*	92.7	7.3	80.5	19.5	
Marginal integrity*	92.7	7.3	70.7	29.3	
Proximal contact	92.7	7.3	85.4	14.6	
Discoloration of the margin*	100.0		85.4	14.6	
Integrity of the tooth	85.4	14.6	80.5	19.5	
Integrity of the restoration	90.2	9.8	87.8	12.2	
Occlusion	92.7	7.3	90.2	9.8	
Sensitivity test	100.0		100.0		
Postoperative symptoms	100.0		100.0		
Patient compliance	100.0		100.0		

*Af (Anatomic form), * statistical difference*

Table 4: *Clinical Results for Admira Material*

Admira	**Baseline**			**36 Months**		
	A1	**A2**	**B**	**A1**	**A2**	**B**
	%	%	%	%	%	
Surface texture*	89.7	5.1	5.1	76.9	17.9	5.1
Color match	79.5	15.4	5.1	76.9	17.9	5.1
Af of the complete surface*	92.3	2.6	5.1	79.5	12.8	7.7
Af of the marginal step*	94.9		5.1	76.9	17.9	5.1
Marginal integrity*	94.9	5.1		71.8	25.6	2.6
Proximal contact	94.9	5.1		89.7	10.3	
Discoloration of the margin*	100.0			82.1	17.9	
Integrity of the tooth	92.3	2.6	5.1	89.7	5.1	5.1
Integrity of the restoration	94.9		5.1	92.3	2.6	5.1
Occlusion	97.4	2.6		89.7	10.3	
Sensitivity test	100.0			100.0		
Postoperative symptoms	100.0			100.0		
Patient compliance	100.0			100.0		

*Af (Anatomic form), * statistical difference*

as Bravo, while Charlie and Delta scores indicate clinically unacceptable restorations that are not possible to repair and need to be exchanged immediately. It is important to stress that some of the criteria, such as surface texture or color match score Alpha 2, can be improved and upgraded to Alpha 1 by applying clinical measures, such as polishing with abrasive techniques.

Marginal integrity is one of the most important criteria when evaluating a restoration's success. Better marginal integrity can be expected with indirect restorations than with direct restorations.[41] However, even though the initial marginal adaptation of ceramic inlays is very good, it changes and deteriorates under loading, especially gingivoaproximally in the enamel, where very thin fracture lines are formed. Excellent marginal integrity minimizes the risk that secondary caries will not appear.[42] The loss of marginal integrity can also appear at the

baseline evaluation due to polymerization shrinkage or the removal of cement flash with blunt instruments.[33] The main advantage of indirect composite restorations is that the composite is placed at once and is polymerized before placement, thus avoiding shrinkage. The space between an indirect composite restoration and the tooth itself is filled with composite cement that has excellent bonding ability between the resin composite and tooth structures. Since indirect composite restorations are cemented with composite cement, which has lower mechanical properties and higher wear than resin composite, greater or smaller marginal fractures can be expected. In the current research, the cement excesses that remain after curing were not removed with blunt or sharp instruments. Instead, they were polished with diamond polishing burs and 3M Sof-Lex polishing discs to avoid disruption and fracture of the composite cement.

When mechanically loaded, the teeth are bent and barreled, and they bulge at the mid-portion of the crown. These deformations cannot be compensated for with ceramic material due to its physical properties.[24] Consequently, ceramic inlays cannot absorb the impact stress that results in stress build-up along the gingivoaproximal margin.[14] Ideally, restorative material should have the physical properties of dentin and the same wear resistance as enamel. Hybrid composite has been clinically proven to possess these excellent properties, with an emphasis on marginal adaptation.[43] Also, another disadvantage of ceramic inlays is the need for more demanding laboratory work and higher costs compared to composite inlays.[44]

The current research showed that indirect composite restorations made from the material Grandio scored Alpha 1 (92.7%) and Alpha 2 (7.3%) when evaluated for marginal integrity at baseline, which means that they are clinically excellent or good, respectively. After 36 months, the marginal integrity scores were also Alpha 1 (70.7%) and Alpha 2 (29.3%). Over a period of 36 months, not a single case was noted with a marginal integrity score lower than Alpha 2. This could be attributed to good properties of the dual cure composite cement chosen for the study—Bifix QM, as well as to the ultrasonic insertion technique applied when cementing the restorations. This technique enables an improvement in the properties of composite cement.[40]

The test material Admira from the current study was evaluated for marginal integrity at baseline, and 94.9% of the restorations achieved Alpha 1 and 5.1% achieved Alpha 2, which is quite similar to the results of the Grandio material. After 36 months, the marginal integrity was graded Alpha 1 in 71.8% of all cases and 25.6% of the cases were graded Alpha 2, which are clinical marks for excellent and good. After 36 months, 2.6% of Admira composite restorations received a Bravo score for marginal integrity, which is acceptable. The anatomic form of the marginal step was scored Alpha 1 in 94.9% of the cases at baseline, and 76.9% of the cases received Alpha 1 scores after 36 months, which explains the statistical difference being explained by the sensitivity of the cementing technique and wear of the cement. Also, in places where microfractures appear in composite cement, they worsen over time. A statistically significant difference was found among the results of the marginal discoloration testing of the Admira group of restorations, of which 71.8% were graded Alpha 1 and 25.6% were graded Alpha 2 three years after placement. The Grandio group of restorations was also tested for marginal discoloration; they also displayed a statistically significant difference: 85.4% were graded Alpha 1 and 14.6% were graded Alpha 2 three years post-placement. Discoloration of the margin can be attributed to staining with pigments from food and beverages, as well as smoking. The current research has shown that there is no statistically significant difference between the test Grandio material, a nanohybrid resin composite and the test material used in the current study—Admira, an Ormocer composite material over a clinical test period of 36 months, according to the results of the Mann-Whitney test ($p>0.05$).

The results of the current study show a success rate of 70.7% for Grandio and 71.8% for Admira 36 months after placement, according to the percentage of restorations graded excellent (Alpha 1). Scheibenbogen and others reached a success rate of 93% at two years after placement.[24] Manhart and others reached a 90% success rate for composite inlays after two years.[33] Monaco and others describe results for Targis Ceromer inlay and onlay restorations that scored ideal and clinically acceptable in 100% of cases after 18 months.[24] Leirskar quotes 95% clinically successful results for three kinds of indirect resin composite inlays/onlays after four to six years.[5] Kaytan shows clinical success rates for ceramic and composite inlays after a 24-month period.[31] Thordrup shows that, after 10 years, around 80% of the inlays placed were in function.[32] Most of today's clinical research into esthetic restoration materials use the criterion established by Ryge in 1971.[36] Also, it is difficult to compare the results of one clinical trial to another, because the trials can significantly differ with the examiners, themselves, the methodology, the restoration procedure and clinical evaluation. USPHS criteria were applied in most of these clinical trials, and they differ from the modified USPHS criteria that the authors of the current study used, since the original criteria does not involve detailed ranking—Alpha 1 and Alpha 2 as subdivisions of an excellent score. Therefore, according to the USPHS criteria, Alpha 1 and Alpha 2 can be combined into a single Alpha score that results in an increased score in the current study's results eval-

uated 36 months after placement. Due to the restriction of this criteria and the need for more detailed and standardized criteria, today, there are pointers and references from Hickel for evaluating dental materials.[45] This set of criteria involves greater detail in the descriptions and evaluation of dental materials, with special attention placed on specifically described methodology and procedures during the research, which is applied to establish a unique model for further evaluation of the materials. Also, Hickel emphasizes the importance of creating standardized hand instruments for the clinical evaluation of dental materials, to be precise, dental probes that should have standardized tip thicknesses to diagnose marginal gaps more precisely and proximal contacts and surfaces.

CONCLUSIONS

In conclusion, indirect composite restorations made of Ormocer or nano-hybrid composite materials are a good treatment choice for severely damaged teeth, and they offer very good clinical results.

(Received 25 April 2009)

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