Clinical evaluation of 107 anterior teeth restored with direct nanofilled resin composite: up to 32 months

Nanofil rezin kompozitlerle restore edilmiş 107 anterior dişin klinik olarak değerlendirilmesi: 32 aylık takip

INTRODUCTION
One of the most significant contributions to dental technology has been the introduction of adhesive dentistry. Regarding the adhesive restorative materials from the time they were introduced to dental clinicians, a significant evolution was observed and with this evolution these materials have gained the advantage of preserving sound tooth tissue and providing acceptable esthetic. Minimal invasive treatments avoid reaching an early end of a “tooth’s lifecycle” and therefore they are more preferable. During the replacement of decayed or missing tooth tissue, dentists achieve excellent esthetic results with direct resin composites with a variety of colors and effects. Microfilled resin composites were developed to eliminate the rough surface characteristic of macrofilled materials. These restoratives have worse mechanical properties instead of improved handling and polishing properties. In an effort to maintain the advantages of both conventional and micro-

SUMMARY
Aim: This study evaluated the clinical performance of a nanofill resin composite in Class III and IV cavities.

Materials and Methods: One hundred and seven Class III and Class IV restorations were performed with a nanofill resin composite. Restorations were evaluated using the modified USPHS/FDI criteria. The changes were analyzed using McNemar and Marginal Homogeneity and Kaplan-Meier tests.

Results: Fourteen absolute failures were encountered resulting in a survival rate of 86.8% (Kaplan-Meier). Nanofill resin composite showed acceptable clinical performance up to 32 months of service.

Conclusion: However color stability and retention decreased at the end of two year follow up instead of fractures.

Key words: Adhesion, class III cavities, nanofilled composite resin

ÖZET
Amaç: Bu çalışmanın amacı, nanofil bir rezin kompozitin klinik performansının sınıf 3 ve sınıf 4 kaviteleleri yapılan restorasyonları ile değerlendirilmesidir.


Bulgular: 14 adet restorasyonda başarsızlık tespiyiyle birlikte %86,8 lik bir restorasyon başarı oranı yakalandı. Nanofil rezin kompozitin 32 aylık periyotta kabul edilebilir bir klin-ik başarı gösterdiği tespit edildi.

Sonuç: 2 yıllık takip sonunda renk stabilitesi ve retansiyonun azalığı belirlendi.

Anahtar kelimeler: Adezyon, class III cavities, nanofil kompozit rezin

Received: 18 April 2016
Accepted: 23 June 2016
DOI: 10.5505/yeditepe.2016.87587
filled resins, hybrid resin composites were introduced to clinicians. These materials have a smoother surface characteristic due to smaller particular ingredients. Further efforts in filler technology resulted in microhybrid composites named as universal composites which are used for both anterior and posterior areas. Apart from conventional resin composites, nanofill and/or nanohybrid adhesive restorative materials represent the state of the art in terms of filler ingredient and have a similar or slightly better performance. In addition to the advantages of nano fill and/or nanohybrid resin composites such as strength, low wear, and polishability these materials generally have different shades, allowing the natural dental tissue reproduction in an efficient way, with the stratification technique. Nanofill resin composites are composed of both nanomer and nanoclusters, whereas nanohybrid is a hybrid resin composite with nanofiller in a prepolymerized filler (PPF) form.

The knowledge that is necessary for the decision of restorative material by clinician is reserved from the results of in vitro and in vivo literature. Even though in vitro evaluations have the advantage of high reproducibility, in vivo literature is necessary for the final evaluation of a restorative material due to factors which can not be simulated in vitro conditions. In daily practice, an evidence-based approach and clinical observations are becoming more expected of dentists. Clinical evaluations of direct adhesive restorations showed good wear resistance and adaptation to tooth tissues; however they also have a high replacement rate due to secondary caries and low color stability. Although there were various clinical evaluations of direct posterior composite restorations, reliable data about the clinical performance of direct anterior restorations is rare. Thus the aim of this study was to evaluate the clinical performance of a nano hybrid resin composite (Filtek Ultimate) in Class III and IV cavities.

MATERIALS AND METHODS
The brands, manufacturers and chemical composition of the materials used in this study are listed in Table 1.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Type</th>
<th>Manufacturer</th>
<th>Chemical Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dycal</td>
<td>Calcium hydroxide</td>
<td>Degussa, Germany</td>
<td>Base paste: Disocyanate ester of 1,3-butanediol, dimethylamine, dibutylamine; diluent: dibutylamine, dibutylamine oxide, iron oxide, copper oxide, carbon black; activator: dibutylamine, dibutylamine oxide, iron oxide, copper oxide, carbon black.</td>
</tr>
<tr>
<td>Filtek Ultimate</td>
<td>Nanofilled resin composite, light-cured, universal</td>
<td>3M ESPE, St. Paul, MN, USA</td>
<td>Filler type: Zirconia, silica, zirconia/silica cluster fillers.</td>
</tr>
<tr>
<td>Adper Single Bond 2</td>
<td>Two step etch and rinse adhesive</td>
<td>3M ESPE, St. Paul, MN, USA</td>
<td>2-HEMA, Bis-GMA, Dmethacrylates, Amine, MethacryloylTEF: Functional co-polymer of polyacrylic and polytetrafluoroethylene.</td>
</tr>
</tbody>
</table>

### Patient inclusion/exclusion criteria
The inclusion and exclusion criteria were as follows:

**Inclusion Criteria:**
1. Good general health.
2. Having at least two Class III and/or Class IV carious lesions or existing defective restorations, including proximal surfaces in permanent maxillary anterior teeth, which were asymptomatic.

**Exclusion Criteria:**
1. Absence of adjacent and antagonist teeth.
2. Severe periodontal diseases and poor oral hygiene.
3. Symptoms of pulpitis, such as spontaneous pain or sensitivity to pressure.

### Tooth preparation
One operator with experience in adhesive dentistry, more than 12 years since graduation, placed a total of 107 restorations in 34 patients (18 female, 16 male; mean age 35.4±13.5 years old, range: 18-57 years old) with the help of a dental assistant. The teeth were cleaned and the color was determined by the custom shade guide and Vita Shade Guide (VITA Zahnfabrik, Germany). After the shade selection preparations were cut-under the local anesthesia if it was necessary. The cavity design (restricted to the elimination of carious tissue or defective restorations) was prepared using diamond and stainless steel burs (Diatech, Heerbrugg, Switzerland) and all buccal enamel cavosurface margins were beveled. All preparations were performed as adhesive-only cavities. The pulp tissue was...
protected with calcium hydroxide (Dycal, Dentsply De- trey; Konstanz, Germany) in deeper cavities when when the remaining dentin on the cavity floor was close to the pulp. Glass ionomer liner (Glass-Liner, Willmann & Pein GmbH, Hamburg, Germany) was applied to cover the calcium hydroxide; therefore, most of the dentin surface was left exposed for adhesion.

Restorative procedure
The teeth were restored esthetically with a nano hybrid resin composite using etch-and-rinse technique. Isolation was achieved with cotton rolls and suction instead of rubber dam and retraction cords (Ultrapak, Ultradent, USA) were used to minimize crevicular fluid flow. To ensure optimal adhesive bonding, a two-step etch and rinse adhesive system (Adper Single Bond 2, 3M ESPE, St.Paul, MN, USA), which is included the etching procedure with phosphoric acid (3M ESPE, St.Paul, MN, USA) was used. Enamel surfaces were conditioned for 30 seconds while dentin surfaces were conditioned for 15 seconds with phosphoric etching gel. After etching, the cavities were water rinsed thoroughly for 30 s with water, and afterwards chlorhexidine antibacterial solution (Con-sepsis, Ultradent South Jordan, UT, USA) to remove the acidic agent and the teeth were dried by gently air blowing. Adhesive was applied with a disposable brush and tooth sur-faces were scrubbed with brushing motion for 20 s. This application was repeated second-ly with a new drop of adhesive with 20 s waiting period in between the coats. The surfaces were dried with gentle air blowing and then medium at least 5 s and light cured for 20s (Gui-lin Woodpecker Medical Instrument Co., Ltd, China) according to the manufactur-er’s instructions.

The nanofil resin composite (Filtek Ultimate) was used for the composite build-ups due to its good handling property and shade matching. The resin composite was placed and polymerized using incremental layering tech-nique as dentin, body and enamel composite to simulate natural tooth color and translucency. Restorations were light-cured for 40 sec-onds each from facial and lingual directions. Particular attention was given to the con-touring of the apical finish line of the restorations. After polymerization checking the oc-clusion, finishing and pol-ishing of the restorations took place with finishing burs, polish-ing discs Opti Disc (Kerr Corporation, CA, USA) and rubbers HiLuster PLUS Polishing System (Kerr Corporation, CA, USA).

Evaluation
Two calibrated observers different from the operator evaluated the restorations at base-line, at 6 months, and at final recall. For maximum validity, both examiners were cali-brated by using the recommended web-based train-

Statistical analysis
Survival analyses were performed with statistical software program (SPSS 21.0; SPSS Inc, Chicago, IL, USA) using Kaplan-Meier test to obtain the survival rates in rela-
tion to observation time. P values less than 0.05 were considered to be statistically significant in all tests. To compare changes in the quality parameters between ob-
servations, the marginal homogeneity test was used.

Results
Results of the clinical evaluations of the 107 restorations at baseline, 6 months, 1 year and final recalls are shown in Table 2. In total, no drop-out was experienced yielding to the evaluation of 107 direct anterior restorations. The mean observation time was 22.4 ± 7 months with a minimum observation period of 9.63 months and maximum 32.10 months. Of these 107 direct restorations 3 resto-

ing and calibration tool. According to these criteria, clinically excellent restorations were scored as 1, clinically good restorations as 2, clinically sufficient restorations as 3, and clinically unsatisfactory and clini-

poor restorations as 4 and 5, respectively. The res-
torations were inspected visually with a dental mirror and probe. Caries, chipping, debonding, fractures, and severe discoloration were considered as absolute fail-
ures. Pa-tients were instructed to call the researchers in the event of any kind of failure. In case of an unfavorable event, such as chipping of direct adhesive restorative ma-

terials, the date of the event was recorded. If it was impos-
sible to identify the exact date of a defect, or the defect was detected only during the recall observation, the date of the unfavorable event was accepted as the date when the dentist observed the damage. All data were recorded by typing directly into an anonymous database.

When a complete restoration was lost or was impossible to repair, or the restarted tooth required root canal treat-
ment, the restoration was deemed a failure. When less damaging events occurred, such as minor composite fractures, chipping fractures, marginal gaps, caries, or color or surface deterioration, the restorations were re-
paired, polished, and the type of unfavorable event was documented in the patients’ record. These cases were de-
ined as survival cases. Restorations having no failure or unfavorable event were classi-fied as a success.
any of the teeth. At the 1-year recalls, 106 restorations (99.06%) restorations were classified as successful.

### Table 2: Summaries of USPHS Evaluations at baseline, six months and final recalls.

<table>
<thead>
<tr>
<th>USPHS/FDI criteria</th>
<th>Color stability and translucency</th>
<th>Anatomic form</th>
<th>Fracture and retention</th>
<th>Marginal adaptation</th>
<th>Periodontal response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 year recall (1 failed restoration)</td>
<td>1</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Final recall (14 failed restorations)</td>
<td>1</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>3</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
</tr>
<tr>
<td>4</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>6</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>7</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>11</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>12</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>13</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>14</td>
<td>-</td>
<td>-</td>
<td>Clinically unsatisfactory</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

One restoration (0.9%) was retreated due to the chipping at the margins and recorded as failure. One (0.9%) restorations showed unfavorable event (chip fracture not affecting the marginal integrity) was repolished and accepted as survival case. During the follow-up periods, 92 (86.8%) restorations were accepted as clinically acceptable; 18 (16.9%) were repaired and they were accepted as survival cases. Fourteen (13.2%) restorations were classified as failures, due to color mismatches, chipping and fractures and were retreated and recorded as failure (Table 3). The data for survival without failure and unfavorable events are shown in a Kaplan-Meier plot in Figure 1 and 2, with a survival rate, after 1 year of 99.1 and up to 32 months, of 86.8. The mean survival time (± standard error) was 30.1±0.6 months [95% C.I.=(28.97-31.23)].

### Table 3: The distribution of failures according to the evaluated USPHS/FDI criteria.

The clinical evaluations of the 107 restorations at baseline, 6 months, and final recalls are shown in Table 2. The statistically significant differences were observed for the criteria of color stability at six month (p=0.016). Seven restorations showed minor deviations in translucency and scored as clinically good. At one year recall except the failed restoration three restorations showed deterioration in color; two of them were highly translucent while the other was more darker (p=0.012). At final recalls the statistically significant differences were observed for the criteria of surface luster (p<0.001), surface staining (p<0.001), color stability and translucency (p<0.010), fracture and retention (p=0.008) and marginal adaptation (p<0.001). For the criteria of surface luster 14 restorations were observed as slightly dull. However they were not noticeable from speaking distance. Minor marginal and surface staining were observed at 15 restorations and...
they were re-moved by repolishing. These restorations were accepted as survival. Three restorations were too darker that they were corrected by repair and accepted as failure. Eight restorations were scored as clinically unacceptable for the criteria of “fracture of material and retention”; six of them showed chipping that damages marginal quality while bulk fractures were observed at two restorations. Larger irregularities with the necessity of repair were observed at the other two restorations. These restorations were also accepted as failure.

In the present investigation, a two-step etch and rinse adhesive system was used to ensure optimal adhesive bonding after the etching of enamel surfaces for 30 seconds with phos-phoric etching gel. The marginal quality of the restorations were observed generally successful at final recalls due to the etch and rinse adhesive procedure applied in the study. Some studies reported that etch & rinse adhesives or additional etching exhibited higher percentages of gap free margins in enamel after thermo-mechanical loading when compared to two-step self-etch adhesives. Ermis et al. also mentioned in their clinical study that additional etching of the enamel margins improved the marginal quality of restorations bonded with this adhesive system.

The most obvious reason for failures in anterior restorations are directly or indirectly related to the esthetic appearance of a tooth or restoration, while secondary caries is seldom the reason for replacement and endodontic complications are limited. Anterior restorations generally behave differently from posterior restorations. The restoration loss of anterior region is more present than in posterior teeth and esthetic appearance plays an obvious role in the desire of the patient to have a restoration replaced. In our study the patients are satisfied with the esthetically appearance of their final restorations. Failures at final recalls were generally related with the loss of retention or fracture or bad marginal quality. Only 3 restorations were retreated due to the criteria of color stability and translucency. The perception of aesthetics itself may vary among individuals according to their age, educational level, and environment to which they are exposed. The higher patient satisfaction scores in our clinical observations can be related with these aspects.

The available literature is still insufficient to determine the longevity of direct anterior adhesive restorations. Many variables, like the size, location and type of restoration and the patient’s dentition affect the longevity of composite restorations. In anterior teeth, Class IV restorations involving the incisal edge are subjected to high masticatory loads, with fracture as a possible clinical outcome over time. The lack of mechanical retention in most Class IV restorations may lead to a greater challenge to the tooth-restoration bonded interface. van Dijken and Pallesen found a higher prevalence of failure in Class IV restorations performed with different materials in bruxers, indicating that over-loading in individuals with occlusal disturbances may increase the mechanical stresses in

![Figure 1: Kaplan-Meier plot with the survival rate showed the survival without failure and unfavorable event after 1 year.](image1)

![Figure 2: Kaplan-Meier plot with the survival rate showed the survival without failure and unfavorable event after up to 32 months.](image2)

**DISCUSSION**

Resin composites have gained popularity as restorative materials due to their aesthetic and adhesive properties since their introduction to dentistry and currently, accepted as the first choice to restore both anterior and posterior teeth. There are several journals observing the clinical behavior of posterior resin composite restorations in the literature. These journals usually revealed that posterior resin restorations might present low annual failure rates and long-lasting survival, with failure reasons such as secondary caries and fracture. Despite the extended usage of resin composites in anterior restorations, there is a lack of evidence from clinical observations regarding the performance of anterior restorations especially in long term.
the restorations, making them more prone to fracture. Lucarotti et al.\(^\text{27}\) reported that involvement of the incisal angle in incisors and canine teeth resulted in an associated reduction in median survival time. In our clinical observation we performed 48 Class III and 79 Class IV restorations. This repair protocol can be accepted as sufficiently flexible to allow for improving the shape, surface luster, or marginal staining even after long clinical periods.

At final recalls 8 restorations were retreated due to the chipping, fracture and loss of restorations and all of them were Class IV restorations. These scores can be related with the high masticatory loads that the restorations were exposed. It seems that failure behavior in anterior restorations is different from posterior teeth, with less secondary caries presented.\(^\text{22}\) No secondary caries was observed for any of the restorations.

Spinas\(^\text{28}\) reported that, despite repairs of restorations, interventions like repolishing were alternative procedures that could be repeated several times as necessary. The survival rate in our study provides evidence that minimal repair procedures, such as repolishing, can be accepted as an important factor in prolonging the clinical success of direct adhesive restorations. Daily clinical experiences show that minor unfavorable events are generally easy to repair.\(^\text{16}\) Reuses et al.\(^\text{29}\) observed microfilled and hybrid anterior restorations and observed higher marginal discoloration for the microfilled resin composite. They accepted that hybrid resin composites performed well as an anterior restorative material. Microfill restorations were polishable but were weak because of their relatively low filler content. This, since then, the particle size of the conventional composites has been reduced through further grinding to produce more advanced restorative materials. Microhybrid resin composites were generally accepted as universal composites, with these materials used for most anterior and posterior regions. When combined, these materials improved strength and polishability characteristics.\(^\text{5}\) Narhi et al.\(^\text{30}\) evaluated the clinical behavior of microhybrid anterior restorations after 1 year and found the performance of the restorations to be clinically acceptable, similar with the clinical observations of Peumans et al.\(^\text{31,32}\)

One of the biggest innovations could be the development of nanofill and nanohybrid res-in composites. Nanohybrid properties, such as flexure strength and modulus, tend to be similar to those of microhybrids; however, they can be considered, as a group, to be in the lower range of the microhybrids, with both being superior to previous microfills.\(^\text{5}\) Similar to the preceding resin composites, nanofill anterior restorations showed acceptable clinical behavior in our in vivo evaluations after up to 32 months.

CONCLUSIONS

Within the limitations of the current design and recall period, the following could be concluded:

1. Direct Class III and IV restorations made of nanofilled resin composite presented 86.8% survival.
2. Repair and maintenance protocols were practiced to prolong the restoration lifetime already after 6 months to improve marginal adaptation, surface staining and luster and morphology which deteriorated in some cases up to clinical service time of 32 months.

Acknowledgement

The authors acknowledge dental assistants Miss B. Yildiz from Istanbul Medipol University, School of Dentistry, Department of Restorative Dentistry Clinics, for organizing the recalls of the patients.

Conflict of interest

The authors did not have any commercial interest in any of the materials used in this study.

REFERENCES

10. van Dijken JW Longevity of new hybrid restorative
Clinical Evaluation Of Anterior Resin Composite Restorations
