Clinical performance of posterior metal-free polymer crowns with and without fiber reinforcement
One-year results of a randomised clinical trial

Brigitte Ohlmann a,*, Jens Dreyhaupt b, Marc Schmitter a, Olaf Gabbert a, Alexander Hassel a, Peter Rammelsberg a

a Department of Prosthodontics, University of Heidelberg, Im Neuenheimer Feld 400, Heidelberg 69120, Germany
b Department of Medical Biometry and Informatic science, University of Heidelberg, Im Neuenheimer Feld 305, Heidelberg 69120, Germany

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ABSTRACT

Objectives: The aim of this study was to evaluate the clinical performance of posterior, metal-free polymer crowns with and without a glass-fiber framework, in comparison to metal–ceramic crowns.

Methods: After randomisation, 80 single crowns, manufactured from a newly designed polymer composite, were set in posterior teeth. Half of these received a glass-fiber framework, while half were prepared without any framework stabilisation. All polymer crowns were adhesively luted with resin cement. As the control group, 40 conventional metal–ceramic crowns were inserted with hybrid cement. Documentation included failures and other complications, as well as gingival/plaque status and aesthetic performance.

Results: During the 12-month observation period, eight polymer crowns and three metal–ceramic crowns showed clinically relevant complications. The most frequent complications were root canal treatments (n = 4) and decementation (n = 4) of the crowns. A total of two crowns (one polymer crown with fiber network and one crown of the control group) had to be replaced.

After 12 months, polymer crowns with glass-fiber framework exhibited significantly higher plaque accumulation (p = 0.005) and gingival index (p = 0.04) than metal–ceramic crowns, while no significant differences could be demonstrated for polymer crowns without fiber reinforcement.

Postoperative sensibility and aesthetic performance did not differ significantly between the groups.

Conclusions: Within a 12-month observation period, posterior polymer crowns with and without glass-fiber framework demonstrated acceptable stability and aesthetic performance.

Polymer crowns with fiber framework showed significant higher plaque accumulation and gingival index than metal–ceramic crowns.

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Metal and metal–ceramic crowns are clinically successful, but the visibility of metal and the change in natural tooth translucency is aesthetically unfavorable. The desire for natural looking restorations has encouraged research in the last decades on metal-free, tooth coloured materials for dental restorations. As early all-ceramic restorations exhibited high failure rates, an alternative has been seen in the use of reinforced composite materials. In recent years, there have been several in vitro and in vivo studies of the properties of these composites and promising results have been reported for crowns, and for fixed partial dentures.

However, although these materials seem to provide excellent aesthetics, some authors do not recommend composite materials for permanent restorations because of their unstable aesthetics, their increased wear and their liability to plaque accumulation. With the introduction of polymer composites, it seemed to be possible to eliminate these disadvantages of composites and to exploit their advantages, including the simple laboratory procedure, the lower costs and the possibility of repair. Additionally, this new generation of composites has given promising results in vitro with respect to colour change, wear and fracture resistance. Meanwhile, initial promising results from clinical studies on metal-free polymer crowns have been presented. However, the lack of randomised control groups prevents unbiased comparison with conventional metal–ceramic crowns. Furthermore, the clinical benefit of fiber reinforcement remains unclear, since in vitro results have demonstrated acceptable fracture resistance values with non-reinforced posterior single molar crowns.

The objective of this present prospective clinical study was then the assessment of the clinical performance of a new experimental microfilled polymer material (Trend HP) with or without fiber network stabilisation for manufacturing posterior crowns, compared with a metal–ceramic control group.

### 2. Material and methods

Participants for this study were recruited from patients visiting the Department of Prosthodontics. The university’s review board approved the study and all patients signed an informed consent form. Criteria for excluding patients from the study were being under the age of 18 or being incapable of taking out a contract, pregnancy or lactation, unacceptable oral hygiene status, clenching or grinding of teeth or known allergic reaction to the applied materials, all evaluated from answers to specific questions by the examiner.

The study group consisted of 66 patients (37 females and 29 males), aged between 22 and 73 years, with a mean age of 46 (S.D.: 11.9) years. These 66 patients received a total of 120 posterior single crowns, divided into three groups: 40 polymer crowns with framework stabilisation (group 1), 40 polymer crowns without framework stabilisation (group 2) and 40 metal–ceramic crowns (control group). Patients received a maximum of three crowns. If the indication for three crowns was given, one crown from each of the two test groups as well as the control group was randomly assigned to the abutment teeth. Patients with the indication for two posterior crowns received two crowns, randomly assigned to the abutment teeth, from different groups.

Clinical treatment – from six dentists – and laboratory procedures followed a standardised scheme. After the removal of old restorative materials and caries excavation, the teeth were built up with Rebilda SC (Voco GmbH, Cuxhaven, Germany), according to the manufacturer’s instructions. The minimal occlusal reduction was 1.5 mm and the axial reduction (chamfer design) was set at 0.8 mm. An attempt was made to keep the convergence preparation angle to the target of 6°. Impressions were made using polyether material (Impregum, 3MEspe, Seefeld, Germany). Stone casts (Fujirock, GC Europe, Leuven, Belgium) were poured and mounted in an articulator and the crowns were then fabricated by three previously trained dental technicians.

The polymer crowns were made of a polymer material (Trend HP, Ivoclar Vivadent, Ellwangen, Germany), consisting of a microfilled urethane dimethacrylate material, polymerised under heat and pressure according to the manufacturer’s protocol. Polymer crowns of group 1 received a glass-fiber framework (Vectris, Ivoclar Vivadent), while polymer crowns of group 2 were made without any additional stabilisation.

When manufacturing polymer crowns with Vectris stabilisation, the stone casts were insulated twice using a model separator (Vectris model separator, Ivoclar Vivadent) and the woven fiber prepags (Single, Ivoclar Vivadent) were adapted to the working dies and deepdrawn in a vacuum pressure process onto the insulated casts, after preparation of the working dies with a thinly flowing resin (Glume, Ivoclar Vivadent). During this process the woven fibres were formed into a cap (thickness 0.5 mm) and were light cured for 10 min (Vectris VS 1; Ivoclar Vivadent). The laminate copings were then cut, using silicone burs, 0.5–1 mm above the finishing line. After airborne abrasion with 50 μm alumina oxide particles, the surfaces were silane coated (Vectris wetting agent, Ivoclar Vivadent) for 60 s and light cured for 20 s (Targis Quick, Ivoclar Vivadent) after coating with a liner (New Composite liner, Ivoclar Vivadent).

For polymer crowns without framework stabilisation, the working dies were coated three times with insulation material (Vectris model separator) and, by following the same scheme as for reinforced crowns, a liner (thickness 0.2–0.3 mm) was added to the insulated casts.

The shapes of the crowns were modelled with the veneering material (Trend HP) according to the manufacturer’s instructions, finished using carbide and silicone burs, and polished with polishing paste (Universal Polierpaste, Ivoclar Vivadent), preserving a minimum thickness of 1.5 mm. As control group, metal–ceramic crowns (IPS d.Sign96; IPS d.Sign; Ivoclar Vivadent) were made according to the manufacturer’s instructions.

After try in and clinical occlusal adjustment, the polymer crowns were repolished using a polishing paste (Universal Polierpaste, Ivoclar Vivadent), preserving minimum occlusal dimensions of 1 mm. Prior to cementation, the inner surface...
was sandblasted with 100 µm aluminium oxide at 1 bar, silanised with Monobond S® (Ivoclar Vivadent) and immediately before cementation bonded with Heliobond® (Ivoclar Vivadent). The Heliobond® was applied to the internal aspects of the restoration and dispersed into a thin layer by use of clean, dry air. Until seating of the restoration the restoration was protected from ambient light and was not light cured before cementation. In patients with supragingival margins, the crowns were cemented under a rubber dam (n = 6). If fixation of the rubber dam was impossible, cotton rolls and retraction cords were placed, to avoid contamination with saliva or sulcus fluid. The abutment teeth were etched with 37% phosphoric acid (Gel Etchant®, Kerr Hawe, Bioggio, Switzerland) for 15 s, rinsed and gently air dried. Primer (Syntac®, Primer, Ivoclar Vivadent) and dentin adhesive (Syntac®, Adhesive, Ivoclar Vivadent) were applied for 15 and 10 s, respectively, and gently air dried. Polymer crowns were cemented with dual-cure resin cement (Variolink® II, Ivoclar Vivadent) and each surface was light cured for 40 s. The metal–ceramic crowns were cemented using a hybrid cement (Protec cem®, Ivoclar Vivadent) after pre-treatment of the abutments with Protec cem® Conditioner® (Ivoclar Vivadent).

All patients received an oral hygiene briefing after cementation. Recalls were scheduled after 2 weeks (recorded as "baseline") and after 12 months. Clinical evaluation was performed by one of the six dentists who was not involved in the treatment of the individual patient.

Documentation included sensitivity and percussion tests, gingival index (GI) and plaque index (PI).20

Complications like caries, endodontic treatment, fractures of the facing or the core material, debonding and discolorations were recorded using USPHS criteria.21 The aesthetic and functional performance of the crowns was subjectively evaluated by visual rating scales (VAS), from 0 (completely inadequate) to 10 (perfect). As regards postoperative sensitivity, subjects were asked to grade the sensibility using a VAS where 0 = no pain and 10 = extreme pain. No tactile, cold or evaporative air stimuli were applied.

Both the patients and the examiners were blinded to the previous results.

3. Statistics

Statistical analysis was performed using both SPSS (Version 13.0; Ill., USA) for descriptive statistics and SAS (Version 9.1; SAS Institute Inc., NC, USA) for the regression analyses.

On the basis of the analysis of one or more crowns per patient, mixed effect regression models were used allowing an investigation of the effects of the individual patient. Because of the ordinal structure of all outcome variables, the nlmixed procedure in SAS 9.1 was used to fit the mixed effects models. The nlmixed procedure produces estimates of the parameter values. The ratio of the parameter estimate with its standard error produces a t-value. The p-values based on this t-distribution.

The influence of the material of the crown on PI, GI, aesthetic and functional performance, and postoperative sensitivity was investigated. Both, the outcome variables at baseline and the outcome variables at 12 months were analysed.

In all statistical models, the single patient was included as a random effect. Statistical significance was accepted at p < 0.05. An adjustment for multiple testing was not done.

4. Results

One patient left the study without giving reasons and one patient changed his address and could not longer be contacted.

Thus, a total of 117 crowns (38 Trend HP with Vectris, 40 Trend HP without Vectris and 39 metal–ceramic crowns) were included in statistical analysis.

During the 12-month observation period, a total of 11 complications occurred: one total fracture in group 1, two delaminations of veneers (one in group 2 and one in the control group) and four loosened crowns (three in group 2, one in control group) were observed. All loosened crowns were recemented and the delamination in group 2 was repaired with composite.

In each group, endodontic problems occurred (two in group 1, one in group 2 and one in the control group) that were successfully handled by root canal treatment.

Only two crowns involved in these 11 complications had to be replaced (delamination in control group as a result of the delamination size and the total fracture in group 1).

At baseline, the mean value for PI was 0.63 (S.D.: 0.91) for group 1, 0.50 (S.D.: 0.82) for group 2 and 0.41 (S.D.: 0.60) for the control group, without significant difference between the test groups and the control group.

After 1 year in service, a significantly higher PI in group 1 (0.97; S.D.: 0.91) compared with the control group (0.51; S.D.: 0.61) could be demonstrated (p = 0.005). No significant differences between PI in group 2 (0.73; S.D.: 0.73) and the control group could be seen (p = 0.08) (Fig. 1).

At baseline, the mean value for GI was 0.97 (S.D.: 0.85) for group 1, 0.58 (S.D.: 0.68) for group 2 and 0.67 (S.D.: 0.84) for control group. The mean value for GI in group 1 was significantly higher (p = 0.05) than in the control group,
whereas no significant differences could be observed between group 2 and the control group ($p = 0.75$). After 12 months, the mean GI for group 1 (0.92; S.D.: 0.84) was significantly higher than GI of the control group ($p = 0.04$), while GI in group 2 (0.73; S.D.: 0.84) did not differ significantly from the control group ($p = 0.27$) (Fig. 2).

The patients’ subjective ratings for the aesthetic performance exhibited a mean value of 8.03, without any statistically differences between the test groups and the control group ($p = 0.68$ for group 1 and $p = 0.85$ for group 2).

The dentists’ subjective ratings for the aesthetic performance of the test groups were lower than those of the patients (6.38), without significant differences between the test groups and the control group ($p = 0.80$ for group 1 and $p = 0.51$ for group 2) (Fig. 3). No discolorations could be observed.

The patients’ subjective ratings of postoperative sensibility displayed no significant differences between the test groups and the control group ($p = 0.25$ for group 1 and $p = 0.61$ for group 2 at baseline).

Furthermore, no significantly higher postoperative sensibility could be seen when profound caries or pulp aperta was documented preoperatively on the abutment teeth or not ($p = 0.36$) (Fig. 4).

### 5. Discussion

If polymer crowns are to be used as an alternative to conventional metal–ceramic crowns, the polymer crowns have to meet some basic demands:

First of all, the material has to withstand posterior mastication forces: Several in vitro and in vivo studies have studied fracture resistance of composite crowns. Although the use of glass-fiber framework seems to increase the fracture strain of polymers, high fiber content does not necessarily lead to a greater flexural strength because failures of these dental restorations seem to be affected by a variety of factors including the polymer matrix, the fibers or the interface.

However, the flexural strength of reinforced crowns and of crowns without network stabilisation nevertheless lies above the expected mastication forces of approximately 500 N. The clinical performance of polymer crowns in the present study revealed no clinically relevant influence of fiber reinforcement on the stability of posterior single crowns. In contrast, the only total failure caused by a fracture appeared in the reinforced group.
Thus, the results of the present study are in accordance with the conclusion of Behr et al.\(^1\) that single molar composite crowns do not benefit from fiber reinforcement.

Moreover, the high plaque accumulation of polymer crowns with fiber framework in the present study indicates a clinically relevant disadvantage of fiber reinforcement. Although the fibers of the framework are covered with the veneering composite, the possibility cannot be excluded that fibers may be exposed to the oral cavity in marginal areas of crowns or during polishing.\(^{26}\) Thus, the fibers may attract plaque and cause gingival inflammation.\(^{27}\) This could explain the significantly higher GI of the fiber reinforced crowns in the present study. However, measures of gingival index have to be interpreted carefully, since the risk of bleeding was also associated with subgingival crown margins\(^28\) and even minute overcontoured crowns.\(^29\)

Furthermore, as the close association of iatrogenic factors with periodontal breakdown has been recognised,\(^30\) the relationship between dental restorations and periodontal health has been thoroughly investigated for many years and it has been reported that the composite material too has some negative effects on the quantity and quality of subgingival plaque.\(^31\)

An explanation for these phenomena may be plaque adherence on microporous materials. It has been demonstrated that rough surfaces are significantly more prone to bacterial accumulation and plaque formation than smooth surfaces.\(^32,33\) Thus, in accordance with the non-significant differences in plaque accumulation between non-reinforced polymer and metal–ceramic crowns of the present study, the reduced porosity and better surface finishing obtained by using heat and pressure treated polymers\(^34\) might be useful in reducing plaque accumulation.

An additional criterion for the clinical success of polymer crowns is the absence of complications. The most frequent complication of fiber reinforced resin crowns seems to be delaminations, whereas polymer crowns predominantly exhibited chipping (28% after 4 years),\(^35\) indicating the weak point of FRC is the bond between the veneering composite and the fiber substructure. The bond between the glass fibers and the composite is determined by the kind of mechanical and chemical fixation achieved by silanization and formation of carbon double bonds.\(^36\) Although the pre-impregnated fibers of the Vectris\(^6\) substructure are optimized by the silanization process, it must be kept in mind that after the curing process the number of carbon double bonds decreases. Furthermore, after water storage the interfacial strength of bonding glass fibers to polymer matrices may be reduced\(^3\) and thus, the risk of delamination over time might be increased.

Apart from bonding behavior, the mechanical properties of the veneering composite also determine the success of reinforced and non-reinforced crowns. Voids and cracks in the laminate enable water to enter and, furthermore, voids are oxygen reserves inhibiting polymerization of the matrix.\(^37\) The purpose of heat and pressure polymerization in this study is to minimize the voids in the polymer material but manufacturing faults and thus air entrapment during manufacture cannot be excluded. This may explain for the cohesive fracture inside composites and the observed delamination in group 2.

However, in the present study, decementation was the most frequent complication, apart from endodontic treatment. The results of other clinical investigations of polymer crowns showed a higher 1 year decementation rate of 37%\(^38\) than in the present study (3.8% for test groups), but these data described the complication rate of six different resin crown systems, placed by 46 dentists, indicating that the type of complications depended on the resin material.

Although it is accepted that bonding strengths between etched dentin and composite resin are effective, it must considered that the adhesive cementation is technique sensitive and, moreover, that as possible variations in cementation technique as variations in retentive preparation design cannot be excluded with any certainty which may affect decementation rate.

Another explanation of the high decementation rate in this present study may be that the bonding agent in the study was not separately light cured\(^39\) in order to avoid inaccurate fit of the restorations.

Apart from the survival rate of dental restorations, the aesthetic appearance of restorations is proposed to play a major role in rating clinical success. Even the parent veneering composite (Targis\(^8\)) provided excellent aesthetics\(^10\) and no aesthetic impairments were observed in the present study either.

However, it has to be considered that the present study represents the results of short-time observation. Since the number of discolorations may increase over time,\(^31\) the aesthetic results must also be evaluated over a longer observation period.

Additionally, when predicting the overall clinical success of present experimental crowns, it has to be born in mind that clinical results for at least 12 months are needed to make valid predictions about the potential longevity of these restorations.

6. Conclusions

Within a 12-month observation period, posterior single polymer crowns with and without glass-fiber reinforcement gave acceptable stability and aesthetic performance.

Polymer crowns with fiber framework gave significantly higher plaque accumulation and gingival index than metal–ceramic crowns.

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