

Dentin-like versus Rigid Endodontic Post: Eleven-year Randomized Controlled Pilot Trial on No-wall to Two-wall Defects

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Dentin-like vs. rigid endodontic post: 11-year randomized controlled pilot trial on no- to two-wall defects

Acknowledgement

The authors deny any conflicts of interest related to this study.

Abstract

Introduction: This is the first long-term randomized controlled trial to evaluate dentin-like glass-fiber posts (GFP) compared to rather rigid titanium posts (TP) for postendodontic restoration of severely damaged endodontically treated teeth (ETT) with two or less remaining cavity walls.

Materials and Methods: Ninety-one subjects in need of post-endodontic restorations were randomly assigned to receive either a tapered GFP (n = 45) or TP (n = 46). Posts were adhesively luted using self-adhesive resin cement followed by composite core build-up and preparation of 2mm ferrule design. Primary endpoint was loss of restoration for any reason. Kaplan-Meier curves were constructed, and log-rank test was calculated (p < .05).

Results: After a follow-up of 132 months, 17 GFP and 20 TP restorations survived, 19 failed (12 GFP; 7 TP). Failure modes were for GFP: root fracture (n = 4), core fracture (n = 1), secondary caries (n = 1), endodontic failure (n = 2), extraction due to tooth mobility grade III associated with insufficient design of removable partial denture (n = 1), tooth fracture (n = 1), changes in treatment plan (n=2); for TP: endodontic failure (n = 5), root fracture (n = 1), one extraction for other reasons. Cumulative survival probability was 58.7% for GFP, and 74.2% for TP. Log-rank analysis revealed no significant differences between both post systems (p=0.156).

Conclusion: When using self-adhesively luted prefabricated posts, resin composite core build-up and 2mm ferrule to reconstruct severely damaged ETT tooth survival is not influenced by post rigidity. Long-term sSurvival decreased rapidly after 8 years of observation in both groups.

Keywords: endodontic post; post and core; glass-fiber post; titanium post; randomized controlled trial; long-term clinical trial

Registration number: CCM03.02.2003 RelyX Unicem; registry: Ethical Review Committee of the Charité - Universitätsmedizin Berlin, Charitéplatz 1, 10117 Berlin

Introduction

Compared with vital teeth the complication rate of prosthetic restorations on [endodontically treated teeth](#) (ETT) is increased, and may eventually result in tooth loss (1, 2). A post-and-core restored abutment tooth shows regions of stress concentration and increased tensile stresses in residual dentin, which results in lower fracture strength (3). Much research over the past decades has focused on the question [of](#) which post-and-core material to use (4). A wide range of post materials with different mechanical properties, such as gold alloys (5), stainless steel (6), titanium (7), zirconia (8) or more “flexible”, dentin-like materials [such](#) as fiber post (9) are available. A representative survey among dentists in Germany shows that choice of post material depends on final prosthetic restoration (10). Unequivocal guidelines do not exist.

[In vitro](#) research has demonstrated that stress distribution in teeth with post-and-core restorations is influenced by mechanical properties such as the Young’s modulus, i.e. modulus of elasticity E, of the post material (11). A Young’s modulus closer to dentin is thought to result in favorable stress distribution and is therefore frequently recommended. However, clinical studies comparing different post materials are scarce and results are inconclusive (12). [A systematic review reported that both metal and fiber posts had a similar incidence of root fracture and comparable survival rates](#) (13). In contrast, a systematic review including one [randomized controlled trial](#) (RCT) with a high level of bias describes a higher risk of failure when metal posts were used (4). Again, this conclusion is not confirmed by another systematic review [that included](#) 10 RCTs (14). The high risk of bias of the available studies was emphasized elsewhere (13), [and](#) Schmitter and co-workers were not able to give a final clinical conclusion due to the limited number of available high-quality studies (15). There is consensus about the need for well-designed clinical studies that investigate the long-term survival of post systems in particular with regard to defect size (4, 16).

Thus, the primary objective of this pilot RCT was to evaluate patient recruitment, retention and event (failure) rate of severely damaged ETT teeth, i.e. teeth with two or less remaining cavity walls, which were adhesively restored with either GFP or TP. [A](#) secondary aim was to explore determinants of restoration failure of ETT restored in this way.

Materials and Methods

This study was conducted according to the revised Consolidated Standards of Reporting Trials (CONSORT) statement (17) updated in 2010 (18). It is registered at clinicaltrials.gov (No. NCT01520766).

Experimental Design

A randomized parallel-group clinical pilot study was designed to evaluate the long-term survival of post-endodontic restorations with glass-fiber and titanium post systems.

Subject Population

Between January 2003 and April 2004, participants were recruited for post-endodontic treatment in the Department of Prosthodontics, Geriatric Dentistry and Craniomandibular Disorders, [Charité – Universitaetsmedizin Berlin, Berlin, Germany](#). Subjects 18 years and older were assessed for eligibility. The following inclusion criteria applied:

1. Defect size: 2 or less remaining cavity walls of abutment tooth
2. Residual root canal thickness at the orifice of more than 1mm
3. Symptom-free tooth with root canal filling without [radiographoc](#) visible periapical lesion
4. Minimum radiologic root-to-alveolar bone ratio of 2 after prospective crown lengthening (22)
5. No or treated periodontitis with a maximum probing depth of 4mm and no bleeding on probing
6. Tooth mobility not more than Score II
7. Willingness to return for a follow-up examination for at least 5 years
8. Tooth without intention to be used as telescopic crown abutment
9. Final restoration definitely cemented within 3 months after post placement

Two operators (GST and MN) informed participants about [the](#) study details, [explaining them of both the risks and benefits](#). Informed consent of participation was given [in writing](#).

The study was performed in compliance with Good Clinical Practice and Declaration of Helsinki (last revised Edinburgh 2000). The approval of the study protocol was

given by the Ethical Review Committee of the [Charité - Universitätsmedizin Berlin](#) (approval number: CCM 03.02.2003 RelyX Unicem). Each participant received only one endodontic post restoration [during](#) this study.

Treatment

The endodontic treatments were performed by dental students of the Department of Operative Dentistry and Periodontology, [Charité-Universitätsmedizin Berlin](#). Surgical crown lengthening was performed in 13 cases by one operator (TD) to ensure a 2mm ferrule preparation. One experienced operator (GS) with expertise and training in post-endodontic treatment procedures performed post placement, core build-up procedure, and final crown preparation at one single appointment. Guttapercha was removed with Gates-Glidden burs after a minimum of 24 hours after endodontic therapy. The post space was prepared with a tapered drill ($\varnothing = 1.4$ mm, Fiberpoints Root Pins Post Kit; Schuetz Dental Group, Rosbach, Germany) to achieve an intraradicular post length of 9mm. At least 4mm of root canal filling were left to guarantee an apical seal. With an air abrasion system (DentoPrep Aluminium Oxide Microblaster; RØNVIG Dental, Daugaard, Denmark and Cojet; 3M ESPE, Seefeld, Germany) root canal and tooth surface were cleaned. The post space was rinsed with 2ml 99.6% ethanol solution and dried with paper points. Randomization for post system took place [during](#) this step. The posts (Fiberpoints Root Pins Titanium or Fiberpoints Root Pins Glass, Schuetz Dental Group) were cleaned with acetone. For the titanium posts a tribochemical silica coating was performed (2.8 bar, 13 sec., Rocatec Soft, 3M ESPE). A thin layer of silane (ESPE-SIL, 3M ESPE) was applied and [air-dried](#) after 60 seconds. The posts were adhesively luted with self-adhesive resin cement (RelyX Unicem, 3M ESPE) (19). The luting material was applied on the post and within the post space. After initial light curing for 2 sec. (Optilux Light-curing Unit; Demetron Research Corp, Orange, CA), [any](#) excess of material was removed. For 1 min, final light curing was performed. According to the manufacturers' instructions, direct composite cores using an etch-and-rinse adhesive (NewBond and Clearfil Core; Kuraray Europe, Duesseldorf, Germany) were built up. The dentine was etched with phosphoric acid for 15 sec. (Total Etch; Ivoclar Vivadent, Schaan, Lichtenstein). Transparent strip crowns (Frasaco Strip Crown; Frasco GmbH, Tettngang, Germany) were used as matrices for the core build-up procedure. Thereafter, the crown preparation was performed. The ferrule design was considered

due to a finishing line of the final restoration of at least 2mm apical to the composite build-up. When the post was exposed after crown preparation, bonding material was applied to avoid water absorption of the fiber posts. Final restorations were placed by dental students in the Department of Prosthodontics, Geriatric Dentistry and Craniomandibular Disorders, [Charité Universitaetsmedizin Berlin](#). All participants received a porcelain fused to metal single crown or fixed partial denture. In 12 cases a removable partial denture was additionally placed. Final restorations had to be placed within 3 months after post placement. Crowns were luted using the self-adhesive resin cement RelyX Unicem (3M ESPE, Seefeld, Germany).

Follow-up Procedure

The date of post placement was defined as the baseline for all further analyses. Participants were recalled at 3, 6 and 12 months, thereafter in a yearly recall up to 132 months after post placement for clinical examination. Significant efforts were made to retain patients in the study, using a number of approaches that also evolved somewhat over time. Up to six attempts were made to contact patients by phone at various times and days of the week, including weekends. If this was unsuccessful, letters were sent requesting patients to contact the study centre. If contact data were not valid, [Web-based phone number registers](#) and social networks (facebook.com, stayfriends.de, plus.google.com, xing.com) were consulted to enhance the possibility of finding lost participants.

Patients were offered a check-up and a free professional tooth cleaning as well as reimbursement of travel expenses. If patients were unwilling to attend a follow-up appointment, survival of the restoration/tooth was ascertained by patient's self-report. The 132- to 144-month clinical examination was performed by a blinded calibrated operator (MvS). Follow-up examinations were performed with a dental probe to detect marginal gap formations of restorations. Radiographs were taken when indicated and examined by one operator (MN) to exclude the possibility of radiographic signs of failure (e.g. periodontal or periapical lesions).

Outcome Measures

The primary endpoint was the loss of restoration for any reason. Secondary endpoints were tooth loss, post debonding, post fracture, vertical or horizontal root fracture, endodontic or peri-radicular conditions requiring endodontic retreatment,

secondary caries and failure of core build-up, and loss of restoration because of technical failures.

Sample Size Calculation

No a priori sample size calculation was performed for this pilot study. Restricted random allocation was performed (MN) by blocking with a block length of 4 based on a computer-generated random list to achieve [a balance of size](#) between groups. Then, randomization and allocation concealment according to the participant identification number were established. Participants were randomly assigned to 1 of the 2 intervention groups. For allocation concealment consecutively numbered, sealed envelopes were utilized. They were stored and opened by the dental assistant immediately before post placement.

Statistical Analysis

Summary statistics were calculated for all variables at baseline for each group as appropriate. For the primary endpoint, data were censored for the survival time of the final restoration according to the intention-to-treat analysis. Kaplan [– Meier](#) survival-table and plots were generated using IBM SPSS Statistics 23 (SPSS Inc, Chicago, IL). Annual failure rates were calculated based on Kaplan [– Meier](#) estimate. Differences between survival functions were evaluated using the log-rank test. ~~For testing the impact of baseline parameters on survival of restorations, Hazard Ratios (HR) and 95% confidence intervals were calculated using Cox regression analyses.~~ All statistical tests and confidence intervals were double-sided. The level of significance was set at $\alpha=0.05$.

Results

A total of 98 participants gave written informed consent to participate. Two withdrew consent to participate before randomization and five did not match the inclusion criteria. Ninety-one participants were included for randomization (Fig. 1). ~~Table 1 shows descriptive data of participant and tooth characteristics.~~ Four participants in the glass-fiber group dropped out prematurely and were not available for the first recall after 3 months. One participant was unavailable and did not return for the first recall. Two participants did not receive the final restoration within 3 months after post placement and were therefore excluded according to the inclusion criteria. Two teeth failed after 9 (secondary caries) and 10 (horizontal tooth fracture at gingival level) months. One tooth was extracted due to a change of the prosthetic treatment plan. Hence, 87 participants were included in the modified intention-to-treat analysis (Table 1). The overall mean observation time was 98 months (SD; min/max: 43;12/154). A total of 31 participants did not complete the 132-month follow-up period (35.6%) (Table 1). Two participants with GFP restorations and 7 participants with TP restorations gave self-report by phone. The modified intention-to-treat analysis revealed a survival rate of 58.7% for GFP and 74.2% for TP restorations (Fig. 2). ~~There was no statistically significant difference between the survival functions ($p = .156$; Fig. 2).~~ The calculated overall annual failure rate up to 154 months amounted to 4.2% (GFP) and 2.3% (TP). ~~Cox regression analyses between different baseline characteristics and calculated HRs revealed no statistically significant differences between Hazard ratios of different baseline parameters (Table 4).~~ Failure modes (secondary endpoint) and characteristics of corresponding teeth are displayed (Table 2).

Discussion

The present study investigated the survival of endodontically treated, severely damaged teeth with glass-fiber vs. titanium post-based restorations. An adhesive approach was chosen using self-adhesive resin cement and composite core-build-up to ensure an adhesive mono-block. No statistical comparisons of the data are presented. Because of the small sample size and lack of power no conclusions can be drawn. The danger of presenting statistical analysis of an underpowered study is that "no statistical difference" may be interpreted by the reader as equivalence, which is not the case. A much larger sample size would be necessary to show equivalence. Data from this pilot study are useful to calculate sample size calculations for future studies. For example, to detect a difference in survival of 60% vs. 70% (corresponding to a hazard ratio of 0.7) at alpha=0.05 with 90% power, assuming a drop-out of 35% would require enrolment of 1094 patients (n=547 per group). After a minimum time of observation of 132 months, 35.6% of subjects were lost to follow-up (29.3% (GFP), 41.3% (TP)). Failures mainly occurred due to loss of restoration for any reason in 29.3 % (GFP) and 15.2% (TP), corresponding to an average annual failure rate of 4.2 (GFP) and 2.3%, respectively.

The drop-out rate in long-term studies is a well-known challenge (20), and attrition as high as approximately 50% has been recently reported (8). Participants of the present study were not in a recall program associated with a general check-up. Most patients had their own dentist in private practice or consulted the university clinic on an irregular basis. Most drop-outs were due to missing current contact data (address, phone number). In addition, over the years, study participants became more and more reluctant to return for follow-up visits, due to a lack of perceived direct benefit. Offers of free check-ups, including free professional tooth cleaning and reimbursement for travel expenses did persuade some participants to return to the study centre, but were not sufficient to persuade many. Payment of participants has been demonstrated to increase retention markedly, and should be considered in future studies where possible. Nine participants were assessed by self-report on the phone. A former prospective study reported 39 cases of clinical examination of GFP-restored teeth in accordance with the patient's self-report (9). Based on these results we decided to include the nine cases of self-report.

The cumulative survival rates in this study of GFP (59.8%) are comparable to a 10-year prospective observational study on GFP restorations (9) in which the

[survival rate was 59.6%](#). The annual failure rate of GFP restorations was 4.6% and the amount of remaining coronal hard tissues was identified as predictor of tooth survival. Anterior teeth failed [three](#) times more frequently than posterior teeth. To the best of our knowledge these data [from 2012](#) are the only published prospective long-term data on “dentin-like” GFPs. One limitation of this study was, that [if needed no crown lengthening was performed to ensure a ferrule design of 2mm dentin height. in cases with insufficient residual crown height no crown lengthening was performed to ensure a ferrule design of 2mm dentin height.](#)

Short-term clinical studies with a maximum follow-up time of 36 months report survival rates [comparable with](#) as the present study for this time interval (21-24). An RCT comparing the survival of glass-fiber and metal screw posts (25) over 5 years showed notably lower survival rates for glass-fiber (71.8%) and metal screw posts (50%) compared with the present study after 5 years (glass fiber 86.4%; titanium 92.5%). An RCT on prefabricated and customized glass-fiber posts placed in premolars only showed an overall survival rate of 94.1% after 6 years of observation (26). These data show that more “flexible” fiber post-based restorations can achieve a wide range of survival rates from only fair to high in the midterm. For comparison, 10-year results of retrospective study with very rigid zirconia ceramic posts as a tooth-colored, non-metallic alternative to fiber posts show [a survival probability of 81.3%](#) (8). However, the drop-out rate in this study was high [at 49.4%](#).

Overall, there appears to be marked heterogeneity with regard to the long-term survival rates of post-based restorations in the literature, and the reasons for this are unclear. Reasons for failure are diverse, and many failures appear to be related to factors other than the choice of post material or the restoration itself, such as caries and changes in treatment plans due to failures elsewhere in the dentition. These competing risks for failure increase sample size requirements for any definitive randomized trial of post materials on restoration survival. ~~While the results of the present pilot study have to be cautiously interpreted, we certainly found no evidence that fiber posts perform better than titanium posts in terms of long-term restoration survival. The study also provides data for sample size calculations for future studies, e.g., to detect a difference in survival of 60% vs. 70% (corresponding to a hazard ratio of 0.7) at alpha=0.05 with 90% power, assuming a drop out of 35% would require enrolment of 1094 patients (n=547 per group).~~

ETT supporting prosthetic restorations present reduced survival rates compared with vital teeth (27). Nevertheless, overall the survival rates up to 8 years emphasize that the reconstruction of severely damaged teeth – if appropriately treated – can achieve satisfying results prior to considering the option of choosing a dental implant (28).

It is known from the 10-year observational study mentioned above, that anterior teeth have a higher risk of failing than posterior teeth (9). This finding is supported by other research (25, 29). Higher non-axial loads in the anterior region were described as being a source of mechanical failures (30). Within our sample, the failures occurred among all types of restoration and tooth types. However, the present study did not achieve enough power to discuss hazard ratios. in the present study there was no statistically significant difference between anterior and posterior teeth. It may be explained by strictly following of the ferrule concept. It is well known, that the ferrule and its effect is one of the key factors in post-endodontic restorations in particular on teeth with severe hard tissue loss (31). Due to the small sample in the present study, a statistical testing of correlations between failure and type of restoration could not be performed.

Regarding the number of remaining cavity walls, i.e. defect size, the distribution was well balanced with 42 cases with no and 45 cases with one or two cavity walls. Our analyses showed – in accordance with other prospective studies – a slightly, not significant higher risk to fail for teeth with no remaining cavity wall (25, 26).

In the present study mechanical failures occurred such as four horizontal non-restorable root fractures. General practitioners report endodontic failures and fractures as the main problem (10). Intracanal loss of hard tissues due to endodontic and post space preparation increases the deformability of the root (31). A recently published systematic review concluded that the incidence of root fractures does not differ between metal and fiber posts (13), although for years a favorable biomechanical behavior of glass-fiber posts due to a dentine-like Young's Modulus (32, 33) was postulated. Finite element analyses revealed that this property may lose its impact when – due to aging processes – the bonding of the post / cement / root dentin interface fails and concentrates higher stress within the root (34).

In summary, no baseline parameters had a statistical significant effect. This may seem unsatisfactory, but shows that within our sample either the effect of these

~~baseline parameters is too low or it is the consequence of adhesive monoblock, post as such, irrespective of its Young's modulus, and ferrule design on restored ETT.~~

It appears that to date the ultimate type of restoration of ETT with a severe hard tissue loss has not yet been found. In contrast to ferrule height the type of endodontic post and its rigidity is probably not a key factor and it is not possible to draw global conclusions from only two post systems.

Conclusion

- ~~1. When using self-adhesively luted prefabricated posts in severely damaged abutment teeth, post-endodontic restorations achieve a moderate long-term survival rate, irrespective of the post material and its rigidity.~~
- ~~2. Teeth restored with glass-fiber and titanium post show no favorable failure patterns on the long run.~~
1. Survival rates of post-endodontic restorations in severely damaged abutment teeth achieve good results up to 8 years of observation and decrease thereafter progressively, in particular for glass-fiber posts.
2. The sample size in this study was too small to draw any statistical inferences, but the data has value in designing a larger, statistically strong study and may have value for meta-analysis if pooled with other data sets.

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Michael Naumann and Guido Sterzenbach contributed equally to this article.
The authors deny any conflicts of interest related to this study.

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Figures

Figure 1. CONSORT Flow diagram of participants according to study design and to the CONSORT statement

Figure 2. Kaplan – Meier plots representing the cumulative survival probability in both intervention groups.

Tables

Table 1. Primary outcome at the 132-month follow-up

Table 2. [Failure modes and characteristics of teeth in both intervention groups](#)