Randomized Clinical Trial Comparing the Effects of Post Placement on Failure Rate of Postendodontic Restorations: Preliminary Results of a Mean Period of 32 Months

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Abstract

Introduction: The aim of this randomized clinical trial was to assess whether the placement of a fiber post (DT Light Post) (DT) and the amount of residual coronal dentin affect the time to failure of single-unit postendodontic restorations. **Methods:** Ninety patients providing 120 teeth were selected. Three groups (n = 40) were defined on the basis of the amount of residual coronal dentin: 2-walls group, 2 or more coronal walls; 1-wall group, 1 coronal wall; no-wall group, no wall exceeding 2 mm above the gingival level. Within each group teeth were randomized and allocated to 2 intervention groups (n = 20), including subgroups no post (no root canal retention) and subgroups post (placement of DT). **Results:** After a mean observation period of 32.4 (13.7) months in subgroups no post, the failure rates were 10%, whereas in subgroups post, failure rates of 7% were observed (P = .318). In no-wall group post placement significantly affected the time to failure of total restorations (P = .029, log-rank test). Teeth without post retention revealed a significantly higher failure rate (31%) compared with teeth restored with post retention (7%). **Conclusions:** Within the observation time of the present study, fiber post placement was efficacious to reduce failures of postendodontic restorations only with teeth that exhibited no coronal walls. Post insertion for teeth showing a minor substance loss should be critically reconsidered. *(J Endod 2009;35:1477–1482)*

Key Words

Adhesive luting, failure rate, fiber posts, postendodontic restoration, randomized clinical trial

Restoration of endodontically treated teeth with fiber-reinforced composite (FRC) posts has been proposed as a viable alternative to metal posts (1, 2). Clinical studies demonstrated heterogeneous failure rates (3–7) of up to 32.5% after 5 years (8) for FRC posts. Varying performance of the posts has been attributed to differences in study design, inclusion criteria in general, and included subjects as well as differences in observation periods (9). The loading capability of endodontically treated teeth is affected by the number of adjacent teeth (10), the tooth type, position, and its function in the dental arch, as well as by degree of coronal substance loss (8, 11–13). In addition, the final coronal restoration might affect the survival of endodontically treated teeth (14, 15), and preparation of a circumferential dentin collar of at least 1.5–2 mm in height (ferrule effect) has been demonstrated to influence the load-bearing capacity of endodontically treated teeth (16, 17).

The effect of post placement on the fracture resistance of endodontically treated teeth *in vitro* has been discussed controversially. On the one hand, some studies indicated a significant effect of the amount of residual tooth structure on the fracture resistance of endodontically treated teeth, whereas post placement did not significantly affect the fracture load (18, 19). On the other hand, post placement revealed a significant effect on the fracture resistance of endodontically teeth (20–22). These contradicting results might be attributed to the different tooth types investigated in the respective studies.

Published reviews on the clinical performance of fiber posts highlighted the need of prospective clinical trials to assess the influence of the remaining tooth structure and the type of post on the treatment outcome (23–25). Recently, 2-year and 3-year survival rates of endodontically treated premolars restored with and without post retention have been reported (9, 26). In this prospective clinical trial with solely premolars (9), six experimental groups were defined according to the amount of residual tooth structure. Within each group teeth were restored with either a fiber post (DT Light) or no additional post retention. A single-unit metal ceramic crown was placed as definitive coronal restoration irrespective of the coronal substance loss to standardize the study design as much as possible. Three-year survival rates were 91% and 63% for restorations with and without posts, respectively. Cox regression analysis showed that after exclusion of teeth retaining 4 intact walls, the presence of root canal retention was a significant factor for survival.

The aim of the present study was to investigate the time to failure of endodontically treated anterior and posterior teeth restored with a single-unit final restoration with and without posts. For this purpose teeth were divided into 3 different groups according to the coronal substance loss and restored either with or without post retention. The final coronal restoration was chosen as indicated by the clinical situation and the coronal substance loss.

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The study was planned as a non-inferiority trial with an assumed margin of equivalence of 15% (ie, the working hypothesis was that the post has no relevant influence on failure); consequently, the null hypothesis (H_0) was that failure rates differ more than 15% in subgroups post and subgroups no post.

Materials and Methods

Between April 2004 and May 2007, 100 patients in need of a postendodontic restoration were screened and assessed for eligibility in the Department of Operative Dentistry and Periodontology, Charité-Universitätsmedizin Berlin, Germany. The following inclusion criteria had to be met: (1) the amount of residual tooth structure had to fit into the following 3 groups: 2-walls group, 2 or more coronal walls exceeding 2 mm above the gingival level; 1-wall group, 1 coronal wall remaining that exceeds 2 mm above the gingival level; no-wall group, no coronal wall exceeding 2 mm above the gingival level but preparation of a ferrule of 2 mm possible; (2) symptom-free tooth with a root canal filling without periapical lesion and with a minimum apical seal of 4 mm; (3) no or no untreated advanced periodontitis with a maximum pocket depth of 5 mm without bleeding on probing; (5) tooth mobility no more than score 1; (6) furcation involvement no more than grade 1; and (7) willingness of the patient to return to recall intervals for at least 3 years. Each subject had to give written informed consent before entering the study, which was approved by the Ethical Review Committee of the Charité-Universitätsmedizin Berlin in 2004 (vote number 226-03a).

One-hundred patients were screened for eligibility. Ten patients were excluded; 5 patients did not meet the inclusion criteria, and 5 patients refused to participate. Ninety patients providing 120 teeth met the inclusion criteria and were included into the study (Fig. 1) (27). According to the substance loss, each tooth received an identification number and was randomly assigned to 1 of 2 intervention groups. Block randomization with a block length of 10 was performed on the basis of a random number list provided by the Department of Clinical Epidemiology and Biometry, Charité-Universitätsmedizin Berlin, Germany. Following 10 assigned teeth, 5 teeth were assigned to each subgroup. The allocated intervention was performed according to the random number list, which was strictly followed by all operators.

In subgroups no post, gutta-percha was removed from the root canals by using Gates Glidden burs (VDW, München, Germany) to a depth of 3 mm from the canal orifice, and the core build-up was performed by using Clearfil Core/New Bond (Kuraray, Osaka, Japan) according to the manufacturer's instructions. Dentin was etched with phosphoric acid (Total etch; Ivoclar Vivadent, Schaan, Liechtenstein) for 15 seconds, and New Bond was applied. In cases of direct composite restorations, the build-up was performed by using Tetric Ceram/Syntac Classic (Ivoclar Vivadent) according to the manufacturer's recommendations.

In subgroups post, DT Light Post (VDW) was placed with a length of 7–8 mm, leaving at least an apical seal of 4 mm of the root canal filling. Post size (2 or 3) was chosen according to the root diameter. The post was tried-in and shortened to a minimal coronal length of at least 3 mm, depending on the clinical situation. Subsequently, the post was cleaned by using 2-Propanol (Merck, Darmstadt, Germany) and dried with oil-free air. Root canal and dentin were etched by using phosphoric acid (Total etch) for 15 seconds, and New Bond was applied into the canal and onto the surrounding dentin as well as onto the post surface. Post luting and core build-up were performed by using Clearfil Core as described previously (28).

No more than 3 restorations per patient were included. In each case, posts and final restorations were placed by 1 of 4 experienced operators with expertise in the field of postendodontic treatment working at the Department of Operative Dentistry and Periodontology, Charité-Universitätsmedizin Berlin, Germany. Operators were calibrated before the study with respect to the treatment procedures that included post insertion and core build-up as well as preparation guidelines of all investigated restorations. Final restorations were chosen according to the amount of the coronal substance loss to preserve as much of sound tooth structure as possible and indicated. Direct composite restorations were indicated for teeth that exhibited a minor coronal substance loss including 2 or more remaining coronal walls. Partial crowns were selected for large occlusal and proximal defects with intact buccal and/or oral walls that required cuspal coverage of the teeth. Ceramic partial crowns were indicated for situations with high aesthetic demands, and if isolation with rubber dam was possible. Full crowns were chosen for teeth with a high coronal substance loss (ie, 1 or no coronal wall remaining). Crown preparations were performed with a circumferential ferrule of at least 2 mm.

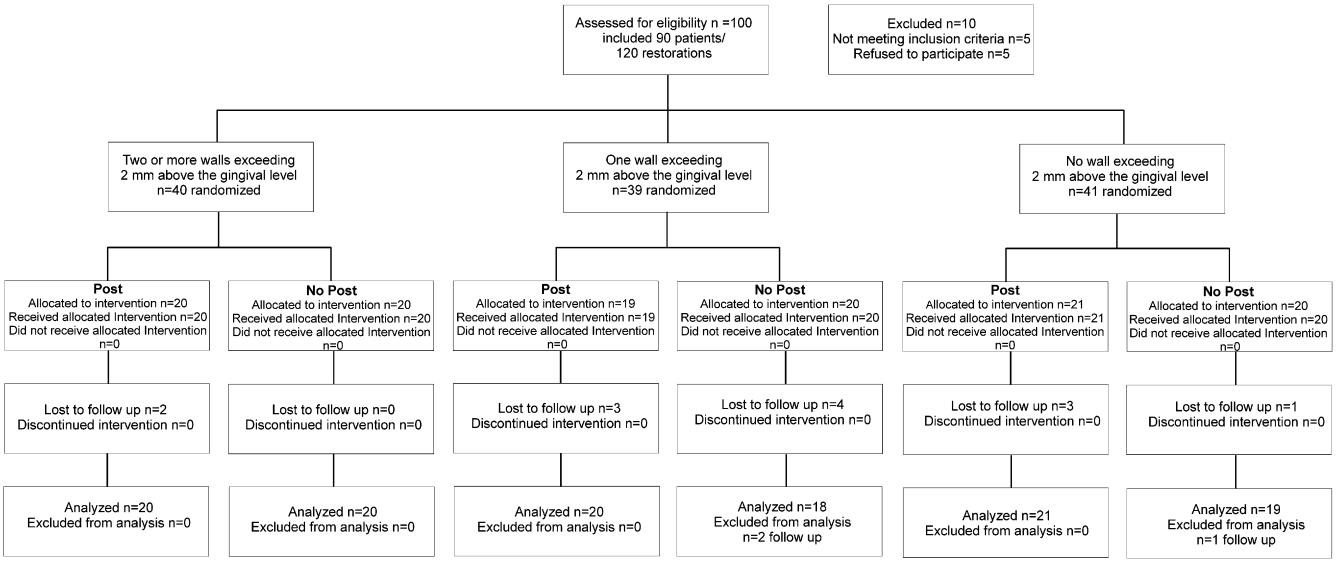

Figure 1. Flow diagram of the study design according to CONSORT statement.

TABLE 1. Tooth Type and Final Coronal Restoration in Subgroups No Post and Post

Group	Subgroup no post			Subgroup post		
Tooth type	Anterior	Premolar	Molar	Anterior	Premolar	Molar
(number)	10	13	37	15	20	25
Coronal restoration (number)						
Metal-ceramic full crown	4	9 (3)	22 (3)	9 (2)	15	16
Gold partial crown	0	0	4	0	1	6
Metal full crown	0	0	3	0	0	2
Ceramic partial crown	0	3	1	0	3	0
All-ceramic full crown	2	1	3	6 (1)	1	1
Direct composite restoration	4	0	4	0	0	0

Failed restorations are indicated in parentheses.

At baseline examination the following data were recorded: age and gender of the patient, dental and periodontal status, included tooth type, radiograph of the root filling of the included tooth, post type (DT Light Post Size II or III), and final coronal restoration (Table 1). The patients were recalled at 6, 12, 24, 36, and up to 56 months. After 12 and 36 months radiographs were taken in a modified parallel technique and examined by one blinded operator at 4.5× magnification to exclude the possibility of radiographic symptoms of failure, eg, periodontal or periapical lesions. Primary end point was loss of the restoration for any reason. Secondary end points were post debonding, post fracture, vertical or horizontal tooth fracture, failure of the core portion requiring a new coronal restoration, endodontic or periradicular conditions requiring endodontic retreatment, and tooth loss. Evaluation of success or failure was performed by one examiner who was not the operator by using a mirror and a probe to detect marginal gap formation of the restorations. The study was planned as a non-inferiority trial. The margin of equivalence was set at 15%; the level of significance was 0.05. Accordingly, a sample size of 50 teeth restored with and 50 teeth restored without posts had a minimal power of 80% to reject the null hypothesis. Statistical analyses were performed with SPSS version 16.0 software (SPSS, Chicago, IL). For descriptive purposes Kaplan-Meier plots were calculated for each subgroup. Differences in time to failure in each group were calculated by using log-rank test. R-package (A language and environment for statistical computing, version 2.9.0; R Foundation for Statistical Computing, Vienna, Austria) was used to calculate differences of failure rates including 95% confidence intervals and the corresponding illustrations (Fig. 2). The level of significance was set at $\alpha = 0.05$.

Results

In total, 90 patients received the allocated intervention (Fig. 1). Three patients were excluded from the analyses because they did not attend any recall interval. Eleven patients were lost to follow-up. All in all, this setup resulted in minimum and maximum observation periods of 6 and 56 months, respectively. The mean (standard deviation) observation period was 32.4 (13.7) months. Forty-two men and 49 women aged 24–80 years [50 (15) years] were included. Twenty-five anterior teeth (20.8%) and 95 posterior teeth (79.2%) were analyzed. Operator 1 treated 55 teeth, operator 2 seven teeth, operator 3 thirty-nine teeth, and operator 4 nineteen teeth.

Final and failed restorations are described in Table 1. All restorations demonstrated at least 1 proximal contact. The overall failure rate after 3 years was 8%. In subgroups no post, the failure rate was 10%, whereas in subgroups post, 7% of the teeth failed. This difference was not significant ($P = .318$, log-rank test). The difference of failure rate (DFR) was 3% (95% confidence interval for DFR, −9.05% to 14.99%) (Fig. 2).

In no-wall group, post placement had a significant effect on the survival rate ($P = .029$, log-rank test). Teeth without post retention revealed a significantly higher failure rate (31%) compared with teeth restored with post retention (7%). In 1-wall group, no effects of post placement on the failure rate could be demonstrated ($P = .353$, log-rank test). In 2-walls group, no analysis could be performed because no failure occurred. The Kaplan-Meier plots for 1-wall group and no-wall group are presented in Fig. 3. Radiographic examinations revealed no periapical lesions requiring endodontic retreatment.

In 1-wall group 3 failures occurred. In subgroup no post, 1 vertical root fracture was observed. Subgroup post showed loss of retention of post and core build-up in one situation, whereas in another situation a vertical root fracture occurred. Vertical root fractures resulted in the extraction of the teeth.

In no-wall group 6 failures were observed; in subgroup no post, all failures (5 teeth) showed a loss of retention of the core build-up. Two of these failures occurred in combination with a vertical root fracture, and the teeth had to be extracted. In one situation, secondary caries led to the extraction of the tooth. In another particular instance, a pronounced substance loss was observed, resulting in the extraction of the tooth. One of the teeth could be reconstructed. In subgroup post, 1 post fractured, and the tooth could be restored after removal of the post. No other adverse events were observed.

Discussion

The null hypothesis of the present study was rejected because differences in failure rates between the 2 subgroups were not higher than 15%. The null hypothesis of the present study is contrary to superiority studies whose null hypotheses assume equal effects in both groups. This non-inferiority approach was also the basis for the sample size estimation. In no-wall group a secondary analysis was performed to test superiority because in this group subgroup post revealed significantly less failures than subgroup no post. This is in accordance with the Committee for Proprietary Medicinal Products guidelines on "Points to consider on switching between superiority and non-inferiority" (29). A higher failure rate for teeth with no coronal wall remaining that were restored without posts compared with post-retained restorations has been observed previously (9, 26). Accordingly, *in vitro* studies revealed a lower fracture resistance for teeth restored without post retention (20, 22). The survival rate of teeth restored with quartz fiber posts in the present study (92%) was similar to previously published results that showed a 3-year survival rate of 91% for premolars restored with DT Light posts (26).

Compared with that previous investigation (26), heterogeneous coronal restorations as well as a higher number of posterior teeth (if compared with anterior teeth) were included in the present study. Because it is known that risk factors for the restoration of endodontically treated teeth with fiber posts are tooth type and type of final restoration (12), the inclusion of various coronal restorations and tooth types might have affected the present results. Nevertheless, the cited article revealed a 4 times higher failure rate for teeth restored with

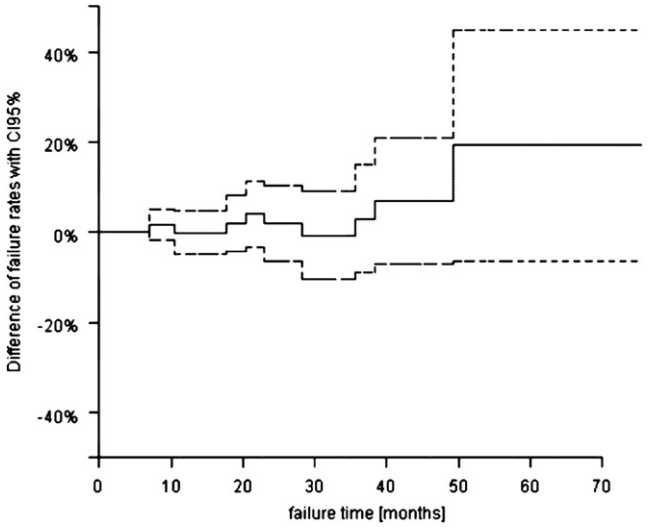

Figure 2. Diagram shows failure rates of restorations without posts minus failure rates of restorations with posts. The broken lines indicate the 95% confidence interval.

single crowns compared with teeth restored with fixed partial dentures (12), whereas the present study included only single-unit restorations. Moreover, the respective restoration forms were chosen according to the substance loss of the affected teeth, and overtreatment for teeth exhibiting 2 or more coronal walls should be avoided. Consequently, direct composite restorations have been included in the present clinical trial too. Although dental literature has emphasized that endodontically treated teeth should be fortified to withstand both vertical and lateral forces and not be subject to fracture, the restorative dentist is frequently faced with the dilemma of deciding how to restore treated teeth in a predictable manner. With this in mind, preservation of sound tooth structure is regarded as the most important aspect in increasing the survival rate of endodontically treated teeth (30). Indeed, preparation of indirect restorations requires the removal of more sound tooth structure compared with direct restorations, and it should be emphasized that a previous article (15) described that ceramic-metal crown coverage did not enhance the clinical performance of endodontically treated teeth when compared with placement of a direct composite restoration during a 3-year period. More recently, direct fiber-reinforced (class II) composite resin restorations demonstrated excellent clinical performance at 1 year in endodontically treated teeth (31). This has been confirmed by the present results, because we did not observe any failures with the direct composite restorations as well (Table 1). Unfortunately, the number of included coronal restorations did not allow any further analysis on the effect of the coronal restorations on the failure rate (Table 1).

Previously, anterior teeth showed a higher failure rate compared with posterior teeth (8). This might explain the lower failure rates for teeth restored with post retention in the present study compared with previously published clinical data (11), because predominantly posterior teeth were included in the present trial. It would have been desirable to include the same number of molars, premolars, and anterior teeth in the present study design to further analyze the failure rate of each respective tooth type. In the present study design, teeth were consecutively included according to the coronal substance loss and randomly assigned to 2 intervention groups. Tooth type was not considered during assignment, and lack of completely standardized conditions might be considered a significant limitation of the present study. Notwithstanding, statistical analysis concerning the effects of tooth

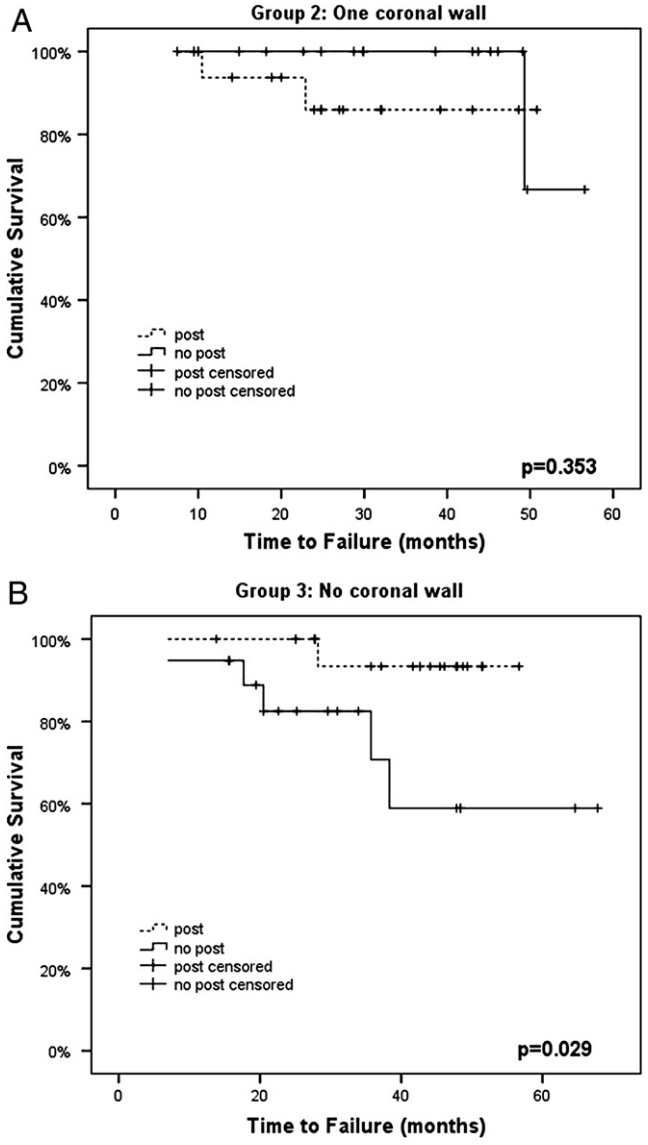

Figure 3. Kaplan-Meier plots comparing subgroups no post and subgroups post for 1-wall group including teeth providing 1 coronal wall (*A*) and no-wall group including teeth with no coronal wall exceeding 2 mm above the gingival level (*B*). *P* values indicate significant differences between subgroups. Survival times are censored if the event (ie, failure of the restoration) has not occurred during the follow-up period.

type on failure rates would have required a much larger sample size. Because this was not feasible, we did not consider the possible influence of tooth type. Consequently, more prospective clinical trials are definitely required to assess the influence of tooth type and post retention on the survival rates of endodontically treated teeth.

Amount of residual tooth structure has been described as a relevant factor for the survival of postendodontic restorations (11, 12, 17, 32). This is in accordance with the present findings, because no failure occurred with teeth that demonstrated 2 or more coronal walls (2-walls group). Within the observation period of the present study, post placement did not affect the overall failure rate and in particular the failure rates of teeth that exhibited 1 or more coronal walls. However, a longer observation period for all included teeth is necessary to allow reliable recommendations. Moreover, the margin of equivalence in the present study was set at 15%, which is a relatively high value

to assume that there are no differences in failure between groups. On the basis of the present results, an estimated hazard for a monthly failure rate of 0.18% was calculated. For a margin of equivalence set at 5% (minimal power, 80%; $\alpha = 0.05$), sample size calculation would result in 630 teeth with 1 or more coronal walls per group (PASS 2008, Version 08.0.8; NCSS, Kaysville, UT) to show that there will be no differences between groups with or without posts (thus necessitating multicenter trials to warrant reliable outcomes). This calculation is based on an assumed assessment time of 3 years and 1 more year of follow-up.

Three failures occurred for post restorations in the present study in 1-wall group and no-wall group: 1 post fracture, 1 post debonding, and 1 vertical root fracture. Reasons for clinical failures of fiber post restorations have been discussed controversially in the literature. Post debonding has been described as the most frequent unfavorable event for post-retained restorations (5, 9, 26), whereas another study revealed post fractures as the most frequent reason for failure followed by post debonding (41% of all failures), followed by post debonding (34% of all failures) (8). Differences in fatigue resistance of the various investigated post systems (33) as well as the use of different resin cements (34, 35) might have affected these results. However, the limited number of failures in the present study does not allow for further conclusions.

Failure reasons of non-posted roots in no-wall group were loss of retention of the core build-up in all cases. In 2 of these cases vertical root fractures were observed too. This is in correspondence with previously published data (9), in which the authors speculated about a protective role of fiber posts against this most serious type of failure (ie, tooth fracture). However, the present study showed 1 vertical root fracture for posted roots compared with 3 vertical fractures for non-posted roots. With this in mind, it should be emphasized that evaluation of long-term survival data from the present population is mandatory.

Effects of different operators on the treatment outcome cannot be completely excluded; however, 4 experienced operators in the field of endodontic and postendodontic treatment participated in the present study, and differences between operators were minimized by using standardized procedures for endodontic treatment, post insertion, and core build-up and preparation for the coronal restorations, as defined in the study setup. Nonetheless, lack of totally standardized conditions is a drawback that might affect study conclusions. On the other hand, it should be stressed that the current setup provided a platform for generating data that resemble normal clinical use of a product.

No blinding of the examiner was performed; the detection of the failures in the present study (eg, loss of the restoration and core build-up, vertical root fractures, or post fractures) was not likely to be biased by the knowledge of the examiner whether a post was placed or not, because it was obvious on the occasion. For the radiographic analyses, blinding was not possible.

Bonding to intraradicular dentin is still a critical issue (35, 36) and less effective compared with coronal dentin. Establishment of a reliable bond can be hampered as a result of limited visibility, anatomic features (37), and a comparably high configuration factor inside the root canal (38). However, the present study observed only 1 post debonding and 1 post fracture for posted roots, whereas in 5 cases loss of the core portion for non-posted roots could be revealed. This leads to the assumption that bonding to the pulpal floor and to the canal orifice might also be less effective. Moreover, shear stresses occurring during mastication at the adhesive interface at the pulpal floor and the canal orifices could not be compensated without post retention for teeth providing no coronal wall, even though preparation of a circumferential ferrule of 2 mm has been provided. This has also been corroborated *in vitro* (20).

Conclusion

Within the limitations of the present study (inclusion of various coronal single-unit restorations, unequal distribution of the various tooth types, as well as a mean observation period of 32.4 [13.7] months), it can be concluded that quartz fiber post placement is efficacious to reduce failures of postendodontic restorations of teeth that exhibit no coronal wall above 2 mm of the gingival level. Post insertion for teeth showing a minor substance loss should be critically reconsidered to avoid overuse.

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