

## Clinical Research

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# A Multicenter Randomized Double-blind Controlled Clinical Trial of Fiber Post Cementation Strategies

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### Clinical Relevance

Both self-adhesive and regular resin cements obtained good survival rates and could be used for fiber post cementation.

### SUMMARY

**Objectives:** The aim of this prospective randomized multicenter clinical trial was to evaluate the survival rate of glass fiber-reinforced posts cemented with self-adhesive or regular resin cements.

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**Methods:** The sample was comprised of 152 teeth randomized within two centers and in accordance with the adhesive strategies for RelyX U100/U200 (3M ESPE) or Single Bond and RelyX ARC (3M ESPE). The cementation procedures were standardized and performed by previously trained operators. The primary outcome evaluated was post debonding. A trained evaluator, one for each center, assessed all subjects at intervals of 12 months for up to 6 years. Statistical analysis was performed using the Kaplan-Meier method.

**Results:** There was no statistically significant difference in survival rates between the two strategies assessed ( $p=0.991$ ), with a 92.7% survival rate for the self-adhesive cement and 93.8% for the regular cement.

**Conclusion:** Both the self-adhesive and the regular resin cements are good alternatives for glass fiber post cementation.

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## INTRODUCTION

Coronal reconstruction of endodontically treated teeth is frequently required before crown placement, especially when the remaining coronal tooth structure is not enough to provide adequate retention and resistance for the final restoration. Characteristics such as mechanical properties similar to that of dentin,<sup>1</sup> esthetics,<sup>2,3</sup> elimination of the laboratory step,<sup>4</sup> and high survival rates presented by clinical studies<sup>4,5</sup> make fiber posts a feasible alternative for the reconstruction of endodontically treated teeth. They also explain the increasing use of fiber posts in clinical practice.

The use of a resin cement, either with or without an adhesive system, is essential for the cementation of prefabricated glass fiber posts. A self-adhesive or conventional resin cement associated with a photo-activated adhesive system are two feasible alternatives. They present acceptable results in *in vitro* studies<sup>6,7</sup> and show desirable mechanical properties.<sup>8</sup>

Although many *in vitro* studies compared different techniques for fiber post cementation<sup>9,10</sup> and observed different results, the literature is inconclusive about a recommendation for the best clinical strategy for fiber post cementation. In addition, most clinical studies are focused on the type of post used for the restoration of endodontically treated teeth<sup>5,11,12</sup> and not on the cementation strategy for these restorations. The lack of high-level evidence to support clinical decisions on fiber post cementation strategies in randomized clinical trials is noteworthy.

The total etch-and-rinse adhesive systems associated with dual cure cements remove the smear layer and generate a better dentin hybridization.<sup>13,14</sup> However, this strategy needs to be executed using a wet dentin substrate, which is very difficult to control inside the canal space. In addition, it presents the limitation of light transmission decreasing through the root.<sup>15</sup> The self-adhesive resin cements appear to be an interesting alternative, because they do not require any dentin pretreatment before cementation and have presented good bond strength results.<sup>9</sup>

Thus, the aim of this randomized multicenter clinical trial was to compare the clinical performance (survival rates) of two cementing strategies (a two-step total etch adhesive system associated with a conventional resin cement vs a self-adhesive resin cement) with fiber posts. The null hypothesis tested

was that there would be no difference between the two strategies.

## METHODS AND MATERIALS

### Experimental Design and Ethical Aspects

This study was a prospective, double-blinded (patient and evaluator), parallel-group randomized multicenter controlled trial (RCT) registered at ClinicalTrials.gov (NCT01461239). The study was developed at two dental schools and approved by both of their ethical committees (protocols 099/2009 and 0170.1.243.000-09). The report of the results followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

### Inclusion and Exclusion Criteria

The sample was composed of patients who needed post placement and single crowns in any tooth and looked for treatment at either dental school. The inclusion criteria were teeth with a clinically acceptable endodontic treatment and at least 3 mm of apical sealing, missing coronal surface indicating the need of a crown, and simultaneous bilateral occlusal contacts. The exclusion criteria were teeth with a degree of mobility higher than 1 or abutting of a removable or fixed partial denture, any systemic disease that interferes with bone quality, an apical lesion impossible to eliminate with proper endodontic treatment, as well as patients with advanced and untreated periodontal disease.

### Sample Size Calculation

Sample size calculation estimated a failure rate of 10% in the experimental group (self-adhesive cement) and 0% in the control group, with 80% power and the significance level set at 5%. Thus, the sample necessary for each group was 73 teeth. However, to counter possible dropouts during the study, a sample of 76 teeth (N=152) was used.

### Randomization and Allocation Process

The randomization of the experimental procedures was performed by an independent researcher, using a table of random numbers generated by a computer program and stratified considering tooth position (anterior or posterior, the latter was also divided into molars and premolars) and the two centers in which the experiment was conducted. The randomization sequence was allocated into individual consecutively numbered plain brown envelopes. The envelope was only taken and opened after the root canal prepara-

tion to prevent the choice of cement affecting this procedure.

### Operator's Clinical Training

Prior to the experimental procedures, the researchers responsible for the project trained the dentists who performed the experimental procedures. One-month hands-on training and lectures were used so that all procedures were standardized in the two centers. All procedures were carried out by senior year undergraduate students under the main researchers' supervision.

### Clinical Procedures

Previous to the single crown manufacturing, all patients who met the inclusion criteria and were accepted to be part of the study received a complete dental evaluation and had reestablished a healthy oral condition, if applicable. The first patients were included in 2009, and the last patients were included in 2013/2014. Patients were submitted to the procedures described below.

Diagnostic radiographs were performed to determine the working length and selection of the glass fiber post from the White Post DC system (FGM, Joinville, Brazil). The tooth was isolated with a rubber dam, and the root canal was prepared with the system drill until two-thirds of its length was left, keeping at least 3 mm of apical sealing. If the specimen had more than one canal, the larger canal was chosen to be prepared. The post was tested, and a 4-mm coronal length was left.

For cementation procedures, the surface of all posts was cleaned with 70% alcohol, air dried, silanized (ProSil, FGM), and allowed to sit for one minute for complete evaporation of the solvent. The treatment for the root canal dentin for the post cementation followed the manufacturer's recommendations and changed according to the cementation strategy.

Regarding the first strategy, cementation with the self-adhesive resin cement RelyX U100/U200 (RelyX U100/U200 because RelyX U100 was discontinued in 2014; 3M/ESPE, St. Paul, MN, USA), the cement pastes were mixed and taken to the root canal using a Centrix syringe with an Acudose tip and with the aid of the post. Then the post was inserted into the canal, and the excess paste was removed. The post was kept in position for five minutes, and then the cement was light-cured for 40 seconds through the coronal portion of the post.

For the second strategy, cementation with two-step total etch adhesive and conventional resin cement, Single Bond and RelyX ARC (3M/ESPE), the prepared root canal was conditioned with 37% phosphoric acid for 15 seconds. This was followed by extensive washing with water and drying with light air jets and absorbent number 80 paper cones. The Single Bond adhesive system was applied in the canal with the proper microbrush, and the excess was removed with paper cones. Afterward, the adhesive system was light cured for 30 seconds, and the cement pastes were mixed and taken to the root canal using a Centrix syringe with an Acudose tip and with the aid of the post. Then the post was inserted into the canal, and the excess paste was removed. The post was kept in position for five minutes and then, at last, the cement was light-cured for 40 seconds through the coronal portion of the post.

After cementation, a diagnostic radiograph was taken for the baseline. The coronal reconstruction was made using Scotch Bond + Z 250 composite resin (3M ESPE). The coronal preparation was made according to the literature recommendation for metal-ceramic crowns, on the level of gingiva or, at most, 0.5 subgingival, and using a chamfer marginal design. The prepared teeth were impressed with a polyether material (3M ESPE) using an acrylic unitary tray along with a full arch alginate impression. After fabrication, the metal frameworks (CrCo) were verified clinically, a transfer casting was made, and the ceramic color was selected. The Final crowns were verified by cervical fit, occlusal adjustments were made when necessary, and all crowns were cemented with RelyX U100/U200 (3M ESPE) resin cement.

### Evaluation Parameters

Participants were recalled annually for clinical and radiographic examinations. The main outcome evaluated was fiber post debonding. If the fiber post was in place at the moment of evaluation, it was considered a survival. All fiber post debonding was considered as failure. Root fractures were also considered a failure, because studies showed that fiber post decementation could lead to root fracture.<sup>16</sup> When a patient returned for an examination with a tooth lacking a post, the time of failure (post debonding) was based on his/her self-report. Periapical radiographs were taken to evaluate any endodontic problem. If any apical alteration was observed, this was not considered failure but was considered unsuccessful. Failures of metal-ceramic

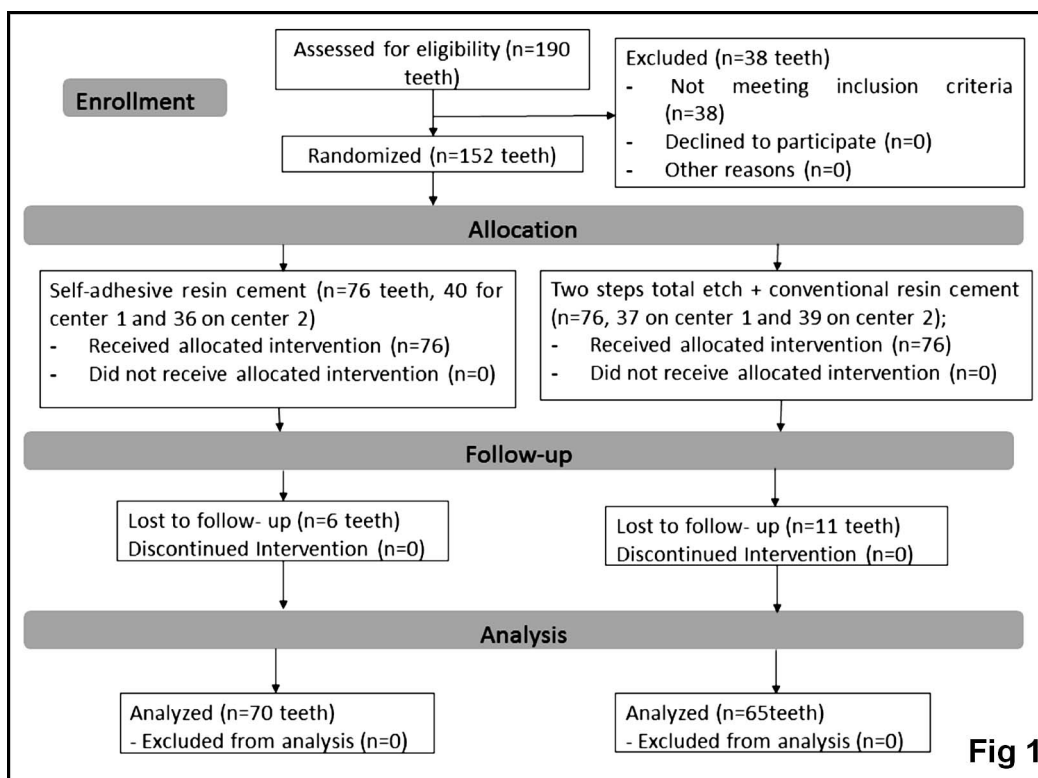


Figure 1. Flowchart of trial phases.

crowns were not considered, because they were not related to the bonding potential of resin cements. The outcome evaluated was the presence or absence of decementation, so the calibration of the evaluators was not necessary. All clinical problems observed or related by patients were treated by the researchers. The latest recalls were performed in the first months of 2016.

### Statistical Analysis

Statistical analysis was performed using the SPSS 22 for Mac software (SPSS Inc, Chicago, IL, USA). Descriptive analysis was used to describe those patients included in the study and the reasons of failures. The longevity of the posts and teeth was assessed using the Kaplan-Meier model and the long-rank test ( $\alpha=0.05$ ).

## RESULTS

### Participants

A total of 129 patients with an average age of 47.7 years, received 152 glass fiber posts. After six years, 15 patients (n=17 teeth) were lost to follow-up (12 patients were unable to be contacted; three patients changed address) resulting in a recall rate of 91.4 %

for the six-year period of the study (Figure 1). A total of 114 patients and 135 teeth were evaluated at the final count. Ninety-five of the patients were women, with a mean age of 47.4 years, and 19 were men, with a mean age of 49.25 years.

In total, 70 fiber posts were cemented with self-adhesive resin cement, and 65 fiber posts were cemented with two-step total etch adhesive + conventional resin cement. From the 135 evaluated fiber posts, 60 were cemented in the anterior teeth and 75 were cemented in the posterior teeth (52 premolars and 23 molars), as shown in Table 1. The mean observation time was 37 months (3.1 years).

### Failures

After six years, nine failures were observed, with five failures for RelyX U100/U200 and four failures for RelyX ARC. RelyX U100/U200 showed a survival rate of 92.7%, and RelyX ARC showed a survival rate of 93.8%, with no statistical difference ( $p=0.991$ ) to each other (Figure 2). Three failures were root fractures (two in the RelyX ARC group and one in the RelyX U100/U200 group), four were fiber post decementations (three in the RelyX ARC group and one in the RelyX U100/U200 group), one was a core fracture (in the RelyX ARC group), and one was a

Table 1: Distribution of restoration evaluated according to patient sex, patient age group, tooth, and class type

Sex	RelyX ARC				RelyX U200				Grand Total
	Ant	PM	Mol	Total	Ant	PM	Mol	Total	
Female (age group in years)	23	20	11	55	25	25	8	57	112
17-40	3	5	3	11	2	4	1	7	18
41-50	10	8	1	19	13	12	4	29	48
51-60	6	4	3	14	8	8	—	16	30
>60	4	3	4	11	2	1	3	6	17
Male (age group in years)	3	4	2	10	9	3	2	14	23
17-40	—	1	1	2	3	—	—	3	5
41-50	2	1	—	3	4	—	2	6	9
51-60	—	—	—	—	—	1	—	1	1
>60	1	2	1	5	2	2	—	4	9
Grand total	26	24	13	65	34	28	10	70	135

Abbreviations: Ant, anterior teeth; Mol, molars; PM, premolars.

post fracture (in the RelyX U100/U200 group). The nine failures occurred in seven patients (two patients presented two failures each), and all the failures occurred in teeth that had few remaining coronal structures (0 or 1 remaining wall).

Considering the location of failure, six failures occurred in the posterior region and three occurred in the anterior region (Figure 3). Considering the tooth type, six failures occurred in the premolars, three occurred in the incisors (two in the lateral incisors and one in a central incisor), and no failures were observed in the molars. The statistical analysis showed no statistically significant difference between them ( $p=0.210$ ).

Regarding the treatment centers (Figure 4), five failures occurred in center 1: three root fractures and two decementations. Four failures occurred in center 2: three decementations and one post fracture. There was no statistical difference found when comparing survival curves between the centers ( $p=0.339$ ).

Periodontal problems and endodontic alterations were not observed during the evaluations at both centers.

## DISCUSSION

The results presented in this study show that the survival rate of glass reinforced fiber posts is not influenced by the type of tested approach to cement fiber posts. Therefore, the null hypothesis was not rejected.

The evaluated cementation strategies present distinctive clinical approaches. Although one requires multiple steps, involving acid etching and dentin moisture control, the other does not need any

steps prior to post cementation. One would expect that those differences could influence the results, but the findings of this study may be related to the fact that all procedures were standardized, all operators were previously trained, and the procedures followed the technique recommended by the manufacturers. For example, the technique used in this study to insert the resin cement into the root canal already generated less voids in the resin cement layer and presented high bond strength values than other techniques.<sup>17</sup>

The survival similarities could be explained by the fact that high bond strength values along all root spaces are not as important to the clinical behavior. It is possible that high bond strength values at the cervical region could be enough to generate the same clinical outcome.<sup>18</sup> However, if this study had a different clinical design (retrospective), the results could be different as most retrospective studies do not have standardized procedures and generally present a higher sample.

Considering the region of the failures, more failures occurred in the anterior teeth and premolars in comparison to molars, as no failures occurred in the latter. It is likely that, different from molars, premolars and anterior teeth receive oblique occlusal forces, which are more dangerous to the restored teeth than vertical forces.<sup>19</sup> Also, molars have a larger structure that may dissipate occlusal strength more evenly. However, important factors such as remaining coronal structure and ferrule height, which were recorded to be used in future statistical analysis, showed no influence on the results. This could be related to the fact that most of the teeth presented no coronal structure. In addition, this characteristic appears to have more influence on

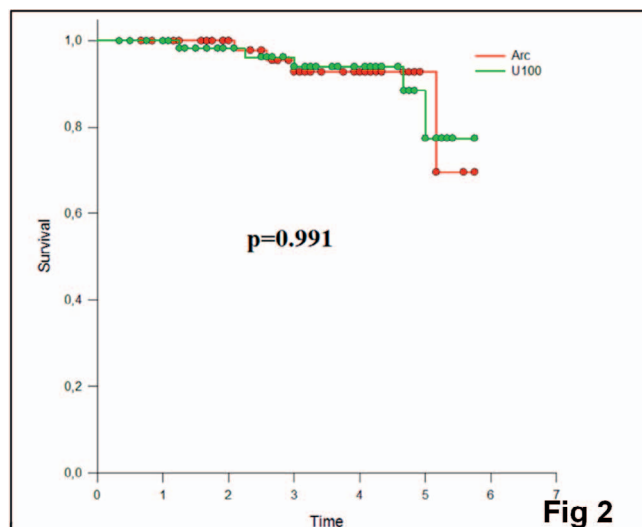


Fig 2

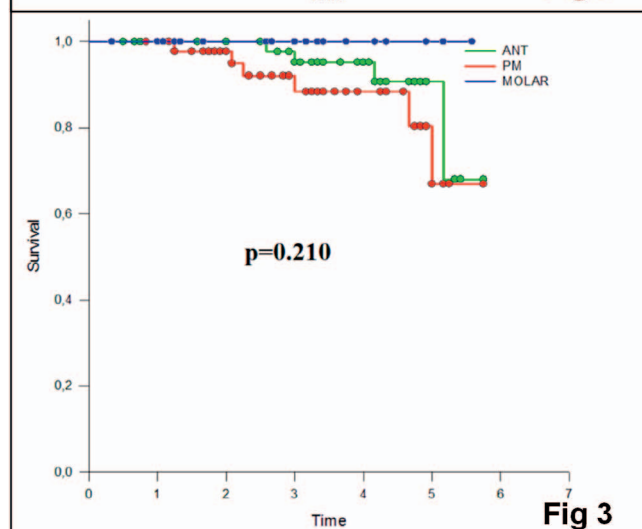


Fig 3

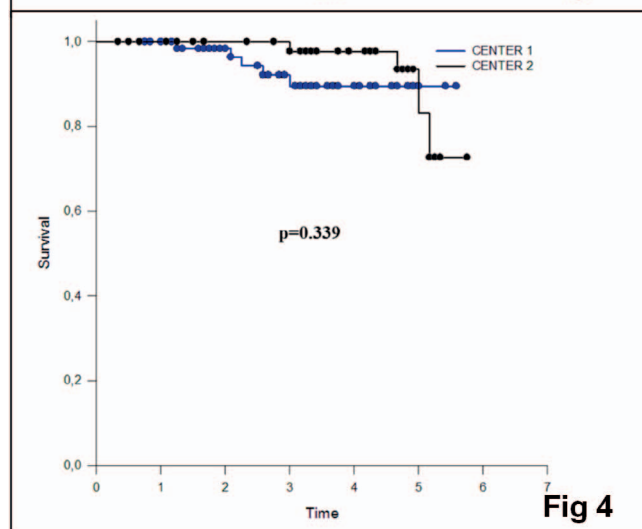


Fig 4

Figure 2. Kaplan-Meier survival curves for the comparison between cementation strategies.

Figure 3. Kaplan-Meier survival curves for the comparison between region.

Figure 4. Kaplan-Meier survival curves for the comparison between the centers.

fracture resistance than on decementation properties.

Another important issue to discuss is that all patients presented a perfect occlusal condition and had no current parafunctional habits. It is a perfect scenario for the dentist to make a single crown; however, it is not always the reality of clinical practice. In the future, it may be important to include all types of patients, so that the influence of these variables on outcomes can be evaluated.

An interesting point is the fact that the patient may influence the results to the same degree or more than the material used for the restoration, as the hygiene habits and the occlusal characteristics may affect the survival of the restoration. In this study, there were nine failures in all, and four of these failures occurred in two patients. Each patient had two failures and that received different cementation strategies, showing that the patient's characteristics are an important issue to be considered.

Although the Kaplan-Meier method estimates survival until the sixth year of observation, the mean time of observation in this study was 3.1 years. Longer observation periods are, of course, always better, and this could be a limitation of this study. However, the survival rates presented in this study are satisfactory compared with other clinical trials with longer (five years) follow-up survival rates, such as Schmitter and others.<sup>20</sup> They found survival rates near 70% for teeth restored with glass fiber posts.

Randomized multicenter clinical trials are important tools to obtain relevant data with a high level of evidence, but they also present some drawbacks. These include achieving the size of the sample, the observation time, the high rates of withdrawal, and the need to follow strict criteria such as the CONSORT statement.

It is also important to highlight the fact that the characteristics of the cities where the study was developed may affect the results. Although no statistically significant differences were found between the survival rates of the centers, in one center there was a higher patient dropout because it is a city with a low fixed permanent residence, with a student and military population that often moves. A more fixed population facilitated the lower dropout in the other city. This is very relevant, as the only difference observed regarding the centers was the follow-up of the patients.

Another important issue is that all the teeth received a metal-ceramic crown as the final restora-

tion, which was performed using the same technique and the same resin cement. The control of these factors also helped to avoid possible bias and allowed for the assessment of the real effects of the resin cement on fiber posts. It is also important to point out that, as the first randomized multicenter clinical trial to evaluate the influence of cementation strategies on the survival of teeth restored with glass fiber posts, the results should be interpreted carefully. From this study, it was found that both resin cements performed adequately, and restorations had adequate survival rates. However, more clinical studies considering critical clinical factors are essential to generate more evidence to help clinicians decide the best clinical protocol when planning restorations with glass fiber posts.

### CONCLUSION

Self-adhesive and regular resin cements are feasible options to cement glass fiber posts, with an adequate survival of the restorations.

### Acknowledgments

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### Regulatory Statement

This study was conducted in accordance with all the provisions of the local human subjects oversight committee guidelines and policies of the Federal University of Santa Maria, Brazil. The approval codes for this study are 099/2009 and 0170.1.243.000-09.

### Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

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