A Preliminary Report on Short-Term Clinical Outcomes of Three-Unit Resin-Bonded Fixed Prostheses Using Two Adhesive Cements and Surface Conditioning Combinations

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Purpose: The aim of this study was to evaluate the survival rate of three-unit surfaceretained, resin-bonded, metal-ceramic fixed dental prostheses (RBFDP) using two adhesive cements and two surface conditioning methods. Materials and Methods: Between 2005 and 2009, a total of 58 patients (34 women, 24 men; mean age: 42.1 years) received 58 three-unit RBFDPs made of a nonprecious alloy (Wirocast Co-Cr). Restorations were cemented employing the following combinations: (1) alumina air abrasion-silane + Panavia F 2.0 (group A1), (2) tribochemical silica coating (CoJet)-silane + Panavia F 2.0 (group A2), (3) alumina air abrasion-silane + Super-Bond C&B (group B1), and (4) CoJet-silane + Super-Bond C&B (group B2). Teeth were conditioned using the adhesives of the cements accordingly. Adaptation, debonding, fracture, and crack and caries formation were considered for clinical evaluation. Data were collected at baseline, 6 months, and annually thereafter. Fortyeight RBFDPs were available for follow-up (mean: 20.3 months, minimum: 6 months, maximum: 42 months). *Results:* The effect of cement type on the survival rate of RBFDPs was not significant (P > .05). The survival rate was also not significantly affected by the location (maxilla: 93.2%, mandible: 92.9%; P = .928). All experienced failures were observed within the first year after cementation. In total, four complete debondings were encountered (two in group A1, one in group A2, and one in group B1 at months 1, 3, 7, and 3, respectively). Group B2 did not result in any failures during the observation period. The failures were adhesive debondings between the metal surface and the cement. **Conclusion:** Early findings did not show significant differences between the cement and conditioning type combinations, with group B2 presenting no failures. Int J Prosthodont 2010;23:353-360.

Resin-bonded fixed dental prostheses (RBFDPs) are a minimally invasive treatment alternative for the replacement of missing teeth when conservation of the

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abutment tooth structure is required. However, the reduced retention of RBFDPs, depending on their geometry and design, is still a clinical concern in prosthetic dentistry. The clinical success of RBFDPs has been attributed to many variables, and evidence-based research has focused on mainly tooth preparation and the design of such restorations.¹⁻⁴ On the other hand, different opinions exist regarding preparation methods to optimize their retention.5-8 While some studies suggest a wider surface area through vertical grooves and rest seats with resistance form for clinical retention,^{3,4,9} others emphasize the extension of the metal framework with a "wraparound" design without preparation to impact clinical longevity.^{3,4,9-13} The principle aim of tooth preparation and framework extension is to reduce stresses at the bonding interface and thereby increase retention and resistance.¹ RBFDP stability can also be attributed to adhesion of resinous cements to the metal framework and etched enamel.

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Insufficient retention and resistance between the retainer and the abutment teeth usually causes debonding of the metal from the abutment teeth under repeated loading after long-term use.¹³⁻²² Clinical reports have revealed survival rates ranging between 40% and 80% for RBFDPs in the first 5 years after cementation with 4methacryloyloxyethyl trimellitate anhydride (4-META)or 10-methacryloyloxydecyldihydrogen-phosphate (MDP)-based adhesive cements.^{12,14,23-26} Regardless of all the developments in bonding techniques and adhesives, the biomechanical aspects of the prosthesis design and tooth preparation methods have been advocated as the predominant factors for unfavorable clinical retention and resistance.^{15,27} On the other hand, RBFDPs have been reported to last longer than their predecessors with improved design.^{15,28,29}

With today's adhesive technologies, adhesion of resin cements to the dental tissues is not a major problem. Conversely, in comparison to dental tissues, the adhesion of resin-based materials to metal surfaces still presents some problems.⁸ Debonding of retainers has been reported with higher clinical failure rates.^{12,14,25} However, in all of these clinical studies, the recent adhesion technologies for conditioning metal surfaces were not practiced. Today, it is possibile to clean, activate the surface energy, and increase the surface roughness of metals using airborne-particle abrasion methods with either alumina or silica-coated alumina particles (silica).^{30,31} The air-abraded surfaces are then treated with a silane coupling agent for better adhesion of the resin cements. Silane molecules react with water to form three silanol groups (-Si-OH) from the corresponding methoxy groups (-Si-O-CH₂).³² The silanol groups then react further to form a siloxane (-Si-O-Si-O-) network with the silica surface. The monomeric ends of the silane molecules react with the methacrylate groups of the adhesive resins by a free radical polymerization process. When surfaces are treated with alumina particles, silanes, with their hydrolyzed silanol groups, could also form chemical adhesion through covalent bridges to the surface hydroxyl groups (-AI-O-Si-).32 Although this could theoretically happen, its clinical relevance is still unknown. Such methods are also applicable using chairside air-abrasion devices that allow for the use of small particle sizes of alumina and silica.³⁰ However, the latter has not been studied clinically in combination with metal RBFDPs.

Resin cements vary depending on their composition. The most frequently used ones, in combination with the metal frameworks of FDPs, are based on 4-META and MDP monomers.^{31,33} Since adhesion has two aspects, namely one to the metal and the other to the tooth surfaces, both aspects should be considered when cementing RBFDPs. Burrow et al³⁴ reported unfavorable adhesion of MDP-based cements to the dental tissues,

whereas they have been reported to work well on metallic and zirconia surfaces.^{30,35,36} On the other hand, adhesion of 4-META resins to dental tissues was found to be superior when compared to MDP-based cements.³⁴ Although the effect of the luting cement on RBFDPs has been studied in vitro,^{14,22} clinical evaluations have concentrated mainly on the prosthesis design and tooth preparation.^{5,6} In this context, the relation between in vitro and in vivo studies remains unclear, even irrelevant in some studies.^{28,37}

Therefore, the purpose of this study was to assess the survival rates of RBFDPs with an emphasis on luting cement type and conditioning methods. The null hypothesis tested was that activation of the metal surfaces would add to the adhesion of the resin cements, thereby increasing survival rates regardless of the cement type.

Materials and Methods

Fifty-eight consecutively recruited patients (34 women, 24 men; mean age: 42.1 years) who needed RBFDP treatment and met the study's inclusion criteria were included in this study. Information was given to each patient regarding the alternative treatment options. All patients were treated at the Prosthodontics Clinics of Ege University, School of Dentistry, Izmir, Turkey, between February 2005 and March 2009 after signing the appropriate informed consent form approved by the university's institutional review board. The inclusion criteria employed comprised the following: all subjects were required to be at least 18 years old, able to read and sign the informed consent document, physically and psychologically able to tolerate conventional restorative procedures, and willing to return for followup examinations as outlined by the investigators. The patients without any active periodontal or pulpal diseases, having sufficient tooth structure, and good oral hygiene were included in the study; patients with parafunctional habits were excluded. Altogether, the patients received 58 three-unit RBFDPs made of non-precious metal alloy (Wirocast Co-Cr alloy, Bego). The materials used in this study are outlined in Table 1.

RBFDP Design

The RBFDPs were retained with metal wings (surfaceretained) according to a previously described design.³⁸ Minimal thickness and height of the retainer wings were maintained at 0.4 mm and 4 mm, respectively.

Tooth Preparation

After preoperative steps including prophylaxis and the replacement of existing restorations where present had commenced, teeth were prepared in a minimally

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 Table 1
 Materials Used in This Study

Brand name	Manufacturer	Chemical composition	Batch no.
Panavia F 2.0	Kuraray Medical	A paste: BPEDMA/MDP/DMA B paste (opaque): Ba-B-Si-glass/silica-containing composite	00037 A 00020 A
Oxyguard II	Kuraray Medical	Polyethyleneglycol/glycerin gel	00471 A
Super-Bond C&B	Sun Medical	Initiator: Tri-n-butylborane derivative Monomer liquid: 5% 4-META in MMA Powder (clear): Pulverized PMMA Green conditioner: 10% citric acid with 3% ferric chloride aq. Red conditioner: aqueous phosphoric acid, organic thickener	TF11 81201 80704 80403
Alumina sand	Korox, Bego	Aluminium trioxide particles, particle size: 50 µm	116459
CoJet-Sand	3M ESPE	Aluminium trioxide particles coated with silica, particle size: 30 µm	165092
ESPE-Sil	3M ESPE	3-methacryloxypropyltrimethoxysilane, ethanol	152745

BPEDMA = bisphenyl-A polyethoxydimethacrylate; DMA = aliphatic dimethacrylate; MMA = methyl methacrylate; PMMA = polymethyl methacrylate.

invasive fashion involving only minor preparations, such as the creation of a path of insertion (guiding planes) and occlusal stops.²⁸ Proximal grooves were avoided at the posterior areas. Preparations were made with a slow-speed handpiece using 80-µm diamond burs and refined using 25-µm diamond burs (TPE Diamond Kit, Shofu). A full-arch impression was made with a vinyl polysiloxane (President, Colténe/ Whaledent) and a low-viscosity impression material (Permagum, 3M ESPE). The impression of the opposing arch was made using an irreversible hydrocolloid impression material (Cavex CA 37) and interocclusal registrations were recorded.

The RBFDPs were fabricated by one experienced dental ceramist. An articulating paper (Horseshoe Full Arch, Ardent) was used to establish the appropriate occlusal morphology and contacts both during metal framework fabrication and try-in. After the ceramic (VMK 68, Vita Zahnfabrik) was glazed, an additional fitting session was performed to harmonize the occlusal and proximal contact areas. The habitual intercuspal positions of the patients were maintained, and the FDPs were adjusted according to the individual occlusal patterns of the patients. Then the restorations were polished to their definitive forms. The finished restorations were approved according to the criteria derived from a previous report³⁹; adaptation (0 = allmargins closed, adjustable minor defects; 1 = margins show unacceptable ditching), debonding (0 = no)debonding, 1 = partial debonding, 2 = total debonding), fracture (0 = no fracture, 1 = chipping, 2 = fracture), crack and caries formation (0 = crack or caries)not present, 1 = crack or caries present), and the location (maxillary or mandibular) were all recorded.

Surface Conditioner and Cement Combinations

The following combinations of two adhesive resin cements (alumina air abrasion-silane and tribochemical silica coating [CoJet, 3M ESPE]-silane) and two surface

Table 2 Distribution of RBFPDs A	According to Location
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Group	Maxilla	Mandible	
A1	11	3	
A1 A2	9	1	
B1	10	4	
B2	8	2	

conditioning methods (Panavia F 2.0 [Kuraray] and Super-Bond C&B [Sun Medical]) were applied on the cementation surfaces of the RBFDPs: (1) alumina air abrasion-silane + Panavia F 2.0 (PF) (group A1), (2) CoJet-silane + PF (group A2), (3) alumina air abrasion-silane + Super-Bond C&B (SB) (group B1), and (4) CoJet-silane + SB (group B2). The groups and distribution of RBFDPs according to location are presented in Table 2. Representative photographs of the outer and the conditioned cementation surface of the RBFDPs are presented in Figs 1a and 1b. The RBFDPs were cemented after the bonding surfaces of the abutment teeth were cleaned with nonaromatic pumice. The teeth were conditioned further using the protocols of the cements accordingly. The patients were recalled 1 week after cementation to assess the oral hygiene and periodontal response. Data were collected at baseline, 6 months, and annually thereafter throughout follow-up.

Clinical Evaluation

All RBFDPs in this study were completed and evaluated by two experienced, calibrated operators who followed meticulous clinical procedures and came to a consensus in the case of any disagreement. The success ratios for each response variable were recorded in periodic controls. Since the time required for the periodic controls differed individually, these ratios were considered definitive measures rather than estimations of

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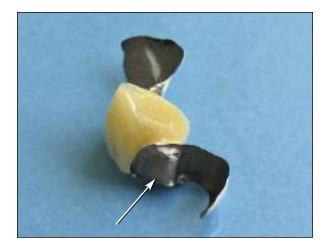




Fig 1a (*left*) Representative three-unit anterior surfaceretained RBFDP. The air-abraded cementation surface is indicated by the arrow.

Fig 1b (*above*) Typical posterior RBFDP design with minor abutment teeth preparation.

1.00 **Cumulative surviva** 0.95 0.90 A1 0.85 A2 B1 B2 0.80 50 n 10 30 40 20 Months

Fig 2 Event-free survival rate of RBFDPs depending on surface conditioner–cement combinations ($n_{A1} = 14$, $n_{A2} = 10$, $n_{B1} = 14$, $n_{B2} = 10$; A1 = 91.7%, A2 = 90%, B1 = 90%, B2 = 100%).

population parameters. Partial or total debonding of the RBFDP was considered a definitive failure. Periapical radiographs were taken only when marginal adaptation failures occurred. Patients were told to call the evaluators in case of failure.

Statistical Analysis

Survival time was calculated starting from the date of cementation to the end of the follow-up period. Survival analyses were performed with a statistical software program (SPSS version 13.0, SPSS) using Kaplan-Meier and log-rank (Mantel-Cox) tests at a significance level of .05 to evaluate results versus time.

Results

Ten patients with 10 RBFDPs (8 from group A1, 1 from group B1, and 1 from group B2; 4 mandibular, 6 maxillary; 7 anterior, 3 posterior) did not participate in the recall visits. The dropout rate was 17.2%. The mean observation period was 20.3 months, with a minimum observation period of 6 months and maximum of 42 months. In total, 42 anterior and 16 posterior RBFDPs were cemented, from which 34 anterior and 14 posterior could be followed.

A total of four failures were documented during the observation period (two in group A1, one in group A2, and one in group B1 at months 1, 3, 7, and 3, respectively). Failures consisted of total debonding of the cement from the air-abraded metal surfaces, with resin being completely present on the teeth. No other failure type was noted.

Failed RBFDPs in group A1 were recemented with protocol A2, those in group A2 with protocol A1, and those in group B1 with protocol B2. This approach was practiced because the adhesion seemed to be appropriate on the tooth surface. For this reason, the other conditioning method was combined with the same cement. After recementation, they remained functional.

The effect of cement type on the survival rate of RBFDPs was not significant (P>.05). Group B2 did not incur any failures during the observation period. Overall, the RBFDPs cemented with SB showed a similar survival rate to those cemented with PF (95% and 91%, respectively; P>.05). Also, regardless of the cement type, the survival rate of RBFDPs in the groups where metal frameworks were silica-coated and silanized were not significantly different than the groups with alumina air-abrasion (90% and 96%, respectively; P>.05) (Fig 2). Cumulative proportions related with time and the confidence intervals are represented in Table 3.

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 Table 3
 Cumulative Survival Time for Treatment Groups

Group	Time (mo)	Survival estimate (SE)
A1	1	96% (0.41)
A2	1	92% (0.56)
B1	7	90% (0.95)
B2	3	90% (0.95)

SE = standard error.

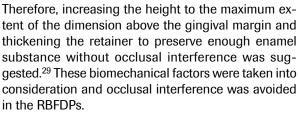
Fig 3 Event-free survival rate of RBFDPs depending on location ($n_{maxilla} = 38$, $n_{mandible} = 10$; maxilla = 93.2%, mandible = 92.9%).

The survival rate was not significantly affected by whether the RBFDP was located in the maxilla (93.2%) or mandible (92.9%) (P = .928) (Fig 3).

Discussion

Modification of the tooth preparation design for mandibular RBFDPs by adding proximal grooves for the purpose of increasing the surface area, and thereby decreasing the possibility of cement failure (ie, debonding), has been advised previously.25,26,40 Retention and resistance are two important principles in prosthetic dentistry. While retention supplies stability against vertical removal forces, resistance serves for the stability of a restoration to withstand lateral forces during function. In this context, some sacrifice from dental tissues to increase retention and resistance may add to the mechanical retention. This may put the importance of the adhesion principles on metal frameworks in guestion when compared to the macromechanical principles. Since the main purpose of this study was to solely study the cross-effects of resin luting cement types and the metal surface conditioning methods on the survival of RBFDPs, no further mechanical retention features (eg, additional grooves) were added to the preparation.

In a finite element study where the effect of loading location on stress distribution of three-unit RBFDPs with various retainer design factors was evaluated, it was shown that lateral occlusal forces acting on the pontic caused an increased risk of failure at the retainer-abutment interface. Although cement was ignored in the finite element model, it can be anticipated that mechanical retention may reduce stress at the cement-metal interface.¹³ Furthermore, the stress values on the remaining tooth and the prosthesis decreased with increased retainer thickness and height.



1.00

0.95

0.90

0.85

0.80

Ω

Mandible

10

30

40

50

20

Months

Maxilla

Cumulative survival

Tribochemical silica coating and silanization was recommended for rebonding of RBFDPs where internal fit was lost due to repeated removal of the substance from the metal framework after alumina air abrasion.^{25,41} The misfit between the framework and the tooth surface could be compensated for by this physicochemical conditioning method. Initially, from both alumina and silica coating, some surface roughening and activation could be expected. Although there were no significant differences in survival rates of all four cement-conditioning method combinations, only in group B2 were no failures experienced during the observation period. As reported previously, while this conditioning method might have served for improved adhesion of the cement on the metal,30 the 4-META-based cement might have created more durable adhesion on the tooth surface.³⁴ Based on the preliminary results of this study, this combination could be suggested for clinical applications, but only longterm results will verify whether the fit is of more importance than the adhesive cementation methods.42 Furthermore, all failures were experienced almost within the first 6 months in function and, therefore, could be considered as early failures. In in vitro studies, the hydrolytic stability of resin adhesion onto alumina air-abraded and silanized surfaces was guestioned.^{30,43} Nevertheless, this could not be verified within the 42-month maximum clinical observation period.

The results of this study should be coupled with the failure types. Since adhesion of the cement has two aspects, one to the metal and the other to the tooth surface, failure sites may indicate the weakest link in bonded joints. The failures (4 of 48 restorations) were observed as total debonding of the cement from the airabraded metal surfaces, with resin being completely present on the teeth. This indicates that the adhesion of the resin cements to the dental tissues surpasses that of adhesion to the metal frameworks. Although the MDP monomer in Panavia F 2.0 presents bifunctional groups that claim to adhere both to metal and tooth substrate, the manufacturer's instructions still advise preliminary alumina air abrasion of the metal framework. In principle, Panavia F 2.0 does not require the use of a silane coupling agent for luting.44 While the rationale for the use of air abrasion methods is to increase the surface energy and roughness in addition to its surface cleaning effect,^{43,45} silanes are suggested to be used to increase the surface wettability and to form covalent bonds between the resin and the hydroxyl groups on the metal.³² In this way, improved adhesion was expected. Since there were no significant differences among groups in this study, the hypothesis was partially accepted. Considering the adhesive failures between the metal and the cement in the failed cases, it can be stated that the adhesion methods seem not to be sufficient to exceed the cohesive strength of the cement.

When adhering substrates on one another, the dilemma in dentistry is whether to obey the instructions of the conditioning method or the instructions of the cement. For instance, when the instructions of the silica coating are complied with, the application of an MPS silane is compulsory. It can then be anticipated that the functional monomers of the adhesive resins are not directly in contact with the sandblasted surface since the silane layer may act as a barrier. In previous studies, while silane application showed a slight but insignificant increase with BisGMA-based cements on nickelchromium (Ni-Cr),³⁵ application of MDP-containing Panavia Ex and Panavia 21 (Kuraray) on alumina airabraded zirconia resulted in three times higher results than that of silica coating and silanization.³⁶ The electrochemical properties of the metallo-siloxane layers on Co-Cr might have affected the results. In fact, the hydrolyzed silanol groups of the silane orient better toward Co-Cr and Ni-Cr alloy surfaces, since there are more bonding sites for silanol groups on these alloy surfaces compared with high-palladium and goldpalladium alloys.³⁰ Although the substrates, test methods, cement types, and aging conditions vary in these studies, whether the application of MPS silane increases or hampers adhesion and wettability of resin cements needs to be clarified in future studies. Silanes in general increase surface wettability and modify surface energy, which may even improve the adhesion of any type of adhesive resin. If they acted as insulating agents, then all groups would suffer from the same failure phenomenon, which was not the case in this study. Theoretically, the active side of MDP and 4-META does not react with the active side of silane. On the acrylic side of silane, however, both may copolymerize through covalent bonding. With this, their active groups are possibly "trapped" in the polymer network. This could have taken place, especially in group B2. Nevertheless, the clinical relevancy of -Al-O-Si- and Si-O-Si- bonds obtained with silanes cannot be stated due to the limited number of failures at this stage. Hence, the clinical relevance of in vitro studies on existing adhesion principles relevant to metals, or at least to Co-Cr, needs to be validated with the long-term follow-up of this study. Clinical observations are also needed without application of silanization.

A thermodynamic equilibrium at a metal-polymer (composite resin) interface is reached by the complete conversion of non-noble metal atoms to stable metal oxides or the reduction of a noble metal oxide to the metal.⁴⁶ The equilibrium is characterized by bringing the interfacial energy of the metal in line with that of the polymer, leading to adhesion promotion between the two adhering partners. The reactions at polymer-metal interfaces are not only controlled thermodynamically by redox potential, but also by factors such as heating and heat pretreatment. Decreasing the activation energy by heating or by plasma pretreatment could be necessary to initiate the interfacial reaction. Since the thermal expansion coefficients of metal (13 to 17×10^{-6} /°C) and polymer-based cement (0.59 to 3×10^{-6} /°C) are different from each other, it seems that adhesion of these two surfaces cannot be compensated for by any of the bonding systems.

Several other factors may affect the longevity of RBFDPs. In this study, Co-Cr alloy was used for the fabrication of metal frameworks due to cost concerns since the patients paid for their treatment privately. Having a higher elasticity modulus, even in thin sections, and the affinity of the metal to oxygen to form oxides on the metal surface might facilitate durable restorations.^{12,42,47} To prevent early failures between the cement and metal, Hansson and Bergström¹⁴ reported that the adhesion of RBFDPs must still be based on mechanical retention. However, they used a copper containing metal-ceramic gold alloy and employed the high-temperature oxidation method. In that study, even though the RBFDPs were cemented with Super-Bond, early failures of the restorations were observed. The reason for the low survival rate was attributed to no or too thin copper oxide layers, yielding to a weak reaction of 4-META with the oxide layers, eventually reducing the cement-gold alloy bond.44 A thicker oxide layer of

© 2009 BY QUINTESSENCE PUBLISHING CO, INC. PRINTING OF THIS DOCUMENT IS RESTRICTED TO PERSONAL USE ONLY. NO PART OF THIS ARTICLE MAY BE REPRODUCED OR TRANSMITTED IN ANY FORM WITHOUT WRITTEN PERMISSION FROM THE PUBLISHER. Co-Cr alloy could be expected to react better with the resin. Similarly, increasing the abutment teeth of RBFDPs was shown to result in significantly higher debonding rates.^{38,42,47} Therefore, the findings of this study may change depending on the alloy type and the increased number of units.

In previous clinical studies, the survival rate of RBFDPs placed in the maxilla was shown to be higher than those in the mandible.^{25,26} This was attributed to the flexion of the restorations in the mandible during mastication. Localization of the RBFDPs was demonstrated to not have a significant effect on the longevity of RBFDPs in an earlier report,¹⁵ while conversely, a higher failure rate for anterior RBFDPs was reported in another long-term clinical study.⁴⁸ Although not being a major parameter investigated in the current study, the results revealed that localization did not have a significant effect on the survival rate.

Partial or total debonding failures were the most common modes of failure in all clinical studies with RBFDP restorations.^{49,50} However, repeatedly debonded RBFDPs should not be rebonded; the etiology of the failure should be determined, and if necessary, other treatment alternatives such as implants or conventional FDPs should be considered.^{7,44,48} As an alternative treatment approach, the application of direct or indirect fiber-reinforced composite (FRC) FDPs is growing. However, none of these other treatment options are problem-free; complications should be communicated with the patients. Today, with the developments in implant dentistry, RBFDPs are being applied less. However, RBFDPs are still indicated when the quality and quantity of the bone are not suitable for implants or if medication-, maintenance-, age-, or economicrelated reasons prohibit other costly treatment options.¹² Also, while full-coverage FDPs jeopardize the cementoenamel junction, leading to periodontal problems in the long run,⁵⁰ indirect FRC FDPs are also prone to high debonding rates.⁵¹ In terms of adhesion aspects, direct FRC FDPs seem to perform more favorably than indirect,52 but unfortunately, no controlled clinical trials exist to date with such materials. Another recent approach to RBFDPs is cantilever FDPs. However, their long-term survival has also been reported to not be very favorable.⁵³ Nonetheless, when the results of this study are compared with those of FRC FDPS (75% success rate and 93% functional survival rate over 5.25 years⁵⁴) and all-ceramic RBFDPs (67.3% with two retainers and 92.3% with one retainer in 5 years⁵⁵), it can be stated that metal-ceramic RBFDPs still have indications for a predictable clinical outcome. The restorations seen in this study are scheduled to be followed for a longer period of time.

Conclusions

No significant effects on the clinical outcome were observed regarding the choice of cement and conditioning type throughout the mean clinical observation period of 20.3 months. The survival rate was not affected by prosthesis location (maxilla versus mandible), while the conditioner-cement combination silica coating and silanization–Super Bond C&B cement combination presented no failures.

This study's preliminary conclusions must be interpreted with caution since the clinical observational time frame was limited. Moreover, the initial power analysis was not calculated, and this may have precluded the detection of relevant differences.

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