Prospective clinical split-mouth study of two-wing retained resin-bonded anterior fixed dental prostheses with metallic and ceramic framework: 5-year results

Short title: Clinical performance of resin-bonded anterior fixed dental prostheses

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Declaration of Competing Interest
The authors do not have any commercial interest in any of the materials used in the study.

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ABSTRACT

**Purpose:** To analyze the clinical performance of two-wing retained resin-bonded fixed dental prostheses (RBFDPs) after 5 years of clinical use with respect to technical and biologic complications as well as survival and success rates. **Materials and Methods:** RBFDPs were either made of 3Y-TZP zirconia layered by hand (LAVA frame veneered with LAVA Ceram; 3M) or made of metal frameworks (Remanium Star, Dentaurum; layered with Reflex, Wieland). The primary endpoints were de-bonding or fracture. The secondary endpoints marginal integrity, marginal discoloration, abrasion of antagonist dentition, patient satisfaction, Gingival Index (Loe and Silness), and side effects were evaluated at baseline and after 5 years. The survival and success rates were calculated using the Kaplan-Meier method. Log-rank test was used to compare the survival and success rates of the different materials. **Results:** The mean observation time was 6 years and 10 months. The estimated cumulative ratio of success after 5 years was 88.9% ± 10% for metal-supported and 33% ± 16% for all-ceramic two-wing–retained RBFDPs. After conversion into one-wing retained RDFDPs, the survival was 100% in both groups. Debonding of one of the two wings was the major complication. One zirconia framework fracture occurred. Metal-based two-wing–retained RBFDPs showed a significantly higher success rate, but lower esthetic evaluation. **Conclusion:** Due to the reduction of technical complication rate and less invasiveness, one-wing–retained RBFDPs should be preferred over two-wing retained RBFDPs whenever possible. *Int J Prosthodont 2022. doi: 10.11607/ijp.7765*
1. Introduction

Maxillary lateral incisors show the highest incidence of agenesis in the anterior region. Bilateral agenesis of maxillary lateral incisors is more common than unilateral agenesis and the prevalence in females is 1.37 times higher than in males [1].

Three fundamental treatment alternatives are available for the management of missing anterior maxillary teeth: Autotransplantation, orthodontic space closure, and prosthetic replacements [2 - 4]. Fixed prosthetic solutions include implant supported single crowns (ISCs), traditional fixed dental prostheses (FDPs), and resin-bonded fixed dental prostheses (RBFDPs). The survival rates reported by systematic reviews after 5 years are 96.3% for ISC, 94.4% for metal-ceramic FDPs, and 91.4% for RBFDPs respectively [5 - 7].

Traditional FDPs require considerable invasiveness, which is critical especially when used in young patients with healthy abutment teeth [8] and is associated with a high rate of serious endodontic complications [9].

In contrast, implants can help preserve healthy teeth from tooth structure removal. However, continuous eruption of the adjacent anterior teeth associated with the facial/dentoalveolar growth of young patients, can compromise a long-term functionally and/or esthetically satisfying outcome [10]. Especially in patients with a short or long face type, further growth can create a serious risk even after the age of 20 years [11, 12].

Resin-bonded fixed dental prostheses (RBFDPs) are often used as an alternative to implant-supported single-crowns, traditional FDPs, or orthodontic procedures in the following clinical situations: (1) implant treatment is contraindicated, (2) extensive surgical interventions should be avoided, (3) the space available is inappropriate for
an implant treatment, (4) the patient is too young for an implant-supported prosthetic restoration, (e) an implant-supported prosthetic restoration is rejected by the patient, or (f) an orthodontic gap closure with canine substitution is not possible or rejected by the patient [13 - 16]. Important requirements for the use of RBFDPs are healthy abutment teeth that are free of caries or fillings, sufficient interocclusal space (approx. 0.8 mm), and sufficient amounts of enamel [14].

Prosthetic restorations with RBFDPs were already described in the scientific literature in the 1970s [17]. With the introduction of metal-based RBFDPs in the 1980s, the invasiveness was lowered and there was no need for unphysiological splinting of the abutment teeth [18]. In the 1990s, glass-infiltrated aluminium oxide ceramic was firstly used in a clinical study to manufacture all-ceramic RBFDP with two retentive wings [19]. RBFDPs made of zirconia appeared to be advantageous with varying 10-year survival rates from 94.4% to 100% [14, 20 - 25]. Besides zirconia, various all-ceramic materials have been used for RBFDPs through the advances in technology like lithium disilicate, glass-reinforced, and alumina-based ceramics [26, 27], whereby mainly metal alloys or zirconium oxide ceramics are used for framework fabrication with a tooth structure removal of 0.5 mm and 0.7 mm recommended for the preparation of the retentive wings [20]. The preparation design - especially a retentive preparation geometry - has been shown to play an essential role for the success of RBFDPs and must be matched with the material properties and the adhesive protocol being used [20, 28, 29]. RBFDPs made of zirconia frameworks presented significantly higher survival rates than other framework materials [7]. De-bonding and framework fracture represent the most frequent technical complications for RBFDPs [7,29,30]. Cantilever RBFDPs demonstrated lower clinical fracture rates, lower de-bonding rates, and higher success rates than two-retainer RBFDPs [7, 31].
Although numerous clinical studies can be found in the scientific literature, there is little evidence on prospective clinical split-mouth studies using zirconia versus metal-based frameworks for anterior RBFDPs. The present prospective randomized split-mouth study analyzed the clinical performance of two-wing retained RBFDPs after 5 years of clinical use. The null hypothesis states that there is no difference between both RBFDP materials after 5 years of clinical use with respect to technical and biological complications as well as survival- and success-rates.

2. Materials and Methods

Within this prospective clinical study patients with bilateral agenesis of maxillary lateral incisors were treated with two different types of two-wing retained resin-bonded anterior fixed dental prostheses, one made applying a metallic, the other one made with a zirconia ceramic framework. The localization of the RBFDP type was randomized in every patient. The clinical study was approved by the ethical committee of the university hospital (Project # 150-08).

2.1. Study population

A total of 9 patients with two congenitally missing lateral incisors of the maxilla in need of a resin bonded fixed dental prosthesis (RBFDP) were included based on the following inclusion and exclusion criteria:

- Indication for a veneered two-wing retained RBFDP with a framework either made of LAVA zirconia (wall-thickness of min 0.5mm) or of non-precious metal (CoCr)
- Minimum age: 16 years
- No planned change in location, patient commitment to attend annual recall appointments
At least average oral hygiene
- Bilateral agenesis of upper lateral incisors
- Caries-free and periodontal stable adjacent teeth (FDI: 13, 11, 21, 23)
- Exclusion of pregnant and lactating women
- Exclusion of patients with parafunctions and bruxism

All patients were informed verbally and in writing about the treatment modalities and gave his/her written informed consent.

2.2. Treatment protocol and restoration fabrication

The restoration--alternatives (zirconia or metal framework) were randomly assigned to the treatment site (first or second quadrant).

After determination of the restoration--alternatives, the preparations were carried out regarding the individual needs and prerequisites similar to the guidelines and recommendations published by Kern et.al. 2017[32] by one skilled prosthodontist: The thin lingual veneer-like preparations of the abutment teeth were limited to the tooth enamel and were not extended further then the proximal contacts in sagittal direction.

Further a fine incisal finishing shoulder and a fine cervical chamfer preparation were conducted. A small box in the proximal areas on the pontic side and a small pinhole in the middle of the palatal surface were prepared. All preparations were carefully smoothened. Figure 1 shows the preparation before impression taking. Impressions were taken using a polyether material (Impregum/Permadyne, 3M, Seefeld, MN, USA) and plaster casts were poured.

The frameworks of the all-ceramic two-wing RBFDPs were designed using a CAD software (LAVA software, 3M, St. Paul, MN, USA) considering an anatomy-driven reduction of the pontic, milled from 3Y-TZP zirconia (LAVA frame, 3M, St. Paul, MN),
and were densely sintered. Subsequently the frameworks were hand-layered using a silicate sinter ceramic (LAVA Ceram, 3M, St. Paul, MN, US). The cross section of the connector of the all-ceramic framework was determined to be at least 6mm², the minimum material thickness of the wing to be 0.5mm. A glazing layer of 0.1mm was designated.

The metal frameworks were digitally designed and milled from non-precious metal alloy (Remanium Star, Composition according to the manufacturer: Co 60.5%, Cr 28%, W 9%, Si 1,5%, < 1% Mn, N, Nb, Dentaurum, Ispringen, Germany) and subsequently hand-layered using a silicate sinter-ceramic/Reflex, Wieland, Pforzheim, Germany). Zirconia surfaces were polished high gloss and glazed afterwards. The mean connector sizes are given in table 2.

During the clinical try-in appointment the marginal fit (fit check c&b, VOCO, Cuxhaven, Germany), the approximal contacts, the static and dynamic occlusion as well as the esthetic appearance were evaluated before the restorations were adhesively bonded. Adhesive attachment was carried out using composite resin cement (Panavia F 2.0, Kuraray Noritake, Japan) in accordance with the manufacturer`s recommendations. Prior to adhesive bonding the metal and ceramic frameworks were air-abraded with aluminium oxide particles (50µm grain size, 2 bar pressure, 10mm distance) and cleaned in an ultrasonic bath with 90% Ethanol for 3min. The MDP containing composite resin cement (Panavia F 2.0) was directly applied to the air-abraded part of the wings of the 3Y-TZP zirconia (Lava Frame). An additional metal-primer was applied to the air-abraded part of the wings of the metal frameworks (Alloy Primer, Kuraray Noritake). In all-ceramic RBFDPs “lite” shaded resin cement with was used, while the metal RDFDPs were attached applying shade “OP”. Isolation was ensured by rubber dam and enamel was etched for 30 seconds using 37% phosphoric acid. Figure 3
displays the bonded restorations in situ. Dynamic occlusion and static occlusion were checked.

2.3. Recalls and evaluation

Patients underwent at least one annual recall and the restorations were analyzed for functionality and esthetics. The primary endpoints were de-bonding or fracture. The survival and success rates were calculated using the Kaplan-Meier method. Survival of a restoration: if a restoration had to be removed and needed replacement due to de-bonding, fracture, chipping, or secondary caries the restoration was rated as “total failure”.

If a de-bonding or fracture occurred, but the restoration could be re-bonded or modified and further used, it was rated as “technical complication” and the success rate could be calculated, as recommended by Kern et al. [20]. Log-rank comparison was used to compare the survival and success rates of the different restoration alternatives (metal versus all-ceramic). In these cases, photographs were taken and clinical procedures documented. A specific case description for all technical complications and the individual solution is given in the result section.

The secondary endpoints were evaluated at baseline and after 5 years:

2.4. Marginal Integrity

The marginal integrity was rated 1) excellent: no margin could be probed, 2) good: minimal probing possible at some areas, 3) critical: probing possible, observation necessary, but no need for renewal, and 4) unacceptable: restoration needs to be replaced.
2.5. Marginal discoloration

The marginal discoloration was rated 1) excellent: no marginal discoloration could be observed, 2) good: light marginal discoloration, but removable by polishing, 3) critical: marginal discoloration that cannot be removed by polishing, observation necessary, but no need for renewal, and 4) inacceptable: heavy discoloration which leads to necessary renewal.

2.6. Abrasion of antagonist

The abrasion of the antagonist was rated at baseline and after 5 years 1) excellent: no abrasion could be observed, 2) good: uniform abrasion perceptible on antagonists and other teeth not referable to the restoration only 3) critical: considerable abrasion perceptible on antagonists referable to the restoration, and 4) inacceptable: massive abrasion perceptible on antagonists referable to the restoration, exposure of dentine.

2.7. Patient Satisfaction

The patient satisfaction was assessed at baseline and after 5 years observation time as 1) very satisfied, no complaints 2) satisfied, minor complaints, 3) fairly satisfied, and 4) unsatisfied, patient demands immediate renewal.

2.8. Gingival Index according to Loe and Silness [32,33]

The Gingiva condition was evaluated at baseline and after 5 years with 0) normal gingiva: natural coral pink gingiva with no inflammation, 1) mild inflammation: slight changes in color, slight edema, no bleeding on probing, 2) moderate inflammation:
redness, edema and glazing and bleeding upon probing, and 3) severe inflammation: marked redness and edema, ulceration and tendency to spontaneous bleeding.

2.9. Side Effects

Possible side effects like secondary caries, endodontic complications, or chipping of the veneering ceramic were evaluated. The secondary endpoints were evaluated at baseline and after 5 years, in accordance with the modified criteria of Ryge [35] and Hickel [36] using ALPHA (clinically excellent), BETA (clinical acceptable), CHARLIE (indication for renewal due to preventive reasons) and DELTA (indication for immediate renewal).

Data were recorded and analyzed using Microsoft Excel (Microsoft, Seattle, WA, US) and SPSS Version 25.0 (SPSS Inc., Chicago, IL, US). The survival and success rates were calculated using the Kaplan-Meier method. Log-rank comparison was used to compare the survival and success rates of the different materials used.

3. Results

The mean observation time was 2,515 ±769 days, which represents 82 months, with a minimum of 1,615 days (53 months) and a maximum of 3,725 days (124 months). The average age of the 6 female and 3 male patients was 27 ±14 years at the time of insertion. During the observation time several technical complications could be observed. The cumulative success rate is displayed in the lifetime survival curve in Figure 4. The pairwise log-rank comparison (Mantel-Cox) showed significant differences between the metal and ceramic RBFDPs (p = 0.011) regarding the technical complications and the success rates, respectively.
The estimated cumulative ratio of success after 5 years was 88.9 ±10% for metal supported and 33 ±16% for all-ceramic two-wing RBFDPs. Despite the high number of technical failures, an individual solution could be found in all cases and all restorations could stay in situ representing a survival rate of 100% over the observation period of 5 years.

3.1. Description of cases and technical failures

In two patients no technical complications were found over a period of 2,491 (83 months) and 3,701 days (123 months) respectively.

In four patients unilateral de-bonding of one retainer wing of the all-ceramic RBFDPs was observed after 940 days (31 months), 1,494 days (50 months), 1,863 days (62 months) and 3,380 days (112 months); twice on the canine, twice on the central incisor. Figure 5 shows an exemplary situation of unilateral de-bonding.

One patient experienced a fracture and loss of one retainer wing of the all-ceramic RBFDP on tooth 21 (624 days, 20 months), one patient showed a total de-bonding of both retainer wings of the all-ceramic RBFDP (744 days, 24 months).

One patient exhibited technical failures in both the all-ceramic and in the metal RBFDP. In the all-ceramic two-wing RBFDPs, the connector of the retainer wing on tooth 13 fractured (247 days, 8 months), in the metal RBFDPs a de-bonding of the retainer-wing on tooth 23 occurred (821 days, 27 months) (Fig. 6).

The debonding occurred predominantly as an adhesive failure on the zirconia side (between the zirconia and the resin). Dependent on the fracture or de-bonding pattern, the de-bonded wing was cut off, and could either be re-bonded or was replaced by a composite filling. The restoration was reshaped and polished and could therefore stay
in situ, then representing a one-wing retained RBFDP. No further side effects or adverse events occurred.

3.2. Marginal integrity
The secondary outcome of the marginal integrity showed better results for the metal than for the all-ceramic RBFDP at baseline. This trend increased after 5 years observation time (Fig. 7).

3.3. Marginal discoloration
The marginal discoloration after 5 years was classified either excellent or good, apart from one case rated critical in the metal PBFDP group (Fig. 8).

3.4. Abrasion of antagonist
Both restoration alternatives caused abrasion of the antagonists after 5 years. Uniform abrasion on all teeth was observed and increased over time in both groups.

3.5. Patient Satisfaction
The satisfaction of patients in the all-ceramic RBFDP was assessed lower after 5 years.
In contrast, the patient’s satisfaction with the metal RBFDP improved over the 5-year observation period. (Fig. 10).

3.6. Gingival Index according to Loe and Silness
The gingival index did not alter significantly over time in both groups.
3.7. Side effects
No severe side effects were reported on during the overall observation time. One tooth in the group of all-ceramic RBFDPs showed a light hypersensitivity at baseline, that could not be identified any more at the next recall after one year. No tooth showed endodontic complications, neither secondary caries. No chipping of the veneering ceramic was observed over the observation period.

4. Discussion
The present study evaluated two-wing RBFDPs with veneered metal frameworks versus frameworks made of veneered 3Y-TZP zirconia over a mean observation time of 6 years and 10 months. 6 of ten patients in this study were female patients. This can be explained in part by the findings in the literature reporting a prevalence of bilateral agenesis of maxillary lateral incisors in females [1]. The results showed a high technical complication rate in the all-ceramic two-wing RBFDPs. However, after clinical interventions (e.g., removal of one retainer) all restorations could stay in situ and could be further used. After removing one of the two retainers, both groups showed excellent survival. Therefore, the null hypothesis stated was rejected.

The estimated cumulative success rate after 5 years of clinical service showed that in 33% of zirconia two-wing RBFDPs only technical complications occurred and individual adaptation, modification, or reshaping was required. Despite the high number of technical complications, a satisfying solution for the patient could be found in all cases. The restorations could stay in situ as one-wing RBFDPs presenting a survival rate of 100% over the observation period of 5 years. The better clinical performance of one-wing RBFDPs is confirmed by literature, where cantilever RBFDPs demonstrated a lower clinical complication rate than two-wing RBFDPs in the anterior region [31, 37].
In addition, the patients in the present clinical study were at young age, where a potential of maxilla and mandible bone growth might occur leading to a possible higher failure rate in two-wing restorations.

In a systematic review on different types of RBFDPs in the anterior and posterior region reported an estimated survival of 91.4% after 5 years and 82.9% after 10 years [7]. De-bonding (loss of retention) of one of the RBFDPs (15%) and chipping of the veneering material (4.1%) were identified to be the most frequent complications over an observation period of 5 years. RBFDPs made of zirconia frameworks combined with a one-wing design showed a significant higher survival rate and significantly lower de-bonding rate than two-wing RBFDPs [38]. Generally, the one-retainer-design should be the design of choice, when it comes to RBFDPs, as several studies confirm [38-41].

Adhesive placement is considered to be a parameter influencing the de-bonding rate. In the present study design the same luting material (Panavia F 2.0, Kuraray Noritake, Japan) was applied for both metal and zirconia frameworks in accordance with the manufacturer’s recommendations. Comparable MDP-containing universal resin cements were successfully used in numerous in-vitro studies and clinical trials with a high success rate and can therefore not be an explanation of the low de-bonding rate observed in the present study [7, 42].

Due to the limited number of restorations in the present split mouth study, the secondary outcome parameters, like marginal integrity, marginal discoloration, abrasion of antagonists, patient satisfaction, gingival index, and side effects did not differ under each other. However, some trends could be observed over the observation time of 5 years: The marginal integrity slightly decreased for the zirconia RBFDPs, whereas the marginal discoloration increased in the metal framework group. In both groups abrasion of the antagonistic canines caused by direct contact to the wing made
of metal or zirconia could be observed. This might be attributed to differences in abutment tooth mobility, which can scarcely be compensated by a rigid framework like non-precious metal or, even more, zirconia with an elastic modulus of above 200 GPa as used in the present study [43 - 45]. This leads to stress concentration in the connector areas between wing retainers and the pontic, as well as shear-forces in the retainer and on the bonding surface. De-bonding can be considered as a kind of stress release in this specific situation, especially in completely rigid ceramic materials [14, 46].

This goes in line with the observations in the present study, where one fracture of a connector was detected and frequent de-bonding of one wing of the two-wing retained zirconia based RBFDPs was observed. Only in one patient a de-bonding of the retainer-wing of the metal RBFDP on tooth FDI 23 occurred after 3 years and 3 months (821 days). This is in conformance with a 5-year clinical study, which evaluated 20 anterior cobalt-chromium-ceramic and 20 glass-infiltrated alumina (In-Ceram) cantilever resin-bonded fixed dental prostheses. No de-bondings were observed with metal-ceramic group, but were detected with the all-ceramic group (n=3) [47]. This is also confirmed by the fact that all-ceramic frameworks seem to be more prone to failure. For example, different types of RBFDPs provided an effective short- to medium-term option, with all-ceramic RBFDPs performing least well and exhibiting the least favorable mode of failure, i.e., catastrophic fracture [48].

In the present study patient satisfaction was rising over time in the metal-ceramic group. However, patients were more unsatisfied with the primary esthetics compared to the antagonistic side (ceramic restoration) at any time. Further on, patient satisfaction dropped in the all-ceramic group, which might be associated to the high number of technical complications, like de-bonding and fractures. However, despite
the number of complications, all patients of the present study were very satisfied with their decision for the RBFDPs restorative solution, because of the low complexity of the treatment. This is in harmony with another study, where one-wing retained RBFDPs were compared to implant supported SCs. The level of quality of life (OHRQoL) was similar irrespective of treatment modality [49].

In the present study, special attention was drawn to accomplish an adequate connector size, especially in vertical dimension. A very important parameter for connector dimension is given by the proximal contact areas (PCA). PCAs decrease from midline to the posterior teeth, because of increasing incisal embrasures. Therefore, vertical PCA height is around 3 mm between maxillary central and lateral incisors, in contrast to 2 mm between maxillary lateral incisors and canines [50]. As a result, about 30% more space is available for vertical connector height in the PCA between central and lateral incisors against the lateral incisor and the canine. Regarding available space for the connector, first choice abutment tooth for cantilever RBFDPs is therefore the intact central incisor. In other words, related to two-wing retained RBFDPs a higher probability of fracture of zirconia frameworks can be expected in the canine/lateral incisor connector area. However, a higher fracture rate in this connector area could not be identified by the results of the present study. Another aspect in this context might be the preparation design, that was conducted similar in both groups; firstly, due to the applied CAD/CAM of both restorations, secondly due to wish for a high level of standardization and comparability.

Against this fact, failure types of metal-ceramic RBFDPs are independent of the framework design, with a high dominance of de-bonding [51]. Nevertheless, one-wing retained RBFDPs represent an excellent treatment alternative to implants with low complexity to replace lateral incisors.
A limitation of the present study is the relatively small number of patients. Moreover, all clinical studies inherently present influence of bias. However, it can be assumed that the split mouth design applied compensated for multiple influences from individual patient related factors, enabling a pairwise comparison. Therefore, the results can be considered representative. Nonetheless, there is further need of well-designed randomized controlled clinical trials with larger sample size to achieve more accurate results about the clinical success rate of different RBFDPs designs in the anterior region [42].

5. Conclusions
1. One-wing retained RBFDPs should be the preferred treatment option over two-wing retained RBFDPs, due to the reduction of the technical complication rate and less invasiveness.
2. Metal-based two-wing retained RBFDPs showed a significant better success rate.
3. The dominant complication was de-bonding. Only one framework fracture occurred in the zirconia group.

Declaration of Competing Interest
The authors do not have any commercial interest in any of the materials used in the study.

Declaration of Competing Interest
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References


FIGURES

**Fig. 1a.** Preparations for two two-wing retained RBFDPs.

**Fig. 1b.** Metal and all-ceramic two-wing retained RBFDPs after adhesive luting.
Fig. 2. Cumulative success rate (Kaplan-Meier) on the basis of technical complications like de-bonding and/or fracture of the restorations. (red: all-ceramic, blue: metal-ceramic)

Fig. 3a. Exemplary situation of unilateral de-bonding of an all-ceramic two-wing retained RBFDP.
Fig. 3b. Modification of failed two-wing retained RBFDPs in the first and second quadrant: The framework of the all-ceramic RBFDP fractured, the wing on tooth 13 stayed in situ and the defect was filled with direct composite. The pontic 12 was re-shaped and polished. One wing of the metal-ceramic RBFDP in the second quadrant de-bonded from tooth 23, was removed, and replaced by a direct composite filling. The pontic 22 was re-shaped and polished. Both restorations could stay in situ.
Fig. 4. Overview over secondary outcomes.
### TABLES

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<thead>
<tr>
<th>Material/Tooth</th>
<th>Upper central incisor</th>
<th>Upper canine</th>
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<tbody>
<tr>
<td>Metal framework</td>
<td>7.7 ± 2.4</td>
<td>6.2 ± 2.8</td>
</tr>
<tr>
<td>Zirconia framework</td>
<td>8.2 ± 3.1</td>
<td>8.8 ± 2.8</td>
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**Tab. 1:** Mean value and standard deviation of connector diameters listed separately according to materials and abutment teeth.