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Prospective Clinical Evaluation of Posterior Monolithic Zirconia Fixed Partial Dentures Using a Complete Digital Workflow: Two-Year Follow-Up

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Abstract

Purpose: To evaluate the clinical performance and survival rate of posterior monolithic zirconia fixed partial dentures over a 2-year period.
Material and Methods: A total of 20 patients, requiring 20 posterior fixed partial dentures were included in the study. Tooth preparations were scanned, and restorations were milled and cemented with a resin cement. The restorations were assessed for the quality of the surface and the color, anatomical form and marginal integrity. Periodontal status was assessed by determining the plaque index, gingival index, pocket depth, and margin index of the abutment teeth. Data were statistically analyzed using the Friedman and the Wilcoxon signed-rank tests with the Bonferroni correction.
Results: The survival rate at 2 years was 100%, and no biological or technical complications were observed. All restorations were assessed as satisfactory. The results obtained for gingival index and plaque index were better at 2 years follow-up, than at baseline. The margin index remained stable throughout the follow-up period. No differences in periodontal parameters were observed between abutment and control teeth.
Conclusions: The high survival rate after 2 years suggest that monolithic zirconia may be an acceptable alternative to metal-ceramic and veneered zirconia restorations in the posterior region. Additional long-term, controlled studies are necessary to confirm the results.

Since the introduction of the first ceramic crowns in the early twentieth century, there has been constant progress in ceramic materials and manufacturing technologies in an attempt to find an optimal solution to esthetic demand.[1–3] Nevertheless, the main drawback of ceramic restorations is their lower resistance to fracture when compared to metal-ceramic (MC) restorations, especially for fixed partial dentures (FPDs) in the posterior region.[4–7]

Zirconia exhibits excellent mechanical properties, allowing for production of FPDs in the posterior regions using computer-aided design and computer-aided manufacturing (CAD-CAM) technology.[8–11] Dental zirconia is of the tetragonal zirconia polycrystals (TZP) type, most commonly stabilized with 3 mol% ytria (3Y-TZP), as it has been proven to have the highest strength and fracture toughness.[1,12–14] Currently, 3 zirconia-generations have been developed.[14] First-generation 3Y-TZPs exhibited high opacity and, the framework must be veneered with feldspathic porcelain for esthetic reasons.[1,13] Clinical studies demonstrated comparable survival rates to MC on teeth-supported FPDs.[15–21] However, significantly lower survival rates were reported on implant-supported FPDs.[22] The main clinical complication of veneered zirconia restorations is the chipping of the veneering ceramic,[1,6,9,15,17,19–29] indicating medium and long-term clinical studies a chipping prevalence of 0% to 54% in FPDs.[4,6,10,16–18,21,22,29] Monolithic zirconia restorations have been recently introduced to solve the chipping problem.[13,30–33] Second-generation 3Y-TZP has a higher translucency, by reducing the concentration of alumina and eliminating porosity, and can be used as monolithic material.[1,13] However, esthetics is still insufficient for the anterior regions.[1] The third-generation zirconia has better optical properties suitable even for anterior regions, by increasing the percentage of yttria (4 or 5 mol%), and the amount of cubic-phase particles.[1,13] However, its strength and toughness decreased significantly.[1,13,14,34]

Monolithic zirconia restorations require minimal tooth reduction, since there is no veneering material.[35] In vitro studies have shown high fracture resistance even at a minimum thickness,[36] and superior mechanical properties when compared to other ceramics.[35–39] The introduction of CAD/CAM technology offers an alternative to conventional technology, and allows the milling of the restorations in full contour.[35] Digital technology has a number of advantages such as: saving time compared to conventional techniques, increasing the accuracy of restorations, and avoiding distortions.[35,40,41] However, due to the recent introduction of monolithic zirconia, there is limited evidence available regarding its clinical behavior, especially in posterior FPDs, and additional studies are necessary before it can be recommended for routine use.

The aim of this prospective clinical trial was to assess the clinical performance and survival of posterior monolithic zirconia FPDs. The null hypothesis tested was that no differences would be found from baseline and 2-year follow-up among the studied parameters.

Material and methods

This prospective clinical trial was conducted at the dental clinic of the Master in Bucofacial Prosthesis and Occlusion (Faculty of Odontology, University Complutense of Madrid, Spain). Fifty-eight patients, in need of posterior maxillary or mandibular 3-unit FPD were screened and examined by an experienced clinician. Out of the 58 patients examined, twenty (6 males, 14 females) fulfilled the inclusion criteria and were enrolled in the study. No power analysis was performed and the sample size was determined based on previous studies.[6,21,24,29,42–44] The age of the subjects ranged from 32 to 72 years. Before treatment, all patients signed an informed consent to participate in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethical Committee of Clinical Trial at S. Carlos University Clinical Hospital (Madrid, Spain) (C.P.- C.I. 15/236-E). Patients were treated between September 19th 2016, and March 10th 2017.

The inclusion criteria were as follow: patients in need to replace one posterior tooth (first molar or second premolar), stable occlusion and presence of natural dentition in the opposite arch, age older than 20 years, without any factor that would affect the survival of the FPDs, such as abutment teeth with inappropriate endodontic treatment, previously crowned abutments, or with periodontal disease, and occluso-gingival height suitable for a connector of at least 9 mm^2. The exclusion criteria included patients requiring FPDs of more than three units, a reduced crown length (less than 3 mm occlusal-gingival height), unacceptable oral hygiene, active caries, active periodontal disease, possible or probable bruxism,[45] or patients who are not willing to attend follow-up visits scheduled. The presence of bruxism was recorded if the patient presented with attrition on teeth, or muscle hypertrophy and/or reported teeth grinding/clenching.

Before dental preparation, the patients underwent a first digital impression with an intraoral scanner (IOS) (Trios 3; 3Shape, Copenhagen, Denmark). The impression consisted of capturing both arch and the occlusal bite registration. The clinical procedures were performed by a single clinician, with experience in placing fixed prostheses, and the use of zirconia restorations. All patients received oral hygiene instructions and underwent a professional tooth cleaning prior to prosthetic treatment.

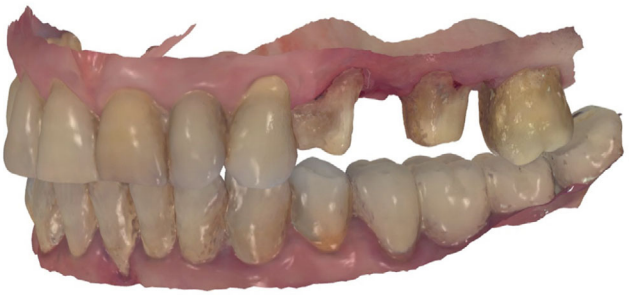

Figure 1 Digital image of one of the scanned maxillary dental preparations.

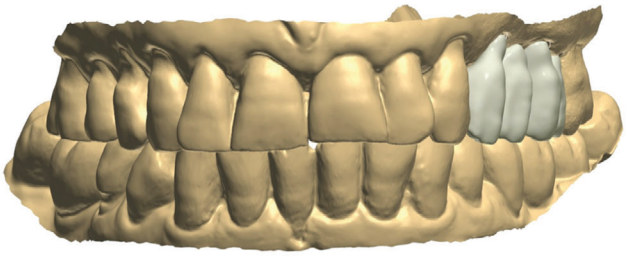

Figure 2 Digital image of one of the FPD design using 3Shape software (3Shape)

The abutment teeth were prepared with a circumferential chamfer (0.8 to 1 mm wide), an axial reduction of 1 mm, an occlusal reduction of 1.5 mm, and a 10° to 12° convergence of the axial walls.[21] The finish line was prepared isogingival. Before impression taking of the prepared teeth with the IOS, dental gingival cord was inserted in the gingival sulcus. Tooth preparations were scanned (Fig 1), and the FPDs were designed using 3Shape software (3Shape) (Fig 2).

Direct provisional restorations (Telio CS C & B; Ivoclar Vivadent, Schaan, Liechtenstein) were made, and cemented with a temporary cement (Telio CS Link; Ivoclar Vivadent). The appropriate shade was selected using the Chromascop Shade Guide (Ivoclar Vivadent). The information was sent to the Zenotec CAM milling software (Zenotec CAM 3.2; Wieland Dental, Pforzheim, Germany), and all FPDs were milled from blanks of monolithic zirconia (Zenostar T; Wieland Dental, Pforzheim, Germany) in the Wieland Zenotec unit (Wieland Dental). Zenostar T is a second-generation zirconia, and is now produced in an improved zirconia disc by Ivoclar Vivadent under the name IPS e.max ZirCAD LT. The restorations were sintered in a furnace (Programat S1 1600; Ivoclar Vivadent) at 1.450°C for 4 hours 50 minutes. Once sintered, the restorations were characterized with Ivocolor Stains, and glazed with Ivocolor Glaze Paste FLUO (Ivoclar Vivadent) at 710°C, with a heating rate of 45 °C/min and long-term cooling to 450°C, following the manufacturer´s instructions during all processing steps (Fig 3).

Figure 3 Final restoration made of a maxillary FPD using Zenostar T (Wieland Dental): (Left) External view. (Right) Internal view

Final restorations were tested in the mouth before cementation to evaluate the interproximal and occlusal contacts and marginal fit. No adjustments were necessary. The inner surface of the FPDs was carefully air abraded with 50 μm alumina particles at a pressure of 1 bar, at 10 mm for 20 seconds (CoJet; 3M ESPE, Seefeld, Germany), cleaned with a universal cleaning paste (Ivoclean; Ivoclar Vivadent) and then cemented using a resin self-adhesive cement (SpeedCEM Plus, Ivoclar Vivadent). The excess cement was carefully removed until the cement had completely cured. No retraction cord was used for cementation. After cementation, occlusal contacts were evaluated, and the adjusted surfaces were polished using a porcelain polishing kit (Optrafine; Ivoclar Vivadent).[46,47] The patients were instructed in oral hygiene education at the end of the treatment and at each recall visit and in the review visits for the scheduled follow-up period.

The restorations were assessed using the California Dental Association´s (CDA) assessment system, which focuses on surface and color, anatomical form, and margin integrity.[5,6,16,21,24,26,29,42,48,49] The 20 FPDs were examined at 1 week (baseline), 6 months, 1 year, and 2 years by 2 calibrated researchers who were not involved in the restorative treatment. Each examiner evaluated the restorations independently, and the worst result was used in the event of discrepancies. The periodontal status was assessed by determining the plaque index (PI), gingival index (GI), pocket depth, and margin index (MI) or margin stability.[50] These parameters were evaluated in the abutment (test) and control teeth (contralateral or opposite not crowned teeth).[6,15,21,24,29,35,43,48,51–52] Standardized parallelized periapical radiographs of the abutment teeth using a X-ray positioner (Rinn; Dentsply Sirona, Charlotte, NC) and clinical photographs of the restorations under standardized conditions were obtained at each evaluation (Fig 4). Success was defined as the FPD without any complication over the entire follow-up period, and survival was defined as the FPD that remained in situ at each follow-up visit.[17,22]

Statistical software (IBM SPSS Statistics 22.0; IBM Corp, ArmonK, NY) was used for the analysis. Descriptive statistics were applied to the data to evaluate clinical outcomes. The comparisons of the baseline and the follow-up values were performed by the Friedman test. The Wilcoxon signed-rank test, with the Bonferroni correction, was used for matched pairs on FPDs to evaluate differences considering the periodontal parameters and CDA ratings, and for comparisons of periodontal parameters between abutment and control teeth. Survival rates were established on the basis of the CDA criteria. Each CDA criterion was ranked on a scale of 1 to 4, where 4 = excellent, 3 = good, 2 = unacceptable (repair), and 1 = unacceptable (replacement).[6,21,29] The periodontal parameters were assessed by assigning a score of 0 to 3 (PI and GI) or 1 to 4 (MI and pocket depth).[6,21,29] The level of significance was set at $\alpha = 0.05$.

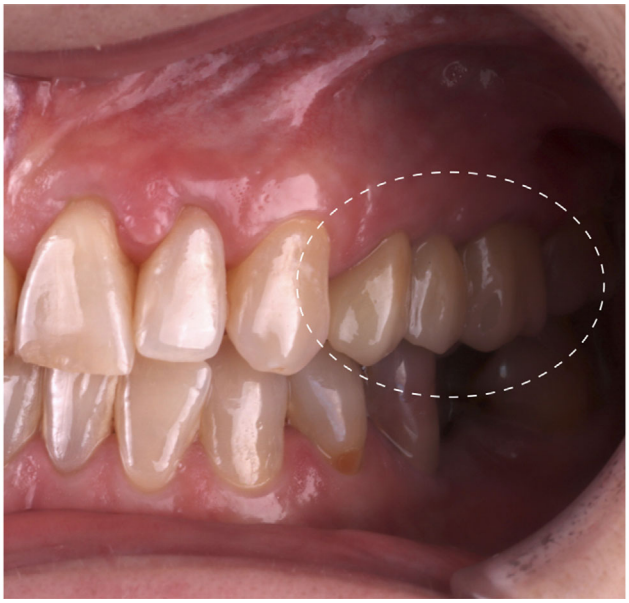

Figure 4 Clinical view of a maxillary posterior monolithic zirconia FPD (from 24 to 26) after 2 years in function.

Results

Twenty patients (with a mean age of 56 ± 10.9 years) received 20 posterior three-unit FPDs. No participants were lost during the observation period (28 ± 2.4 months). The survival and success rate at 2 years was 100%, and no biological or technical complications were observed.

All restorations were assessed as satisfactory. Deviations from the score of excellent are shown in Table 1. Surface roughness was observed in one participant from baseline (5%), that could be polished without esthetically compromising the appearance of the FPD. No differences were observed with respect to baseline for any of the parameters analyzed. In terms of anatomical form, one restoration (5%) dropped from excellent to acceptable at the 1-year follow-up because occlusion was not totally functional in one of the abutment teeth due to wear at the occlusal surface. There was no significant change from baseline to the 2-year follow-up evaluation. The marginal integrity was ranked as excellent in 95% of the FPDs after 2 years, and one FPD showed a slight discoloration on the margin, with no evidence of caries. In the same way, no significant differences were observed from baseline to the 2-year follow-up evaluation.

With respect to the periodontal parameters, significant differences were observed in the abutment teeth from baseline to the 2-year follow-up evaluation for GI ($p = 0.05$), PI ($p = 0.001$), and pocket depth ($p = 0.01$) (Tables 2, and 3). The results

Table 1 Frequency (%) (number) of CDA assessments at baseline, 6 months, 1- and 2-year follow-up evaluations for monolithic zirconia FPDs

CDA Assessment	Score	Baseline	6 months	1 year	2 years
Surface and color	4	85 (17)	85 (17)	80 (16)	80 (16)
	3	15 (3)	15 (3)	20 (4)	20 (4)
	2	0	0	0	0
	1	0	0	0	0
Anatomical form	4	100 (20)	100 (20)	95 (19)	95 (19)
	3	0	0	5 (1)	5 (1)
	2	0	0	0	0
	1	0	0	0	0
Margin integrity	4	100 (20)	95 (19)	95 (19)	95 (19)
	3	0	5 (1)	5 (1)	5 (1)
	2	0	0	0	0
	1	0	0	0	0

Table 2 Gingival Index (GI) (%) scores

Gingival Index	Baseline	6 months	1 year	2 years
0	65% (13)	75% (15)	75% (15)	85% (17)
1	20% (4)	20% (4)	15% (3)	10% (2)
2	15% (3)	5% (1)	10% (2)	5% (1)
3	0%	0%	0%	0%

Table 3 Plaque Index (PI); (%) scores

Plaque Index	Baseline	6 months	1 year	2 years
0	55% (11)	65% (13)	75% (15)	75% (15)
1	25% (5)	15% (3)	15% (3)	25% (5)
2	20% (4)	20% (4)	10% (2)	0%
3	0%	0%	0%	0%

obtained for GI and PI were better at the 2-year follow-up, than at baseline. The results for pocket depth were worse after 2 years compared to baseline. The majority of the measured probing depths at baseline were in the range of 2 to 3 mm (65%). After 2 years, 50% of the abutment teeth remained in the range of 2 to 3 mm, and 50% were in the range of 4 to 6 mm. The MI remained stable throughout the follow-up period. No differences were found between the abutment and control teeth for any of the analyzed parameters.

When comparisons were made among the four observation periods, significant differences were observed. The GI score was better at 2-year compared to baseline ($p = 0.03$). The PI score was better at 1-year ($p = 0.01$) and at 2-year ($p = 0.005$) compared to baseline, and at 2-year ($p = 0.01$) and at 1-year ($p = 0.04$) evaluation compared to 6-months data. The pocket depth score was better at baseline ($p = 0.04$), and at 6-months ($p = 0.04$) compared to 2-year evaluation.

Discussion

The data obtained in the study support the rejection of the null hypothesis, as differences were observed for periodontal parameters from baseline and 2-year follow-up.

Monolithic zirconia has been developed as an alternative to overcome the chipping of the veneering porcelain.[13,30–33,51] In the study, second-generation zirconia was used, as in most of the previous clinical studies.[54] The studies mainly focused on tooth-supported posterior crowns, reporting survival rates at 1 to 3.5 years follow-up in the range of 91.5% to 100%,[35,36,51,53,55–57] and one study reported a survival rate of 76.9% that could be due to the inclusion of patients with bruxism and because monolithic zirconia restorations are stiff and unable to absorb stresses.[54] Nevertheless, studies on posterior second-generation monolithic zirconia FPDs are scarce, reporting a survival rate ranging from 96.7% to 100%, and consistent with the findings of the study.[54,58,59]

The results of the study were also consistent with those reported in the literature after 3 to 5 years follow-up in first-generation veneered zirconia FPDs.[19,21,49,60–62] Nevertheless, other studies reported lower survival rate values after 3 to 10 years,[4,6,16–18,20,29,44,52,63–67] and technical complications were more frequent in patients with bruxism.[4] In this study, patients with bruxism were excluded, and it would be important to include these patients to evaluate techniques and procedures in future studies.[54] Likewise, other risk parameters

have also been excluded as in prior studies, both in first-generation[6,21,29,43,48] and second-generation zirconia,[35,36,54,57] in order to avoid risks not related to the material that could influence the results.

According to the CDA evaluation, a satisfactory rating was obtained for 100% of the FPDs. A change from an excellent to acceptable rating occurred in just one restoration after 2 years of function; however, no differences were observed from baseline. This result is inconsistent with previous studies on first-generation zirconia, that reported a decrease for all variables as the length of clinical follow-up increased.[5,6,15,19–21,24,29,48,49] A possible explanation for this finding could be the good behavior of monolithic zirconia restorations. One restoration showed a loss of occlusion in one abutment tooth because of wear at the occlusal surface that could be due to a loss of the surface coating of the glass resulting in an increased surface roughness.[68] The wear of monolithic zirconia restorations was previously reported, and several factors may be involved such as the surface treatment (glazed or polished), the position of the restorations, or surface roughness.[33,36,68–71] However, previous study reported that zirconia wear, either in vitro or clinical, is normally negligible.[69]

Regarding technical complications, no fractures of the FPDs have been observed. Compared to other ceramics, densely sintered zirconia exhibits the greatest stability as a structural material, with an estimated 5-year fracture rate of 1.9%.[17] In addition, the connector area designed by all the restorations was at least 9 mm^2. In this study, the chipping of the veneering ceramic has been avoided, since the restorations were fabricated in full-contour. A resin-based cement was used in the study, and no decementation or abutment sensitivity were observed, which is consistent with previous studies on first-generation zirconia.[6,18,21]

A good response in the soft tissue for all the restorations was observed. At the 2-year time point, there was a decrease in the GI and PI, contradictory with previous studies on first-generation zirconia which reported an increased risk of gingivitis in the vicinity of a fixed prosthesis.[6,21,48,49] These findings are probably due to the proper oral hygiene of the patients, the good marginal fit, and high biocompatibility of the monolithic zirconia system analyzed.

With respect to the MI, the margin of the restorations remained isogingival, except for one FPD that showed gingival recession after 2 years. This result is consistent with previous findings,[24,43] but inconsistent with other studies that reported differences from baseline probably due to the increment in GI.[6,21,29,48] However, the zirconia tested was not second-generation. The result of the present study could be associated with good plaque control, the adequate marginal adaptation of restorations, and it can also be due to the short observation period.

A complete digital workflow was performed resulting in clinically satisfying outcomes over the observation period, reducing time, and high patient satisfaction.[55,72,73] However, clinical evidence is still limited and further research is necessary.[73]

The limitations of the study were the small sample size, the short follow-up period, the lack of control group and the exclusion of bruxers. Considering this, the results suggest that monolithic zirconia FPDs and complete digital workflow represent a promising prosthetic treatment for the posterior region. A longer observation period and a greater number of patients would be necessary to be able to correctly analyze the behavior of monolithic zirconia FPDs in the medium and long-term.

Conclusions

The promising results after 2 years suggest that monolithic zirconia may be an acceptable alternative to metal-ceramic and veneered zirconia restorations in the posterior region, although bruxers were excluded. However, a longer observation period is required to validate these short-term results.

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