Complications and Patient-Centered Outcomes with an Implant-Supported Monolithic Zirconia Fixed Dental Prosthesis: 1 Year Results

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Keywords
Dental implant; edentulism; mandible; zirconia; dental prosthesis; OHIP-49.

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Abstract

Purpose: To characterize the number and type of complications that occur with a monolithic zirconia fixed dental prosthesis (MZ-FDP) supported by four endosseous implants in the edentulous mandible over time and to quantify the impact of treatment on oral health quality of life (OHQoL).

Methods: Seventeen edentulous participants were enrolled. New conventional dentures were fabricated for each participant. Four Astra Tech Osseospeed TX implants (Dentsply) were then placed in the parasymphyseal mandible, and after a period of healing, a full-arch monolithic zirconia prosthesis (Zirkonzahn) was inserted. Complication data were recorded and OHQoL was evaluated using the Oral Health Impact Profile (OHIP-49), administered on four occasions: enrollment; implant surgery; and 6- and 12-month recalls.

Results: Sixty-eight implants were placed in 17 edentulous individuals aged 30 to 78 (mean 57.9 years). Implant survival was 94% from the subject perspective and 99% from the implant perspective. Prosthesis survival was 88%. Twelve complications occurred in ten participants, whereas seven participants remained complication free. Both OHIP-49 severity and extent scores decreased significantly between enrollment and 12-month recall (p < 0.001). The mean OHIP-49 severity score at baseline was 94.8 (95% confidence interval [CI]: 73.9, 115.8) and declined an average of 76.8 (95% CI: –91.3, –62.3) units per participant. The mean OHIP-49 extent score at baseline was 17.2 (95% CI: 10.8, 23.6) and declined 16.3 (95% CI: –20.2, –12.4) units per participant on average.

Conclusions: Implant survival was high, and few complications related to the MZ-FDP were observed. The most common prosthetic complication was tooth chipping in the opposing maxillary denture, which accounted for 50% of all complication events. Substantial and clinically important improvements in OHQoL were achieved with both conventional dentures and the implant-supported MZ-FDP. The data of this short-term study indicate that the implant-supported MZ-FDP is a therapeutic option with particular advantages in the edentulous mandible that warrants further long-term study.

The prevalence of edentulism in the United States is declining. Yet continued population growth, current dental practice trends, and an increased proportion of older individuals within the population generate a continued need for edentulous therapy.1 Edentulism results in reduced oral and social function.2,3 It is associated with poorer health status across a wide range of measures, including physical health, nutrition, disability, and self-esteem.2 Conventional dentures address the problems associated with edentulism, but do so incompletely and introduce their own set of related problems.3 The rapid rate of bone resorption observed in the edentulous mandible is of particular concern due to the accompanying instability of a mandibular denture, often the most troublesome complaint of denture patients.4,5

Dental implant therapy offers advantages over conventional denture therapy in the treatment of mandibular
edentulism by providing significant improvements in prosthesis function and comfort, as well as by aiding alveolar bone preservation. The current literature shows a high level of biologic success when using four to six implants with a fixed prosthesis in the edentulous parasymphyseal mandible. However, the degree of prosthetic success and the magnitude of improvement in patient-centered outcomes for the wide variety of possible prosthesis designs are either debated or unknown.

The most commonly used and most commonly studied implant-supported fixed dental prosthesis (FDP) is the metal-acrylic hybrid prosthesis, which comes with a particular set of technical problems. Common complications for the metal-acrylic hybrid include fracture of the acrylic veneer, wear or debonding of the resin denture teeth, and screw/abutment loosening or fracture. Different prosthesis designs and materials may have entirely different prosthetic outcomes, but little data are available. Zirconia-based materials have generated considerable interest for dental applications and have the potential to address some of the problems previously encountered in the metal-acrylic hybrid. In addition to favorable physical and biologic properties, zirconia can be manipulated using computer aided design/computer aided manufacturing (CAD/CAM) technology. The ability to precisely design a full-arch prosthesis in the virtual world, to store those design files indefinitely, and to predictably fabricate such a device in a highly automated fashion may fundamentally change access to care for the edentulous population. Zirconia is currently used in endodontic dowels, dental implants, dental implant abutments, single crowns, and multiunit FDPs with varying degrees of success. The use of zirconia, specifically monolithic zirconia, has not been rigorously investigated in the fabrication of a full-arch fixed prosthesis. Aside from clinical reports, few longitudinal clinical studies on full-arch zirconia (layered or monolithic) exist.

In addition to biologic and prosthetic outcomes, patient-centered outcomes are becoming more important in evaluating the overall success of a prosthetic therapy. Oral health quality of life (OHQoL) is the most used measure of patient perception, and is considered a more complete valuation of oral disease and its treatment than general measures of “satisfaction.” Oral health impact profile (OHIP) has emerged as one of the most powerful and widely accepted tools for the assessment of OHQoL. The 49-item OHIP (OHIP-49) was developed on the basis of the 1980 World Health Organization’s International Classification of Impairments, Disabilities, and Handicaps (ICIDH). In accordance with the ICIDH, the OHIP-49 comprises seven subscales to evaluate impairment (functional limitation, physical pain, psychological discomfort), disability (physical, psychological, and social disability), and handicap resulting from dental conditions. Assessment of OHQoL in conjunction with biologic and prosthetic outcomes provides additional insights regarding the impact that possible complications have on the perception of dental therapy.

The purpose of this study was to investigate the biologic and technical complications of a full-arch monolithic zirconia FDP (MZ-FDP) supported by four implants in the edentulous mandible over a period of 1 year and to quantify the change in OHQoL.
Materials and methods

This was an Institutional Review Board (IRB)-approved, prospective clinical study using a single-arm design. A consecutive sample of 17 participants was screened and enrolled according to the inclusion and exclusion criteria.

Inclusion and exclusion criteria

Patients aged 18 to 80 at time of enrollment, American Society of Anesthesiologists (ASA) Class I or II, and who were completely edentulous in both the maxilla and mandible or those possessing a terminal dentition requiring extraction were eligible for inclusion. Patients were excluded if they met any of
the following criteria: history of radiotherapy in the head and neck region, uncontrolled diabetes, known alcohol and/or drug abuse, taking medication that might significantly interfere with coagulation and/or patients with bleeding disorders, smoking greater than ten cigarettes per day, vertical bone height less than 10 mm, unrealistic esthetic expectations, and/or psychological problems that prevent acceptance of a removable prosthesis. Pregnant women and ASA Class III or IV patients were also excluded.

Assessment and conventional denture fabrication

A panoramic radiograph and diagnostic casts were used for initial diagnosis and planning. New conventional dentures were fabricated to establish functional and esthetic parameters. A traditional approach that included custom trays, a semi-adjustable articulator, a facebow transfer, and bilaterally balanced occlusion with shallow anterior guidance was employed. Phonares I denture teeth (Ivoclar Vivadent, Schaan, Liechtenstein) were used in the denture tooth setup, and a clinical remount was performed at the time of denture insertion. A radiographic guide was created by duplicating the mandibular denture in radiopaque acrylic. A cone beam computed tomography scan was acquired with the Galileos imaging system (Sirona Dental Company, Long Island City, NY), and the data used for evaluation of implant sites.

Surgical procedures

Four Astra Tech Osseospeed TX implants (Dentsply, Molndal, Sweden) were surgically placed in the parasympyseal mandible using a clear acrylic duplicate of the mandibular denture as a surgical guide.32 The implants were tilted such that screw access holes exited anteriorly through the mandibular lateral incisors and posteriorly through the second premolars (Fig 1). A resonance frequency analysis device (Osstell, Gothenburg, Sweden) was used to assess primary stability (Fig 1). A radiographic guide was created by duplicating the mandibular denture in radiopaque acrylic. A cone beam computed tomography scan was acquired with the Galileos imaging system (Sirona Dental Company, Long Island City, NY), and the data used for evaluation of implant sites.

Zirconia prosthesis fabrication

An abutment level impression was made, and a master cast produced (Fig 2). Maxillomandibular relationships were obtained, and the master cast was mounted against a cast of the upper denture. A polymethylmethacrylate mock-up of the future prosthesis was then fabricated and evaluated intraorally to confirm fit, esthetics, phonetics, and occlusion (Fig 3). The mock-up was then scanned, milled out of monolithic zirconia, stained, and sintered by a dental laboratory (ZirkonZahn, Gais, Italy) (Figs 4–7). The definitive mandibular prosthesis was inserted approximately 16 weeks post-implant surgery. Participants were seen 6 and 12 months after prosthesis insertion for radiographic and clinical evaluation. They were educated on potential post-insertion complications of a biologic or technical nature and instructed to contact the clinic if any arose during the treatment or recall periods.

Biologic and prosthetic outcomes

Implant survival was defined as the implant being present and functional at the time of assessment. Prosthesis survival was defined as the prosthesis being present and functional at the time of assessment. Complications were broadly defined as any event that required additional treatment. The exact nature, frequency, and timing of each complication were recorded. Complications were classified as either biologic or technical.

OHIP

The OHIP-49 questionnaire was first administered at the time of enrollment to obtain baseline values. It was next administered immediately prior to implant surgery to assess the effect of conventional denture therapy, and at 6- and 12-month recall appointments to assess the effect of MZ-FDP therapy. Responses to each of the 49 OHIP items are made on a five-point ordinal scale.

Analytic methods

Two OHIP-49 summary scores were computed as dependent variables. The severity score is the cumulative sum of ordinal responses across all items with a possible range of 0 to 196. For both scores, higher values denote worse OHQoL. The extent score is a count of the number of items a participant reports having experienced “very often” or “fairly often.” In addition to these two summary scores, the seven OHIP-49 subscales were individually examined to identify factors associated with change in OHIP-49 scores. To account for multiple tests, Bonferroni correction reduced the critical significance threshold to \( p < 0.0035 (p = 0.05/14) \). These baseline associations were tested for statistical significance using one-way ANOVA. To correctly account for the hierarchical structure of the data set, serial measurements on the same individual at multiple time points, the statistical approach estimated covariance parameters using two-level fixed slope, random intercept variance components models. These were fitted using the \( \text{xtmixed} \) command in STATA version 12.0 SE statistical software (Stata Corporation, College Station, TX). The OHIP extent and severity scores were the dependent variables, and time of OHIP-49 administration was the exposure of interest. Beta coefficients from the model are directly interpretable as within-subject change in mean OHIP-49 extent and severity scores.

Results

Results are presented for 17 participants, 11 men and 6 women, who ranged in age from 30 to 78 years (mean 57.9 years) at enrollment. Eight were edentulous, and nine had a terminal dentition prior to enrollment.

Biologic and prosthetic outcomes

Sixty-eight implants were placed in 17 participants. One implant failed to integrate, resulting in patient-related and implant-related survival rates of 94% (16/17) and 99% (67/68), respectively. During the MZ-FDP observation period, 12 complications occurred in ten participants. In addition to the one implant failure, six participants chipped maxillary denture teeth,
Implant-Supported Monolithic Zirconia FDPs

Complications by type and timing

Table 1 Complications by participant during MZ-FDP observation period

<table>
<thead>
<tr>
<th>Participant number</th>
<th>Complication (number of occurrences)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>2</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>3</td>
<td>Fractured abutment (1)</td>
</tr>
<tr>
<td>4</td>
<td>Loose abutment (1)</td>
</tr>
<tr>
<td>5</td>
<td>Fractured abutment (1)</td>
</tr>
<tr>
<td>6</td>
<td>Fractured MZ-FDP (1)</td>
</tr>
<tr>
<td>7</td>
<td>Debonded component (1)</td>
</tr>
<tr>
<td>8</td>
<td>Implant failure (1)</td>
</tr>
<tr>
<td>9</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>10</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>11</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>12</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>13</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>14</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>15</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>16</td>
<td>Chipped denture tooth (1)</td>
</tr>
<tr>
<td>17</td>
<td>Chipped denture tooth (1)</td>
</tr>
</tbody>
</table>

Two broke one or more abutments, one had a loose abutment, one had a component of the MZ-FDP debond, and one fractured the distal extension of the MZ-FDP (Tables 1 and 2). Prosthesis survival was 88% (15/17); one prosthesis was lost due to fracture, and one was removed after implant failure. Over the MZ-FDP observation period, 41% (7/17) of the participants were complication-free.

**OHIP scores**

The mean OHIP-49 severity score at enrollment was 94.8 (95% confidence interval [CI]: 73.9, 115.8), and the lowest and highest severity scores were 45 and 168, respectively. Lowest and highest extent scores were 4 and 43, respectively, and the mean extent score was 17.2 (95% CI: 10.8, 23.6).

Differences in mean OHIP-49 severity and extent scores at baseline were not statistically significant on the basis of participant characteristics (Table 3). Over the entire observation period, mean OHIP-49 severity scores decreased significantly by an average of 76.8 (95% CI: –91.3, –62.3) units per participant from an enrollment high of 94.8 to 18.0 at 12 months after prosthesis insertion (Table 4, Fig 8A). A significant reduction in mean OHIP-49 severity score was observed at implant surgery, and a further significant reduction was noted at 6 months after prosthesis insertion; however, the small reduction seen at the 12-month recall was not statistically significant (Table 4, Fig 8A). Mean OHIP-49 extent scores decreased significantly by an average of 16.3 (95% CI: –20.2, –12.4) units per participant from enrollment to 12-month recall (Table 5, Fig 8B). The mean OHIP-49 extent score decreased significantly from enrollment to prior to implant surgery; however, the remaining changes were not statistically significant (Table 5, Fig 8B).

Significant (p < 0.0035) reductions from enrollment scores were observed across all seven dimensions between enrollment and immediately prior to surgery. Further significant reductions occurred in the 6 months post-insertion on dimensions of functional limitation, pain, psychological discomfort, and physical disability, but not on psychological disability, social disability, or handicap (Fig 9). No domain exhibited significant change between the 6- and 12-month recall visits.

**Discussion**

We observed a high degree of implant survival in the edentulous mandible over the course of 1 year and found technical complications to be far more common than biologic. The most common technical complication noted was chipped denture teeth in the opposing removable prosthesis, which accounted for 50% (6/12) of all complication events during the observation period. The etiology of maxillary denture tooth chipping may reflect multiple aspects of this therapy, including potential limitations of tooth arrangement and the physical properties of the selected line of denture teeth. The manufacturer reports a higher inorganic filler content as compared to other available varieties. The higher inorganic filler content adds wear resistance and superb esthetics, but may also increase the risk of chipping. Interestingly, 67% (4/6) of participants who experienced minor chipping of maxillary incisors actually preferred to leave the defect unrepaired, as they felt it added uniqueness to their smile. Two recent systematic reviews on metal-acrylic prostheses report that denture tooth wear and denture tooth fracture of either the implant-supported fixed prosthesis or the opposing complete denture are common issues with this therapy. In this study, we only found chipping complications in the opposing complete denture, not with the zirconia prosthesis.

Few complications related specifically to the MZ-FDP were observed; however, one MZ-FDP did fracture 6 months after insertion. The fracture occurred vertically through the entire body of the prosthesis, resulting in the loss of the distal cantilever segment on the affected side (Fig 10). Several factors may have contributed to this event: cantilever length, anterior-posterior (A-P) spread,37 restorative dimension, and/or the material properties of zirconia.

Each mandibular MZ-FDP possessed bilateral distal cantilevers, designed to restore first molar occlusion. Cantilever length and A-P spread varied with arch form, mental foramen position, and the accuracy of implant placement. The measured cantilever length of the fractured segment was approximately 17 mm, and the A-P spread was approximately 10 mm, yielding a ratio of 1.7 to 1. A ratio of approximately 1.5 to 1 is commonly recommended as the target value for distal extension cantilevers. An increased ratio of cantilever length to A-P spread may have contributed to an unfavorable mechanical...
Table 3  Participant characteristics and OHIP-49 severity and extent scores at enrollment [mean (SD)] (n = 17)

<table>
<thead>
<tr>
<th></th>
<th>N (%)</th>
<th>Enrollment mean (SD)</th>
<th>p-value</th>
<th>Enrollment mean (SD)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>OHIP severity score&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td>OHIP extent score&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>All participants</td>
<td>17 (100.0)</td>
<td>94.8 (40.8)</td>
<td></td>
<td>17.2 (12.49)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11 (64.7)</td>
<td>84.5 (33.1)</td>
<td>0.162</td>
<td>14.3 (10.4)</td>
<td>0.335</td>
</tr>
<tr>
<td>Female</td>
<td>6 (35.3)</td>
<td>113.8 (49.6)</td>
<td></td>
<td>22.5 (15.2)</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50</td>
<td>3 (17.7)</td>
<td>119.7 (34.9)</td>
<td>0.421</td>
<td>23.7 (9.1)</td>
<td>0.335</td>
</tr>
<tr>
<td>50 to 64</td>
<td>6 (35.3)</td>
<td>98.5 (53.2)</td>
<td></td>
<td>19.2 (17.1)</td>
<td></td>
</tr>
<tr>
<td>≥ 65</td>
<td>8 (47.1)</td>
<td>82.8 (31.4)</td>
<td></td>
<td>13.3 (9.2)</td>
<td></td>
</tr>
<tr>
<td>Mandible status, enrollment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Edentulous</td>
<td>7 (41.2)</td>
<td>115.4 (42.6)</td>
<td>0.574</td>
<td>23.1 (15.0)</td>
<td>0.100</td>
</tr>
<tr>
<td>Terminal dentition</td>
<td>10 (58.8)</td>
<td>80.4 (34.4)</td>
<td></td>
<td>13.0 (8.9)</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> Severity is the sum of OHIP-49 responses (potential range 0 to 196); higher scores denote worse OHQoL.

<sup>b</sup> Extent is the number of “fairly often” or “very often” responses (potential range 0 to 49); higher scores denote worse OHQoL.

<sup>c</sup> “..” in Tables 3-5 define how calculation of the OHIP extent score is different than the severity score. “fairly often” and “very often” are specific options on the questionnaire that carry different weight in the calculation.

Table 4  Mean OHIP-49 severity<sup>a</sup> scores at enrollment and changes in this score during treatment (n = 17)

<table>
<thead>
<tr>
<th></th>
<th>Beta coefficient</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment (mean severity score)</td>
<td>94.8</td>
<td>73.9, 115.8</td>
<td>..</td>
</tr>
<tr>
<td>Prior to implant surgery (change since enrollment)</td>
<td>−47.2</td>
<td>−61.7, −32.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Six months post-implant surgery (change since enrollment)</td>
<td>−74.3</td>
<td>−88.8, −59.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Six months post-implant surgery (change since implant surgery)</td>
<td>−27.1</td>
<td>−41.6, −12.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 months post-implant surgery (change since enrollment)</td>
<td>−76.8</td>
<td>−91.3, −62.3</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 months post-implant surgery (change since implant surgery)</td>
<td>−29.6</td>
<td>−44.1, −15.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 months post-implant surgery (change since 6 months postsurgery)</td>
<td>−2.5</td>
<td>−17.0, 12.0</td>
<td>0.773</td>
</tr>
</tbody>
</table>

<sup>a</sup> Severity is the sum of OHIP-49 responses (potential range 0 to 196); higher scores denote worse OHQoL.

Table 5  Mean OHIP-49 extent<sup>b</sup> scores at enrollment and changes in this score during treatment (n = 17)

<table>
<thead>
<tr>
<th></th>
<th>Beta coefficient</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment (mean extent score)</td>
<td>17.2</td>
<td>10.8, 23.6</td>
<td>..</td>
</tr>
<tr>
<td>Prior to implant surgery (change since enrollment)</td>
<td>−12.6</td>
<td>−16.6, −8.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Six months post-implant surgery (change since enrollment)</td>
<td>−15.9</td>
<td>−19.9, −12.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Six months post-implant surgery (change since implant surgery)</td>
<td>−3.3</td>
<td>−7.2, 0.6</td>
<td>0.100</td>
</tr>
<tr>
<td>12 months post-implant surgery (change since enrollment)</td>
<td>−16.3</td>
<td>−20.2, −12.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 months post-implant surgery (change since implant surgery)</td>
<td>−3.6</td>
<td>−7.6, 0.3</td>
<td>0.068</td>
</tr>
<tr>
<td>12 months post-implant surgery (change since 6 months postsurgery)</td>
<td>−0.4</td>
<td>−4.3, 3.6</td>
<td>0.860</td>
</tr>
</tbody>
</table>

<sup>b</sup> Extent is the number of “fairly often” or “very often” responses (potential range 0 to 49); higher scores denote worse OHQoL.

environment that led to the prosthesis fracture, as well as the two abutment fracture events. It is important to note that for this cohort, the mean cantilever length to A-P spread ratio was 2.0 (SD 0.82) to 1, with 77% (13/17) of the participants having a prosthesis with at least one side exceeding 1.5 to 1.

Vertical height of the prosthesis also varied with each participant in this study, depending on the amount of restorative space present after alveolectomy. A minimum restorative dimension, or distance from osseous crest to incisal edge, is thought necessary to allow adequate space for restorative materials, and thus adequate fracture resistance. The vertical height of the distal segment in the fractured prosthesis was approximately 9 mm, which is notably smaller than the mean height of 13.2 mm (SD 3.2) for the other prostheses. Further, the fracture occurred at the distal screw access, where the prosthesis was smallest in cross-sectional area.

Finally, the MZ-FDP fracture could have been related to the material itself. Porosity in the original zirconia blank,
Figure 8  Mean (SE) OHIP-49 severity (A, left) and extent (B, right) scores at enrollment, immediately prior to implant surgery, 6 months post-insertion, and 12 months post-insertion. Scores prior to surgery and at 6 months postsurgery were significantly lower than at enrollment. The postsurgery score did not reduce significantly ($p = 0.685$) in the 6 months following surgery.

Figure 9  OHIP-49 Subscale analysis. Significant ($p < 0.0035$) reductions from enrollment scores were observed across all seven dimensions between enrollment and immediately prior to surgery. Further significant reductions occurred in the 6 months post-insertion on dimensions of functional limitation, pain and discomfort, psychological discomfort, and physical disability, but not on psychological disability, social disability, or handicap. No domain exhibited significant change between the 6- and 12-month recall visits.

Fifteen of the 17 prostheses were made from a single block of zirconia; however, two participants required a prosthesis design variation where one or more single crowns or teeth could be cemented onto or into the main prosthesis to account for error in implant angulation. One limitation of this modification is that it either decreases retrievability or increases the risk of debonding, depending on which type of cement is selected. Another concern with this design modification is the potential reduction in cross-sectional area of the prosthesis.

The other primary aim of this study was to assess the within-subject change in OHIP-49 scores as the participant transitioned from baseline to conventional dentures and from conventional dentures to a mandibular MZ-FDP. Several important observations can be made from this OHIP-49 data. First, the construction of well-made, properly fitting dentures in participants with a terminal dentition or in participants with an ill-fitting prosthesis led to a significant change in OHQoL, indicated by the significant reduction of both OHIP-49 severity and extent scores between enrollment and implant surgery. This finding is consistent with that of several other studies evaluating the effect of complete dentures on OHQoL. $^{8,41,42}$ Second, participants with well-made, properly fitting conventional dentures achieved an additional significant improvement in OHQoL with a mandibular implant-supported MZ-FDP, illustrated by the significant decrease in OHIP-49 severity score from implant surgery to 6-month recall.

The lack of a statistically significant decrease in the OHIP-49 extent score for the interval between 6 and 12 months postsurgery does not undermine the significance of this treatment effect, but rather highlights several potential aspects of the study population, as well as the challenges of a questionnaire-based measure. The “very often” and “fairly often” responses within the population at baseline likely reflected social or esthetic variables more frequently, which were addressed reasonably...
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well by a new set of conventional dentures, resulting in a large improvement in OHIP-49 extent scores at the second administration, and thus allowed little room for further improvement with the mandibular prosthesis at the third administration. The placebo effect may also be of clinical importance here by altering the extent responses after insertion of new conventional dentures, therefore masking further improvement at later evaluations.

Regardless of the nuances, the magnitude of reduction observed in both severity and extent scores is profound. A study by John et al reported on the minimally important difference in OHIP-49 (severity) scores. They found that a change of approximately six OHIP-49 units is required for patients to state that they feel at least "a little better," and that a change of about ten units is required for patients to state they feel "a lot better." Within the limitations of a questionnaire-based measure, the finding of our study, with a mean difference of 76.8 OHIP units, may indicate a profound change in QoL, vastly exceeding mere sense of improvement. Further, the degree of biologic and technical complications observed during the course of the study did not prevent these significant improvements in OHQoL.

Conclusions

A protocol for the treatment of mandibular edentulism using an implant-supported MZ-FDP was presented. Implant survival was high, and few complications related specifically to the MZ-FDP were observed. The most common technical complications were chipped teeth in the maxillary denture, possibly related to the particular type of denture teeth used. Substantial and clinically important improvements in OHQoL were achieved with the MZ-FDP. Specifically, well-made, properly fitting conventional dentures provide significant improvement in OHIP-49 scores among participants with a terminal dentition or an ill-fitting prosthesis, and the MZ-FDP significantly improved OHIP-49 scores for participants with well-made, properly fitting conventional dentures. The data of this short-term study indicate that the MZ-FDP is a viable therapeutic option with particular advantages in the edentulous mandible and warrants long-term study.

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References

1. Douglass CW, Shih A, Ostry L: Will there be a need for complete dentures in the United States in 2020? J Prosthet Dent 2002;87:5-8