Evaluation of Oral Health Related Quality of Life and patient satisfaction in three implant retained mandibular overdentures: A randomized cross-over clinical trial

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Abstract:

**Purpose:** To assess oral health–related quality of life (OHRQoL) and patient satisfaction with a three-implant–retained mandibular overdenture. **Materials and Methods:** In this randomized crossover clinical trial, 20 edentulous patients received a new set of conventional complete
dentures (baseline). Subsequently, three implants were placed in the anterior mandible; two of these were placed in the canine regions bilaterally, and one was placed in the midline. After successful osseointegration, complete dentures were attached to the implants using resilient attachments. The overdenture was retained either by three implants (test group) or two implants (control group). The sequence of treatment was randomized such that each patient experienced both treatment options for 6 months each. OHRQoL was assessed at baseline and after 6 months of function for each treatment option using Oral Health Impact Profile (OHIP-14) and visual analog scale scores. Statistical analyses were performed using Friedman and Wilcoxon signed-rank tests. Results: Conventional dentures resulted in significantly higher OHIP-14 and VAS scores (25.25 + 6.42; 8.55 + 1.73) compared to both the control group (11.15 + 5.39; 4 + 2) (P < .001) and the test group (6.25 + 4.02/2.06 + 1.48) (P < .001). Similarly, significantly higher mean OHIP-14 and VAS scores were noted for the control group compared to the test group (P < .001). Conclusion: Overdentures retained by three implants resulted in better OHRQoL scores and higher patient satisfaction compared to overdentures retained by two implants and conventional complete dentures. *Int J Prosthodont* 2022. doi: 10.11607/ijp.7909

Introduction:
The most conventional approach for rehabilitation has been complete dentures. However, retention and stability have posed as one of the major limitations.\(^1\)\(^2\)
Several treatment protocols have been attempted over the past decades for rehabilitating edentulous patients. Mandibular overdenture supported by two implants is now considered the standard treatment protocol according to the McGill consensus.\(^3\)\(^4\) Although treatment outcomes with implant supported overdentures have been reported extensively, controlled clinical trials comparing the clinical benefits of varying numbers of implants for retaining mandibular overdentures in the same patient are rare.\(^5\)\(^6\)
In a clinical study conducted by Karbach et al, four implants instead of two implants were used in the overdenture which resulted in a statistically significant decrease in the Oral Health Impact Profile (OHIP-14). Furthermore, a systematic review reported that mandibular overdentures supported by four implants showed better results with respect to the survival and success rates than mandibular overdentures supported by two implants. Similarly, clinical studies reported that mandibular overdentures supported by three implants have a similar survival rate as those supported by four and two implants. Patients who mandibular overdentures supported by three implants experienced less rotational movement of the overdenture and also had improved satisfaction as compared to the conventional or two-implant supported overdenture. The number of implants, however, substantially influences treatment costs. Therefore, single implant supported overdenture has been proposed as a promising treatment option in patients of low socio-economic status. Single-implant supported overdentures have demonstrated improved patients satisfaction and Quality of life as compared to conventional dentures. However, a recent study with 10 year follow up period concluded that the denture retained by one median implant required frequent maintenance visits. Similarly, a randomized controlled clinical trial comparing one and two implant supported overdenture concluded that two implant supported overdentures leads to higher patient satisfaction. Recently a cross-over clinical trial evaluated patients satisfaction with 2 and 3 implant supported overdentures. However, in this study all the patients recruited initially received a two implant supported overdenture that was subsequently replaced by three implant supported overdenture. Therefore the treatment intervention was not randomized in this study. To the investigators’ best knowledge, no clinical study in the literature has compared patient reported outcome measures between conventional dentures and overdentures supported by two and three implants in a randomized controlled clinical trial applying a cross-over design. Thus,
the aim of this study was to test whether or not mandibular overdentures supported by three implants lead to better Oral Health Related Quality of Life (OHRQoL) and patient satisfaction as compared to the mandibular overdentures supported by two implants, in a randomized controlled clinical trial with a crossover design. The null hypothesis was that there will be no difference in Oral Health Related Quality of Life (OHRQoL) and patient satisfaction between conventional dentures, two and three implant supported mandibular overdentures.

Material And Methods:

Trial design:

The study was designed as a within subject randomized controlled clinical trial with a crossover design and executed according to the Helsinki protocol. The study was approved by the local ethics committee of the institute (Adm/7505-A/2015). All patients provided informed consent. Twenty completely edentulous patients unsatisfied with the previous prosthesis and in need of a mandibular implant supported overdenture were consecutively recruited at the Department of Fixed and Removable Prosthodontics and Implantology the dental institute. The study was designed and performed applying CONSORT guidelines.

Patient Recruitment:

As shown in the study flowchart (Figure 1), 20 patients in need of a mandibular implant supported overdenture were recruited from October 2015- September 2016 for the study. The inclusion criteria were as follows: Edentulous patients (maxilla and mandible); patients who were systemically healthy; patients who were able to provide informed consent; patients having physical and psychological capacity to complete the study questionnaires in English. Patients with only moderate (Class III and Class IV) and high ridge height (Class I and Class II) as
described by Cawood and Howell’s classification were included in the study. Patients who were able to understand and speak English language were included in the study. Patients were excluded if they exhibited height and width of bone inadequate for implant placement in the anterior mandible in the inter-foraminal region (minimal 6 mm width, minimal 8 mm height); women pregnant at the date of inclusion; smoking of more than 15 cigarettes per day. Only edentulous patients were included in this study as it will ensure standardization among all the subjects.

Implant therapy:
New maxillary and mandibular conventional complete dentures (CD) were fabricated for all the patients recruited in the study. The dentures were fabricated in centric relation, a balanced occlusion scheme was achieved using anatomic acrylic teeth (Ivoclar, Liechtenstein). On each quadrant the teeth were arranged up to second molar. The conventional denture was used by each patient for 6 months. Thereafter, implant surgeries were planned using a CBCT (Cone Beam Computed Tomography) scan with radiographic stents duplicated from the newly fabricated conventional complete denture. Three implants (ADIN, Afula, Israel) were placed in the anterior mandible according to standard protocol using the same stents as guidance. Two implants were placed in the canine region and one in the midline (Figure 2). The final torque ranged between 40-50 NCM for all the implants placed in the study. In order to maintain the standardization, all the surgeries were performed by the same surgeon and implants of same dimension (3.75x8) were placed in all the patients. Transmucosal healing of the implants was allowed. The patients’ conventional dentures were relined using chairside soft liner (Molosil, DETAX, Ettlingen, Germany) and special care was taken to prevent contact between the dentures and the implants.
Randomization:
Randomization codes were generated by block randomization using the randomization software (sealed envelope™). The patients were randomly and equally assigned to one of the two treatment protocols immediately prior to connection of the attachments. The randomization code was kept by a designated employee not involved in the study and was provided in sealed opaque envelopes.

Prosthetic procedures:
The prosthetic intervention was performed after 3 months of implant placement. The attachments (Locator, Alpha-Bio Technologies, Tel Aviv, Israel) were fixed onto the implants using the system’s torque wrench. Patrices (nylon inserts) were picked up intra-orally using cold-cured acrylic resin (Repair resin, Henry Schein, USA). In the control protocol, the overdenture was retained by the two implants in the canine region (2IOD), whereas for the implant in the anterior region, a healing abutment (not contacting the denture) was used (Figure 3). In the test protocol, the overdenture was retained by all three implants (3IOD) (Figure 4). After 6 months of functional loading, the retention modes were interchanged without a wash-out period in order to avoid additional appointments of the elderly patients. In all patients, because the same denture base was used, similar occlusion, vertical dimension and denture base extension was maintained throughout the course of the study. 17 Balanced occlusion was selected for all the patients enrolled in the study as it leads to higher stability considering the opposing arch was edentulous as recommended by Wismeijer et al. 18 The occlusal scheme also ensured elimination of interferences in the eccentric jaw movements. Occlusion was restored upto the 2nd molar.

Outcome measures:
The primary outcome of the study was the Oral Health Related Quality of Life (OHRQoL). All patients rated the OHRQoL using the OHIP-14 as proposed by Slade et al.¹⁹ A standardized and validated version of Oral Health Impact Profile-14 (OHIP-14) questionnaire in English language was used (Table 1). A hard copy of the questionnaire was handed to each patient by a study monitor (RM), who was not involved in the clinical treatment of patients. Patients were then instructed to complete the questionnaire at the end of visit and in the absence of the study monitor. Furthermore, patient satisfaction was assessed using the VAS scores. McGill denture satisfaction questionnaire was used,²⁰ patients were asked to indicate their degree of satisfaction on a 10 cm line, with 0 referring to “completely satisfied” and 10 referring to “completely dissatisfied”.

The outcomes were assessed after the functional use with the new conventional complete dentures (T1) and at the end of each 6-month period, with the test and control treatment (T2/T3). At the end of both trial periods, patients were allowed to choose and given their preferred retention mode (2IOD or 3IOD). The Oral Health Impact Profile-14 questionnaire consisting of fourteen questions on a scale of 0 to 4 (0=never, 1=hardly ever, 2= occasionally, 3=fairly often, 4= Always) was used and were assessed at 6 months (T1) of functional loading. Similarly, OHIP-14 and VAS scores were collected 6 months after the use of 2IOD and 3IOD (T2/T3).
Statistical Analysis:

Sample size calculation:

Sample size calculation was performed based on a Wilcoxon signed rank test, a mean difference of 25 units in the OHIP-14 scores was assumed and the standard deviation of 34 units was considered. 21

A sample size of 20 cases satisfying the inclusion criteria were included in the study. The sample size was selected such that it would produce more than 80.0% statistical power (type II error = 0.20) and 5% type I error probability (α=0.05) to be able to detect the difference in clinical outcomes between the groups.

The results were compiled systematically on a numerical scale of 0 to 4 for OHIP-14 and 0 to 10 for VAS.

Means and Standard Deviations (SD) were calculated for data of continuous variables across the study groups (SPSS software version 21.0, IBM Corporation, USA). Shapiro-Wilk test was performed to assess the normality of the data. The Intra group Comparison was done using Freidman’s test followed by pairwise comparison using the Wilcoxon signed rank test. P<0.05 was considered to be statistically significant.
Results:

20 patients (8 males and 12 females) with a mean age of 61.6 ± 7.1 years were included in the study. The demographic data of the included patients are reported in table 2 and 3. No patients were lost to follow-up.

The OHIP-14 score (mean ± SD) was 25.3 ± 6.4 for the CD, 11.2 ± 5.4 for the 2IODs, and 6.2 ± 3.84 for the 3IODs. Statistically significant differences were detected between the conventional complete dentures and both groups with implant (p-value<0.001) as well as between the 2IOD and the 3IOD groups (Table 3).

Patient satisfaction (mean ± SD) for the CD, and was 7.25 ± 3.07 for the CD, 4.40 ± 1.82 for the 2IODs, and 2.05 ± 1.32 for the 3IODs (Table 3). Patient satisfaction was statistically significantly lower with conventional complete dentures as compared to both groups with implant retention (P-value<0.001). In the 3IOD group, patient satisfaction was statistically significantly higher compared to the 2IOD group (Table 3).

In patients who used 2IODs prior to 3IODs, the OHIP-14 score (mean ± SD) was 11.2 ± 5.4 for the 2IODs and 6.2 ±3.84 for the 3IODs (Table 4, Figure 5). Patient satisfaction (mean ± SD) was 4.4 ±1.81 for the 2IODs and 2.05 ±1.32 for 3IODs (Table 3, Figure 6).

In patients who had 3IODs before 2IODs, the OHIP- 14 score (mean ± SD) was 6.2±3.84 for the 3IODs and 11.2 ± 5.4 for the 2IODs (Figure 7). Patient satisfaction (mean ± SD) was 4.4 ±1.82 for the 2IODs and 2.05 ± 1.32 for the 3IODs (Table 3, Figure 8).

When asked for the preferred choice of treatment at the end of the study, all patients chose the retention by 3 implants (3IOD).
Discussion:

The present clinical study demonstrated that a mandibular overdenture supported by implants results in higher patient satisfaction and as well as higher OHRQoL as compared to a conventional complete denture. In addition, adding a third implant in the midline of the mandible to a mandibular overdenture already retained by 2 implants further increased patient satisfaction and OHRQoL.

Edentulism is defined as the loss of all permanent teeth and is the terminal outcome of a multifactorial process involving biologic processes as well as non-biologic factors related to dental procedures.\textsuperscript{22,23} Long-term edentulism is associated with decreased masticatory function, unfavourable esthetics due to loss of support of facial muscles, decreased vertical dimension, and speech impairment.\textsuperscript{24} Conventional complete dentures are most commonly used for rehabilitation of edentulous patients. However, loss of retention and stability are the most common complications associated with conventional dentures supported only by resilient tissues.\textsuperscript{25,26} Therefore, an implant supported overdenture is considered as the standard treatment of care for the edentulous mandibles.\textsuperscript{3,23} Patient satisfaction is considered to be one of the most important indicators for treatment success and quality of care.\textsuperscript{27} In this study, it was observed that patients experienced a statistically significantly higher satisfaction and comfort with the implant supported overdenture (2IOD or 3IOD) as compared to the conventional complete denture. This is in agreement with multiple studies in the literature\textsuperscript{28-30} In a retrospective study the quality of life in edentulous patients with conventional dentures and implant supported overdentures were assessed over at least 23 years.\textsuperscript{28} They observed statistically significantly higher patient satisfaction with implant supported overdentures compared to conventional complete dentures. Similarly, a recent systematic review analysing randomized controlled clinical trials comparing quality of life in patients treated with implant supported overdentures and conventional complete dentures concluded that implant supported overdentures led to a
higher quality of life. Implant supported overdentures have been reported to improve retention, stability, occlusion, and function.

In this study a comparison was also performed between overdentures supported by two or three implants. All the patients experienced a better oral health related quality of life with overdenture supported by three implants as compared to overdenture supported by two implants. The results of the present study are in agreement with a recent cross over study. They observed that the conversion from a two implant to a three implant supported overdenture resulted in higher patient satisfaction due to increased stability of the prosthesis. This could be explained by a decrease in movement of the prosthesis as the third implant in the midline region eliminates the hinge axis. This was also noted in an in-vitro study. They observed that the two implant supported overdenture dislodged in the vertical direction upon anterior loading and the addition of a midline implant prevented this hinge movement of the denture. Therefore, the time and need of maintenance care may be reduced by a third midline implant. The patients experienced improved functional, psychological and social comfort with 3IOD as compared to 2 IOD. This is in agreement with the study performed by Karbach et al. They observed that Oral Health Related Quality of life (OHRQoL) increased in patients who switched from 2IOD to 4IOD. They concluded that the number of implants influences the OHRQoL in edentulous patients.

The results of the present study, however, are contradictory to the study performed by Sheikh et al. In a randomized controlled clinical study clinical outcomes and prosthetic complications of overdentures supported by two or three implants were not different. Similarly, Beresford et al observed no significant difference in patient satisfaction, when edentulous patients were restored with 2 or 3 implant supported overdentures. One limitation of the latter study may have been the study design. A randomized controlled clinical trial may not be considered as an ideal methodology as only one type of intervention is experienced by each
patient. A cross-over study design eliminates the interpatient variables as each patient experiences different treatment interventions. Therefore, the true effect of an additional retention provided by the third implant in a mandibular overdenture can be experienced by the same patient.

The present study showed that for an implant-supported overdenture in the mandible, patients may prefer three implants over two implants. Limitations of this study were the small sample size and that the economical aspect was not included in the patient’s evaluation. A clinical study showed that only 47% of the patients would agree to pay a large increase in cost for the third implant.\textsuperscript{11} In this study the shape of the alveolar process of mandible and its effect on denture stability was not analysed. Also, the anxiety of the recruited patients was not evaluated in this study. Further clinical trials with a similar study design should be undertaken evaluating the economic aspects of the treatment as well as the effect of the shape of the residual ridge on the stability of the denture.
Conclusion:
In the mandible overdentures retained by three implants resulted in better Oral Health Related Quality of Life and patient satisfaction as compared to overdentures retained by two implants and to conventional complete dentures.

References:


33. Beresford D, Klineberg I. A Within-Subject Comparison of Patient Satisfaction and

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Conflict of Interest: The authors declare no conflict of interest.

Source of Funding: No funding was received for this project
Tables:

Table 1: OHIP-14 Questionnaire:

<table>
<thead>
<tr>
<th>A) Functional limitation</th>
<th>Never</th>
<th>Hardly ever</th>
<th>Occasionally</th>
<th>Fairly often</th>
<th>Always</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?</td>
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<td></td>
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<td>2) Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?</td>
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<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>B) Physical pain</th>
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<tbody>
<tr>
<td>3) Have you had painful aching in your mouth?</td>
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<tr>
<td>4) Have you had discomfort/pain in eating any food because of problems with your teeth, mouth or dentures?</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>C) Psychological discomfort</th>
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<tr>
<td>5) Have you been self-conscious because of your teeth, mouth or dentures?</td>
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<tr>
<td>6) Have you felt tense because of problems with your teeth, mouth or dentures?</td>
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<tr>
<td>D) Physical disability</td>
</tr>
<tr>
<td>7) Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?</td>
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<tr>
<td>8) Have you had to interrupt meals because of problems with your teeth, mouth or dentures?</td>
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<tr>
<td>E) Psychological disability</td>
</tr>
<tr>
<td>9) Have you found it difficult to relax because of problems with your teeth, mouth or dentures?</td>
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<tr>
<td>10) Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?</td>
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</table>
with your teeth, mouth or dentures?  

F) Social disability

11) Have you been irritable with other people because of problems with your teeth, mouth or dentures?

12) Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?

D) Handicap

13) Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

14) Have you been totally unable to function because of problems with your teeth, mouth or dentures?
Table 2: Age, gender and mean values for VAS and OHIP-14 scores of patients included in the study. Data of patients receiving 2IOD followed by 3IOD (CD: conventional overdenture. 2IOD: overdenture retained by 2 implants. 3IOD: overdenture retained by 3 implants, OHIP: Oral Health Impact Profile, VAS: Visual Analog Scale)

<table>
<thead>
<tr>
<th>No</th>
<th>Age</th>
<th>Gender</th>
<th>OHIP-14 score</th>
<th>VAS score</th>
</tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td>CD</td>
<td>2IOD</td>
</tr>
<tr>
<td>1</td>
<td>67</td>
<td>M</td>
<td>25</td>
<td>11</td>
</tr>
<tr>
<td>2</td>
<td>71</td>
<td>M</td>
<td>21</td>
<td>7</td>
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<tr>
<td>3</td>
<td>66</td>
<td>F</td>
<td>13</td>
<td>7</td>
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<tr>
<td>4</td>
<td>72</td>
<td>F</td>
<td>21</td>
<td>15</td>
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<tr>
<td>5</td>
<td>50</td>
<td>M</td>
<td>36</td>
<td>26</td>
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<tr>
<td>6</td>
<td>60</td>
<td>F</td>
<td>34</td>
<td>8</td>
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<tr>
<td>7</td>
<td>49</td>
<td>M</td>
<td>29</td>
<td>9</td>
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<tr>
<td>8</td>
<td>58</td>
<td>M</td>
<td>25</td>
<td>9</td>
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<tr>
<td>9</td>
<td>61</td>
<td>F</td>
<td>21</td>
<td>6</td>
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<tr>
<td>10</td>
<td>68</td>
<td>F</td>
<td>18</td>
<td>12</td>
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<td>11</td>
<td>65</td>
<td>F</td>
<td>18</td>
<td>3</td>
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<tr>
<td>12</td>
<td>62</td>
<td>M</td>
<td>30</td>
<td>7</td>
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<td>13</td>
<td>59</td>
<td>F</td>
<td>36</td>
<td>8</td>
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<td>14</td>
<td>68</td>
<td>F</td>
<td>29</td>
<td>6</td>
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<td>15</td>
<td>66</td>
<td>F</td>
<td>22</td>
<td>9</td>
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<td>16</td>
<td>48</td>
<td>F</td>
<td>26</td>
<td>10</td>
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<td>17</td>
<td>58</td>
<td>F</td>
<td>23</td>
<td>3</td>
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<td>18</td>
<td>70</td>
<td>F</td>
<td>26</td>
<td>6</td>
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<tr>
<td>19</td>
<td>53</td>
<td>F</td>
<td>19</td>
<td>4</td>
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<tr>
<td>20</td>
<td>60</td>
<td>F</td>
<td>33</td>
<td>11</td>
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Table 3: Mean values and standard deviations (SD) of OHIP-14 and VAS scores as well as significance levels for the three treatment groups (2IOD: overdenture retained by 2 implants, 3IOD: overdenture retained by 3 implants)

<table>
<thead>
<tr>
<th>Outcomes analysed</th>
<th>Conventional Denture (CD)</th>
<th>2 IOD</th>
<th>3 IOD</th>
<th>Chi square value</th>
<th>p-value of Friedman test</th>
<th>P-value of Wilcoxon ranked test</th>
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<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>OHIP-14</td>
<td>25.25</td>
<td>6.42</td>
<td>11.15</td>
<td>5.39</td>
<td>6.20</td>
<td>3.84</td>
</tr>
<tr>
<td>VAS score</td>
<td>7.25</td>
<td>3.07</td>
<td>4.40</td>
<td>1.82</td>
<td>2.05</td>
<td>1.32</td>
</tr>
</tbody>
</table>

P-values determined by Friedman test and Wilcoxon ranked test. P-value <0.05 was considered to be statistically significant.
Figure legends:

Figure 1: Study flowchart

Figure 2: A patient mandible showing three implants in the inter-foraminal region.

Figure 3: A patient mandible with locators connected to the two implants in the canine region (overdenture retained by 2 implants (2IOD)). The implant in the midline carries a healing cap.

Figure 4: A patient mandible with locators connected to all three implants (overdenture retained by 3 implants (3 IOD))

Figure 5: OHIP-14 scores in patients receiving CD followed by 2IOD and 3IOD.

Figure 6: VAS scores in patients receiving CD followed by 2IOD and 3IOD.

Figure 7: OHIP-14 scores in patients receiving CD followed by 3IOD and 2IOD.

Figure 8: VAS scores patients receiving CD followed by 3IOD and 2IOD.
Patient recruitment (n=20)

Fabrication of Conventional denture (n=20)

OHIP-14 & VAS scores 6 months after conventional denture

Patients receiving 3 Implants (n=20)

Randomization

2 Implants attached with locators (2IOD) (n=10)

3 Implant attached with locators (3IOD) (n=10)

OHIP-14 & VAS scores 6 months after use of 2IOD/3IOD

3 Implant attached with locators (3IOD) (n=10)

2 Implants attached with locators (2IOD) (n=10)

Crossover

OHIP-14 & VAS scores 6 months after use of 2IOD/3IOD

Figure 1: Study Flow Chart
OHIP-14 Score in patients with CD followed by 3IOD & 2IOD

Subjects

CD  3IOD  2IOD

0  10  20  30  40