Patient satisfaction and crestal bone changes with one-piece and two-piece single implant-retained mandibular overdenture: A randomized controlled clinical study

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Abstract

Purpose: The present study was done to assess patient satisfaction and crestal bone changes with one-piece and two-piece single implant-retained mandibular overdentures (SIMOs).

Methods: The participants included in Group 1 (n=12) received one-piece SIMOs; the participants in Group 2 (n=12) received two-piece SIMOs. Scheduled follow-ups were done at 1 month and 1 year after implant placement. Patient satisfaction and crestal bone changes were evaluated. The data obtained were analyzed statistically with independent Student t-test.

Results: Visual analogue scale (VAS) score for patient satisfaction with one-piece and two-piece SIMOs were statistically significant at 1-year of follow-up. The patient satisfaction level on the VAS score increased (38.1 to 51.1) with group one-piece SIMOs and two-piece SIMOs (36.6 to 46.8) at baseline to 1 month (P=0.13). The patient satisfaction level increased (38.1 to 56.6) with group one-piece SIMOs and two-piece SIMOs (36.6 to 52.2) at baseline to 1 year (P=0.03). At the 1 year follow-ups, group 1 had mean crestal bone loss of 0.80±0.49 mm and group 2 had 1.24±0.90 mm (P=0.16). Crestal bone loss was greater in the two-piece SIMOs group at 1 month and 1 year follow-ups, but statistically it was insignificant.

Conclusion: One-piece SIMOs seemed to be a viable treatment option with increased patient satisfaction on a VAS. Crestal bone loss was greater in the patients with two-piece SIMOs during follow-up. One-piece SIMOs was comparatively simple with less invasive procedures and needed fewer components, so considerable number of patients requiring implant retained dentures could be benefited.

Keywords: Bone resorption, Complete denture, Dental Implants, Overdenture, Patient satisfaction

1. Introduction

Mandibular arch is usually rehabilitated with two implant-retained overdentures (IODs) in clinical practice and studies also support that two implants may be adequate for clinical success[1–5]. McGill’s consensus statement proposed IODs on two implants as the choice of treatment in rehabilitating completely edentulous mandibular arch[6]. Unfortunately, sometimes even two IODs are not afforded by patients in developing nations, so single IODs are preferred. Kronstrom et al. and Nogueira et al. have found in their studies that single implant retained overdentures could achieve clinical outcomes similar to those of multiple implants[7,8]. Researchers had found that the procedure for single IODs are less invasive, with improved patient satisfaction at a reduced cost[9–14].

The microgap present at the implant–abutment junction and violation of the biological width causes microleakage, and inflammation of the soft tissues surrounding the implant leading to initial bone loss in two-piece implants[15–17]. The two-piece implant sometimes produces a weak link at the implant-abutment junction (IAJ) and has the problem of screw loosening[18]. One-piece implant system were designed to minimize crestal bone loss due to their technical and clinical advantages over two-piece implants, such as unibody design, comes in immediate function with single-stage implant procedure, and absence of micro gap at the IAJ[19–22]. Is “one-piece implants have few disadvantages too”, such as the angulation of the abutment cannot be corrected after implant placement and necessitates immediate restoration in the esthetic zone, which may result in overload during initial healing phase[23].

As there are insufficient studies available, comparing the success of one-piece and two-piece single implant-retained mandibular overdentures (SIMOs), hence this study was undertaken to compare the patient satisfaction and crestal bone loss with one-piece and two-piece SIMOs, with immediate loading protocols. The null hypothesis was that there would be no difference in patient satisfaction...
and crestal bone loss with one-piece and two-piece SIMOs restored with immediate loading protocol.

2. Materials and Methods

2.1. Trial design

The present prospective randomized clinical trial (RCT) was a single center study comparing the patient satisfaction, crestal bone changes and soft tissue response with one-piece and two-piece SIMOs. The ethical committee of the institute had approved the study and registered the study with research ethics reference number RRDC&H/PG-122/2016-2017, dated 28/11/2016.

2.2. Inclusion and exclusion criteria

The patients presented to the Prosthodontics Department, between 1st January 2017 to 30th June 2017, with existing conventional complete dentures (CCDs) with complaints of soreness, difficulty in speaking, instability, and compromised retention of mandibular dentures, were assessed for potential inclusion in the trial. Edentulous female or male participants between 50-70 years of age, wearing CCDs for 1-3 years were only included. Participants having enough bone to accommodate endosseous implant of dimension 3.3 mm x 13 mm in the mandibular arch were included. The participants were included in the class III category, according to the Prosthodontic Diagnostic Index classification for the edentulous arches[24]. The participants had adequate interarch space, with class I maxilla-mandibular relationship. The residual alveolar bone height in the mandibular arch was more than 15mm and does not require any bone augmentation procedures before/during implant placement.

Participants with alcohol or smoking habits, drug abuse, mental disorder, health state which preclude surgical procedures, malignant tumor, history of radiation therapy at the implant site, participants unable to come for follow up, and participants requiring bone graft at the site of the implant were not included in the study. Participants with soft tissue hypertrophy or hyperplasia were also not included. The implant treatment modalities and post-loading follow-up for 1 month and 1 year were explained to the participants in their local language. The signed consent was obtained from the participants, after explaining the possible consequences during and after the trial.

2.3. Patients intervention

Existing CCDs of the study participants were evaluated by a prosthodontist for acceptance, based on the guidelines proposed by Owen CP[25]. The dentures which were not acceptable aesthetically or technically were altered, and if required new dentures were made. The participants who got new dentures were re-examined and further included in study after 3 months of denture use.

2.4. Sample size calculation and randomization

The sample size estimation was based on 100mm VAS scores for patient’s satisfaction and followed a previous study having a difference of 15mm in VAS scores between groups with an expected standard deviation of 25mm[26]. The number of participants required for the trial was calculated based on a power calculation. Assuming a 2-sided alpha level of 0.05 and clinically meaningful marginal difference of 15mm (on the 100mm VAS Scale) between the groups, a minimum of 10 participants per group was needed to achieve 80% statistical power. Expecting a withdrawal/dropout rate of 10%, final sample size was estimated to be 12 participants per group.

The study was designed as RCT, with an allocation ratio of 1:1. Random permuted block method (block size as 4) was utilized to make sure that a definite proportion of patients receive the two treatment modalities. There were 6 possible permutations (numbered as 1, 2, 3, 4, 5, and 6 respectively). The allocation numbers were generated by using 6 numbers, and were randomly assigned with research randomizer web (https://www.randomizer.org) for random generation of sequence to two equal groups (12 participants each). Patients in Group 1 received one-piece SIMOs and Group 2 received two-piece SIMOs.

The allocation concealment was done by an investigator, who was not aware of the participant’s selection and treatment. The randomized key was numbered serially and placed in sealed covers. Each participant was instructed to select a cover and the examiner who knew about the randomization procedure inform about the group allotted, and the treatment was done accordingly. Participants and the investigators (S.S., S.K.M., R.C.) could not be blinded to the implant placed, but investigators were mandated not to disclose the treatment given to the participants. The data processor and statistician were also blinded in the study.

This trial followed the CONSORT 2010 statement and performed in accordance with the Declaration of Helsinki[27]. Participants who agreed for the treatment procedure and periodic follow-up were enrolled in the study (Table 1).

2.5. Pre-operative examination

Panoramic radiograph and cone beam computed tomography (CBCT) were taken to assess the amount of available residual bone and the location for the implant placement. A GuttaPercha cone was used as the marker over the denture to assess the implant osteotomy site. The osteotomy site was anesthetized and bone sounding was done with a periodontal probe to determine the depth of the overlying gingiva and location of the underlying bone[28]. The amount of bone available bone was written in detail under the heading pre-operative radiographic assessment.

2.6. Surgical procedures

Participants were given 2g of amoxicillin orally 1 hour before surgery. Full-thickness flap was raised under local anesthetics only at the site of the surgery with a mid-crestal incision connected with relieving incision in the labial mucosa. Osteotomy was performed with standardized drilling procedures as prescribed by the company. Osteotomy was done in the mid symphyseal region of the mandible.

Twelve participants in Group 1 received a one-piece implant with diameter of 3.3 mm and length of 13mm (Myriad snap, Myriad implant system, Equinox medical technologies, Switzerland) with an abutment having 3mm long polished collar that transitions to a ball head (Fig. 1). Other twelve participants in Group 2 received two-piece implant with diameter of 3.3 mm and length of 13 mm (MIS lance internal hex implant, MIS implant system, MIS implant technologies, United States) in the mid symphyseal region. An insertion torque of 25Ncm was ensured for initial stability. Dalla Bona overdenture attachment of almost similar dimensions to that of one-piece implants was selected and connected to two-piece implants. An abutment...
collar height of 2mm above mucosa was ensured and secured with a torque wrench to 25Ncm\(^*[12]\).Implants used in both groups were self-tapping implants. The position of the implant was evaluated with an orthopantomogram. The soft tissues were approximated with a surgical suture and participants were kept on strict analgesic and antibiotic regime. Post-operative instructions were given to the participants.

2.7. Prosthetic procedures

The existing mandibular dentures (n=24) of the participants were used to connect the surgically placed implants. The intaglio surfaces of the dentures were modified to create housing for the matrix of the attachment. The appropriate space for housing and interferences were checked using pressure-indicating silicone media (Fit Checker\(^*\), GC, Asia Dental Pte Ltd). A small circular rubber dam sheet was adapted over the matrix to prevent contact of the soft liner with the sutures. The denture was lined by the final soft reline material (Mucopren-Soft, Kettenbach GmbH & Co\(^[29]\)). The sutures were removed one week after the surgery, and the chairside direct pickup relining technique was done to secure the matrix attachments of Dalla Bona on to the dentures with autopolymerizing resin (GC Unifast, GC Dental). The occlusion was evaluated and adjusted and the participants were advised not to wear dentures at night. Participants were also instructed to follow plaque control measures and restricted on soft diet for 6 weeks.

2.8. Outcome measurement

2.8.1. Primary outcome

The primary outcome evaluated was the patient’s satisfaction with one-piece and two-piece SIMOs performed on a visual analog scale (VAS) based on general satisfaction, chewing function, esthetics, speech and comfort of the prosthesis (Table 2\(^[30]\)). The rating was evaluated on a VAS of 100 mm (‘0’-not at all satisfied and ‘100’-extremely satisfied)\(^[31]\). Higher the score was given by the participants on VAS, the better the prosthesis. The responses of VAS questionnaire were recorded at baseline (2 weeks post prosthesis insertion), 1 month, and 1 year follow-up.

### Table 1. Details of participants, dentures and implants used

<table>
<thead>
<tr>
<th>Description of different category</th>
<th>Study subject and implant details</th>
<th>One-piece SIMOs</th>
<th>Two-piece SIMOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>Total subjects</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td>Denture details</td>
<td>Current dentures use of more than 12 months but less than 18 months</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Current denture use of more than 18 months</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Maxillary arch</td>
<td>Completely edentulous</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Implant dimensions</td>
<td>3.3mm in diameter</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>13mm in length</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Total implant placed</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

Male and female participants in each group, time period of denture use and implant dimensions was presented for group one-piece and two-piece single-implant-retained mandibular overdentures.

SIMOs, single-implant-retained mandibular overdenture.

### Table 2. Items included in the VAS questionnaire

**General satisfaction**

1) In general, are you satisfied with your lower prosthesis?

2) In comparison with a natural dentition, are you satisfied with your lower prosthesis?

**Physical function**

3) Retention: Are you satisfied with the retention of your lower prosthesis?

4) Stability: Are you satisfied with the stability of your lower prosthesis?

5) Occlusion: Are you satisfied with the occlusion of your prostheses?

6) Comfort: Is your lower prostheses comfortable?

7) Ease of cleaning: How easy you find to clean your lower prosthesis?

8) Ease of speaking: How easy you find to speak with your prostheses?

9) Ease of chewing: How easy you find to chew fresh white bread?

   Idem for: hard cheese, dry sausage, raw apple and raw carrot, lettuce and walnuts.

10) Quality of bolus: Are the pieces of fresh white bread well-chewed before swallowing?

   Idem for: hard cheese, dry sausage, raw apple and raw carrot, lettuce and walnuts.

**Psychosocial function**

11) Esthetics: Are you satisfied with the appearance of your prosthesis?

The patient’s satisfaction with one-piece and two-piece SIMOs was evaluated based on general satisfaction, chewing function, esthetics, speech and comfort of the prosthesis.
2.8.2. Secondary outcome

The secondary outcome evaluated was the crestal bone loss (in millimetres), prosthetic complications and soft tissue complications. The crestal bone loss was measured at baseline and compared at 1 month and 1 year of follow-up. Presence of pain or mobility with implant was regarded as loss of osseointegration. The soft tissue was evaluated for color, texture, pain, infection, discomfort and paresthesia. The width of keratinized mucosa and peri-implant biotype was measured at the implant site with a graduated plastic probe[32,33].

2.9. Post-operative radiographic evaluation

A standard radiographic protocol was followed to take the digital radiograph (Figs. 2 and 3) with the paralleling technique. Participants were seated with their heads in an upright position and Frankfort horizontal plane parallel to the floor. A custom made film holder device was used to take the radiographs, to obtain a similar angle and position during subsequent film exposures during follow-up. Radiographic images were visualized on the computer monitor maintaining the similar dimension. The distance between the alveolar crest level of the implant and tip of the implant body was recorded on either side of the implant with a computer software program (Eigentool; Henry Ford). The implant length was also measured across the long axis to normalize the reading using the formula suggested by Patil and Nimbalalkar-Patil[34]. Three values were recorded for each implant to get an average value at baseline, 1 month, and 1 year of follow-up.

2.10. Statistical analysis

Statistical analyses were performed with Statistical package for social sciences (Windows, Version 24.0. Released 2016. Armonk, NY: IBM Corp.). The VAS scores and mean crestal bone loss between one-piece and two-piece implants at different time intervals were compared with independent Student t-test. The significance level (p-value) was set at p<0.05.

3. Results

3.1. Participant flow

The study sample included 24 (n=15 females; n=9 males) completely edentulous patients; aged between 50 and 70 years. Twelve implants were included in each group. Twenty-two participants completed 1 month and 1 year of follow-up, without any implant failure in both the groups. One participant of two-piece SIMOs group had attachment fractured within 1 month and participant not reported for its repair. One participant in one-piece SIMOs group was not available for 1 month follow-up because of ill health. These two participants were not included for analysis (Fig. 4).

3.2. Patient satisfaction on VAS

The patients overall satisfaction level increased from 38.1 to 51.1 in group one-piece SIMOs and 36.6 to 46.8 in group two-piece SIMOs (baseline to 1 month; P=0.13). The patient satisfaction level increased from 38.1 to 56.6 in group one-piece SIMOs and 36.6 to 52.2 in group two-piece SIMOs (baseline to 1 year; P=0.03) and the difference was statistically significant (Table 3).

The patients general satisfaction with the lower prosthesis increased from 37.9 to 51.5 in group one-piece SIMOs and 35.7 to 46.3 in group two-piece SIMOs (baseline to 1 month; P=0.006). The patient general satisfaction with the lower prosthesis increased from 37.9 to 57.9 in group one-piece SIMOs and 35.7 to 53.6 in group two-piece SIMOs (baseline to 1 year; P=0.010). There was a significant difference in general satisfaction with the lower prosthesis with one-piece and two-piece SIMOs at 1 month and 1 year of follow-up.

When the questionnaire was asked that “in comparison with a natural dentition, are you satisfied with your lower prosthesis?” no significant difference in satisfaction with lower prosthesis on VAS score was found with one-piece and two-piece SIMOs at 1 month (P=0.338) and 1 year of follow-up (P=0.116). Significant difference in the satisfaction with the retention of the lower prosthesis was found with one-piece and two-piece SIMOs at 1 month (P=0.012) and 1 year of follow-up (P=0.009). No significant difference in the satisfaction
with the stability of the lower prosthesis was found with one-piece and two-piece SIMOs at 1 month ($P=0.083$) and 1 year of follow-up ($P=0.055$). In 1 month, follow-up patients with one-piece SIMOs seem to be more satisfied with the occlusion of their prosthesis and the difference was significant ($P=0.030$) but at 1 year of follow-up the difference was insignificant ($P=0.058$).

The patients with one-piece SIMOs seem to be more comfortable with their lower prosthesis compared to two-piece SIMOs and difference was statistically significant at 1 month ($P=0.016$) and 1 year of follow-up ($P=0.012$). The patients with one-piece SIMOs find it easier to clean their lower prosthesis compared to two-piece SIMOs and difference was statistically significant at 1 month ($P=0.004$) and 1 year of follow-up ($P=0.001$).

No significant difference was found in the satisfaction with the speech and chewing with the prosthesis in one-piece and two-piece SIMOs group at 1 month ($P=0.055$ and $P=0.169$) and 1 year of follow-up ($P=0.054$ and $P=0.098$) respectively. In 1 month, follow-up patients with one-piece SIMOs seems to be more satisfied with the appearance of their prosthesis and the difference was significant ($P=0.009$) but at 1-year follow-up the difference was insignificant ($P=0.053$).

### 3.3. CBL measurement

In 1-month follow-up, group one-piece SIMOs had the mean crestal bone loss of $0.59 \pm 0.02$ mm and group two-piece SIMOs had $0.73 \pm 0.28$ mm ($P=0.11$). In 1 year follow-up, group one-piece SIMOs had mean crestal bone loss of $0.80 \pm 0.49$ mm and group two-piece SIMOs had $1.24 \pm 0.90$ mm ($P=0.16$). Crestal bone loss was more in the two-piece SIMOs group at a 1 month and 1 year follow-up period but statistically it was insignificant (Table 4).

### 3.4. Prosthetic complications

Prosthetic problems were very few, with 3 participants in one-piece SIMOs group needing relining of their dentures. In the two-piece SIMOs group, 1 participant needed mandibular denture repair due to midline fracture of the denture, two participants needed relining of dentures, and one participant had an attachment fracture (Table 5).

### 3.5. Soft tissue complications

In most of the participants, the soft tissue health and plaque control was acceptable except in one participant in the one-piece SIMOs group who had soft tissue hypertrophy around the implant, which was successfully excised. The width of keratinized mucosa in both the groups was $\geq 2$ mm around the implant. Both the study groups had thick peri-implant biotype.

### 4. Discussion

The present study analyzed the null hypothesis that no difference would exist in patient satisfaction and crestal bone loss with one-piece and two-piece SIMOs restored with immediate loading protocol. The null hypothesis was not proven.

Studies had reported that denture wearers had reduced masticatory efficiency (14% to 25%) compared to dentulous individuals[35,36]. Van Kampen et al, in their study found that two IODs enhance the masticatory performance and patients satisfaction[37]. The benefits of mandibular overdenture retained with two implants had made it the choice of treatment for the rehabilitation of edentulous mandibular arches since many years[38]. In the past two decades, researchers had found that the masticatory efficiency of the elderly individuals improved significantly with the utilization of single IODs also when compared to CCDs[9,13,39]. Single IODs are an acceptable treatment modality for patients who find it difficult to bear the cost of two IODs[10–14].

In this study, patient satisfaction with one-piece SIMOs was more compared to two-piece SIMOs and was statistically significant at 1-year follow-up ($P=0.03$). The patient satisfaction level on the VAS score (at baseline to 1 year) increased in group one-piece SIMOs (38.1 to 56.6) and two-piece SIMOs (36.6 to 52.2). Crestal bone loss was greater in the two-piece SIMOs group at 1 month and 1 year follow-ups, but statistically it was insignificant. Prosthetic complications were few, but a participant in the two-piece SIMOs group had an attachment fracture within one month. The width of keratinized mucosa in both the groups was $\geq 2$ mm around the implant. Both the study groups had thick peri-implant biotype.

Cheng et al found improved patient satisfaction and masticatory efficiency with two piece SIMOs using the stud and magnetic attachments in a RCT with cross-over design[9]. Taha et al compared clinical and patient reported outcomes following the use of two retention systems, a ball and a stud type Equator attachment used for two-piece SIMOs and found significant improvement in patient sat-
satisfaction irrespective of the attachment used[40]. Naing et al studied the clinical efficacy (retention, stability, tissue scores, satisfaction level and masticatory capacity) of one-piece SIMOs and found that one-piece SIMOs resulted in significant increase in almost all parameters of clinical efficacy[41]. Similar result was obtained in present study with slightly more satisfaction of patients with retention, stability, mastication and comfort of prosthesis with one-piece SIMOs in one year of follow-up.

The present study showed a significant increase in satisfaction of the participants with the retention of the denture with one-piece SIMOs (P=0.009). In this very preliminary study, the reason for significant increase in patient satisfaction with the retention of the denture with on-piece SIMOs was unknown and needs confirmation with

<table>
<thead>
<tr>
<th>VAS questions</th>
<th>Group</th>
<th>Mean VAS Score (baseline)</th>
<th>SD</th>
<th>t-value</th>
<th>P-value</th>
<th>Mean VAS Score (baseline)</th>
<th>SD</th>
<th>t-value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>In general, are you satisfied with your lower prosthesis?</td>
<td>One Piece SIMOs</td>
<td>51.5 (37.9)</td>
<td>3.44</td>
<td>3.064</td>
<td>0.006*</td>
<td>57.9 (37.9)</td>
<td>3.51</td>
<td>2.833</td>
<td>0.010*</td>
</tr>
<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>46.3 (35.7)</td>
<td>4.14</td>
<td></td>
<td></td>
<td>53.6 (35.7)</td>
<td>3.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In comparison with a natural dentition, are you satisfied with your lower prosthesis?</td>
<td>One Piece SIMOs</td>
<td>47.1 (33.1)</td>
<td>4.23</td>
<td>0.979</td>
<td>0.338</td>
<td>54.8 (33.1)</td>
<td>5.65</td>
<td>1.640</td>
<td>0.116</td>
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<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>44.9 (31.1)</td>
<td>5.40</td>
<td></td>
<td></td>
<td>51.3 (31.1)</td>
<td>3.45</td>
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<tr>
<td>Are you satisfied with the retention of your lower prosthesis?</td>
<td>One Piece SIMOs</td>
<td>52.3 (39.7)</td>
<td>4.11</td>
<td>2.727</td>
<td>0.012*</td>
<td>57.4 (39.7)</td>
<td>3.56</td>
<td>2.863</td>
<td>0.009*</td>
</tr>
<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>47.2 (37.0)</td>
<td>4.36</td>
<td></td>
<td></td>
<td>52.1 (37.0)</td>
<td>4.61</td>
<td></td>
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</tr>
<tr>
<td>Are you satisfied with the stability of your lower prosthesis?</td>
<td>One Piece SIMOs</td>
<td>51.4 (35.4)</td>
<td>3.17</td>
<td>1.822</td>
<td>0.083</td>
<td>57.1 (35.4)</td>
<td>4.14</td>
<td>2.034</td>
<td>0.055</td>
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<td></td>
<td>Two Piece SIMOs</td>
<td>48.7 (36.7)</td>
<td>3.42</td>
<td></td>
<td></td>
<td>53.2 (36.7)</td>
<td>4.32</td>
<td></td>
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</tr>
<tr>
<td>Are you satisfied with the occlusion of your prostheses?</td>
<td>One Piece SIMOs</td>
<td>52.2 (37.9)</td>
<td>3.62</td>
<td>2.323</td>
<td>0.030*</td>
<td>56.8 (37.9)</td>
<td>5.09</td>
<td>2.006</td>
<td>0.058</td>
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<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>48.2 (36.6)</td>
<td>4.01</td>
<td></td>
<td></td>
<td>52.4 (36.6)</td>
<td>4.53</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is your lower prosthesis comfortable?</td>
<td>One Piece SIMOs</td>
<td>52.7 (38.6)</td>
<td>4.19</td>
<td>2.625</td>
<td>0.016*</td>
<td>57.7 (38.6)</td>
<td>4.06</td>
<td>2.751</td>
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<td>Two Piece SIMOs</td>
<td>47.3 (37.2)</td>
<td>5.01</td>
<td></td>
<td></td>
<td>52.4 (37.2)</td>
<td>4.42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How easy you find to clean your lower prosthesis?</td>
<td>One Piece SIMOs</td>
<td>55.8 (44.9)</td>
<td>4.02</td>
<td>3.237</td>
<td>0.004*</td>
<td>58.9 (44.9)</td>
<td>3.64</td>
<td>3.663</td>
<td>0.001*</td>
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<td></td>
<td>Two Piece SIMOs</td>
<td>49.7 (40.1)</td>
<td>4.34</td>
<td></td>
<td></td>
<td>52.6 (40.1)</td>
<td>4.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How easy you find to speak with your prostheses?</td>
<td>One Piece SIMOs</td>
<td>51.2 (37.7)</td>
<td>4.37</td>
<td>2.029</td>
<td>0.055</td>
<td>57.5 (37.7)</td>
<td>5.30</td>
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<td></td>
<td>Two Piece SIMOs</td>
<td>47.2 (38.2)</td>
<td>4.33</td>
<td></td>
<td></td>
<td>52.4 (38.2)</td>
<td>5.83</td>
<td></td>
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<tr>
<td>How easy you find to chew fresh white bread?</td>
<td>One Piece SIMOs</td>
<td>48.1 (37.9)</td>
<td>5.23</td>
<td>1.424</td>
<td>0.169</td>
<td>54.8 (37.9)</td>
<td>4.41</td>
<td>1.730</td>
<td>0.098</td>
</tr>
<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>45.1 (36.3)</td>
<td>4.24</td>
<td></td>
<td></td>
<td>51.3 (36.3)</td>
<td>4.51</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the pieces of fresh white bread well-chewed before swallowing?</td>
<td>One Piece SIMOs</td>
<td>46.9 (36.4)</td>
<td>4.87</td>
<td>1.913</td>
<td>0.070</td>
<td>53.3 (36.4)</td>
<td>3.93</td>
<td>1.370</td>
<td>0.185</td>
</tr>
<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>43.2 (35.8)</td>
<td>3.56</td>
<td></td>
<td></td>
<td>50.9 (35.8)</td>
<td>3.86</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are you satisfied with the appearance of your prosthesis?</td>
<td>One Piece SIMOs</td>
<td>52.9 (40.0)</td>
<td>4.40</td>
<td>2.884</td>
<td>0.009*</td>
<td>56.8 (40.0)</td>
<td>4.75</td>
<td>2.055</td>
<td>0.053</td>
</tr>
<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>47.3 (38.3)</td>
<td>4.27</td>
<td></td>
<td></td>
<td>52.7 (38.3)</td>
<td>4.07</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Satisfaction</td>
<td>One Piece SIMOs</td>
<td>51.1 (38.1)</td>
<td>2.58</td>
<td>1.731</td>
<td>0.13</td>
<td>56.6 (38.1)</td>
<td>1.57</td>
<td>2.362</td>
<td>0.03*</td>
</tr>
<tr>
<td></td>
<td>Two Piece SIMOs</td>
<td>46.8 (36.6)</td>
<td>1.77</td>
<td></td>
<td></td>
<td>52.2 (36.6)</td>
<td>0.78</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mean, standard deviation (SD), t-value and P-value at different time intervals for group one-piece and two-piece single-implant-retained mandibular overdentures (SIMOs). Asterisk sign indicates significant difference between two groups. *Statistically significant (P<.05).
due to loosening of the abutment\[22,23\]. The one-piece implant has immediate function. Its non-split parts prevent the problem arising. Its unibody design can be quite useful in single-stage surgery with rehabilitation of edentulous patients belonging to low economic status. overdenture and is a viable treatment option\[43\].

has a success rate equivalent to the two-piece implant supported denture and found that single piece implant supported overdenture the crestal bone loss around single-piece implant supported overdenture, statistically it was insignificant. Raza et al evaluated though the bone loss was more in two-piece SIMOs as compared to one-piece SIMOs and 1.24± 0.90 mm with two-piece SIMOs. Al during 1 year follow-up, but statistically it was found to be insignificant\[42\]. In present study, one-piece SIMOs had the mean crestal bone loss of 0.59± 0.02 mm and two-piece SIMOs had 0.73± 0.28 mm at 1 month follow-up. During 1 year follow-up, mean crestal bone loss was 0.80± 0.49 mm with one-piece SIMOs and 1.24± 0.90 mm with two-piece SIMOs. Although the bone loss was more in two-piece SIMOs as compared to one-piece SIMOs, statistically it was insignificant. Raza et al evaluated the crestal bone loss around single-piece implant supported overdenture and found that single piece implant supported overdenture has a success rate equivalent to the two-piece implant supported overdenture and is a viable treatment option\[43\].

One-piece SIMOs can be a viable treatment option for the rehabilitation of edentulous patients belonging to low economic status. Its unibody design can be quite useful in single-stage surgery with immediate function. Its non-split parts prevent the problem arising due to loosening of the abutment\[22,23\].The one-piece implant has disadvantages too such as; it is not possible to alter the angulation of abutment, so accurate implant placement is very important. The other disadvantage is that if implant is placed in esthetic zone, an immediate restoration is required and it may increase the risk of overloading of implant during initial healing. The one-piece implant is an effective choice for patients having surgical sites with less bone, not enough to support prosthesis. A one-piece implant can be preferred in cases requiring immediate function and in cases of fresh extraction sockets where immediate implant placement is required\[22,23\].

In a study by El Damarisy et al, both one-piece implant group and two-piece implant group showed bone loss surrounding the implant during 6 months (0.51± 0.11 mm and 0.72 ± 0.10 mm respectively) and 1 year (0.9± 0.09 mm and 1.11± 0.14 mm respectively) follow-up, but statistically it was found to be insignificant\[42\]. In present study, one-piece SIMOs had the mean crestal bone loss of 0.59± 0.02 mm and two-piece SIMOs had 0.73± 0.28 mm at 1 month follow-up. During 1 year follow-up, mean crestal bone loss was 0.80± 0.49 mm with one-piece SIMOs and 1.24± 0.90 mm with two-piece SIMOs. Although the bone loss was more in two-piece SIMOs as compared to one-piece SIMOs, statistically it was insignificant. Raza et al evaluated the crestal bone loss around single-piece implant supported overdenture and found that single piece implant supported overdenture has a success rate equivalent to the two-piece implant supported overdenture and is a viable treatment option\[43\].

As per the author’s knowledge, the present RCT is first of its type, comparing the success of one-piece and two-piece single SIMOs, but still, it had certain limitations, so the result of the present study must be interpreted with caution. The sample size was small with 22 implants in 22 participants with 1 year of follow-up. In this study platform switching concept was not followed, which might reduce the bone loss in two-piece SIMOs. Platform switching concept is a prosthetic concept in two-piece implants, where an abutment with a smaller diameter than the diameter of the implant shoulder is used, so that the microgap is located more distant to the first bone-implant contact. This concept reduces the crestal bone loss by providing increased space to establish the biologic width around implant and reducing the extension of the junctional epithelium apically\[44,45\].

Different implant systems were used in the two groups which might be one of the reasons for difference in patient satisfaction and bone loss among the two groups. As the study compared one-piece implants with two-piece implants so in order to maintain standardization, implants of two different systems having similar dimensions of implants with matching thread design were used.

Long-term studies required with increased sample size, similar implant system and platform switching concept with two-piece implant group to further analyze the patient satisfaction and crestal bone loss with one-piece and two-piece SIMOs. The big study with multi-centers should be carried out to obtain strong evidence.

### Table 4. Comparison of mean crestal bone loss (in mm) using an independent Student t-test

<table>
<thead>
<tr>
<th>Time</th>
<th>Group</th>
<th>N</th>
<th>Mean</th>
<th>SD</th>
<th>t-value</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Month</td>
<td>One-piece SIMOs</td>
<td>11</td>
<td>0.59</td>
<td>0.02</td>
<td>1.654</td>
<td>0.11</td>
</tr>
<tr>
<td></td>
<td>Two-piece SIMOs</td>
<td>11</td>
<td>0.73</td>
<td>0.28</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Year</td>
<td>One-piece SIMOs</td>
<td>11</td>
<td>0.80</td>
<td>0.49</td>
<td>1.424</td>
<td>0.16</td>
</tr>
<tr>
<td></td>
<td>Two-piece SIMOs</td>
<td>11</td>
<td>1.24</td>
<td>0.90</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mean, standard deviation (SD) and P-value at different time intervals for group one-piece and two-piece single-implant-retained mandibular overdentures (SIMOs).

### Table 5. Prosthetic complications in one-piece and two-piece single-implant-retained mandibular overdentures (SIMOs)

<table>
<thead>
<tr>
<th>Prosthetic complications</th>
<th>One-piece SIMOs group</th>
<th>Two-piece SIMOs group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment fracture</td>
<td>00</td>
<td>01</td>
</tr>
<tr>
<td>Denture fracture</td>
<td>00</td>
<td>01</td>
</tr>
<tr>
<td>Dentures need relining</td>
<td>03</td>
<td>02</td>
</tr>
</tbody>
</table>

Prosthetic complications were more in two-piece SIMOs at one year follow-up.
5. Conclusion

Within limitations of this study, one-piece SIMOs seemed to be a viable treatment option with more patient satisfaction. Two-piece SIMOs had greater crestal bone loss at 1 month and 1 year follow-ups when compared to one-piece SIMOs, but statistically it was insignificant. One-piece SIMOs could be an optional treatment modality, as it is comparatively simple with less invasive procedures and needs fewer components, so a considerable number of patients requiring implant retained dentures could be benefited.

Conflicts of interest

There is no conflict of interests to declare.

References


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