Comparison Between Patient Satisfaction And Biting Force In A Single Implant Overdenture And Two-Implants Overdenture: A Randomized Clinical Trial

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Abstract

Background: Mandibular implant overdenture retained by two implants was considered the minimum requirement for treatment of mandibular edentulous jaw. However, the financial cost of this treatment is relatively high that could not offered by many patients, especially in developing countries.

Aim: This study was made to ascertain if the mandibular overdenture retained by one implant at satisfaction and biting force parameters.

Methodology: A total of 56 edentulous patients have met the selection criteria. After randomized sampling system, one or two implants were inserted in the mandible following delayed surgical protocol, and locator attachments were screwed to implants at the second stage of surgery. The patient’s satisfaction was rated and the biting force was measured at baseline (before implant) and at 3, 6, and 12 months after implant loading.

Results: The study sample comprised of 56 patients (32 male AND 24 female), with a mean age of 58.2 years. All patients attended the 12-month follow-up without dropout. The two-implant group present a significant improvement in both patient satisfaction and biting force throughout the follow-up period in comparison with single implant group.

Conclusion: The two implants mandibular overdenture still the minimum standard treatment modality for completely edentulous cases rather than single implants mandibular overdenture.

Clinical Significance: The mandibular overdenture retained by single implant at the midline can provide a beneficial treatment outcome over 1 year observation period, especially for low-income patients.

Keywords
Biting force, dental implants, locator attachment, patient satisfaction, single implant overdenture

Introduction

Patients with conventional complete denture mainly complain from decreased retention, denture instability, decreased satisfaction, and reduced masticatory efficiency. These complaints are, especially, related to the mandibular denture. The rehabilitation of the edentulous jaws by implant overdentures overcomes most of these problems by increasing the denture stability, retention and improves the masticatory function. But, which implants number is superior or the best treatment option is still a controversy issue.1,2

Long-term studies comparing two and four implants overdentures reported no significant difference between them in clinical, radiographically parameters, and patient satisfaction as well.3,4 However, as a wide consensus, the mandibular implant overdenture retained by two implants is regarded as the minimum standard of care for treatment of mandibular edentulous jaw.5

Unfortunately, two-implant is considered outside the financial capacity of several edentulous patients, especially in developing countries.6 Therefore, a mandibular overdenture retained by only one implant at midline has been suggested as an alternative option. Many studies evaluated the single implant overdenture in comparison with a complete conventional denture or alone as a case
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report or case series. They claim that single implant overdentures have a promise results both clinically, radiographically, and better patient satisfaction, in addition to being time-saving, less surgical intervention, and cost-effective.14,15

However, there are only a few clinical trials that evaluate the single implant overdenture in comparison with the minimum standard of care (i.e., two implants mandibular overdenture). These studies reveal the insignificant difference between two treatment modalities in terms of survival rate, peri-implant bone loss, and patient satisfaction. None of the previous studies gave information about all of the patient satisfaction items that contained in visual analog scale (VAS) which include overall patient satisfaction, chewing ability, stability, speech, and esthetic. In contrast, they reported only the patient overall satisfaction.12-15

In addition, the biting force is considered as an important criterion for the masticatory efficiency and directly related to the masticatory performance.16,17 It has been found that the biting force of conventional complete denture was increased up to twice when the two implants mandibular overdenture used.18 However, to the best of our knowledge, there is no published study comparing the biting force of single implant overdenture to those of two implants overdenture.

This study aimed to answer the question; whether the mandibular overdenture retained by one midline implant is equivalent to mandibular overdenture and retained by two implants in terms of patient satisfaction and biting force or not? The hypothesis was that there would be no difference between mandibular overdentures retained by one or two implants regarding the patient satisfaction or the biting force.

Materials and Methods

Trial design and setting

This study was designed as a randomized clinical trial, parallel group with 1:1 allocation ratio. This study was approved by the Ethics Committee of Faculty of Oral and Dental Medicine, Cairo University. It was registered on the Pan African Clinical Trial Registry (PACTR) with a registration number (PACTR201411000595327). A total of 56 patients were recruited from the outpatient clinic in prosthodontics department - Faculty of Oral and Dental Medicine Cairo University - Egypt, according to the pre-specified inclusion and exclusion criteria as listed in Table 1. The patients received written informed consent to be signed in before their participation in the study.

Conventional complete denture fabrication

A conventional complete denture was constructed for each patient according to the traditional steps. Preliminary impressions were made using irreversible hydrocolloid (alginate ) impression material, whereas the final impression was made using zinc oxides and eugenol impression material19 after border molding by greenstick compound20. Then, a maxillary face bow record was obtained to mount the maxillary cast on a semiadjustable articulator21 Cross-linked acrylic resin teeth with 20° cusp angles of appropriate shape, size, and shade were arranged following the balanced occlusion concept. All necessary adjustments, occlusal refinements, and finally, the post-insertion instructions were performed in the traditional manner.

Randomization and patient grouping

All patients, after receiving the complete dentures, were randomly assigned into two identical groups each of which 28 patients using research randomizer website9. Group I was received a single implant in the mandibular midline, whereas Group II was received two implants at canine areas to retain overdenture. Only one investigator, not involved in the selection of the patients, was aware of the randomization sequence and could have access to the randomization lists stored in his password-protected computer. The randomized codes were enclosed in sequentially numbered, identical, opaque, sealed envelopes. Patients were asked to select one of the envelopes, and the investigator who is aware of the randomization process was asked about the specific group and treated accordingly.

Implant surgical and prosthetic procedures

During CBCT imaging, the patient was instructed to wear his/her lower stent and upper complete denture to stabilize the

Table 1: The inclusion and exclusion criteria

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<thead>
<tr>
<th>Inclusion criteria</th>
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<tr>
<td>Patients with completely edentulous maxillary and mandibular arches who need a new denture construction</td>
<td>Severely atrophied ridges</td>
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<td>Patient’s age ranged from 40 to 70 years old</td>
<td>Class II and III skeletal relationship</td>
</tr>
<tr>
<td>Moderate ridge with an adequate amount of keratinized mucosa</td>
<td>Irradiated patient or patient undergoing chemotherapy</td>
</tr>
<tr>
<td>Skeletal Class I patients with adequate interarch distance with parallel ridges</td>
<td>Smokers</td>
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<tr>
<td>Free from temporomandibular disorders</td>
<td>Patients with a history of parafunctional habits</td>
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<td></td>
<td>(e.g., clenching or bruxism)</td>
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<td></td>
<td>Osteoporosis and hyperparathyroidism</td>
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<td>Systemic diseases with known effect on implant surgery</td>
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<td>as uncontrolled diabetic</td>
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* Cavex Holland B.V, Holland.
† Cavex: Netherlands.
‡ Kerr: Kerr UK limited: Netherlands
§ Bio-art, facebow and semi-adjustable articulator BRAZIL.
¶ (https://www.randomizer.org).
stent during the imaging process. All necessary measurement including bone length and width at proposed implant site was performed.

A surgical stent was constructed by duplicated the lower denture in the transparent acrylic resin at aid to determine the point of entry and relative parallelism of implants during a surgical procedure. Patients have received either single implant at midline area for Group I or two implants at the interfemoral area for Group II according to randomization process following two stages surgical protocol.

After 3 months, the implants were uncovered using a small crestal incision and cover screws were removed and replaced with healing abutments for 2 weeks. A periodontal probe was used to measure the height of soft tissue thickness around the implant to select the proper height of locator attachment accordingly. The appropriate locator attachments were screwed to implant, and a white spacer was placed before a covering metal housing connection. Then, a pickup procedure was made intraorally by making small holes at the lingual side of lower denture opposing connection. Throughout pickup procedure, the patients were instructed to close slightly in a centric position to ensure proper occlusal relationship thereafter. Immediately after finishing the pickup procedure, the black procession cap was replaced with red nylon cap [Graphs 1 and 2].

**Outcome measurements**

A 100 mm uninterrupted VAS representing a continuum of feelings, with totally unsatisfied at one end and totally satisfied at the other, was used to evaluate patient satisfaction. Each patient asked to rate his or her response to the following question: “How would you evaluate your overall satisfaction, chewing ability, denture stability, speech, and esthetics with your lower denture?” The patients indicate a mark X on the line corresponding to their estimated agreement of perception. The mark was translated into a number by superimposing a template with 100 numbered intervals. The baseline measurements were performed after 1 month of conventional denture insertion and before implant installation, and thereafter, at 3, 6, and 12 months following implant loading.

The patient biting force was measured using load star sensor device. The patient was seated in an upright position. The sensor was placed horizontally at the first molar area starting with the right side. The patient was instructed to clench maximally, whereby the direction of applied force was vertical. The highest 10 readings were selected from the recorded table and the mean value was calculated. The mean of the left- and right-side values was considered as one value. The maximum biting force was measured at baseline (i.e., 1 month after conventional denture insertion) and at 3, 6, and 12 months intervals after implant loading.

**Results**

All patients attended the 12-month follow-up without dropouts. The overall survival rate of implants was 100% at the end of 12 months in both groups. The results of the patient satisfaction as regarding speech, stability, chewing ability, esthetics, and general satisfaction score for both groups along the different follow-up intervals are shown in Graph 3. Meanwhile, the results of the biting force for both groups along the different follow-up intervals are shown in Table 2.

Regarding the patient satisfaction, at baseline, the difference between the two groups was statically insignificant. However, thereafter, the Group II showed the higher value of patient satisfaction compared to Group I as shown in Graph 4.

Furthermore, at baseline, Group II showed the higher value of biting force compared to Group I, but the difference between the two groups was statically insignificant. While at 3, 6, and 12 months follow-up, Group II showed the higher value of biting force compared to Group I and the difference between the two groups were statically significant [Graph 5].

**Discussion**

The null hypothesis was rejected because the results reveal a significant difference in patient satisfaction and biting force between the two groups. The conventional complete dentures were constructed for all patients before dividing the patients into two groups to ensure equal managements for all patients preventing any potential bias at this step. We start the evaluation of patient satisfaction and biting force after 1 month of denture delivery to allow for proper denture adjustment and period of adaptation with the new denture. For standardization purpose, during biting force measurements, the patients were instructed to apply steady continuous pressure on the sensor for 30 s and the mean for highest ten records was taken for all patients.

Within the group, when patient satisfaction scores measured at the 12-month follow-up compared with baseline values,

<table>
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<th>Follow-up</th>
<th>Group I</th>
<th>Group II</th>
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<tr>
<td>Baseline</td>
<td>25.84</td>
<td>32.43</td>
</tr>
<tr>
<td>3 months</td>
<td>29.19</td>
<td>32.48</td>
</tr>
<tr>
<td>6 months</td>
<td>30.24</td>
<td>34.38</td>
</tr>
<tr>
<td>12 months</td>
<td>38.90</td>
<td>41.58</td>
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Max: Maximum recorded value, Min: Minimum recorded value, SD: Standard deviation.
a significant improvement was found in both groups. This supports the argument that the implant overdenture produced

Graph 1: (a) A single midline implant after healing abutment removal to measure the soft tissue thickness at the 2nd stage surgery for Group I, (b) the locator attachment with white spacer, (c) locator metal housing attached, (d) a small hole prepared in the denture opposing to the attachment area, (e) the final pickup with black processing cap, (f) pickup procedure for Group II, the locator attachment with white spacer and metal housing in place

Graph 2: (a) Two interforaminal implants with the healing abutments at 2nd surgical stage for Group II, (b) the soft tissue thickness measured with a periodontal probe to select appropriate locator attachments, (c) the locator attachments screwed to the implants, (d) the white spacer placed over the attachment, (e) the metal housing placed over the corresponding attachments, (f) the final pickup with functional red cap replaced the black processing one

a significant patient satisfaction than a conventional complete denture regardless the implant number whether one or two implants[14,21,22]. The explanation for this is that the implant improves retention, stability, and masticatory performance to a large extent which seems to be logic and in accordance with most previous studies that done on this subject.[13,23-28]

Between the groups, at baseline and at 3-month follow-up periods, the difference in the patient satisfaction between single and two implant groups was not significant which was compatible with the result of many previous studies.[13,15] However, at 6 and 12 months follow-up periods, the satisfaction scores revealed a statistically significant difference between single implant group and two implant group in preference of two implant group. The explanation may be due to the fact that the two implants provide more stability and retention that reflected in more patient satisfaction. Also the position of implants in the dental arch at the midline in the first group, which act as a fulcrum, decrease the denture stability. In contrast, the implants position in the group 2, at the canine area bilaterally (i.e., at the corner of the mouth), produce more stability and reduce the possible rocking effect of the single midline implant. This finding disagrees with the previous studies.[13,15]

The results reveal a significant increase in the maximum biting force when baseline measurements (i.e., the patients wear only the conventional dentures) compared to those measurements at 3, 6, and 12 months’ intervals after implant loading in both groups. This is in part due to improvement in denture stability and retention that in turn results in more patient comfort and more ability to bite without fear from loss of retention or discomfort that was accompanied with a conventional complete denture.

Another explanation of biting force increases after implant loading in both groups that the dental implants improved the functional state of the masticatory apparatus and aided in the establishment of better neuromuscular coordination by improving the support, stability, and retention of the prosthesis. In this case, muscle activity was totally devoted to and directed toward masticatory function and no effort was required to stabilize or retain the prosthesis, and hence, less effort was required from the muscles to execute the same functions.[29]

Within each group, the biting force for Groups I and II increased with time from baseline to 12 months. This increase in biting force was more prominent when baseline compared to 12 months in both groups. The explanation for this may be attributed to the gradual building up experience and patient adaptation to the new prosthesis which supported by previous studies.[30,31]

When the biting force of Groups I and II compared, the results revealed a statistically non-significant difference at the baseline. However, at the following intervals 3, 6, and 12 months, the difference between them was highly significant in preference of Group II. To clarify this significant increase between two groups, four logic causes may be acting in combination. First, the increase in implants number produced an increased denture stability, retention, comfort, and masticatory performance in the
form of biting force. Second, the position of implants in Group II was close to the area of biting force measurement at first molar resulting in more biting force. In contrast, in the single implant group, the implant was placed at the midline farther from the area of measurement. Third, the patients’ confidence more apparent in the two implants group than in the one implant group exerting more force accordingly. Furthermore, in the single implant group, some patients feared from the fracture of their dentures during maximum biting. Fourth, the difference in gender distribution may affect the results as the two implants group include more males (10 males) than the single implant group (6 males) as the male has more biting force than female because of their increased muscular mass and arch size.\(^{(32,33)}\)

Consequently, despite the apparent advantages of single implant overdenture as a cost-effective and time-saving treatment modality, the mandibular overdenture retained by two implants still the minimum standard of care for the completely edentulous patients due to its superiority over the single implant option on the long-term evaluation.

Three limitations associated with this study include, first, the unequal gender distribution between the two groups which may have a direct effect on the results, especially the biting force parameter. A randomization process can overcome this limitation, but a larger sample size is required. Second, the blinding for the patient toward the implant numbers was impossible. Hence, the subjective assessment of satisfaction by the patients themselves might have been biased by the disappointment of participants who received only one implant. Hence, the risk of bias toward the two implants against only one implant still presents to a large extent. In addition, the educational level was low for most of the patient may be reflected as a non-precise rating for their actual response. Finally, the follow-up of 1 year may be relatively short to produce confirm and valid judgment for such treatment modality.
In conclusion, the mandibular implant overdenture retained by single midline implant produces significantly less patient satisfaction scores and biting force values compared to those produced by two implants overdenture. The two implants mandibular overdenture is the minimum standard of care for rehabilitation of completely edentulous cases.

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