

Single Versus Two Dental Implant Retained Mandibular Overdenture: Study Protocol for a Randomized Controlled Trial

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Abstract

Background: The consensus is that the standard treatment of choice for the edentulous mandible should be a two implant retained mandibular overdenture. Some clinicians have tried single median implant to retain the mandibular overdenture, however, there is lack of scientific information with single implant retained mandibular overdenture. Therefore the purpose of the current randomized clinical trial is to test the hypothesis that a single median implant in edentulous mandible will result in a clinical outcome comparable to two implants.

Methods/design: This prospective randomized controlled clinical trial is in preparation to commence. The final patient with 1 year follow up will complete the trial in 2017. In total, 66 edentulous patients between 45 and 85 years of age with mandibular complete dentures will be treated with either single median implant (experimental group, N=33) or two implants (control group, N=33). The existing complete dentures will immediately be supported by the implants using locator attachment/s. The patients will be followed up at intervals of 1 month and 12 months after implant loading. The primary outcome measures are implant success rate, masticatory performance and patient satisfaction level and. The secondary outcome measures encompass effect on oral health related quality of life and clinical, technical and subjective variables.

Discussion: This clinical trial will give information on the ability of single median implant to retain a complete mandibular denture when immediately loaded. If viable, this treatment option is advantageous in regards to simpler procedure, reduced treatment cost and reduced risk of surgical morbidity.

Keywords: Implant supported overdenture; Implant therapy; Mandibular complete denture; Single midline implant

Introduction

Implant-supported dentures, either complete overdentures or hybrid prosthesis significantly improve the quality of life of edentulous patients as compared to conventional removable complete dentures. Consensus statements (made by expert teams) in 2002, 2009 and 2011 from symposia in Canada, England and the U.S. have respectively suggested that the first-choice standard of care for an edentulous mandible should be two-implant retained mandibular overdentures (TIMOD) [1]. In this regard the TIMOD for edentulous patients have become the standard line of treatment. The concept of a single-implant retained mandibular overdenture (SIMOD) was introduced by Cordioli [2] in 1993 and the first 5-year results were published in 1997 with implant success rates of 100% [3]. Another randomized clinical trial with 86 edentulous patients, compared mandibular overdentures retained by one or two implants [4]. Walton et al. [4] studied patient satisfaction and prosthetic outcomes with mandibular overdentures retained by one or two implants and they have observed within the follow up period of 12 months, SIMOD provided comparable patient satisfaction with lower treatment costs and treatment times, suggesting a viable treatment option. In these investigations, implants were left unloaded during healing period. In 2007, Liddelow and Henry [5] reported on a 100% implant-survival rate of immediately loaded implants after 36 months of observation when implants with oxidized surfaces were used. When biomechanical rationale of a SIMOD system was studied, the dome-type magnet or ball attachments had biomechanical effects similar to TIMOD in terms of lateral forces to the abutment and denture base movements under molar functional loads [6]. Liu et al. [7] evaluated strain distribution in peri-implant bone, stresses in the abutments and denture stability of mandibular overdentures anchored by different numbers of implants under various loading conditions, through the 3-dimensional finite element analysis (FEA) and concluded that the number of implants does

not significantly affect the stresses and strain distribution. The strain distribution produced in the supporting bone by SIMOD and TIMOD was observed to be comparable. Liu et al. also observed that the SIMOD did not show damaging stress concentration in the bone around the only implant. There is a need to conduct more study to compare the SIMOD and TIMOD with immediate loading protocol for implant survival rate, masticatory performance and patient satisfaction.

Methods/Design

Ethical approval for the proposed study was obtained from the Joint Committee for Research and Ethics of the International Medical University, Kuala Lumpur, Malaysia (IMUR 148/2014). The information obtained during the data collection will be kept strictly confidential. In order to maintain anonymity, a random code number will be assigned to each participant of this study. Informed written consent will be obtained from every participant prior to the commencement of this study. This study is designed as a parallel grouped randomized controlled clinical trial. It will conform to the CONSORT-2010 statement [8]. The study is designed according to Malaysian guidelines of Good Clinical Practice (GCP), the principles of the Declaration of Helsinki (2008) and standards for professional conduct.

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Participants

Patients wishing to participate in this clinical trial should meet the following inclusion criteria:

- Able to provide consent and participate in the treatment provided including attending recall appointments.
- Healthy male or female patient with at least 3 months experience of wearing lower conventional complete dentures.
- Seek improvement for lower complete denture due to unsatisfactory existing denture in terms of retention and stability
- No contraindications for insertion of implants (after initial screening tests like vital signs, blood sugar level and other necessary investigations).
- Should be medically/psychologically fit for receiving implant treatment.
- Sufficient bone in the anterior mandible to place implants without augmentation procedures.
- Patients with any of the following conditions will be excluded:
- Insufficient alveolar bone height in the anterior mandibular region for implant(s) placement (<6 mm),
- Need for additional pre-prosthetic surgery
- Previous dental implant treatment in the mandible
- Medical conditions contraindicating implant treatment eg. History of head and neck radiotherapy; on Bisphosphonates therapy.
- Unable to communicate and follow-up.
- Heavy smoker- more than half a packet a day.

The study site

The study is planned to be conducted at the Oral Health Centre, School of Dentistry, International Medical University, Kuala Lumpur, Malaysia. All investigators are GCP (Good Clinical Practice) certified and are responsible for patient examinations, patient treatment (implant placement, attachment of retentive components to the implant and denture) and follow-up visits.

Study population

The success rate of a single median implant after 1 year as the primary endpoint of the study is a binomial random variable and success probability is assumed to be 97% in the control group as well as in the experimental group. A maximum inferiority of 10% in the experimental group is regarded as clinically acceptable due to the benefits for these patients, i.e. reduced cost, significant reduction in risk for nerve/vessel injury during surgery/surgical complications, less surgical time, less post-surgical maintenance time, less denture modification time, and elimination of the need to place implants parallel to each other. Under these assumptions, a one-sided test of binomial parameters at a 5% significance level has a power of 80% to reveal the non-inferiority of the SIOD if the sample size is 54 (27 per group). Taking into account a loss to follow-up rate of approximately 20%, a total of 65 patients (33 per group) was considered necessary [9,10]. It was assumed that the reasons for loss to follow-up would be random with respect to treatment assignment. According to Lehr's equation, the minimum

sample size required was calculated by taking the reference of standard deviation from the similar research by Liddelow and Henry [11] and Turkyilmaz et al. [12]. The minimum sample size was calculated to be 27 participants in each group with addition of 20% samples in anticipation of failure to follow-up requiring it to have 33 participants in each group.

Sampling Method and Recruitment:

The subjects from the routine outpatient department (OPD) from the Oral Health Centre of IMU will be recruited. The subjects can be recruited from the pool of respondents to the advertisements, information pamphlets, existing patients etc. Subjects from old age homes who fulfil the inclusion criteria shall also be recruited. Recruitment of patients will be performed in two steps. Edentulous patients who have signed the informed consent will be screened according to the inclusion and exclusion criteria applying standardized examination forms. Patients who meet the inclusion criteria, but whose lower complete dentures are judged technically unacceptable will be referred for denture revision or new dentures. They will be offered the opportunity to be examined again after these improvements to the denture for possible inclusion in the trial if the dentures can be worn for at least 3 months before the recruitment period ends. Patients meeting the inclusion criteria regarding denture status, denture satisfaction will undergo a radiographic examination (panoramic x-ray with reference marker) to determine whether the residual bone height of the mandible meets the inclusion criteria. The width of the bone at implantation site is estimated by 'bone sounding' method. The Cone Beam CT (CBCT) scan is taken in special situations where bone width and length is not predictable with conventional radiographs and bone sounding. If all inclusion criteria are met, patients will be included in the study.

Methods of intervention

Experienced clinicians (also co-investigators in the study) shall perform the surgical and prosthetic procedures according to the standardized protocol in order to ensure uniformity in terms of quality and consistency in the treatment. All the intervention providers are skilled clinicians in the specific dental implant treatment in this study with more than 6 years of clinical experience. Intervention is carried out in three steps:

A) Complete denture evaluation and necessary minor modifications: The existing complete dentures of the patients are evaluated for primary technical soundness. The dentures are also evaluated to ensure that retention, stability and support are satisfactory. If required, minor modifications can be carried out on the denture before implant placement.

Technically acceptable dentures [13]

- Hard densely processed acrylic resin bases without missing parts, fractures, visible porosities or other structural defects.
- Periphery of denture bases within usual anatomical parameters.
- Maxillary denture retentive when denture wearer opens the mouth to a gap of 15 mm between incisal edges.
- Mandibular incisors within anatomical boundaries of the ridge crest and the labial vestibule.
- Posterior teeth on mandibular denture placed no higher than 3 mm above the retromolar pad and within the triangular zone outlined by the width of the retromolar pad and the tip of the canine.

- Comfortable interocclusal rest space for the denture-wearer. Centric occlusal contacts within 2 mm of centric relation.
- No cheek biting.

B) Implant placement and attachment of locators: Regular sized (3.5 mm width and 11 mm or 13 mm length) (may vary according to need) threaded titanium implants are used for all patients. All implants used are from the same manufacturer to maintain same standards of implant placement. The overdenture abutment is placed during the surgery instead of healing abutment to facilitate immediate loading. Usually the overdenture-abutment with 3mm collar height is preferred.

C) Attachment of retentive components to the denture: Locator attachments are used as the retentive components for the denture. The locator attachments are attached to the denture using chairside direct relining technique with hard relining material (auto-polymerizing acrylic resin).

Definition of intervention group: The randomly selected participants receiving 1 implant in edentulous mandible just lateral to the mid-symphysis region along with a Locator attachment which is immediately loaded by adding the retentive components into the existing denture-base will form the interventional group.

Definition of control group: The randomly selected participants receiving 2 implants in the canine region in edentulous mandible, along with Locator attachments which are immediately loaded by adding the retentive components into the existing denture-base will form the control group.

Method of randomization: After obtaining informed written consent from every potential participant of this study, a lottery will be conducted using their registration numbers to randomly allocate each participant into the intervention and control groups with allocation ratio of 1:1.

Stratification is done according to the patient's residual bone height (Class II or III according to McGarry et al. [14]). All interventions are conducted according to defined standard operating procedures.

Method of blinding: Due to the obvious visible differences in treatment, it is not possible to blind the investigator or the participating patients. But the person who is conducting the statistical analysis will be kept blinded about the individual identity of the participants.

Study instruments: Three instruments will be used:

1. Evaluation of the implant success rate by calculating crestal bone loss using intra-oral periapical radiograph (IOPA)

An intraoral periapical (IOPA) radiograph will be taken immediately after implant placement, at 1 month and 1 year recall visits with the 'parallel angle technique' following standard protocols [15-17].

The distance in mm (least count 0.01 mm) between the tip (lower-most end) of the Implant body and the crest of the ridge will be calculated on both the sides of the implants at baseline, 1 month follow-up and 1 year follow-up IOPAs with the aid of a graduated 3x magnification loupe and a Vernier Caliper. Two individual investigators will complete the radiographic measurements independently and their results will be averaged. The distances on IOPA are proportionally calculated using following formula (in case of possible chance of foreshortening or elongation) to minimize the errors (Figure 1).

Actual relative bone level at baseline $b_0 = B_0 \times \text{Actual Implant body length} / A_0$

A = Distance between white and orange line = Length of the implant body

B = Distance between white and yellow line = Distance between implant-apex to crest of bone

Similarly 1 month recall (b_1) and 1 year recall (b_2) bone levels are calculated

$$\text{Crestal bone loss at 1 month recall } (Z_{1 \text{ month}}) = (b_0) - (b_1)$$

$$\text{Crestal bone loss at 1 Year recall } (Z_{1 \text{ Year}}) = (b_0) - (b_2)$$

All readings are repeated for mesial (M) and distal (D) side of the implant on each IOPA of each recall visit and average is taken.

2. Evaluation of the masticatory performance with two-colour chewing gums

The masticatory performance will be assessed with a modified method using two-colour chewing gums as described by Schimmel et al. [18]. The patients are given five samples of a two-colour chewing gum to chew for 20 cycles. All samples are taken out and are flattened to 1 mm thick 'wafers'. These 'wafers' are scanned using Epson Scanner. The scanned image (JPEG file) is copied into an image of fixed size (1175 X 925 pixels) and stored in Adobe Photoshop format (.psd). Computerized analysis is performed by means of the software package 'Adobe Photoshop Elements'. The 'Magic Wand' tool of the 'Adobe Photoshop Elements software' is used to measure the unmixed color.

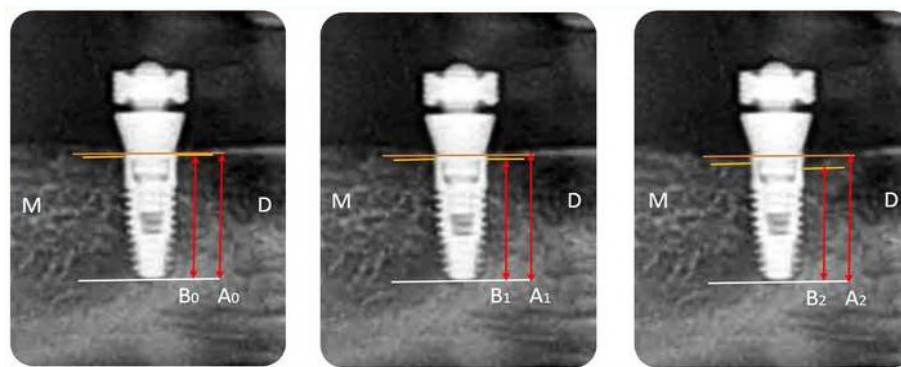


Figure 1: Sample photograph showing the distance of the upper most end of the implant body (Orange line) to the crestal bone level on mesial and distal sides (Yellow line) of each implant at different follow-up intervals.

As a reference scale a scanned piece of unmixed gum is copied in each image (area of 4779 pixels). Then the 'magic wand' tool is used to select the unmixed colour parts of the image. The numbers of selected pixels are recorded from the histogram for each side and at each tolerance (tolerances 20, 25, 30) and mean of those figures are calculated. Subsequently a ratio is computed for the Unmixed Fraction (UF) using the following formula.

$$\frac{(\text{Pixels Unmixed colour side a} + \text{Pixels Unmixed colour side b}) - 2 \times \text{Pixels of Scale}}{2 \times \text{Pixels All}}$$

To create baseline data 20 un-chewed samples are measured and analysed in the same way. The difference between UF at baseline and 1 month and baseline and 1 year is calculated.

3. Evaluation of the patient satisfaction level on visual analogue scale (VAS)

Self-administered questionnaires that followed the VAS method were completed by patients preoperatively and at each scheduled recall to assess oral comfort and function. Each VAS questionnaire consisted of a 100-mm line anchored at the beginning and end by opposing responses/statements such as "not at all satisfied" to "totally satisfied" [11]. The participants mark a vertical line on the horizontal VAS line to indicate their satisfaction level. Scores are determined by measuring the distance (in mm) from the left starting point of the line to the intersection of the response line. The millimetre reading is presented as a percentage.

There are 5 questions gauging participant's satisfaction, i.e., [16]:

- General satisfaction
- Social life
- Mastication of hard food
- Comfort
- Fit of the denture.

Termination criteria

a) A sample termination criteria

A participant will be removed from the trial if any of the following occur:

- Any complication during implant insertion.
- A minimum insertion torque of 30 Ncm is not achieved.
- An allergic reaction to titanium.
- A serious adverse event related to the implantation.
- Any relevant deterioration in the health of the subject possibly affecting participation in the trial.
- Failure to comply with trial requirements.
- Withdrawal of consent [19].

Study termination criteria: In case of an implant failure in the experimental group, the patient will be treated according to the protocol of the control group with new implants.

Those patients will be excluded from the trial before retreatment. If more than 20% of the implants fail in any group within the first 3 months after implant placement, the study will be terminated. This criterion will be checked every 6 months after the inclusion of the first patient.

Data collection procedure:

Evaluation of the implant success rate: The crestal bone loss is calculated in mm as described in 'Study Instruments point-14' at 1 month and 1 year recall visits. The data referring to the bone loss in mm are entered in a Microsoft Excel spread sheet and are given to the statistician who is blinded.

Evaluation of the masticatory performance: Masticatory performance is assessed with a modified method using the two-colour chewing gum technique described in the 'Study Instruments point-14'. The UF is calculated by the formula at Baseline, 1 month and 1 year recall visits. The difference in UF values of both the groups are entered in the Microsoft Excel spread sheet and given to the statistician who is blinded.

Evaluation of the patient satisfaction level: The VAS scores are calculated as described in 'Study Instruments point-14' in all five categories namely General satisfaction, Social life, Mastication of hard food, Comfort and Fit. All scores determined at baseline, 1 month and 1 year recall are recorded. The degree of improvement after 1 month and 1 year are also calculated with reference to baseline values and are given to the statistician who is blinded.

Outcome assessment: All the three parameters are assessed at baseline, 1 month and 1 year follow-up.

Primary outcomes

- Assessment of implant success rate using radiographic crestal bone loss around implant.
- Improvement in masticatory performance.
- Improvement in patient satisfaction level.

Secondary outcomes

- Evaluation of frequency of different prosthetic complications like denture base fracture, need for relining, replacement of retentive elements etc.
- Oral Health related quality of life (OHRQoL) will also be evaluated by using the questionnaire Oral Health Impact Profile-14 (OHIP-14) as a secondary objective [20]
- Evaluation of the implant mobility [16], pocket probing depth and plaque Index [16] Plaque index (Silness and Loe) [21]. Clinical probing depth measured using the University of North Carolina probe; and Clinical implant mobility measured manually and recorded as yes or no.
- Comparison of cost between the two groups.

Complication assessment: Prosthetic complications and maintenance intervals are recorded and compared with control group. Adjustment or exchange of retention elements, fracture of the denture base, relining and so on.

Data analysis: The data collected will be tabulated and analysed by using the Statistical Package for Social Sciences (SPSS) version 17.0. For the statistical analysis of implant success rate with reference to crestal bone loss, one-way repeated-measures analysis of variance (ANOVA) will be used to determine differences between means of bone level at baseline, 1-month and 1-year bone level, both within group differences and between group differences. Improvement in masticatory performance is analysed by replication of UF with the non-parametric sign rank test. The baseline satisfaction level (for each of 5

questions) between the groups is calculated statistically with the median VAS score using the Wilcoxon/Mann-Whitney nonparametric rank test and *t* test). The median VAS score improvement at 1 month and 1 year recall visits are recorded and analysed using Wilcoxon/Mann-Whitney test and *t* test. Changes within each group are analysed using signed-rank tests. Also, the median improvement in overall satisfaction from baseline to 1 year is calculated. Intention to Treat Analysis (ITT) will be done for lost to follow-up cases.

Non-superiority analysis will be done if the intervention does not significantly differ from standard regimens. In this study, a *p*-value < 0.05 will be considered as statistically significant.

Discussion

From a biomechanical point of view, during mastication, the occlusal forces on the posterior teeth of the TIMOD cause maximum movement of the denture around the fulcrum line joining two attachments; hence the freedom of movement is limited to around one axis. In SIMOD cases the denture is free to move in all directions and effective stress concentration around the crestal bone may be reduced when compared to two implants. Hence a clinical study, comparing the implant success, masticatory performance and patient satisfaction, between SIMOD and TIMOD can provide clinicians valuable information so that the cost of the treatment can be reduced while maintaining the advantages of TIMOD. Immediate loading protocols are followed for advantages like avoiding the burden of a second procedure, having a stable denture directly after surgery and possibly reduced postoperative pain and discomfort, since the soft tissue of the surgical wound is not loaded with the denture during healing [8]. Patients from poor economic strata worldwide can afford to receive a similar standard of care by reducing the number of implants from two to one and a large population can benefit from implant retained overdentures.

Therefore, the present study is designed to test the hypothesis that the implant success and satisfactory masticatory performance can be obtained by single median implant used in the edentulous mandible to retain a complete mandibular denture. In addition it is the aim of this trial to evaluate effect of SIMOD on patient satisfaction; oral health related quality of life, frequency of prosthetic complications as compared to TIMODs. This clinical trial will give information on the ability of a single median implant to successfully retain a complete mandibular denture when immediately loaded. If viable, this treatment option will improve everyday dental practice with reduction in cost, surgical complication risk and treatment time.

Ethical Approval

Ethical approval for the proposed study was obtained from the Joint Committee for Research and Ethics of the International Medical University, Kuala Lumpur, Malaysia (IMU R 148/2014).

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