Comparative Clinical Study of Conventional Dental Implants and Mini Dental Implants for Mandibular Overdentures: A Randomized Clinical Trial

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ABSTRACT

Background: Dental implant-retained overdentures have been chosen as the treatment of choice for complete mandibular removable dentures. Dental implants, such as mini dental implants, and components for retaining overdentures, are commercially available. However, comparative clinical studies comparing mini dental implants and conventional dental implants using different attachment for implant-retained overdentures have not been well documented.

Purpose: To compare the clinical outcomes of using two mini dental implants with Equator[®] attachments, four mini dental implants with Equator attachments, or two conventional dental implants with ball attachments, by means of a randomized clinical trial.

Materials and methods: Sixty patients received implant-retained mandibular overdentures in the interforaminal region. The patients were divided into three groups. In Groups 1 and 2, two and four mini dental implants, respectively, were placed and immediately loaded by overdentures, using Equator[®] attachments. In Group 3, conventional implants were placed. After osseointegration, the implants were loaded by overdentures, using ball attachments. The study distribution was randomized and double-blinded. Outcome measures included changes in radiological peri-implant bone level from surgery to 12 months postinsertion, prosthodontic complications and patient satisfaction.

Results: The cumulative survival rate in the three clinical groups after one year was 100%. There was no significant difference (p < 0.05) in clinical results regarding the number (two or four) of mini dental implants with Equator attachments. However, there was a significant difference in marginal bone loss and patient satisfaction between those receiving mini dental implants with Equator attachments and conventional dental implants with ball attachments. The marginal bone resorption in Group 3 was significantly higher than in Groups 1 and 2 (p < 0.05); there were no significant differences between Groups 1 and 2. There was no significant difference in patient satisfaction between Groups 1 and 2 but it was significantly higher than that in Group3 (p < 0.05).

Conclusions: Two and four mini dental implants can be immediately used successfully for retaining lower complete dentures, as shown after a 1-year follow up.

KEY WORDS: clinical implant performance scale, implant stability quotient, mini dental implant, primary stability

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INTRODUCTION

Mini dental implants have been widely used in clinical practice because of their benefits. There is no need for complex surgery, the required surgical intervention might be flapless mostly, the implants can be immediately loaded. One of the most useful treatments is to retain mandibular overdentures using mini dental implants. Mini dental implants for

overdentures are mostly one piece with diameters from 1.8 to 3.0 mm and various lengths from 10 to 18 mm. Mini dental implants sometimes have two-piece designs to provide an advantage in replacing abutments. According to the Glossary of Oral and Maxillofacial Implants (GOMI), the term mini dental implant has been defined as "implant fabricated of the same biocompatible materials as other implant but of smaller dimensions." With their small size, bone augmentation is not necessary and the surgical procedure is quite simple. The use of mini dental implants to retain removable partial and complete dentures is widely documented. 3-8

Mini implants can retain maxillary or mandibular removable prostheses. The supporting bone should be of Type D 1 or D 2 according to the classification by Misch⁹ for appropriate long-term success.² Mini implants may also provide a solution by immediate retention of complete removable dentures in edentulous patients with atrophic alveolar ridges edentulism, and the success rate is related to primary stability of the implants. When the implants are placed in denser types of bone, with an insertion torque of at least 30 Ncm,² they may be immediately loaded to retain an overdenture. After implant placement, the retainer is embedded within the acrylic base of the denture in a pick-up technique. The patient immediately has a stable and functional denture after completing the procedure. The treatment is inexpensive and expeditious compared with standardized implant treatment.

Eventually, in dense bone, failure can occur. Occlusal forces may overload the implant and cause a failure. Survival analyses demonstrate the long-term high performance of mini dental implants used for denture stabilization. Survival analyses of mini implant revealed survival rates greater than 90%, depending on methodology and survival criteria.⁴

According to Feine and colleagues 2002, due to overwhelming evidences, a 2-implant overdenture should become the first choice of treatment for the edentulous mandible. However, for mini dental implants, the minimum number of mini implants required for appropriate retention of complete removable dentures may be six in the maxilla and four in the mandible. The disparallelism of mini implants for overdentures should not exceed 20° generally, to avoid nonseating of the denture and conversion of axially directed loads to off-axial loads by the

angled position of the implant. A surgical guide may be needed to ensure close parallelism for miniimplant placement. Therefore, it is necessary to study the success rate of mini implants for mandibular overdenture retention.

The purpose of this study was to compare clinical outcomes of using mini dental implant and conventional dental implant, assuming that there is no significant difference between the three groups of implant protocols regarding to marginal bone, patient satisfaction, and prosthodontic complication as null hypothesis.

MATERIALS AND METHODS

Patients were recruited according to the following inclusion and exclusion criteria listed in Table 1. Every patient was given a random subject identification number. A blinded investigator (one who was involved in the screening, treatment, follow-up, data collection or analysis) used computer software (List Randomizer, Waterloo, Ireland) to randomize the subject identification numbers into one of the three groups. This information was concealed in sealed envelopes, which were opened immediately before surgical treatment. Neither the surgeon nor the patient was aware of the group assignment until the surgery visit. The study course followed the flow chart given in Figure 1. Many factors can affect implant stability quotient (ISQ), such as bone quantity and quality, implant design, length, and diameter. 11 Due to the diameter, mini dental implants used in the study were sent to the Osstell company (Osstell, Gothenburg, Sweden) to have the RFA for standard curve calibrated. The randomized clinical study was approved by the Human Experimentation Committee of the Faculty of Dentistry, Chiang Mai University (No. 35/2556).

Surgical Protocol

Patients were randomly allocated to three groups (Groups 1 and 2: test groups; Group 3: control group). Each group contained 20 patients as follows (sample size analysis was calculated based on an α error of 5% and a power of 80%):

Group 1: Four mini dental implants (PW plus®, Nakhon Pathom, Thailand) (diameter = 3.0 mm, length = 12 mm, were placed in the anterior mandible

TABLE 1 Inclusion and Exclusion Criteria

Inclusion criteria: General Exclusion criteria

Completely edentulous arches, requiring complete dentures

No contraindication for minor oral surgery (ASA \leq 2)

No psychosis, dementia, or other psychiatric disorders

No uncontrolled bleeding disorders

No smoking or smoking of less than 10 cigarettes day during the last five years (questionnaire)

No intravenous injection of bisphosphonate drugs

Never received radiotherapy of the mandibular or cervical regions

Ability to maintain good oral health, denture and dental implant care

Good attitude for denture insertion and understanding of treatment procedures

To be able and to agree to undergo treatment and follow up at least 7–10 times

Inclusion criteria: Local

Maxillary complete denture must have good marginal fit and retention with acceptable esthetics.

Mandibular complete denture must have proper marginal fit and its thickness at the areas of the implants must be at least 6 mm.

Occlusal plane of denture should be parallel to interpupillary line, ala-tragus line and no severe occlusal interference Oral hard and soft tissues without pathoses

Implant site must reveal a zone of at least 4 mm of keratinized mucosal width, the keratinized mucosal width may be corrected simultaneously with the implant installation: vestibuloplasty or free gingival grafts)

Alveolar ridge width of at least 6 mm (measuring point 5 mm below the alveolar crest) is required at the implant site (labio-lingual dimension).

Alveolar ridge height of at least 14 mm is required at the implant site (vertical dimension).

Conditions that would prevent completion of study participation

Conditions requiring chronic routine use of antibiotics or requiring prolonged use of steroids

History of leukocyte dysfunction or deficiencies, bleeding disorders, neoplastic disease requiring radiation or chemotherapy, metabolic bone disorder, uncontrolled endocrine disorders, HIV infection

Alcoholism or drug abuse and heavy smoking (> 10 cigarettes a day)

Pregnancy

Erosive lichen planus or other diseases lesions of the oral

Local irradiation history

Intra-oral infection

Inadequate oral hygiene

Osteoporosis

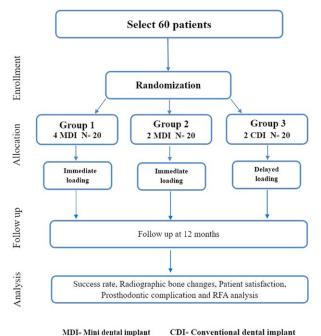
(interforaminal region); subsequently, resonance frequency analysis (RFA) and digital periapical radiographs were recorded; the denture was connected to the implants immediately.

Group 2: Two mini dental implants (PW plus) (diameter = 3.0 mm, length = 12 mm), were placed

in the anterior mandible (canine region); subsequently, RFA and digital periapical radiographs were recorded; the denture was connected to the implants immediately.

Group 3: Two conventional dental implants (PW plus) (diameter = 3.75 mm, length = 10 mm), were





MD1- Milli delicai impiant CD1- Conventional delicai impi

Figure 1 Flow chart of the study.

placed in the anterior mandible (canine region); subsequently, RFA and digital periapical radiographs were recorded. Patients in this group resumed the use of the denture two weeks after stage I surgery. Mandibular dentures were relined with a soft reliner. Stage II surgery and denture connection to the implants occurred after three months.

Patients were recalled on the postoperative day as well as at one, four, and eight weeks and at six and 12 months after surgery. At the postoperative visits, digital periapical radiographs were recorded. Prosthodontic complications, patient satisfaction, success rate and clinical implant performance scale (CIP scale), and overall evaluation were assessed. Final radiographic examination with reproducible parameters were recorded 12 months after implant placement.

Test Groups (Groups 1 and 2)

Implant Placement and Immediate Loading. All the surgical procedures were performed by one experienced surgeon. Two or four mini dental implants per subject were inserted under local anesthesia, following administration of prophylactic antibiotic medications consisting of 2 g amoxicillin one hour before the surgical procedure. After flapless surgery by smallest soft tissue punch (size 3.5 mm), a full thickness punch of gingival tissue was removed carefully without

damaging the adjacent soft tissue margins. The osteotomy site was prepared following the drilling sequence described in the manufacturer's surgical manual. The implant site was drilled using round bur with surgical guide (patient's denture), pilot drills and twist drills of 2.5 mm diameter were used as the final drills. The implant position planning was performed using CT scan planning and surgical guides. Axes of the implants were evaluated for parallelism using guide pins to avoid biomechanical problems (Figure 2).

The implants were placed within a range of insertion torque values of 30–55 Ncm. If insertion torque was lower than 30 Ncm the denture was not connected to the implant and the patient was excluded from the study, but the implant treatment was completed following the standard delayed protocol. RFA according to the Osstell implant stability quotient (ISQ) scale was assessed immediately after dental implant surgery using an Osstell device (Osstell, Gothenburg, Sweden). 12,13

For the test group, Equator® abutments (Rhein83, Bologna, Italy) were secured on the implant at 20 Ncm torque. The denture was immediately connected to the implants after Stage I surgery. The Equator cap attachments which is elastic nylon retentive caps in metallic housing with retentive force of 0.6 kg, (yellow code) were picked up intraorally using cold curing resin (Figure 2). To avoid resin flowing into the undercut of the denture, a circular portion of a sterile rubber dam sheet was adapted on the cap attachment during the pick-up procedure. The occlusion and the adaptation of the denture to the residual ridges was then checked and adjusted if necessary and the patient dismissed. The patients were given no limitations to chewing function. The patients in the test groups were instructed not to remove the denture for a week. According to postsurgical instructions, the patients were asked not to brush the operated areas but to rinse instead with a 0.12% chlorhexidine solution for one minute twice a day for two weeks. The patients were prescribed 400 mg ibuprofen for analgesia.

Control Group (Group 3)

Stage 1: Implant Placement (Two-Stage Procedure). The same surgeon performed all the surgeries. Two implants (PW+) per subject were inserted under local anesthesia (4% articaine with epinephrine 1:100,000) following administration of prophylactic

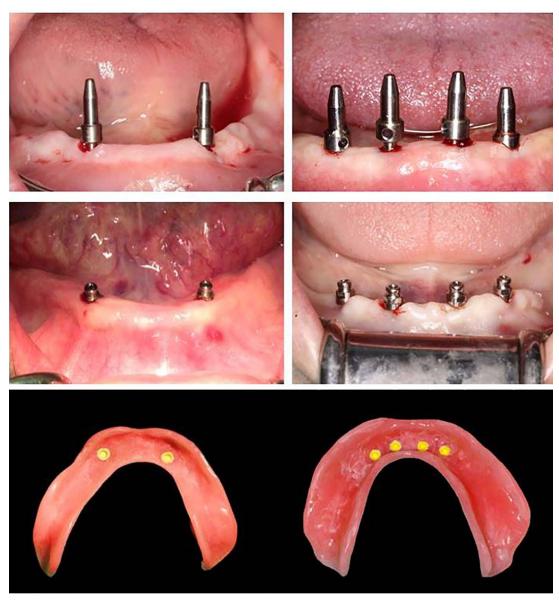


Figure 2 Surgical and prosthodontic protocol for group 1 and 2.

antibiotic medications consisting of 2 g amoxicillin one hour before the surgical procedure. After making a crestal incision, a full thickness flap was elevated. The osteotomy site was prepared following the drilling sequence described in the manufacturer's surgical manual. The implant site was drilled using round burs followed by pilot drills. Twist drills of 3.75 mm diameter were used as the final drills. The implant position planning was performed using CT scan planning and surgical guides. The axes of the implants were evaluated for parallelism using guide pins to avoid biomechanical problems. The implant was placed with a cover screw and submerged under the oral mucosa, and the patients followed the standard,

delayed postoperative protocol (Figure 3). The flaps were sutured. Primary closure was achieved using 5–0 polypropylene, interrupted sutures. Patients in the control group were not allowed to wear the denture for two weeks. As postsurgical instructions, the patients were instructed not to brush the operated areas but to rinse instead with a 0.12% chlorhexidine solution for one minute twice a day, for two weeks. The patients were prescribed 400 mg ibuprofen for analgesia. Sutures were removed after two weeks.

Stage 2 Surgery. Study participants of Group 3 were seen after three months for the second stage surgery. All patients in Group 3 were anesthetized and the crest was sounded to locate the cover screws. On

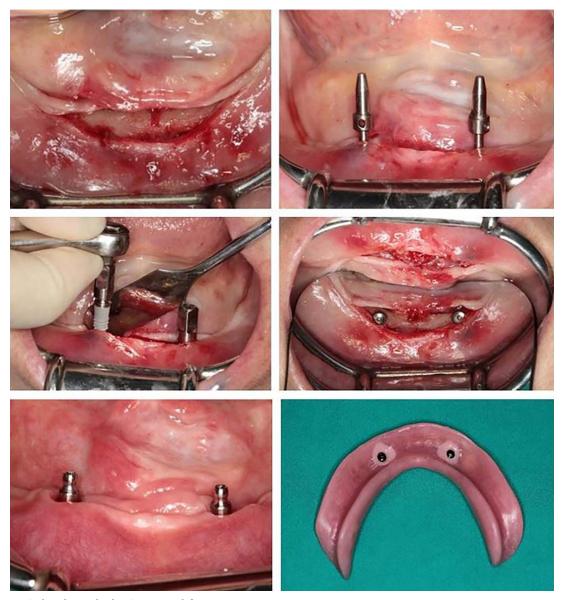


Figure 3 Surgical and prosthodontic protocol for group 3.

localization, a minimal crestal incision was made and a conservative full thickness flap was elevated. Cover screws were replaced with the Equator abutment and the flaps sutured with resorbable 5–0 chromic gut interrupted sutures.

Prosthodontic Treatment. The subjects of Group 3 resumed the use of the denture two weeks after Stage I surgery. The dentures were used with a soft reliner until the implants were uncovered. The dentures were connected to the implants at 12 weeks. The housing with silicone O-ring connected to ball attachments were picked up intraorally using normal curing resin (Figure 3). To avoid resin flowing into the undercut of the denture, a circular portion of a sterile rubber

dam sheet was adapted on the cap attachment during the pick-up procedure. The occlusion and the adaptation of the denture to the residual ridges were then checked and adjusted if necessary and the patient dismissed. The patients were given no limitations to chewing function.

EVALUATION OF OUTCOME VARIABLES

The following clinical parameters were evaluated:

Success Rate and Clinical Implant Performance Scale (CIP Scale) (at 12 Months)

The success rate criteria of the Concensus Conference of the International Congress of Oral Implantology in Pisa, Italy in 2007 were followed.¹⁸

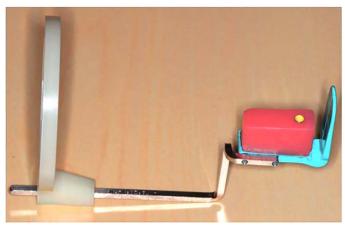




Figure 4 Film holder with attachment and digital image receptors.

To compare the clinical results in the three groups, all surgical, prosthodontic, radiographic, and peri-implant complications that occurred from the day that the new dentures were attached to the implant until one year from that date, were compared. With these data, a CIP scale^{14–17} was constructed. The CIP comprises a range of surgical and prosthodontic complications as follows:

- 0 = Success, no complications.
- 1 = Minor complications.
- 2 = Complications with a chance of recovery or stabilization of the present situation.
- 3 = Serious complications that may lead to failure of the implant system.
 - 4 = Failure of the implant system.

Minor complications (CIP =1) include gingival hyperplasia, relining of maxillary or mandibular denture, readjustment of occlusion and articulation, clip loosening, coping screw loosening, broken abutment, a slight disturbance of the mental nerve, a radiographic score of 0 along with PD \geq 5.5 mm, or a radiographic score of 1 along with a PD < 5.5 mm.

Complications with a chance of recovery or stabilization of the present situation (CIP = 2) include correction of a nonfitting superstructure, fracture of the superstructure, a severe sensory disturbance of the mental nerve, a radiographic score of 1 along with a PD \geq 5.5 mm or a radiographic score of 2 along with a PD \leq 5.5 mm.

Serious complications (CIP = 3) include a radiographic score of 2 along with a PD \geq 5.5 mm or a radiographic score of 3.

Failure of the implant system (CIP = 4) is removal of one (or two) implants after the superstructure is placed. All participants were assessed using this scale. The number and nature of prosthesis complications between the three groups were compared.

Radiographic Evaluation (at 12 Months)

Periapical radiographs using the paralleling technique were recorded at the implant placement visit after surgery and at every visit for one year. The film holder was indexed on the Equator attachment so that the film position could be reproduced for the follow-up radiographs. Panoramic radiographs were recorded only at 12 months after surgery (Figure 4).

Radiographic bone level changes (RBL) was measured on digital periapical radiographs. Radiographs were scanned in the Tiff format at 800 dpi and coded and read using image analysis software (I Green PACS system, Thailand). One examiner made the bone height measurements. The distance between the implant platform and the most coronal level of the bone deemed to be in contact with the implant surface was measured. Mesial and distal bone height measurements were averaged for each implant. The measurements of the bone level at implant placement was considered as baseline.

- 0 = No apparent bone loss.
- 1 = Reduction of the bone level not exceeding more than 1/3 of the implant length.
- 2 = Reduction of the bone level exceeding 1/3 of the implant length but not exceeding 1/2 of the implant length.

3 = Reduction of the bone level exceeding 1/2 of the implant length.

Prosthodontic Complications

The complications encountered were associated with the overdentures, and were recorded as indicated in Table 4¹⁹:

The recall visits took place one year after implant placement, 60 patients (20 each in Groups 1, 2, and 3, with a total of 120 implants completed a follow-up period of one year. The total number of complications in each group was recorded and compared between groups.

Patient Satisfaction

Patient satisfaction with the overdenture was investigated by validated questionnaires (Table 2) based on a visual analogue scale (VAS) at one year, in which patients gave their answers as a crossed mark on a scale from 0 to 100 mm. (worst, low, middle, high, best).¹⁹

RFA Analysis

RFA analysis was performed immediately after implant placement and at one-year follow-up using the Osstell® ISQ (Integration Diagnostic AB, Goteborg, Sweden) according to the manufacturer's instructions. A Smartpeg was connected to the implants. After Smartpeg mount removal, the RFA assessment was performed with the measurement probe on the handheld instrument. The probe was held close to the top of the Smartpeg without touching it until the instrument emitted a beeping sound and the ISQ value was shown. Two measurements were conducted, one from the buccal direction and one from the mesial direction. The two ISQ values were recorded and averaged.

Statistical Analysis

The radiographic bone level change (RBL) was the main response variable used to evaluate the clinical performance of the three implant groups. A RBL of 0.4 mm is considered to be of clinical relevance. By results of a previous randomized trial performed to compare the clinical outcome implant-retained mandibular overdentures, a minimum sample size of 18 subjects (36 implants) for each group were essential to provide an α error of 5 and 80% power. Normality tests (Kolmogorov–Smirnov test) are used to determine if a data set is well-modeled by a

normal distribution. Radiographic bone level changes, patient satisfaction and ISQ scores were evaluated using one-way ANOVA and prosthodontic complications were analyzed by Chi-square analysis using SPSS 22.0 software (SPSS Inc, Chicago, IL). The difference between experimental groups was considered to be statistically significant at p < 0.05.

RESULTS

All participants (n=60) completed the study. They were randomly allocated to Group 1 (n=20), 2 (n=20), or 3 (n=20). All participants received treatment according to the groups to which they were randomly assigned. Groups were similar at baseline in sex (Group 1: male = 11, female = 9; Group 2: male = 12, female = 8; Group 3: Male = 11, female = 9) and mean age (Group 1 = 69.2 ± 11.2 y; Group 2: 66.65 ± 6.28 y and Group 3: 73.8 ± 10.4 y). Results of the treatment course up to the 12-month follow-up are reported.

Success Rate

According to the criteria established at the Consensus conference of the International Congress of Oral Implantology¹⁸ (ICOI) in Pisa, Italy, in 2007, at one year follow up, the overall success rates in the three groups were 100%.

In Groups 1 and 2, sixteen cases showed a CIP score of zero, which means success without complication. In each group, there was one case with CIP score 1 due to relining of mandibular overdenture and three cases in each group were considered CIP score 2 due to fracture of mandibular denture.

In Group 3, thirteen cases showed a CIP score of zero. Seven cases in this group had fracture of mandibular denture (CIP score 2). However, no serious complications (failure of implant system) were found in any group (Table 3).

Radiographic Investigations: Marginal Bone Level Changes

Analysis of marginal bone loss mesially and distally at the implant showed no statistical differences; therefore, all sites were combined for the final analysis. Radiographic bone level changes for each group are shown in Figure 5. The average RBL values after one year were 0.53 \pm 0.41, 0.60 \pm 0.45, and 1.33 \pm 0.67 mm in Groups 1, 2, and 3, respectively. Statistically, there was no significant difference in bone level change between Groups 1 and 2, but radiographic

TABLE 2	Questionnaires	for Patient	Satisfaction
Evaluatio	n		

Questionnair	e Content			
1	How do you find your prosthesis in general?			
2	How well does your prosthesis remain in			
	place?			
3	How well can you eat with your prosthesis?			
4	How well can you talk with your prosthesis?			
5	How do you find the appearance of your prosthesis?			
6	Describe the extent of discomfort with your			
	upper denture.			
7	Describe the extent of discomfort with your			
	lower denture.			
8	How would you rate the fit of your upper			
	denture?			
9	How would you rate the fit of your lower			
10	denture?			
10	Do you have difficulties speaking with your			
11	prosthesis? How often does your prosthesis affect your			
11	socializing?			
12	Are there activities you avoid because of the			
	possibility of being embarrassed by your			
	prosthesis?			
13	How often does your prosthesis affect your work?			
14	How difficult is it for you to bite off soft			
	foods?			
15	How difficult is it for you to bite off hard			
	foods?			
16	How difficult is it for you to chew soft			
17	foods? How difficult is it for you to chew hard			
17	foods?			
18	How satisfied are you with the healing since			
	your implant surgery?			
19	Do you think your implant-supported pros-			
	thesis is actually part of you?			
20	To what extent has your implant-supported			
	prosthesis improved your social and work			
	relationships with other people?			

bone loss was significantly higher in Group 3 (p < 0.05).

Prosthodontic Complications

After one year of evaluation, there were many prosthodontic complications, regarding the abutments

(loosening and wear), retention element (O ring or retentive cap corrosion/tear or loose) and in the dentures (denture fracture). The frequency of prosthodontic complications occurring within 1 year per group is shown in Table 4 (some patients came up with complications more than once during 1 year follow up), Comparison of the attachment complications (Table 4) revealed that, in Group 3, replacement of the O-ring (30 times in 20 patients) and trans mucosal abutment screws loosening (four times in four patients) occurred most often; in Group 2, replacement of the Equator caps (12 times in twenty patients) was the most common; and in Group 1, replacement of the Equator caps (14 times in 20 patients) and one trans mucosal abutment screw loosening (one time in one patient) occurred.

According to Table 4, Group 3 revealed more prosthodontic complications than did Groups 1 and 2. The number of complications in Group 1 was slightly higher than in Group 2. The most common complication in all groups were found regarding the retention element, such as corrosion or tearing or lossening or loss of any attachment. In Group 3, wearing of the O-ring requiring replacement was the most common complication. Fracture of mandibular overdentures was found in seven cases.

Patient Satisfaction

Overall patient satisfaction (Figure 6) with the overdenture was high, (score > 60). The average patient satisfaction in Groups 1, 2, and 3 were 67.83 ± 5.26 , 70.88 ± 4.12 , and 60.85 ± 8.54 , respectively. There were no significant differences in patient satisfaction between Groups 1 and 2. However, patient satisfaction in these two groups was statistically higher than Group 3 (p < 0.05).

RFA Analysis

After one year-follow up, the lowest mean ISQ score was 66.0 in Group 2; the highest mean ISQ score was 79.0 in Group 3. Analysis of variance (ANOVA) showed no statistically significant differences in the mean ISQ score between the three groups (Figure 7).

DISCUSSION

The increasing use of MDI has been widely published in the past 5 years. The advantages of MDI are: reduced surgical time, reduced postoperative pain, the

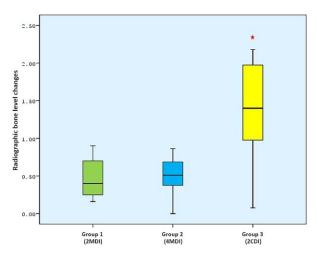


Figure 5 Comparison of radiographic bone level changes (RBL) in the three groups.

possibility of immediate loading, and cost effectiveness. However, cautions for bone quality and good oral hygiene should be maintained. For dentists, proper training, the quality of the patient's current prosthesis, selection of implant site, implant size, and patient variables are key factors in successful clinical outcomes. Many studies have reported high success rates for MDI overdentures.²² Clinical and radiographic peri-implant tissue responses of immediately loaded MDIs supporting a mandibular overdenture have been shown to be favorable after three years.²¹ According to the criteria established at the ICOI Consensus Conference,¹⁸ the one-year success rate in our study was 100%. In the edentulous arch, four mini dental implants are considered to be more stable than two standard implants. Multiple MDI might better offset any fulcrum or tipping problems that can occur with two conventional implants positioned in the canine area.²²

Tomasi²³ reported that the overall satisfaction of MDI resulted from improvement in retention, chewing, and speaking. Ali²⁴ compared two versus three narrow-diameter implants. There was no significant difference in radiographic and clinical parameter between two groups. That study showed that it is not necessary to insert more than two narrow-diameter implants. However, failure of treatment could occur. The causes of MDI failure are poor bone density, torque of more than 60 Ncm (which may lead to pressure necrosis or implant failure), using too few implants, nonparallel implant placement of more than 20° (which may cause biomechanical problems and complication during treatment, for example, bone perforation or nerve damage). Most failures occur in the first six months.³

These failures may be due to placement in inadequate bone sites or to the use of implants of inadequate length. Mini-implants may require a minimum length of 11.5 mm to be successful. Because of the small diameter of mini-implants, the longest possible implant should be placed to increase the bonepresenting profile and reduce the force per square millimeter that is applied to the bone under load.²

Group	Treatment	Score 0	Score 1	Score 2	Score3	Score 4
1 (2MDI) N = 20	5 A	16	1	3	-	-
2 (4MDI) N = 20	B a a a	16	1	3	-	-
3 (2CDI) M = 20	1 1	13	-	7	-	-

Complications	Group 1 (2:NEDI) (N = 20 Patients Total)	Group 2 (411131) (N = 20 Patients Total)	Group 3 (2CDI) (N = 20 Patients Total)	
Abutment				
Abutment loosening	-	_	5	
Abutment wear	4	2	5	
Abutment fracture	-	-	-	
Adjustment of occlusion	7	7	11	
Screw loosening	-	-	7	
Screw fracture	_	_	_	
Implant fracture	-	-	-	
Retention element				
Metal housing looseiloset	1	-	4	
0 ring or retentive cap corrosionutear	14	12	30	
0 ring or retentive cap loosening	14	12	30	
Replacement of 0-ring	_	_	30	
Replacement of retentive cap	14	10	-	
Denture				
Reline denture	4	3	7	
Rebase denture	_	_	-	
Denture fracture	3	3	7	
New overdenture made	3	3	7	
Total number of complications	64	52	138	

From our study, the average marginal bone loss in group one is 0.53 ± 0.41 , in group two is 0.60 ± 0.45 , and in group three is 1.33 ± 0.67 mm. The possible of more marginal bone loss in group three may be related to the surgical procedure, which is two-stage approach, whereas in group one and two we used flapless approach surgical procedure. Mini dental implants used in this study are two-pieces implant with internal connection. Trans mucosal abutment is changeable when they are corroded,

Scepanovic and colleagues,⁸ reported 0.4 mm, periimplant bone loss around mini dental implant retained overdenture after 1 year. Visser and colleagues reported marginal bone loss around regular dental implant supporting mandibular overdenture with bar attachment about 1.6 mm after 5 years,²⁵ whereas Ilser and colleagues report 0.93 mm, marginal bone loss for two regular dental implant supported mandibular overdenture with gold caps.²⁶ Naert and colleagues evaluated mean marginal bone loss for splinted

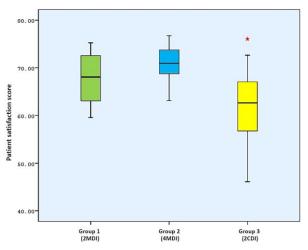


Figure 6 Patient satisfaction.

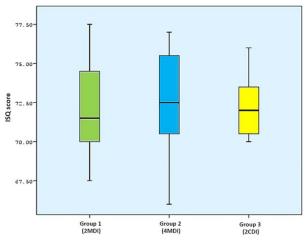


Figure 7 ISQ score.

and unsplinted regular dental implant retained mandibular overdenture 1.15 mm for bar group, 0.53 mm for magnet group, and 0.9 mm for the ball groups after 10-years evaluation.²⁷

Implants require osseous support for proper osteointegration and long-term function. Without proper support, osseous dehiscences or fenestrations may lead to early or late failure under load. In a study by Shatkin and colleagues³, the failures resulted from mobility or fracture. Mini-implant failures are attributed to mobility, with or without suppuration. These failures occur usually within six months following implant insertion. 2,3,28,29 The number of prosthodontic maintenance visits made by patients in the three loading groups was similar. Most patients reported for minor denture adjustments, whereas thirteen cases presented with implant-housing area fracture of the lower denture (Group 1, n = 3; Group 2, n = 3; Group 3, n = 7). That number of fracture of mandibular denture in group 3 is high may corresponded to size of metal housing. A metal housing of group 3 are bigger than group 1 and 2 for matching to size of conventional implants. Due to the reason, thickness of acrylic resin of denture in Group 3 is lesser than Group 1 and 2. The implant-housing area is weak point of denture and easily prone to be fracture.

Preoteasa and colleagues³⁰ reported that overdenture fracture is a frequent problem in the mandible. However, in this study, the clinical outcome has been evaluated for one year only. Further long-term evaluation will be conducted and reported later.

RFA analysis is a technique for implant stability measurement. Many factors influence implant stability. In this study, implant length in Groups 1 and 2 was slightly greater than in Group 3. However, implant diameter in Group 3 was slightly larger than in Groups 1 and 2. There were no significant difference between the three groups. The influence of implant length and diameter on RFA measurement is still unclear and varies between studies.³¹ Bone density is the main factor correlating with ISQ score. Many studies have reported a positive correlation between the height and thickness of crestal cortical bone and ISQ score.^{32–34}

However, the size of MDI and regular dental implants used in this study may be arguing due to the small difference in diameter (3.0 mm vs 3.75 mm). Considering the

design of both implants, the MDI body has a significant smaller body than the regular dental implants because it does not need the space for other components such as retaining screw and abutments. Therefore, the results of the study can be comparatively represented the difference clinical outcome.

The limitation of this randomize clinical trial are the using of only one examiner to measure bone loss on the digitized radiograph as opposed to the preferred method of two examiners calibrated with Kappa statistics. However, this study is a one-year report study, the results should be further followed after 5-year and 10-year.

CONCLUSIONS

Within the limitations of this study, it can be concluded that Groups 1 and 2 using equator attachment with flapless approach surgical procedure. All groups have 100% success rate. Group 3 had the highest number of prosthodontic complications. Two MDIs can be used for mandibular overdentures without any significant difference regarding to marginal bone level changes and prosthodontic complications when compared to four-MDI-retained overdentures. Groups 1 and 2 had significantly higher levels of patient satisfaction compared to group 3. The results rejected the null hypothesis of this study.

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