

## COMPUTER GUIDED FLAPLESS VERSUS FREE HAND FLAP SURGERY FOR IMPLANTS SUPPORTING ALL-ON-4 FIXED PROSTHESIS IN ATROPHIED MANDIBLE. ONE YEAR CLINICAL AND RADIOGRAPHICAL RESULTS OF A RANDOMIZED TRIAL

Shaimaa Saieed Nasr\* and Ramy Moustafa Moustafa Ali\*\*

### ABSTRACT

**Aim:** The purpose of this study was to evaluate clinical and radiographical outcomes of computer guided flapless versus Free hand flap surgery for implants used to anchor All-on-4 fixed prosthesis in atrophied mandible.

**Materials and methods:** Twelve completely edentulous patients with atrophied mandibular ridges were randomly assigned into two groups Group1 (Free hand flap surgery, control): received 4 implants using the All on four protocol and free hand flap surgery and metal guide. Group2 (computer guided flapless surgery, study): received 4 implants using computer guided flapless surgery and stereolithographic surgical guide. Implants were immediately loaded by acrylic prosthesis then full arch ceramometal fixed prosthesis was used as a final restoration. Plaque Index, Gingival Index, pocket depth, stability of the implants, and crestal bone loss were evaluated at baseline, 3, 6, and 12 months after loading.

**Results:** The survival rate of the implants after one year was 95.8% and 91.7% for group 1 and group 2. For both groups, implant stability significantly decreased from insertion to 3 months, and increased again at six months. For both techniques, crestal bone loss significantly increased with time. For all time intervals, flap group showed significant higher plaque index, gingival index, probing depth and crestal bone resorption than flapless group.

**Conclusion:** Within the limits of this short-term randomized trial regarding the small sample size, computer guided flapless approach may be recommended for all on four implant rehabilitation of edentulous mandibles than conventional flap surgical approach as it was associated with favorable clinical and radiographical peri-implant parameters.

\* Lecturer, Department of Oral Medicine and Periodontology, Fayoum University, Egypt.

\*\* Lecturer, Department of Removable Prosthodontics, Faculty of Dentistry, Fayoum University, Egypt.

## INTRODUCTION

For completely edentulous patients, teeth loss for a long period is usually associated with severe atrophy of the alveolar ridge specially in the posterior regions with superficialization of mandibular nerve<sup>1</sup>. This condition is associated with a loss of retention and stability of conventional denture with pain and discomfort during mastication<sup>2</sup>. The inadequate bone height posterior to the mental foramina precludes implant placement in posterior mandibular area to avoid damage of mandibular alveolar nerve<sup>3</sup>. In such a situation, the use of axial and posterior tilted implants in the interforaminal area of the mandible presents a viable treatment alternative to bone augmentation, and other surgical invasive procedures which are usually associated with increased morbidity in elderly patients<sup>3-5</sup>.

The introduction of All-on-4 Concept was made by Malo et al.<sup>5-7</sup> and comprised the use of four implants in the area from the right first premolar to left first premolar of the jaw to support provisional immediately loaded fixed restoration which is replaced by final restoration after osseointegration. The two anterior implants are placed axially and the two posterior implants are tilted 30° distally<sup>7, 8</sup>. This concept has several advantages such as; shortening of cantilever length, reduction of bone grafting procedures, avoidance of mandibular nerve displacement, immediate restoration of function and aesthetics by immediate loading of the implants using interim acrylic prosthesis, the possibility of using implants with increased length which increases bone to implant contact and optimum prosthesis support<sup>9, 10</sup>.

Immediate loading of the implants by professional restoration achieves higher patient satisfaction; where immediate restoration of mastication and aesthetics are provided without the need to wear dentures during osseointegration. However, uncontrolled loading may induce micromotions at implant/bone interface and cause crestal bone

loss<sup>11</sup>. Crestal bone loss may be influenced by the surgical technique for implant installation<sup>12</sup>. The flapless implant placement has several merits such as reduced surgical trauma, short observation period, reduced postoperative pain, and swelling, increased patient satisfaction and rapid healing<sup>13, 14</sup>. On the other hand, the flap surgical approach provides good visualization of anatomical structures, ridge shape and landmarks at implant placement which reduces the risk of bone fenestration and perforation, despite of being associated with increased postoperative edema and discomfort<sup>15, 16</sup>.

The original protocol for implant placement introduced by Malo for all on 4 concept includes raising a full-thickness mucoperiosteal flap, and placing the implants freehand using U-shaped metal template designed to be anchored to the bone to direct the drills in the correct position and angulation. With the evolution of computer guided surgery, Computer-Assisted virtual planning (based on cone beam CT obtained before surgery) and CAD/CAM constructed stereolithographic guides make the implant placement more accurate. Moreover, the fixture installation can be performed without raising flap (flapless technique) which significantly reduces ablation time, postoperative edema and discomfort, and greatly improve patient satisfaction for overall treatment<sup>17</sup>.

Reviewing the literature, limited number of studies have evaluated computer guided flapless surgical approach for all on four implant placement<sup>18-20</sup>. Unfortunately, these studies did not concern with evaluation of crestal bone loss around implants. Moreover, there is no existing randomized trials comparing the clinical and radiographic outcomes of conventional freehand flap surgery and computer guided flapless surgery for implants used for All on 4 implant rehabilitation. Therefore, this study was conducted to evaluate the clinical and radiographic outcomes of computer guided flapless versus Free hand flap surgery for implants used to anchor All-

on-4 fixed prosthesis in atrophied mandible. The null hypothesis of the authors was no significant difference will be obtained in outcomes between the 2 techniques.

## MATERIALS AND METHODS

### The patient cohort and study design

A sample of 12 completely edentulous patients (6males and 6 females) with atrophied mandibular ridges participated in this study. The patients were selected from those attending the clinic of the Prosthodontic Department, Fayoum University seeking prosthetic aftercare. The inclusion criteria are; 1) lack of retention/stability and dissatisfaction with mandibular conventional dentures due to atrophied mandibular ridges, 2) sufficient bone volume between the mental foramina to receive 4 implants of (3.7- 4.2 mm in diameter and 11-13 mm in length). A cone beam computed tomography was performed to assess bone quantity before surgery, 3) at least one year from the last extraction. Exclusion characters include the following conditions; diabetes mellitus, intravenous bisphosphonates, irradiation in the head region, blood disorders, and smoking habit. The objectives and the aim of this study were described to all participants then they signed an informed consent. Placements of the declaration of Helsinki on clinical research ethics were followed in this study and was approved by the local ethical committee of the Faculty of dentistry, Fayoum University.

The participants were randomly assigned into two groups (ratio: 1:1) using computer-generated numbers (in Excel spreadsheet). Dental personnel who were not involved in the study enclosed the numbers in sealed, opaque envelopes using a simple randomization approach. The surgeon opened the envelope of the patients immediately before surgery. Group1 (Free hand flap surgery, control): included six participants who received 4 fixtures in the region between the mental foramina

according to the All on four concept using free hand flap surgery and the U-shaped metal guide. Group2 (computer guided flapless surgery, study): included six participants who received four implants in the interforaminal area according to the All on four concept using computer guided flapless surgery and stereolithographic surgical guide.

### Surgical and prosthetic interventions

For all participants, the existing dentures were evaluated to verify aesthetics, vertical dimension, occlusion, border extension, and stability. If the dentures did not fulfill these items, new dentures were constructed and the patients were instructed to wear the dentures for at least one month to enhance neuromuscular adaptation. Cone beam computed tomography was performed to assess the amount of residual bone, identify anatomical structures, and to evaluate the location of implants. Prophylactic antibiotics (amoxicillin and clavulanic acid, 1gm) were given one hour before surgery and continued for five days after surgery.

For group 1, a crestal incision was made from premolar area on one side to premolar area on the other side, then a full-thickness mucoperiosteal flap was elevated. A U-shaped metal guide (J DentalCare, Italy) designed specifically for all on four implant placement was fixed to the mandibular bone. A 2mm pilot drill was used to make a hole in the midline of the mandible, then the metal pin of the template was fixated in the hole. Using the guide, 4 implant fixtures ( Dentaurum, Germany) were inserted in the region between the mental foramina according to the all on 4 protocol<sup>5,6</sup>. Two implants were inserted with 30° posterior inclination just anterior to the mental foramen on each side, and 2 implants were inserted vertically parallel to each other in lateral /incisors or canine areas (fig 1).

For group 2, a duplicate of mandibular denture was performed to be used as a radiographic guide. Gutta percha markers were attached to the buccal

and lingual surface of the mandibular dentures, then the dual scan protocol was performed (one scan while patients wearing the dentures, and the other scan for the lower denture alone). The data of the two scans were overlapped and downloaded on a three-dimensional planning software (OnDemand). A three-dimensional image of the mandibular ridge was constructed. The implants were planned on the software according to the All on four concept similar to Group 1. The plan was utilized to fabricate a soft-tissue borne stereolithographic surgical guide by rapid prototyping technology (In2Guide). During surgery, rubber base interocclusal record was used for stabilization of stereolithographic guide on mandibular mucosa, then fixation of the guide

to the mandibular cortical bone was performed using fixation pins of the cortical drilling. The guide was supplied by the surgical kit that includes metal sleeves fixed to the guide and hand sleeves precisely fit it into the metal sleeves of the guide. The hand sleeves fitted to long drills with successive increasing diameter were used to prepare implant osteotomy using flapless approach.

For both groups, the minimum torque obtained at implant insertion was at 35 Ncm to provide good initial stability needed for immediate loading. Multiunit abutments were threaded into implant fixtures (two 30° abutments were used for posterior inclined implants and two straight abutments were used for anterior vertical implants). The position of

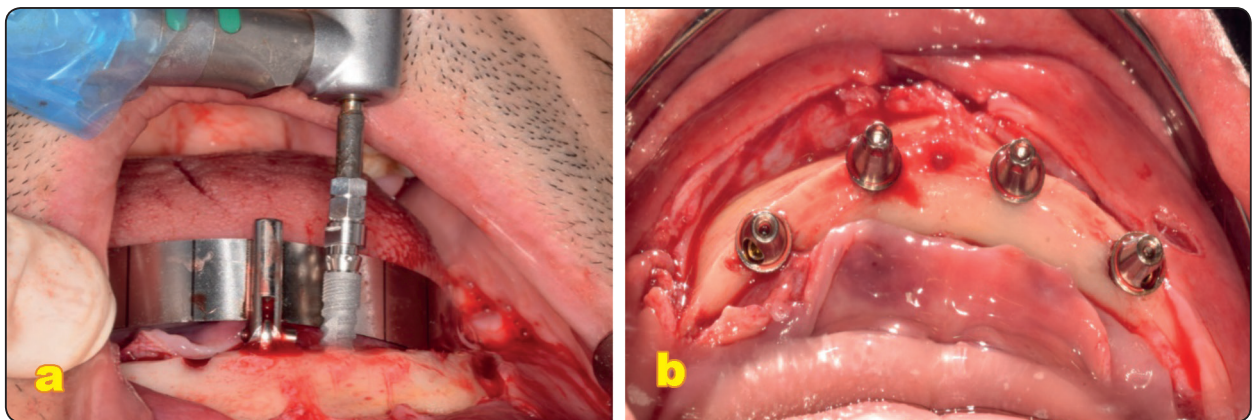


Fig. (1) Group 1 (freehand flap surgery); a, implant installation using the metal template, b, straight and angled abutments connected to the implants before flap closure.

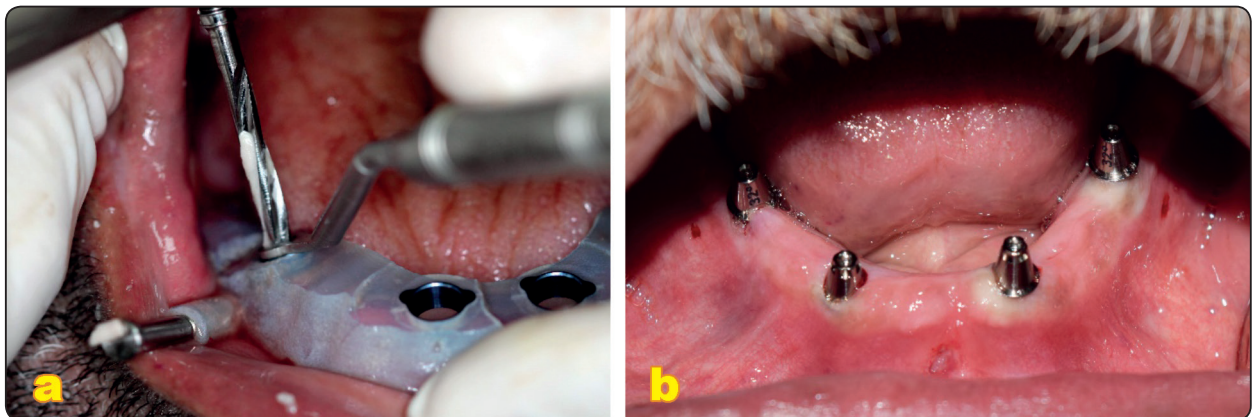


Fig. (2) Group 2 (guided flapless surgical approach); a, implant installation using the printed stereolithographic guide, b, straight and angled abutments connected to the implants.



multiunit abutments for angled implants is in the area of the first molar artificial teeth. This position allows shorter cantilever length, and increases the anteroposterior spread<sup>3</sup>. All abutments were torqued at 25Ncm. For group 1, the flap was closed around multiunit abutments with interrupted sutures. For both groups, titanium temporary cylinders were threaded to the multiunit abutments. The lower dentures were adjusted using denture conversion technique to allow immediate loading of the implants. This modification includes removal of the denture flanges and making the horse opposite to the metal caps. Then, the denture was attached to metal cylinders using self-cure resin. The cylinders were cut and the excess resin was removed and the dentures were finished and polished. The second molar artificial teeth of the dentures were removed and the occlusal contact were relieved over the posterior teeth to prevent excessive occlusal forces on the tilted implants (fig 3a). The participants were instructed to perform oral hygiene and maintaining soft diet during the healing period. Postoperative corticosteroid medications (Dexamethazone®), Analgesics (Ketolac® 10mg) were given on the day of surgery and postoperatively for the first 4 days. Any necessary occlusal or denture adjustments were performed during follow-up visits.

Three months after implant insertion, abutment-level open tray impression was taken to construct the final prosthesis. The impression copings were screwed to the multiunit abutments and splinted together with Duralay acrylic resin (Reliance, USA) to avoid mobility of the transfers. Light Viscosity rubber base impression (Zhermack®, Italy) were delivered around the copings then putty material was used for overall impression. The abutment analogues were connected to the impression transfers before pouring. Plastic cylinders were connected to multiunit abutments and the cast was scanned using a digital scanner (AmannGirrbach, Germany). Using the software of the CAD/CAM machine (exo-cad), mandibular fixed screw retained hybrid

metal ceramic prosthesis was designed with 12 teeth (from first molar tooth on one side to first molar tooth on the side). The prosthesis replaces lost teeth, bone and gingiva using pink porcelain. The design was printed in castable resin using prototyping method then verified intra-orally for passive fit and occlusion. The resin pattern was invested and cast in cobalt-chromium alloy, then tried in patient mouth for passive fit using single screw test. The opaquer was painted on the frame, then porcelain powder (VITA Zahnfabrik, Germany) was mixed and added over the opaquer, fired, and finished. The prostheses were delivered to the participants after making occlusal adjustments (fig 3 b and c). Postoperative panoramic images were performed to ensure the passivity of the prosthesis. Follow-up visits were scheduled for participants and oral hygiene measures were reviewed and reinforced.

## **Evaluation of clinical and radiographic parameters**

### **Clinical peri-implant parameters**

Plaque scores were evaluated using implant Mombelli index<sup>21</sup>; scores: 0 = Absence of plaque, 1 = plaque can be identified by a periodontal probe, 2 = plaque is seen by the eye, 3 = large amount of soft material. Gingival scores was evaluated according to implant Löe and Silness index<sup>22</sup>; score 0: no inflammation, 1: slight inflammation; 2: moderate inflammation, 3: severe inflammation. The vertical distance between mucosal border and the depth of the pocket around implants was measured using plastic periodontal probe in mm. Plaque scores, Gingival scores, and pocket depth were measured at mesial, distal, buccal and lingual implant surfaces. The degree of implant stability was detected using the Periotest device. The hand piece of the device was oriented perpendicular to the implant axis from the labial side. Three successive measurements were made for each implant and the mean was used. The device readings are Periotest values (PTVs) which ranged from -8 to 0 which represent good implant stability<sup>23</sup>

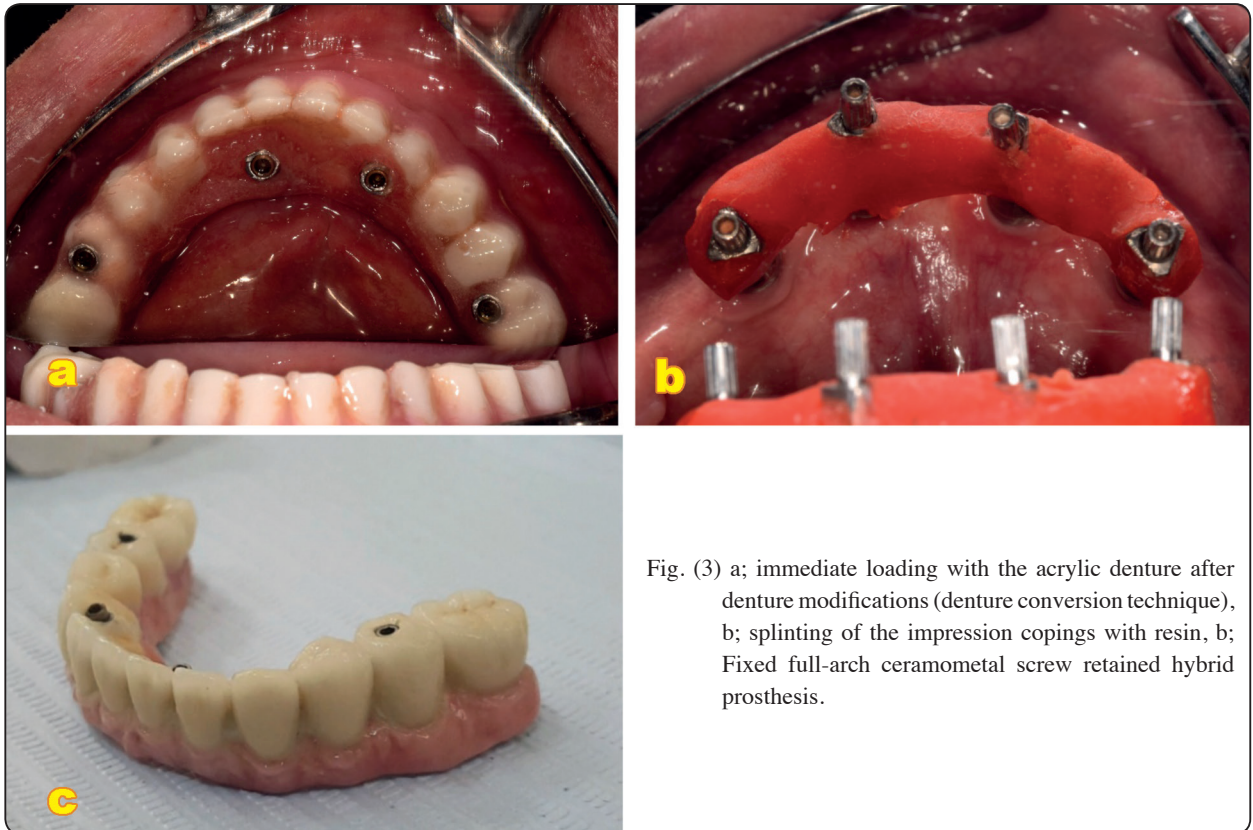


Fig. (3) a; immediate loading with the acrylic denture after denture modifications (denture conversion technique), b; splinting of the impression copings with resin, b; Fixed full-arch ceramometal screw retained hybrid prosthesis.

### Radiographic parameters (crestal bone loss)

Crestal bone height changes around implants were assessed using digital periapical radiography (Digora, Soredex) with paralleling technique. Dental films were exposed using standardized parameters and standardized method. For each implant, compound bite jig was used to maintain the position of the plastic film holder during subsequent film exposures for standardization. The actual measurements of bone heights at mesial and distal aspects of each implant were estimated using the known dimensions of the implant to avoid magnification errors. Reference points for the linear measurements were the implant abutment junction (point A) and the and the most coronal point of bone-to-implant contact (point B). crestal bone loss was calculated by subtracting crestal bone levels after 3, 6, and 12 months from values at baseline (day of implant insertion). Crestal bone loss was

measured at mesial and distal to each implant and averaged one patient level.

Clinical and radiographic parameters were measured at implant placement (immediate loading), 3, 6 months and 12 months after immediate loading. Two blinded examiners performed the measurements to assess interexaminer reliability.

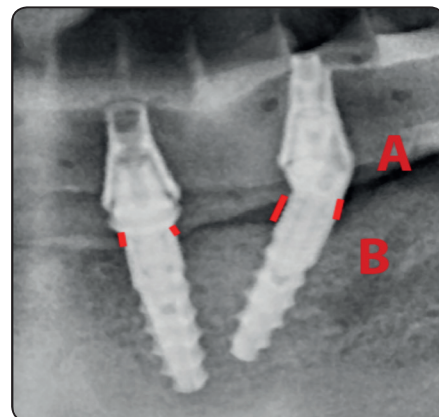


Fig. (4) Measurement of crestal bone height on periapical radiographs.

### Statistical analysis

IBM SPSS software version 22.0 was used for data analysis. To test the interexaminer reliability of the measurements,  $\alpha$  Cronbach test was utilized. Shapiro Wilk test of normality was used. Plaque and Gingival indices were compared between time intervals using Friedman test followed by Wilcoxon test for post hoc comparisons. Plaque and Gingival scores were compared between groups using 'Mann-Whitney' test. Probing depth, implant fixture stability, and crestal bone loss were compared among measurement times using repeated ANOVA followed by Tukey post hoc comparisons and between- group comparisons were made using independent samples t-test. P is significant at the 5% level.

### RESULTS

One posterior implant in the flap group failed after 3 months of loading. Another 2 inclined implants in one patient failed to integrate during the first 2 months after implant loading in the flapless group. The survival rate of the implants after one year was 95.8% for the flap group and 91.7% for the flapless group without a statistically significant difference between groups (log rank test,  $p=.147$ ). The failed implants were associated with increased mobility and crestal bone loss but without suppuration. The failed implants were removed, bone grafting procedures were performed, and the patients were scheduled for future implant placement. However, the two patients were excluded from the study. The study was completed on the rest of the patients according to the "intentions to treat principle". The data of clinical and radiographic outcomes were compared between examiners using  $\alpha$  Cronbach test and correlation coefficient of the test was  $> 80\%$ , which means that there was high agreement between examiners and the data were considered reliable.

Comparison of plaque and gingival indices between groups (freehand flap group and computer guided flapless group) and among—different

observation times is presented in table 1. Plaque and gingival indices differed significantly between time intervals for both groups. Pairwise comparison of plaque and gingival indices between each two loading times is presented in the same table. For both groups, plaque scores increased significantly from baseline to 3 months, then decreased significantly from 3 months to 6 months. No difference in plaque scores was detected between 6 months and 12 months. At baseline, there was no significant difference in plaque scores between groups. However, for all observation times flap group achieved significant higher plaque scores than flapless group. For both groups, gingival scores increased significantly from baseline to 3 months, then decreased significantly from 3 months to 6 months. No difference in gingival indices was detected between 6 months and 12 months. For all observation times flap group achieved significant higher Gingival scores than flapless group.

Comparison of probing depth, implant stability and crestal bone loss between groups (freehand flap group and computer guided flapless group) and between different observation times is presented in table 2. A significant difference in the pocket depth, implant stability and crestal bone loss between observation times was detected. Multiple comparison of these parameters between time intervals is presented in the same table. For flap group, pocket depth increased significantly from baseline to 3 months. No significant difference in the pocket depth between 3 months and 6 months, then pocket depth decreased significantly from 6 months to 12 months. For flapless group no difference in the pocket depth between baseline and 3 months, then pocket depth increased significantly from 3 months to 6 months, then decreased significantly again at 12 months. For all time intervals, the flap group showed a significant pocket depth than flapless group. For both groups, implant stability significantly decreased from insertion to 3 months, then significantly increased again at six months, and no significant difference in implant stability between

TABLE (1): Plaque and gingival scores of the freehand flap group and computer guided flapless group at different observation times

	Base line (Immediate loading)	3 months after loading	6 months after loading	12 months after loading	Friedman test (P value)
<b>Plaque score</b>					
Flap group Median (Mini-maxi)	.00(.00-0.0) a	2.0(1.5-2.5) b	1.0(.5-1.25) c	1.25(1.0-2.0) c	.035*
Flapless group Median (Mini-maxi)	.00(.00-0.0) a	1.0(.75-1.25) b	.5 (.25-.75) c	.75(.25-1.0) c	.041*
Mann-Whitney test	1.00	.002*	.015*	.026*	
<b>Gingival score</b>					
Flap group Median (Mini-maxi)	1.00 (.75-1.5) a	2.0(1.5-2.5) b	1.0 (0.5-1.3) a	.75(0.25-.75) a	.039*
Flapless group Median (Mini-maxi)	.25(.00-0.50) a	1.0(.75-1.25) b	.25(.00-.5) a	.00(.00-0.0) a	.043*
Mann-Whitney test	.010*	.027*	.031*	.043*	

Mini: minimum, maxi: maximum, St: standard deviation. \*: p is significant at 5%. Different letters showed a significant difference between each two loading times (Tukey test,  $p < .05$ ) and similar letters showed no difference.

TABLE (2): Pocket depth, stability of the implants and crestal bone resorption of the freehand flap group and computer guided flapless group at different observation times

	Base line (Immediate loading)	3 months after loading	6 months after loading	12 months after loading	Repeated ANOVA (p value)
<b>Pocket depth</b>					
Flap group Mean $\pm$ St	1.1 $\pm$ .31 a	1.9 $\pm$ .52 b	2.2 $\pm$ .64 b	1.6 $\pm$ .64 c	.020*
Flapless group Mean $\pm$ St	.55 $\pm$ .25 a	.65 $\pm$ .28 a	1.1 $\pm$ .32 b	.75 $\pm$ .28 a	.048*
Independent samples t-test	.022*	.003*	.001*	.004*	
<b>Stability of the implants</b>					
Flap group Mean $\pm$ St	-4.8 $\pm$ 1.6 a	-3.7 $\pm$ 1.9 b	-4.3 $\pm$ 1.3 a	-4.7 $\pm$ 1.3 a	.028*
Flapless group Mean $\pm$ St	-4.7 $\pm$ 1.9 a	-4.0 $\pm$ 1.8 b	-4.6 $\pm$ 1.4 a	-4.9 $\pm$ 1.5 a	.034*
Independent samples t-test	.38	.23	.69	.32	
<b>Crestal bone resorption</b>					
Flap group Mean $\pm$ St	- a	0.84 $\pm$ .32 a	1.1 $\pm$ .31 b	1.8 $\pm$ .27 c	.018*
Flapless group Mean $\pm$ St	- a	0.41 $\pm$ .25 a	0.67 $\pm$ .29 b	1.2 $\pm$ .32 c	.003*
Independent samples t-test	-	.036*	.027*	.015*	

Mini: minimum, maxi: maximum, St: standard deviation. \*: p is significant at 5%. Different letters showed a significant difference between each two loading times (Tukey test,  $p < .05$ ) and similar letters showed no difference.



6 months and 12 months. No significant difference in implant stability between techniques was noted at all observation times. For both techniques, crestal bone loss significantly increased with passage of time. Multiple comparisons of parameters between each two-time interval are presented in table 2. There was a significant difference in bone loss between each two-time interval. For all time intervals, the flap group showed a significant higher crestal bone loss than flapless group.

## DISCUSSION

The survival rate of the implants after one year was 95.8% and 91.7% for group 1 and group 2. Although the difference in survival rate was not significant between groups, higher survival rate was observed for the flapless group. This was in line with Malo et al.<sup>8</sup> who reported 96.7% survival for implants inserted with flap approach after six months. The increased survival rate flapless group concurred with Browaeys et al.<sup>18</sup> was found 100% survival rate for maxillary and mandibular implants inserted by the computer guided flapless approach to support All on four prostheses. The high survival rate could be attributed to the good bone density in the interforaminal area of the mandible which provides higher implant stability that can withstand micromotions of immediate loading.

For both groups, plaque scores increased significantly from insertion to 3 months, then decreased at 6 months. This could be attributed to the presence of professional acrylic denture which was made with increased the bulkiness around the abutments to resist the fracture and have spaces around the implants. This may hinder adequate cleaning by the patients. When professional restoration was replaced by ceramometal restoration, plaque scores decreased after six months due to the smooth convex surface of the prosthesis and the high adaptation of the prosthesis to the abutments. The decreased plaque scores after six months were similar to finding of another study<sup>24</sup> in which was

also noted a significant decrease in plaque around implants supporting fixed immediate prostheses according to All on 4- protocol. The increased plaque accumulation could be responsible for the increased gingival index after three months. The progressive degrees of gingival index after six months were in line with findings of another study<sup>1</sup>. The decrease in plaque and bleeding index after 3 months was in agreement with the finding of other studies<sup>25, 26</sup> and may be attributed to the wider inter-implant distance, which provides an increased possibility of performing adequate oral hygiene<sup>10, 27</sup>. However, flap group recorded significant higher plaque and gingival indices than flapless group at all observation times. The flap surgery may discourage the patients to perform adequate cleaning to avoid pain in the surgical site. Even after healing the wound, they develop the habit of avoiding cleaning to avoid discomfort. The increased plaque scores could be responsible for increased gingival scores in the flap group due to peri-implant mucosal inflammation.

For the flap group, pocket depth increased significantly from baseline to 3 months, then decreased thereafter. The increased pocket depth after three months could be attributed to peri-implant mucosal enlargement caused by suturing the flap over to the multiunit abutments together with increased peri-implant bone loss<sup>28</sup>. It was interesting to find that the pocket depth increased significantly from 3 months to 6 months, then decreased in the flapless group. In this group, increased bone resorption after 6 months could be responsible for the increase in probing depths. However, for both groups, probing depths significantly decreased after one year. This may be attributed to the complete healing of the soft tissue around the implant together with mucosal recession caused by mastication and cleaning. Similarly, Landázuri-Del Barrio<sup>29</sup> reported a stable soft tissue situation with a reduction of pocket depths for All on four implants supporting mandibular fixed prosthesis. Flap group showed significant

higher pocket depth and flapless group. This could be attributed to the increased bone resorption in this group. Moreover, flap reflection and re-adaptation to the abutments may cause gingival enlargement the increased pocket depth. On the other hand, the flapless approach provides gap free connection with optimum mucosal barrier free of bacterial accumulation that may protect the soft tissue and allow establishment of a tissue collar overlapping the bone implant interface with decreased pocket depth<sup>30</sup>. The increased pocket depth was computer guided flapless approach for all on four implants compared with our results of another study<sup>19</sup>

For both groups, implant stability significantly decreased from insertion to 3 months, then increased again at six months. The decreased implant stability after 3 months of could be attributed to the micromotions applied to the implants as a result of increased load caused by immediate loading. The increased load may cause a reduction in one to implant contact and may be related to bone remodeling<sup>31</sup>. However, after osteointegration, the increased bone to implant contact along the implant surface as a result of healing and reorganization of bone may be responsible for increasing the implant stability again. No difference in implant stability between the 2 techniques were noted. This may be due to increased bone density in anterior mandibular area.

For both techniques, crestal bone loss significantly increased with time. This unavoidable time-dependent bone loss usually occurs as a result of wound healing, reorganization of bone, and bone reaction to increased occlusal load<sup>32</sup>. For the flapless group, the mean bone loss (1.2mm) is located within the normal physiological limits of crestal bone loss reported in the literature (1.2mm in the first year)<sup>33</sup>. However, for the flap group, the mean bone loss (1.8mm) in the first year exceeds this for a certain limit. This could be an alarming sign and should be evaluated in longer-term prospective studies to assess the prognosis and the survival rate of the implants and the flap group.

The most important finding of this study is that flap group showed significant higher crestal bone loss than flapless group. One explanation is related to flap elevation that causes mucoperiosteal stripping, interference with blood supply to peri-implant bone and contact of the bone with oral bacteria<sup>34-36</sup> which may decrease oxygen supply and stimulate osteoclast activity which may cause increased bone loss<sup>34-36</sup>. On the other hand, the flapless procedure has no contamination of the wound as no sutures exist. Moreover, there is no disruption of the blood supply of the mucoperiosteum. This minimizes bone resorption, improve clinical, and immunologic outcomes compared with flap surgery<sup>37</sup>.

Similarly, a systematic review reported that flapless approach has better clinical outcomes than the flapped procedure in a short-term<sup>38</sup>. Also, Maier et al.<sup>39</sup> reported that flapless approach for implant insertion reduced peri-implant crestal bone loss than installation of the implants using flap surgical reflection. They also recommend flapless approach as a protective and promising. However, several studies have found no difference in crestal bone loss between the flap and flapless surgery<sup>40, 41</sup>. The reduced bone resorption in the flapless group was in contrast with finding of another author who reported unacceptable ongoing bone loss in 49.2% of the patients treated with All on 4 implant protocol using computer guided flapless approach<sup>18</sup>. The difference in the results could be justified according to Browaeys and colleagues, studied bone loss around both maxillary and mandibular implants together<sup>18</sup>. It is well-known that maxillary bone resorption around implants might be higher mandibular bone resorption due to reduced bone density, and angulation of the implants and the premaxilla. However, in the current study bone loss around mandibular implants only were evaluated.

Overall, the null hypothesis was rejected as there was a significant difference in clinical and radiographic outcomes between flap and flapless

approach. However, the limits of this investigation include the small patient cohort and the short observation period. Therefore, longer-term studies with sufficient sample size are still needed.

## CONCLUSION

Within the limits of this short-term randomized trial regarding the small sample size, computer guided flapless approach may be recommended for all on four implant rehabilitation of edentulous mandibles than conventional flap surgical approach as it reported good clinical and radiographical peri-implant parameters

## REFERENCES

- Weinstein R, Agliardi E, Fabbro MD, Romeo D, Francetti L. Immediate rehabilitation of the extremely atrophic mandible with fixed full-prosthesis supported by four implants. *Clin Implant Dent Relat Res* 2012; 14: 434-441.
- Capelli M, Zuffetti F, Del Fabbro M, Testori T. Immediate rehabilitation of the completely edentulous jaw with fixed prostheses supported by either upright or tilted implants: a multicenter clinical study. *The International journal of oral & maxillofacial implants* 2007; 22: 639-644.
- Krekmanov L, Kahn M, Rangert B, Lindstrom H. Tilting of posterior mandibular and maxillary implants for improved prosthesis support. *Int J Oral Maxillofac Implants* 2000; 15: 405-414.
- Capelli M, Zuffetti F, Del Fabbro M, Testori T. Immediate rehabilitation of the completely edentulous jaw with fixed prostheses supported by either upright or tilted implants: a multicenter clinical study. *Int J Oral Maxillofac Implants* 2007; 22: 639-644.
- Malo P, Friberg B, Polizzi G, Gualini F, Vighagen T, Rangert B. Immediate and early function of Branemark System implants placed in the esthetic zone: a 1-year prospective clinical multicenter study. *Clin Implant Dent Relat Res* 2003; 5 Suppl 1: 37-46.
- Malo P, de Araujo Nobre M, Lopes A, Francischone C, Rigolizzo M. "All-on-4" immediate-function concept for completely edentulous maxillae: a clinical report on the medium (3 years) and long-term (5 years) outcomes. *Clin Implant Dent Relat Res* 2012; 14 Suppl 1: e139-150.
- Malo P, Rangert B, Nobre M. All-on-4 immediate-function concept with Branemark System implants for completely edentulous maxillae: a 1-year retrospective clinical study. *Clin Implant Dent Relat Res* 2005; 7 Suppl 1: S88-94.
- Malo P, Rangert B, Nobre M. "All-on-Four" immediate-function concept with Branemark System implants for completely edentulous mandibles: a retrospective clinical study. *Clin Implant Dent Relat Res* 2003; 5 Suppl 1: 2-9.
- Pozzi A, Sannino G, Barlattani A. Minimally invasive treatment of the atrophic posterior maxilla: a proof-of-concept prospective study with a follow-up of between 36 and 54 months. *J Prosthet Dent* 2012; 108: 286-297.
- Francetti L, Agliardi E, Testori T, Romeo D, Taschieri S, Del Fabbro M. Immediate rehabilitation of the mandible with fixed full prosthesis supported by axial and tilted implants: interim results of a single cohort prospective study. *Clin Implant Dent Relat Res* 2008; 10: 255-263.
- Romanos GE, Nentwig GH. Immediate versus delayed functional loading of implants in the posterior mandible: a 2-year prospective clinical study of 12 consecutive cases. *Int J Periodontics Restorative Dent* 2006; 26: 459-469.
- Prati C, Zamparini F, Scialabba VS, Gatto MR, Piattelli A, Montebugnoli L, Gandolfi MG. A 3-Year Prospective Cohort Study on 132 Calcium Phosphate-Blasted Implants: Flap vs Flapless Technique. *Int J Oral Maxillofac Implants* 2016; 31: 413-423.
- Chrcanovic BR, Albrektsson T, Wennerberg A. Flapless versus conventional flapped dental implant surgery: a meta-analysis. *PLoS One* 2014; 9: e100624.
- Rousseau P. Flapless and traditional dental implant surgery: an open, retrospective comparative study. *J Oral Maxillofac Surg* 2010; 68: 2299-2306.
- Cannizzaro G, Leone M, Consolo U, Ferri V, Esposito M. Immediate functional loading of implants placed with flapless surgery versus conventional implants in partially edentulous patients: a 3-year randomized controlled clinical trial. *Int J Oral Maxillofac Implants* 2008; 23: 867-875.
- Cannizzaro G, Felice P, Leone M, Checchi V, Esposito M. Flapless versus open flap implant surgery in partially edentulous patients subjected to immediate loading: 1-year results from a split-mouth randomised controlled trial. *Eur J Oral Implantol* 2011; 4: 177-188.
- Faeghi Nejad M, Proussaefs P, Lozada J. Combining guided alveolar ridge reduction and guided implant placement for

- all-on-4 surgery: A clinical report. *J Prosthet Dent* 2016; 115: 662-667.
18. Browaeys H, Dierens M, Ruyffelaert C, Matthijs C, De Bruyn H, Vandeweghe S. Ongoing Crestal Bone Loss around Implants Subjected to Computer-Guided Flapless Surgery and Immediate Loading Using the All-on-4(R) Concept. *Clin Implant Dent Relat Res* 2015; 17: 831-843.
  19. Malo P, de Araujo Nobre M, Lopes A. The use of computer-guided flapless implant surgery and four implants placed in immediate function to support a fixed denture: preliminary results after a mean follow-up period of thirteen months. *J Prosthet Dent* 2007; 97: S26-34.
  20. Pomares C. A retrospective study of edentulous patients rehabilitated according to the 'all-on-four' or the 'all-on-six' immediate function concept using flapless computer-guided implant surgery. *Eur J Oral Implantol* 2010; 3: 155-163.
  21. Mombelli A, van Oosten MA, Schurch E, Jr., Land NP. The microbiota associated with successful or failing osseointegrated titanium implants. *Oral Microbiol Immunol* 1987; 2: 145-151.
  22. Loe H, Silness J. Periodontal Disease in Pregnancy. I. Prevalence and Severity. *Acta Odontol Scand* 1963; 21: 533-551.
  23. Olive J, Aparicio C. Periotest method as a measure of osseointegrated oral implant stability. *Int J Oral Maxillofac Implants* 1990; 5: 390-400.
  24. Ayub KV, Ayub EA, Lins do Valle A, Bonfante G, Pegoraro T, Fernando L. Seven-Year Follow-up of Full-Arch Prostheses Supported by Four Implants: A Prospective Study. *The International journal of oral & maxillofacial implants* 2017; 32: 1351-1358.
  25. Agliardi E, Clerico M, Ciancio P, Massironi D. Immediate loading of full-arch fixed prostheses supported by axial and tilted implants for the treatment of edentulous atrophic mandibles. *Quintessence Int* 2010; 41: 285-293.
  26. Agliardi E, Panigatti S, Clerico M, Villa C, Malo P. Immediate rehabilitation of the edentulous jaws with full fixed prostheses supported by four implants: interim results of a single cohort prospective study. *Clin Oral Implants Res* 2010; 21: 459-465.
  27. Francetti L, Romeo D, Corbella S, Taschieri S, Del Fabbro M. Bone level changes around axial and tilted implants in full-arch fixed immediate restorations. Interim results of a prospective study. *Clin Implant Dent Relat Res* 2012; 14: 646-654.
  28. ELSyad MA, Denewar BA, Elsaih EA. Clinical and Radiographic Evaluation of Bar, Telescopic, and Locator Attachments for Implant-Stabilized Overdentures in Patients with Mandibular Atrophied Ridges: A Randomized Controlled Clinical Trial. *The International journal of oral & maxillofacial implants* 2018; 33: 1103-1111.
  29. Landázuri-Del Barrio RA, Cosyn J, De Paula WN, De Bruyn H, Marcantonio E. A prospective study on implants installed with flapless-guided surgery using the all-on-four concept in the mandible. *Clin Oral Implants Res* 2013; 24: 428-433.
  30. Omran M, Abdelhamid A, Elkarargy A., Sallom M. Mini-Implant Overdenture Versus Conventional Implant Overdenture (A Radiographic and Clinical Assessments). 2013; 9: 89-97.
  31. Pae A, Kim JW, Kwon KR. Immediate loading of two implants supporting a magnet attachment-retained overdenture: one-year clinical study. *Implant Dent* 2010; 19: 428-436.
  32. Hekimoglu C, Anil N, Cehreli MC. Analysis of strain around endosseous dental implants opposing natural teeth or implants. *J Prosthet Dent* 2004; 92: 441-446.
  33. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. *Int J Oral Maxillofac Implants* 1986; 1: 11-25.
  34. Ahn MR, An KM, Choi JH, Sohn DS. Immediate loading with mini dental implants in the fully edentulous mandible. *Implant Dent* 2004; 13: 367-372.
  35. Bulard RA, Vance JB. Multi-clinic evaluation using mini-dental implants for long-term denture stabilization: a preliminary biometric evaluation. *Compend Contin Educ Dent* 2005; 26: 892-897.
  36. Jeong SM, Choi BH, Li J, Kim HS, Ko CY, Jung JH, Lee HJ, Lee SH, Engelke W. Flapless implant surgery: an experimental study. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2007; 104: 24-28.
  37. Tsoukaki M, Kalpidis CD, Sakellari D, Tsalikis L, Mikrogorgis G, Konstantinidis A. Clinical, radiographic, microbiological, and immunological outcomes of flapped vs. flapless dental implants: a prospective randomized controlled clinical trial. *Clin Oral Implants Res* 2013; 24: 969-976.



38. Llamas-Montegudo O, Girbes-Ballester P, Vina-Almunia J, Penarrocha-Oltra D, Penarrocha-Diago M. Clinical parameters of implants placed in healed sites using flapped and flapless techniques: A systematic review. *Med Oral Patol Oral Cir Bucal* 2017; 22: e572-e581.
39. Maier FM. Initial Crestal Bone Loss After Implant Placement with Flapped or Flapless Surgery-A Prospective Cohort Study. *Int J Oral Maxillofac Implants* 2016; 31: 876-883.
40. Bashutski JD, Wang HL, Rudek I, Moreno I, Koticha T, Oh TJ. Effect of flapless surgery on single-tooth implants in the esthetic zone: a randomized clinical trial. *J Periodontol* 2013; 84: 1747-1754.
41. Van de Velde T, Sennerby L, De Bruyn H. The clinical and radiographic outcome of implants placed in the posterior maxilla with a guided flapless approach and immediately restored with a provisional rehabilitation: a randomized clinical trial. *Clin Oral Implants Res* 2010; 21: 1223-1233.