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Two versus four implants supporting fixed full arch screw retained metal acrylic hybrid mandibular prosthesis. (a study of patient satisfaction)

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ABSTRACT

Introduction: This study aimed to evaluate the evaluation of patient satisfaction of two versus four implants supporting fixed full arch screw retained metal acrylic hybrid mandibular prosthesis.

Materials and methods: Six edentulous participants were selected for this study from the patients participated in previous studies in which patients received 2 implants or four implants in edentulous mandibular ridges.The patients were randomly assigned into two equal groups; 1) 4 parallel Group (control): received implant supported mandibular fixed metal acrylic prosthesis on 4 implants that were placed parallely in the interforaminal region.2) two parallel implant group (study):received implant supported mandibular fixed metal acrylic prosthesis on two implants placed according to "All On two concept". Screw-retained definitive frameworks with a sagittal section of at least 3 mm in height and 1.5 mm in width were cast in a non-precious metal alloy.Resin teeth were added and the cross-arch prostheses were screwed onto the implants. Patient satisfaction was evaluated using a visual analog scale (VAS) after 12 months.

Results: For all VAS questions except Retention of maxillary denture, oral hygiene, surgery, All on 4 was associated with the highest satisfaction scores followed by All on 2 and the CD was associated with the lowest satisfaction scores.

Conclusion: Within the limits of this study, implant rehabilitation of edentulous mandible with 2 or 4 fixed full arch prosthesis has comparable outcomes. Both treatment modalities are recommend for rehabilitation of patients with atrophied mandibular ridge.

I. INTRODUCTION

Edentulism is a poor health condition that may compromise patient satisfaction and quality of life. The atrophic mandible has low load-bearing ability and when conventional denture were constructed, pain during mastication, insufficient stability and retention of the mandibular denture .It may further precipitate in psychosocial problems to the patients.

Fixed implant-supported prostheses have shown clinical success and proven functional benefits for use in the edentulous mandible[2, 3]

When rehabilitating edentulous jaws with fixed implant-supported prostheses, usually at least four implants are placed in the interforaminal area. [5 ,4]

Screw-retained 4-ISFMP(4-implant-supported fixed mandibular prostheses)ie (4 axially inserted implants) are recognized as well-proven method in implant-prosthetic rehabilitation of mandibular edentulism.[6, 7]-[8].

Following the “All-on-4” concept the ,distal tilting of the posterior implants [9]

Studies have shown that management of unsatisfactory problems of prosthesis with atrophied mandible can be done successfully by fabricating a fixed prosthesis with distal cantilevers or by 4 implants in the interforaminal areas (All on four concept). [1]

Treatment concept utilizing two or four implants to support a mandibular overdenture has been proposed to improve the retention and stability of the denture and preserve the residual alveolar ridge(Batenburgetal.1998) [10]. [11]

Results from a Cochrane systematic review, and other trials suggested that 2 implant may be sufficient to successfully stabilize a mandibular overdenture. .This type of rehabilitation relies mainly on mucosal support. The 2-implant overdenture can be thought of as a two legged chair. You get good stability but still get some movement on the gums (not flopping around). [12]

While overdentures are considered a cheaper alternative to implant-supported fixed

dental prostheses, they may require a higher prosthetic maintenance for replacing worn-out components, which in the long term might make this treatment option not as cheap as it appears initially.[13][

Recent evidence suggests that it is also possible to load immediately two mandibular implants with total fixed prostheses, though follow-ups are too short to provide definitive conclusions, preliminary results, up to 1 year after loading, suggest that immediately loaded mandibular cross-arch fixed prostheses can be supported by only 2 dental implants. [15 ,14]

It would be interesting to know whether it could be possible to rehabilitate fully edentulous mandibles with a fixed cross-arch prosthesis, supported by only two flapless-placed implants.This randomized trial aims to compare patient satisfaction of two mandibular impalnts fixed prosthesis with four mandibular fixedprosthesis.The null hyposthesis is that be there will be no significant difference in patient satisfaction betwwen both treatment modalities.

II. MATERIAL AND METHOD

Patient selection and study design

Ten patients (age ranged from 45 to 64 years, mean =56 years) were selected from the outpatient clinic, Prosthodontic Department, Faculty of Dentistry, Mansoura University from January2022 to September 2023. This patient sample was calculated to give 80% power according to the results of a previous study[16] which showed a significant difference in CBL between 2 implant and four implant prosthetic options of the mandibles (effect size=.96 and α=.05). The power analysis was performed using the G*Power program (version 3.1.5, Kiel, Germany). The inclusion criteria were: 1) completely edentulous maxillary and mandibular ridges for at least 3 years, 2) reduced patient satisfaction with stability and retention of their ordinarily used mandibular dentures due to mandibular ridge atrophy, 3) adequate bone quantity [class III -V according to Cawood and Howell[17]] in the interforaminal area of the mandible to receive 4 implants (3.8×12 mm) as verified by cone-beam CT (CBCT), and 3) adequate restorative space [12-15mm, Class I according to Ahuja and Cagna[18] for construction of fixed full arch screw retained mandibular prosthesis. Exclusion criteria include; bone metabolic diseases such as diabetes mellitus, irradiation to the head and neck region within the past 3 years, and smoking habits. Details about the treatment plan were given to all patients before signing informed consents. The study was conducted according to CONSORT guidelines and approved by the local ethical committee of the faculty (No. A03040122). The trial was registered in ClinicalTrials.gov under the number (NCT05290766). Patients were equally assigned to one of 2 groups using balanced randomization to ensure comparability between groups regarding confounding factors; 1) Group (I): The patients received four parallel implants; two in the canine areas and two in the first molar areas. 2) Group (II): The patients received two parallel interforaminal implants in the canine region.

Surgical and prosthetic procedures

For all participants, new maxillary and mandibular dentures were constructed with the bilateral balanced occlusal concept using semi-anatomic acrylic teeth. For the construction of mucosal-born stereolithographic guides, 6 gutta-percha markers were placed in the buccal and lingual polished surfaces of the mandibular dentures (2 on the right side, 2 between the mental foramina and 2 on the left side). A dual scan CBCT (i- CAT Vision, Hatfield, PA, USA) was made for each patient (while the patients wearing the dentures and for the mandibular denture alone). The 2 scans were overlapped and downloaded to computer software (OnDemand 3D,Cybermed, Seoul, Korea). The implant position and angulation were virtually planned. The implant planning was used to construct a mucosal-borne stereolithographic guide using laser sintering technology (In2Guide).

Four implants (4.5×13 mm, Neoss ,ProActiveTaperd, USA) were inserted using the flapless protocol by the same oral and maxillofacial surgeon. Implant osteotomies were prepared using a universal surgical kit (In2Guide). The implant insertion torque was at least 35 Ncm to give adequate primary stability.Healing caps were screwed to the multiunit abutments. Post-operative analgesics (ibuprofen 600 mg/ 8 hours) and anti-inflammatory drugs were prescribed in addition to antibiotics and mouth wash for one week after surgery.

After 3 months, straight abutments were screwed to the vertical implants in both groups. For both groups, implant level transfer copings were splinted with resin (GC, America, Alsip, IL) and open tray impression was completed using medium viscosity elastomeric impression (Pentamix, 3M ESPE, USA).

For Group I , two resin cantilevered bar extensions (7 mm in length) were added distally[19]. For Group II , longer cantilevers were used (about 15 mm). The bar/ resin abutments assembly was

milled into titanium alloy, finished, and tried in the patient mouth for passive fit. The bars were returned to the cast. New mandibular screw retained fixed metal acrylic prostheis were fabricated to occlude with maxillary dentures. Mandibular record bases were constructed and used to establish centric and eccentric jaw relations. The upper denture was mounted using face-bow transfer record and the mandibular record base was mounted using centric records. Artificial semi-anatomic acrylic teeth (Vitapan®,Vita Zahnfabrik, Bad Säckingen, Germany) were arranged in bilateral balanced occlusal concept with maxillary denture.Try in for esthetics and occlusion was completed. The dentures were processed using the long curing cycle by the same dental technician .Emphasis on oral hygiene and soft diet instructions were given to all participants.

Study outcomes

A- Patient satisfaction

For both groups of patients, the evaluation of patient satisfaction was performed using the patient satisfaction questionnaire 3 months after each of the following prostheses: New conventional denture (CD) and Fixed metal acrylic denture (FD)

Patient satisfaction was evaluated using a questionnaire based on visual analogue scale (VAS). Patients were asked to mark their answer (amount of satisfaction) on a 100- mm line (with zero refers to not satisfied at all and 100 refers to completely satisfied).[20]

The mean of the answers (length of the lines from zero to the marks in mm) for each question was subjected to statistical analysis. The questionnaire was given to the patients in Arabic

To evaluate patient experiences patients answered twelve questions regarding their satisfaction on (1) comfort with prosthesis, (2) stability, (3) feeling that prosthesis part of him(4) ease of hygiene procedure, (5) difficulty of speaking with prosthesis, (6) difficulty of biting of soft food, (7) difficulty of biting of hard food, (8) difficulty of chewing soft food (9) difficulty of chewing hard food (10) effect on socializing (11) satisfaction with healing since implant surgery and (12) activities avoided due to embarrassment.

III. RESULTS

Statistical analysis

Shapiro-Wilk tests were used to verify the normal distribution of data. The VAS data was parametric and met normal distribution. The descriptive statistics of VAS including mean, and standard deviation. One way ANOVA test was used to compare VAS between groups. Tukey test was used for multiple comparison of data between each two groups. Mann Whitney test was used for multiple comparison of data between each two groups. Graphical presentation of data was made using bar charts with error bar representing 95% confidence intervals. P value is significant if it was less than .05. The data was analyzed using SPSS (statistical package for social science, version 25).

Comparison of VAS questions between groups is presented in table 2.There was a significant difference between groups regarding all questions except comfort of maxillary dentures, and embarrassing .Group I and Group II were associated with significantly increased satisfaction scores compared to CD

For all VAS questions except Retention of maxillary denture, oral hygiene, surgery, Group I was associated with the highest satisfaction scores followed by Group II and the CD was associated with the lowest satisfaction scores.For Retention of maxillary denture, oral hygiene, surgery ,Group II was associated with the highest satisfaction scores followed by Group I and the CD was associated with the lowest satisfaction scores

With the exception of biting hard food and satisfaction with surgery, There was no significant difference in satisfaction scores between Group II and Group I

Regarding biting hard food, Group I showed significantly higher satisfaction than Group II.Regarding satisfaction with surgery, Group II showed significantly higher satisfaction than Group I.

IV. DISCUSSION

In this randomized clinical trial , the null hypothesis was rejected as there was significant difference between both Groups .Group I (4 parallel placed implants) and Group II (2 parallel placed implants),were associated with significantly increased satisfaction scores compared to CD(complete denture). According to the results, CD (Complete Denture) recorded the lowest satisfaction values. This was in aline with Elsyad et al [21] who documented that CD scored significantly lower on all VAS questions than Fixed prosthesis(satisfaction with mandibular prosthesis alone or compared to natural teeth, retention, stability, occlusion, comfort, ease of cleaning, speaking, chewing, quality of bolus, appearance, handling of prosthesis, prosthesis apart from you, and embarrassing).

The increased retention and stability of FP compared to CD could be responsible for increased patient comfort. The increased satisfaction with FP

compared to CD was in line with findings of Allen and McMillan (2002)[22]

In terms of masticatory function, Brennan et al,[23] reported a retrospective study of 62 patients that compared satisfaction levels of edentulous patients treated with implant supported fixed or removable prosthesis. Implant supported fixed prosthesis showed significantly better patient satisfaction in terms of masticatory function, aesthetic and psychological disability.

For all VAS questions except Retention of maxillary denture, oral hygiene, and surgery, Group I (4 parallel placed implants) showed the highest satisfaction values, followed by Group II(2 parallel placed implants).

Regarding surgery, Group II showed higher satisfaction than Group I. As an increased number of implants results in a more complicated and expensive rehabilitation time in terms of prosthetic fabrication (i.e., implant-framework accuracy and passive fit). While fewer implants will not only reduce economic costs but will also shorten surgical treatment time and minimize trauma, encouraging more patients to choose this type of surgery as reported by Cannizzaro[24]

For Retention of maxillary denture, oral hygiene, surgery, Group II was associated with the highest satisfaction scores followed by Group I and the CD was associated with the lowest satisfaction scores. Jacobs et al[25] found greater annual maxillary bone resorption in patients with mandibular implant supported fixed prostheses than in patients with mandibular over-dentures supported by two implants. Authors attributed these findings to the instability of the complete dentures, which contributed to an un-favorable stress distribution among the denture-bearing areas. This can explain why patients in Group II showed a greater satisfaction in retention of maxillary denture than Group I .

The placement of four interforaminal implants as in Group I is uasually associated with difficult oral hygiene measures. This is leading to increase in plaque accumulation with subsequent gingival inflammation and bone resorption as mentioned by several clinical studies.[26][27][28] These studies stated that the increased PL for a four vertically placed dental impants group compared to a four inclinedly placed group according to “all on four “ concept group may be attributed to the decreased inter-implant distance, which may enhance PL accumulation and decrease access for adequate cleaning. In contrast, the wider inter-implant distance in the inclined group provides adequate access for proper oral hygiene. Similarly, other authors reported that wider distances between the implants are associated with reduced PL accumulation on the surfaces of the implants. [28]

Regarding biting hard food, Group I showed significantly higher satisfaction than Group II . This was in a line with a study by Elsyad et al 2014 who proved that four implant-supported overdentures seem to present a functional advantage versus two implant- supported overdentures, independent of the chosen attachment system. Moreover, Carlsson and Lindquist 2011 conducted a study on 10 edentulous individuals initially rehabilitated with complete denture later replaced with fixed implant-retained prosthesis. The biting force has increased significantly from 80 N to 240 N[29]

Increasing the statisfaction in chewing ability in Group I also was the result of the prosthetic design with wider anterior–posterior spread that allows for a more stable occlusal table similar to a four-legged chair than Group II .This was consistent with the findings of other studies [27, 28][30]which may enhance the chewing of hard food

In addition to that, in two implant overdenture, bite forces were less than four implant overdentures. This may be due to the mandibular denture-bearing tissues being more subject to compression, denture shifting, and resultant painful irritation which is the case in Group II.

In contrast, full prostheses supported by osseo-integrated implants despite their numbers and distribution in edentulous mandibles has shown considerable improvement in muscular activity and mandibular movements, mainly because of their association with a more stabilized occlusion, satisfaction, and comfort of patients [31] Similarly, Jacobs & van Steenberghe[25] found no significant difference in muscle activity of patients rehabilitated by means of overdenture (on two or four implants connected by a bar) or patients rehabilitated with an implant-supported fixed prosthesis on four to six implants in either the maxilla or the mandible.

Regarding comfort , Patients often express dissatisfaction with their mandibular CDs. Complaints include decreased retention, stability, difficulty with mastication, and verbal communication [32]This was in accordance with our results which indicated that patients were less satisfied with their mandibular CDs(Table 1).

V. CONCLUSION

Within the limits of this study, implant rehabilitation of edentulous mandible with 2 or 4 fixed full arch prosthesis has comparable outcomes. Both treatment modalities are recommend for

rehabilitation of patients with atrophied mandibular ridge.

Conflict of interest

The authors declared no conflict of interest. The study was self-funded

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Tables

Table 1: Comparison of VAS between groups

	CD		4mplants		2implants		One way ANOVA P value
	X	SD	X	SD	X	SD	
Comfort_mandibular	49.33a	5.51	88.33b	2.89	85.00b	5.00	<.001*
Comfort_maxillary	89.33a	6.03	89.00a	3.61	85.00a	5.00	.531
retention_md	38.00a	8.54	92.67b	2.89	91.33b	2.52	<.001*
retention_mx	74.00a	5.29	84.67b	2.89	83.67b	6.03	.035*
prostheis_is_part	73.67a	10.26	93.33b	4.16	90.33b	2.52	.021*
oral_hygiene	70.33a	5.03	81.33b	3.21	82.33b	2.52	.014*
speaking	41.67a	2.89	94.33b	4.04	91.33b	3.21	<.001*
bite_soft	42.33a	2.52	88.00b	2.65	87.33b	2.08	<.001*

bite_hard	52.00a	4.36	88.33b	2.89	80.67c	1.15	<.001*
chew_soft	42.33a	4.51	90.00b	3.61	89.33b	4.04	<.001*
chew_hard	48.00a	5.29	90.00b	5.00	85.00b	5.00	<.001*
socializing	62.33a	7.51	85.33b	3.51	92.33b	2.52	.001*
surgery	-	-	86.67a	2.89	92.33b	2.52	<.001*
embrassing	51.67a	5.69	40.00a	10.00	30.00a	10.00	.063

*P value is significant at 5% level. Different letters showed a significant difference between each 2 groups (Tukey test, p<.05). Similar letters showed no significant difference between each 2 groups (Tukey test, p>.05)