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IMMEDIATELY LOADED MANDIBULAR FIXED DETACHABLE RESTORATIONS SUPPORTED BY AXIALLY ALIGNED IMPLANTS VERSUS IMPLANTS PLACED ACCORDING TO ALL-ON- FOUR CONCEPT

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ABSTRACT

INTRODUCTION: The alveolar ridge undergoes progressive atrophy following tooth loss, which increases over time, especially in edentulous patients. The fixed detachable implant supported prosthesis represents an established modality for the restoration of edentulous and partially edentulous jaws. Although the all-on-four technique has high predictability, it still has some limitations such as the presence of a cantilever in the prosthesis. Photoelastic analysis of stress distribution shows that increasing implant angulation, results in higher stress exerted on the cervical bone adjacent to the implant. Implants should be aligned in such a way as to allow the prosthesis to be constructed directing the occlusal forces in a vertical direction.

OBJECTIVES: To evaluate and compare clinically and radiographically the peri-implant tissues around 4 mandibular interforaminal implants supporting full arch fixed detachable restorations having tilted posterior implants with posterior cantilevers, versus vertical implants, two in the interforaminal region and two in the first molar region, without posterior cantilevers.

MATERIAL AND METHODS: Fifty six implants were placed in the mandibles of 14 edentulous patients. Four implants were placed for every participant, who were randomly allocated into 2 equal groups. Axial group implants were vertically aligned, two in the interforaminal region and two in the molar region. Tilted group implants had two anterior vertical and two posterior distally inclined implants. Interim screw retained prostheses converted from pre-existing dentures were immediately modified and loaded on the same day of surgery. After 3 months, all participants received fixed detachable metal acrylic resin definitive restorations. A follow-up protocol of 3, 6, and 12 months was scheduled to assess the modified gingival index, modified plaque index, peri-implant probing depth, implant stability, and marginal bone level and bone density changes.

RESULTS: There were no statistically significant differences (P>.05) in the modified gingival index, modified plaque index, peri-implant probing depth, implant stability, bone density and marginal bone level among the studied groups during one year follow-up period.

CONCLUSION: Placing 4 flapless immediately loaded implants in mandibular edentulous patients that supported full arch fixed restorations provided high implant and Prosthetic success rates whether posterior implants were tilted with posterior cantilevers or vertically aligned without posterior cantilevers.

KEY WORDS: Immediate loading, All-on-four concept, axial implants, fixed detachable restorations and Screw-retained restoration.

RUNNING TITLE: Mandibular fixed detachable restorations supported by axial versus tilted implants.

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INTRODUCTION

Prosthetic reconstruction of edentulous patients is sometimes challenging. Tissue changes under complete dentures, anatomic limitations and patients psychological condition in many cases may lead to complications (1).

Most of the individuals are concerned with esthetics as well as function. Treatment options therefore may vary between removable and fixed restorations (2) due to anatomical limitations and patient demands (3). Traditional fixed prostheses might not be suitable in cases of vertical and horizontal bone loss, inadequate number of implants, oral hygiene maintenance, esthetics and phonetics. These limitations can be overcome by using hybrid prosthesis (4).

The hybrid prosthesis was introduced by Zarb (5) in which denture teeth were attached to a cast metal substructure by using heat-polymerized acrylic resin. The anterior segment is supported by implants while the posterior segment is cantilevered. Cantilever extensions have been proven to exert extra stress on implants and therefore should only be used whenever necessary. The length of an appropriate cantilever has also been studied extensively (6).

The all-on-four concept was initially designed by Malo et al (7) in an attempt to reduce the posterior cantilever where only 4 implants located in the interforaminal area were used to support immediately loaded full arch mandibular fixed restorations. The main concern was to address problems associated with reduced posterior bone height Implant distribution involved 2 anterior axially aligned implants together with two posterior implants located anterior to the mental foramina and inclined up to 45 degrees to increase their length and reduce the length of the posterior cantilever. This was thought to reduce stresses on posterior implants (8).

Using 4 vertical implants to support full arch fixed mandibular restorations have been investigated in several studies (9-11). Branemark et al (10) in a 10 year retrospective study compared the survival rates of mandibular restorations supported by four versus six implants.

The survival rates of implants and prostheses were the same. Similarly, a 3 dimensional finite element analysis by Fazi et al (11) showed that configurations that included 4 or 5 parallel implants had similar stress distributions on bone, prosthetic frameworks, and implants.

Eliasson et al (9) examined whether it was possible to restore edentulous mandibles with full arch fixed restorations retained by 4 implants. One hundred and ninety four implants were monitored for 5 years. 98.6% survival rate was reported. The authors concluded that 4 implants were adequate to carry full arch mandibular cantilevered prostheses. Menini et al (12) retrospectively followed up 4 patients with 3 interforaminal axially aligned implants supporting full arch cantilevered prostheses. 100% cumulative implant survival rate was reported at the 11 year follow up.

Studies evaluating the all-on-four concept validated its use to immediately restore edentulous mandibles. High success rates were documented to the extent that it has become more popular among patients and clinicians (13). However, limitations of the all-on-four concept include surgical and prosthetic difficulty in distally tilting the posterior implants, their close proximity to the mental foramen risking injury, unfavorable forces exerted on the tilted posterior implants, and limited length of posterior cantilevers (6,8). Placing 4 axially aligned interforaminal implants have been suggested to overcome the difficulties associated with distal implant tilting. Studies have shown similar results however the length of cantilevers still has to be limited as the anteroposterior spread is even less than in the all-on-four protocol.

From a biomechanical point of view, studies have recommended locating posterior implants as distal as possible to reduce or eliminate posterior cantilevers (14). However, Sadek et al (15) compared restorations supported by all-on-four implants with and without posterior cantilever extensions. Similar results were reported for the 2 groups. The present study was conducted to overcome the drawbacks of distally tilted posterior implants and at the same time make use of reducing the number of implants to 4. It aimed to assess and compare 4 vertical implants, two in the anterior region and two in the first molar region, versus 4 mandibular interforaminal implants having tilted posterior implants, to immediately restore edentulous mandibles with full arch fixed detachable restorations without versus with posterior cantilevers respectively. The null hypothesis comprised the absence of clinical or radiographic significant difference during the evaluation period between the 2 implant configurations.

MATERIAL AND METHODS

The present randomized controlled clinical trial was performed after receiving approval of the Ethics Committee of the Faculty of Dentistry, Alexandria University, Egypt (IIRB NO: 00010556-IORG 0008839). The ethical principles of the Helsinki declaration were followed. Inclusion criteria involved mandibular ridges with heights allowing placement of 12 mm long implants, and a buccolingual ridge width of at least 6 mm. Measurements were verified by cone beam computed tomography scan (CBCT) (Scanora 3DX; Soredex). Exclusion criteria involved mandibles with knife edge ridges requiring bone reduction, systemic diseases that may compromise osseointegration and heavy smokers (more than 10 cigarettes I day). An informed consent was signed by all participants.

Adopting 80% power of the study in sample size calculation, 56 implants in total were placed in 14 healthy edentulous participants (10 males and 4 females). Their mean age was 48 years (range 40 to 65 years). Participants were randomly divided into 2 equal groups. Axial group: received 4 implants (Dentium superline; Dentium Co Ltd), 2 placed in the lateral incisor region and the other 2 in the first molar region (12 mm in length and 3.6 mm in diameter). Tilted group: received 4 interforaminal implants 2 anterior vertically aligned (12 mm in length and 3.6 mm in diameter) and 2 posterior distally inclined implants (14 mm in length and 3 .6 mm in diameter).

Fourteen tissue supported surgical guides were constructed (one for every participant). All guides were printed (Form2; Formlabs) (16). For that purpose, radiographic guides were fabricated. Interocclusal records (radiographic index) were also fabricated by using an occlusal registration material in the form of poly vinyl siloxane (Any-flex bite; Mediclus Co, Ltd). The dual-scan technique was employed (17,18). Both scans were later on superimposed, referenced by the radiopaque fiducial markers. They were then uploaded into an image planning software (Blue Sky Plan· Blue Sky Bio) to plan the location of the implants. Surgical guides were designed and printed (Form 2; Formlabs). During surgery, tissue-supported surgical guides were attached in place using 3 fixation screws (Dentium; Dentium Co Ltd) referenced by the maxillary denture together with the radiographic index. Drilling was performed in a flapless manner following manufacturer's instructions until reaching the final drill. A driver in the kit was used to position the implants providing full guidance.

All implants were placed flapless by the same operator (LAM) following the manufacturer's instructions. Implant stability was assessed immediately

after implant placement. A resonance frequency analysis (RFA) device (Osstell Mentor; Osstell AB, Goteborg, Sweden) was used to record the implant stability quotient (ISQ) values (19,20). A smart peg was assembled onto each implant. Four recordings were made on the lingual, buccal, distal and mesial sides. The mean values for ISQ were above 65 for all implants, indicating sufficient primary implant stability to allow for immediate implant loading (21).

After implant placement and surgical guide removal, straight multiunit abutments with appropriate heights were connected to the 2 anterior vertical implants in the tilted group and all implants in the axial group. Angulated (30 degree) abutments were connected to the posterior implants in the all-on-four group to achieve proper alignment with the anterior implants as seen in Fig lA, lB. Temporary metal cylinders were connected to the abutments and the participants' existing mandibular complete dentures were modified and converted into transitional screw retained prostheses (22). All the artificial teeth distal to the second premolars in the tilted group and distal to the first molar in the axial group were removed leaving the transitional restorations without cantilevers or flanges. Occlusion was adjusted to balanced occlusion without interferences. The provisional resin-based prostheses were delivered on the day of implant surgery and secured with 4 screws. Oral hygiene instructions were given to participants who were later on instructed to maintain good oral hygiene.

The acrylic resin transitional restorations were used by participants for 3 months after which definitive restorations were started. The 4 implants in the definitive prosthesis were splinted by using a cast framework superstructure (cobalt-chromium) having a posterior extension reaching to the first molar tooth (17). For the tilted group, a short one tooth cantilever was extended posteriorly (first molar) with less than 1.5 times the anteroposterior distance between the anterior and posterior implants as seen in Fig 2A (23). No cantilever was performed for the axial group as seen in Fig 2B. The passivity of the metal framework was verified intraorally by using the single screw test (24). Non-passive fit was corrected by sectioning and soldering. Heat-polymerizing acrylic resin was used to veneer the metal superstructure. It was fabricated onto the framework following standard laboratory procedures. Prefabricated acrylic resin teeth were also used (Acry Rock Ruthinium). All prostheses were screw retained and included 12 resin-veneered units (including 1 molar) in balanced occlusion.

Clinical and radiographic follow up was performed for all participants. Clinical evaluation involved assessment of the modified plaque index (MPI) (25-27), modified gingival index (MGI) (40-42), and peri-implant probing depth (PD) (27-29). Measurements were made to the nearest 0.5 mm. A pressure sensitive calibrated periodontal probe (PDT sensor probes• DenMat) was used. PD was measured around every implant at four locations (Mesial, lingual, distal and buccal). Peri-implant soft tissue assessments (MPI, MGI, and PD) were made at 3, 6 and 12 months following implant insertion. Implant stability was measured by using resonance frequency analysis. The Osstell device was used for that purpose at the time of implant placement (baseline) and then 3, 6 and 12 months following implant placement (30,31). One investigator (LAM) made all measurements for standardization purposes.

Marginal bone level (32,33) and bone density (6,20,34) changes surrounding the implants were evaluated immediately following implant placement (baseline) and then after 3, 6, and 12 months. Measurements were made on a standardized CBCT scan. A special software program (OnDemand 3D; Cybermed Inc) was used. Measurements were made at the buccal, lingual, distal and mesial surfaces of every implant. The mean was then calculated. Marginal vertical bone level was evaluated according to the technique described by Elsyad et al (33). The distance between implant abutment connection and bone implant contact was measured. Vertical bone loss was determined by measuring the difference in bone height measurements made at the various follow-up sessions. CBCT scan was used to measure bone density in relative Hounsfield unit (HU) that was given with a grayscale reading (31).

Data were collected and statistically analyzed. A software program (IBM SPSS Statistics, v21; IBM Corp) was used (35). The normality of distribution of variables was verified using the Kolmogorov-Smirnov test. Student t-test was used to compare the 2 groups for normally distributed quantitative variables while repeated measures ANOVA with a Bonferroni adjusted post hoc test was assessed for the comparison of different periods. (0.05 for all tests).

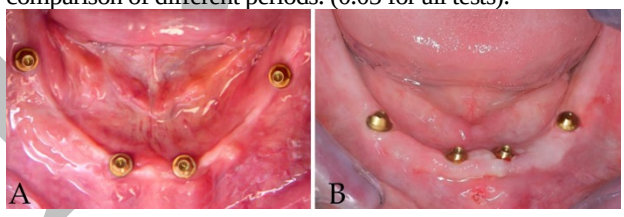

Figure 1: Multiunit abutments attached to implants. A, Axial group. B, Tilted group.

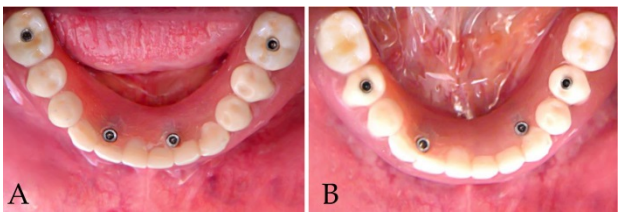

Figure 2: Definitive fixed detachable restoration screwed in place. A, Tilted group. B, Axial group.

RESULTS

No implant failures were detected. A success rate of 100% was recorded. None of the definitive prostheses fractured during the study period. The mean values and standard deviations for all parameters are presented in Table (1).

The MGI mean values in the axial and the tilted groups were alike with no statistically significant differences within or between the groups during the follow-up period (P>.05). The mean values of the MPI

and ISQ between the 2 test groups showed no statistically significant differences (P>.05). However, statistically significant differences were reported within each group in the study periods (P<.05).

No statistically significant differences were found concerning the mean values for the PD, the marginal bone level and bone density changes between the test groups (.P>.05) within each group during the different study periods, Statistically significant differences were found (P<.001).

Table 1: Comparison between studied groups throughout the evaluation period

	Group I (n = 7)	Group II (n = 7)	t	p
Plaque Index				
3 Month	1.05 ± 0.25	0.95 ± 0.29	0.670	0.516
6 Month	0.88 ± 0.12	0.84 ± 0.17	0.581	0.572
12 Month	0.87 ± 0.16	0.80 ± 0.21	0.652	0.527
p_1	0.025*	0.014*		
GI				
3 Month	0.84 ± 0.35	0.63 ± 0.46	0.983	0.345
6 Month	0.77 ± 0.34	0.61 ± 0.35	0.881	0.396
12 Month	0.63 ± 0.39	0.59 ± 0.38	0.173	0.865
p_1	0.113	>0.05 (NS)		
PIPD				
3 Month	3.40 ± 0.17	3.45 ± 0.17	0.541	0.599
6 Month	3.16 ± 0.18	3.35 ± 0.17	2.029	0.065
12 Month	3.12 ± 0.18	3.31 ± 0.17	2.041	0.064
p_1	<0.001*	<0.001*		
Implant stability				
Baseline	83.69 ± 5.12	81.53 ± 5.41	0.767	0.458
3 Month	76.78 ± 4.82	74.80 ± 6.20	0.669	0.516
6 Month	78.35 ± 4.33	76.32 ± 5.28	0.789	0.445
12 Month	80.70 ± 5.08	78.61 ± 6.74	0.656	0.524
p_1	0.008*	0.032*		
Bone Density				
Baseline	929.6 ± 8.57	928.1 ± 9.21	0.311	0.761
3 Month	848.4 ± 13.56	852.0 ± 9.72	0.561	0.585
6 Month	827.2 ± 9.39	827.3 ± 11.0	0.016	0.987
12 Month	899.4 ± 7.36	899.2 ± 6.78	0.046	0.964
p_1	<0.001*	<0.001*		
MBL				
Baseline	0.65 ± 0.10	0.65 ± 0.14	0.022	0.983
3 Month	0.85 ± 0.21	0.88 ± 0.18	0.316	0.758
6 Month	0.93 ± 0.25	0.97 ± 0.16	0.396	0.699
12 Month	0.95 ± 0.25	1.00 ± 0.15	0.439	0.669
p_1	0.003*	<0.001*		

t: Student t-test
p: p value for comparing between the studied groups
p_1: p value for Post Hoc test (**adjusted Bonferroni**) for ANOVA with repeated measures for comparing between **first periods** and **12 Months**
*: Statistically significant at $p \leq 0.05$

DISCUSSION

Restoring edentulous mandibles by using implant supported fixed restorations can be achieved with high levels of success and patient satisfaction (10,36). Flapless implant placement together with immediately loading the restoration and implants significantly improves patient satisfaction (9,37,38). The mandibular interforaminal region has always been the preferred site for implant placement, however distally tilted posterior implants, from a surgical point of view, may be technically challenging. The presence of a posterior cantilever can also exert unfavorable forces on supporting implants (39). The null hypothesis was accepted as the clinical outcome of implants in both groups was comparable.

No participants or implants were lost during follow-up. The high success rate reported in the study, that was consistent with similar clinical trials, can be attributed to strict inclusion and exclusion criteria, patient compliance relative to soft diet adherence, together with careful organization of occlusion with the opposing maxillary complete denture imposing significantly reduced occlusal forces. Computer generated treatment planning and surgical guide construction were used in the current study to ensure standardization of implant positioning and alignment, reducing operator personal variability. They also facilitated flapless implant placement with minimal risk of complications (16,17). Immediately loading implants was preferred over delayed loading as it showed high levels of success and patient satisfaction. It was also reported that bone density was higher around immediately loaded implants than delayed loaded ones (34).

Standardization of the implant size (length and diameter) together with the number of prosthetically restored teeth was made for all participants to prevent variability and not to compromise chewing ability and. participants' satisfaction. No statistically significant difference was found in The MPI and MGI scores between the 2 groups throughout the study period. Slightly higher readings were recorded at the 3 months follow-up period than at the 6 months which can be attributed to the hesitation of participants to perform postoperative oral hygiene instructions. The MPI and MGI scores showed improved values in the subsequent visits which can be a result of the frequent oral hygiene instructions given to patients, which was in harmony with other studies (26,27).

No statistically significant differences were found between the peri-implant PD values in the study groups which were similar to studies of Neiva et al, (29). RFA was used to evaluate implant stability by using RFA. At the time of implant placement and during every follow-up session The ISQ values were measured. During the evaluation period, no statistically significant difference was recorded between the study groups. The mean ISQ values demonstrated a statistically significant decrease after implant insertion to 3 months.

This might be attributed to the remodeling activities occurring during the healing phase (20) and are consistent with comparable studies (40). The mean ISQ values showed a statistically significant increase from 6 months to 12 months of prosthesis insertion indicating improved implant osseointegration (40).

No statistically significant changes were recorded regarding bone density changes, among the study groups. However, a statistically significant decrease was recorded

during the first 3 months in both groups, that can be explained by the surgical trauma associated with implant surgery (6). A statistically significant increase in Bone density measurements were recorded in periods from 3 to 12 months. This indicated favorable bone response to applied forces. These results matched those of Yunus (20) and El-Wahab et al (31).

Along the study period, the marginal bone level between the 2 study groups showed no statistically significant differences. Crestal bone loss showed highest values 1 mm after the first year which can be considered within the acceptable limits recorded in similar studies (32,33).

CONCLUSIONS

Based on the outcomes of the present study, the following conclusions were drawn:

1) Four implants are adequate to support immediately loaded mandibular full arch fixed prostheses opposed by complete dentures.

2) Similar clinical and radiographic outcomes are obtained for flapless immediately loaded 4-Implant supported full arch mandibular restorations whether implants were placed in the interforaminal region with distally tilted posterior implants and posterior cantilevers or vertical without posterior cantilevers.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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