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Axial versus Tilted Distal Implants in All-on-4 Mandibular Screw-Retained Prosthesis: A Randomized Controlled Clinical Trial

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Abstract

Background: The all-on-4 concept presents an ideal solution that enables using four dental implants placed in the inter-foraminal region to retain a prosthesis. This study aimed to compare the implant survival and bone loss of axial versus tilted distal implants in mandibular screw-retained prosthesis.

Methods: Twenty-eight completely edentulous patients were randomly assigned into two groups; each group received four inter-foraminal implants; Group 1: received two axially placed anterior implants and two axially placed distal implants. Group 2: received two axially placed anterior implants and two distally inclined distal implants. All patients received mandibular screw-retained implant prosthesis and maxillary complete dentures. After a follow-up period of 2 years, implant survival was evaluated and bone loss was measured at 6, 12, and 24 months follow up periods.

Results: No implant losses were observed in both groups, representing a survival rate of 100%. Regarding marginal bone loss, When comparing the two groups, a non-statistically significant difference was revealed between anterior implants at 6, 12, and 24 months with p-value of 0.931, 0.684, and 0.846, respectively. In addition, there was no statistically significant difference between posterior implants at 6, 12, and 24 months with p-value of 0.834, 0.765, and 0.904, respectively.

Conclusion: The angulation of distal implants in all-on-4 mandibular screw-retained prosthesis does not influence implant survival or peri-implant marginal bone loss (MBL).

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1 Introduction

Completely edentulous patients can sometimes present a problem to the dental practitioner in the placement of dental implants due to bone resorption. Conventional procedures to treat this resorption, such as nerve transportation, sinus lifting, and bone grafting procedures, are complex procedures that increase the operating time, patient discomfort, and risk of surgical complications. Bone grafting is excellent in treating horizontal bone resorption, but in restoring vertical bone resorption is less effective. The all-on-four concept resolves all these problems [1].

The all-on-4 concept is an ideal solution that enables using four dental implants placed in the inter-foraminal region to retain a prosthesis. Paulo Malo provided completely edentulous patients with full arch restoration using only four implants by developing the all-on-4 concept by applying either angled or straight multi-unit abutments [2].

Screw-retained prosthesis offers adequate esthetics and phonetics comparable to the fixed prosthesis. Furthermore, it can provide better functional and biomechanical stability than overdentures [3]. The prosthesis framework can be retained by four implants with screws torqued into the implant fixtures with terminal cantilevers [4].

Tilted posterior implants advocated in the All-On-4 concept enable the use of longer implants that enhance bone anchorage without interfering with the mental foramen. The concept also improves inter-implant distance, increasing prosthetic support with a shorter cantilever arm [5].

Distal implants can be placed obliquely at different inclined angles (15, 30, and 45). Different angles of distal implants influence the stresses on the implant and the surrounding bone under dynamic load.

The degree of distal implant angulation influences the cantilever length of the screw-retained prosthesis. The use of four implants with inclined distal implants increases stress on peri-implant cortical bone. Nevertheless, when combined with a short cantilever, inclined implants help reduce stress on the peri-implant cortical bone.

Previous studies have evaluated the influence of axial and tilted distal implants on peri-implant bone, but to our knowledge, there are no randomized controlled clinical trials on this subject [6-9].

Therefore, the objective of this clinical trial was to compare implant survival and the peri-implant bone loss of axial versus tilted distal implants in mandibular All-on-4 screw-retained prosthesis.

2 Material & Methods:

Edentulous patients (16 males and 12 females) were randomly recruited from the outpatient clinic of the Removable Prosthodontics Department, Faculty of Oral and Dental Medicine Dentistry, Delta University for Science and Technology, Egypt.

2.1 Inclusion criteria:

Completely edentulous patients of age range 50-65 years with a mean age of 56.62 ± 9.52 years. They complained of being unable to eat properly with dentures, suffering from uncomfortable dentures, and giving up on removable prosthesis. Patients with an adequate volume of bone for housing four dental implants were included.

2.2 Exclusion criteria:

Medically compromised patients, patients with a history of radiotherapy or chemotherapy, smokers, and patients with parafunctional habits. Patients suffering from uncontrolled diabetes or poorly controlled cardiovascular problems. Patients taking Bisphosphonates.

The research ethics committee of Delta University for Science and Technology approved the trial (DU-2020-00107). A description of all the details of the procedures was done, and all patients signed informed consent before inclusion.

Patients were asked to select a sealed envelope enclosing a computer-generated random number to determine his/her group; then allocation concealment was performed. Each group received four inter-foraminal implants; Group 1: received two axially placed anterior implants and two axially placed posterior implants. Group 2: received two axially placed anterior implants and two distally inclined posterior implants. All the patients received mandibular screw-retained implant prosthesis.

2.3 Presurgical prosthetic preparation

Complete dentures were constructed for all patients to be used for prosthetically driven implant placement and as a temporary denture.**Figure 1A** CBCT scanning was performed for all patients using a tray with ready-made extraoral radiopaque markers.**Figure 1B** The markers were placed in relation to the stent laterals and second premolar teeth. The superimposition of these markers on the mandible determines the position of the implant placement.**Figure 1C**

The resulting image was acquired as DICOM (Digital Imaging and Communications in Medicine) data. Virtual planning of the implants was achieved using the blue-sky bio software giving three views, axial, coronal, and sagittal.**Figure 1C** Implant location, type, angulation, and size are described in **Table 1**. Fixation pins were also included in the design to stabilize the surgical guide into place and avoid its movement during drilling.**Figure 1C** The parallelism between all implants was checked in group 1 and between anterior implants in group 2. CAM surgical guide was digitally designed **Figure 1D** and constructed in order to perform a prosthetic-driven implant placement using a flapless technique.**Figure 1E**

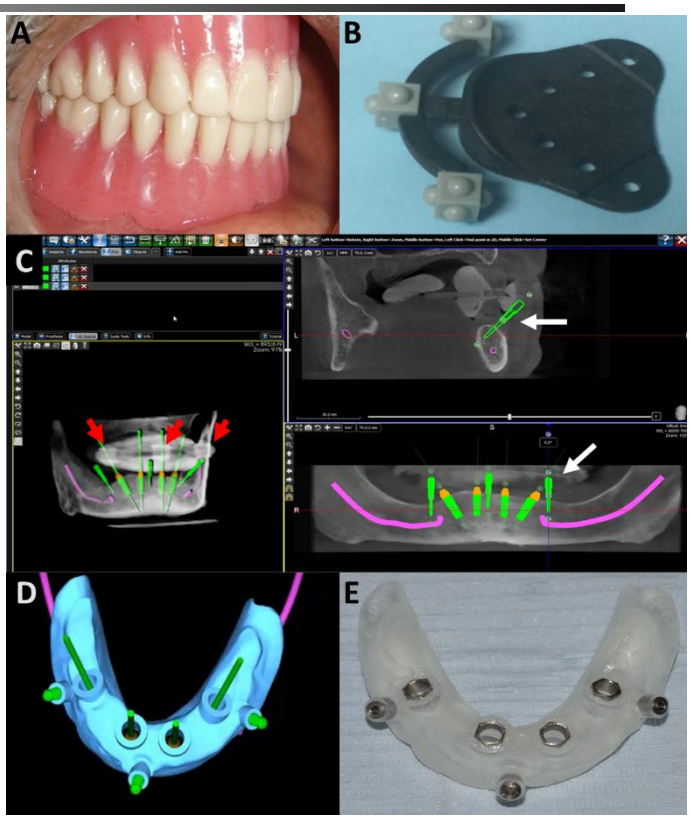

Figure 1. (A) complete denture. **(B)** Ready-made extraoral RO marker **(C)** The superimposition of RO markers (red arrows) on the CBCT, two anterior implants placed axially, and two posterior implants placed with an angle of 30 degrees in group 2, three fixation pins (white arrows) **(D)** CAM Surgical Guide. **(E)** Constructed Surgical Guide.

Table 1. Implant location, type, angulation, and size

Group	Tooth Region	Implant Type	Angulation	Size
Group 1	32 & 42	Tiologic® Implants, Dentaurum, Ispringen, Germany)	0 degree	Width: 3.7mm Length: 11mm
	35 & 45	Tiologic® Implants, Dentaurum, Ispringen, Germany)	0 degree	Width: 4.8mm Length: 11 mm
Group 2	32 & 42	Tiologic® Implants, Dentaurum, Ispringen, Germany)	0 degree	Width: 3.7mm Length: 11mm
	35 & 45	Tiologic® Implants, Dentaurum, Ispringen, Germany)	30 degrees	Width: 4.8mm Length: 13mm

2.4 Surgical Procedure

Prophylactic antibiotics (amoxicillin, clavulanic acid) and mouthwash (chlorhexidine 0.2%) were given to all patients before surgery and continued after surgery for seven days. During the surgery, local anesthesia was given (articainechlorohydrate and epinephrine 1:100,000) then, the CAM surgical guide was placed intraorally and checked for stability, extension, and pressure areas. The surgical stent was fixed into position by fixation pins that were drilled and inserted to stabilize the stent. **Figure 2A** The drilling sequence was then followed. The implants were then inserted, and primary stability was checked.

Patients of group 1 (14 patients) received four axially placed inter-foraminal implants with a total of 56 implants (28 anterior axial implants and 28 posterior axial implants). Patients of Group 2 (14 patients) received two anterior implants placed axially and two posterior implants placed with an angle of 30 degrees **Figure 2B** with a total of 56 implants (28 anterior axial implants and 28 distally tilted implants). The distal screw access hole was made between the second premolar and first molar.**Figure 7**

Postoperative CBCT was performed for the patients of the two groups.**Figure 2C** The patient was given post-operative instructions, medicated with analgesia and antibiotics, and followed up. Temporization was done with the pre-constructed complete denture.

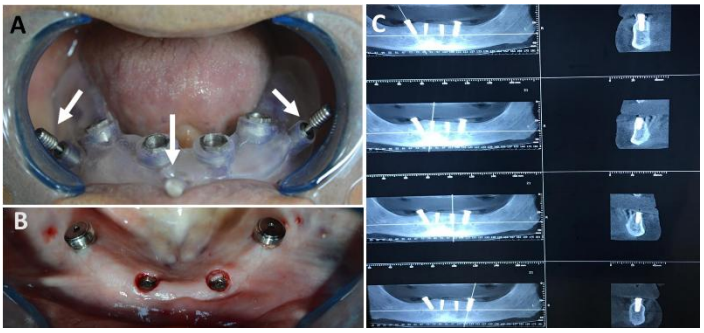

Figure 2. (A) the surgical stent was fixed into position by fixation pins (white arrows). **(B)** Two anterior implants were placed axially, and two posterior implants were placed with an angle of 30 degrees in group 2. **(C)** Post-operative CBCT showing angled distal implants in (group 2).

2.5 Prosthetic Procedures

Patients were recalled after a 4-month healing period. The cover screws were removed, and the permanent transmucosal titanium abutments were torqued to 30 Ncm utilizing a torque ratchet over the implants.**Figure 3A** The final open tray impression was carried out using a rubber base (Putty and light consistency addition silicone, elite HD+, Zhermack, Italy).**Figure 3B ,C** Artificial soft tissue material was placed around the implant analog (Gingifast rigid consistency addition silicone, Zhermack, Italy) **Figure 3C** prior to pouring the final impression.**Figure 3D** A verification jig was used to verify the master casts for accuracy.**Figure 3E**

Using duralay resin plastic burnout cylinders (temporary plastic non-engaging abutment) were fixed to the implants' analogues and joined together. Wax pattern was fabricated over the duralay frame assembly **Figure 4** and tried in the patient's mouth, then cast into chrome cobalt alloy.**Figure 5**

For new bite registration record, occlusion blocks were constructed followed by setting of teeth and try-in. The final prosthesis was constructed and then finished and polished. A torque wrench was then used to tighten the prosthesis screws to 25 Ncm.

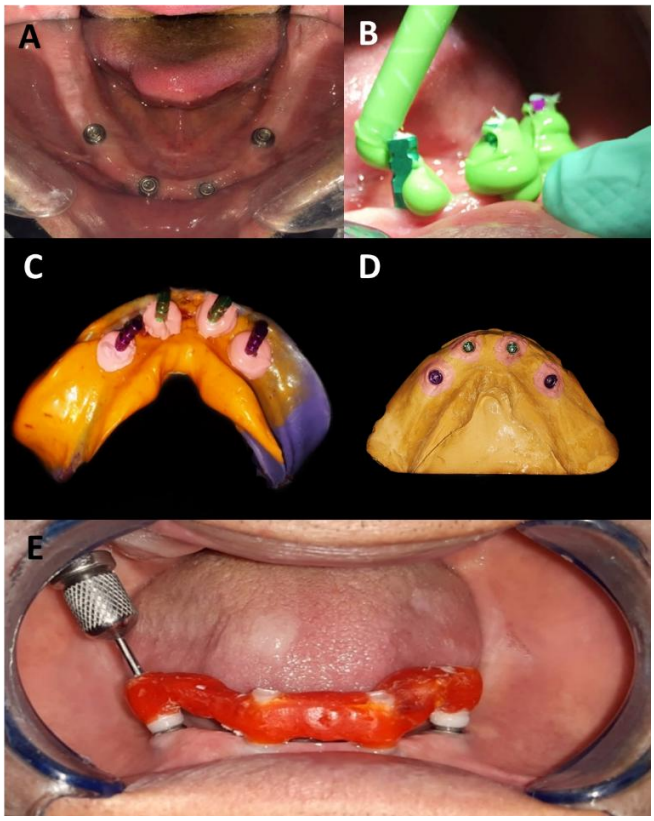

Figure 3. (A) Permanent transmucosal titanium abutments torqued to the four axial implants in group 1. **(B)** final open-tray impression using a rubber base (light consistency addition silicone applied around the impression coping). **(C)** Final open-tray impression (note the pink material is artificial soft tissue material). **(D)** Master cast. **(E)** Verification jig.

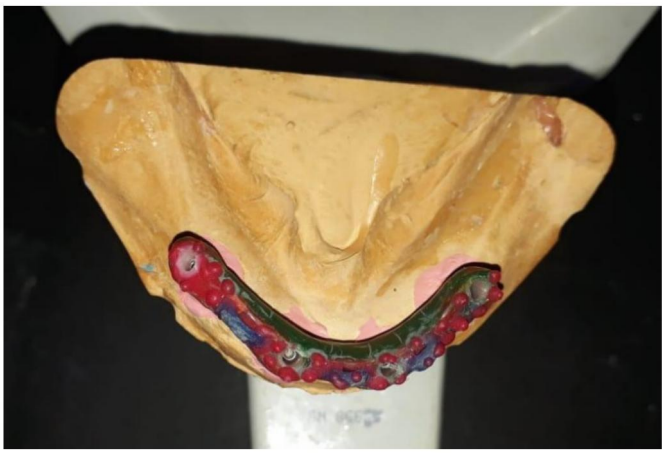

Figure 4. Wax pattern constructed over the duralay frame structure in group 2 with distal angled implants.

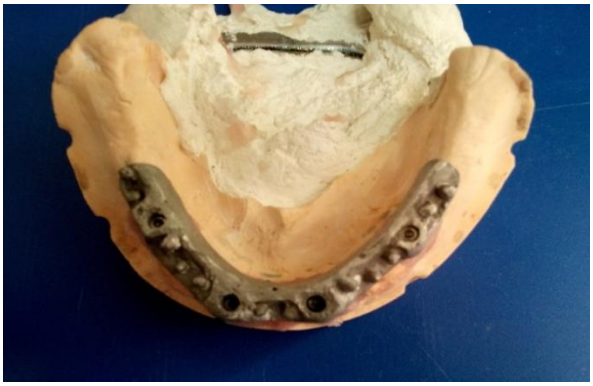

Figure 5. Casted framework on cast. To be screwed onto the four axial implants in group 1.

The Screw holes were filled with polytetrafluoroethylene (PTFE) to avoid the adherence of the composite to the screw.**Figure 6A** Composite resin (Kerr) of appropriate shade was used to fill the screws involved in the acrylic teeth holes, while pink-colored acrylic resin was used to fill the screw holes on the base. Isolation, bonding, incremental application of resin, curing, and finishing were performed **Figure 6B**, and the final prosthesis was delivered.**Figure 7**

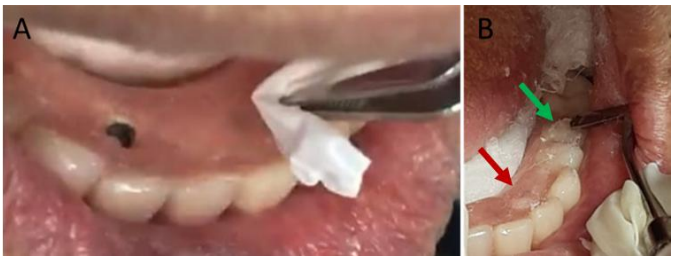

Figure 6. (A) The screw access holes filled with PTFE. **(B)** Composite was used to seal the screw access holes (green arrow), and pink acrylic resin was used to fill the screw access holes on the base (red arrow).

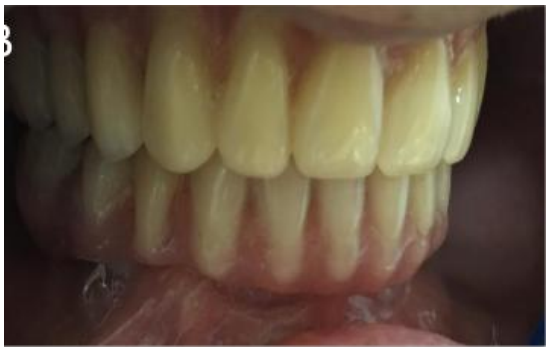

Figure 7. Final prosthesis in occlusion.

2.6 Follow-up

After a follow-up period of two years, implant survival was evaluated. Bone loss was measured after six months, then 12 months, and after 24 months. Marginal bone loss was assessed by two independent assessors (WI and DE).

The assessment was done with periapical radiographs using paralleling technique. Crestal bone loss concerning the implant shoulder was measured in mm at each implant's mesial and distal surfaces, and the mean was calculated and statistically analyzed. Baseline postoperative radiographs with crestal implant placement were compared with the six months, 12 months, and 24 months radiographs [8].

Comparisons were made between anterior and posterior implants within each group. Additionally, comparisons were made between both groups' anterior and posterior implants (i.e. anterior implants in group 1 vs. anterior implants in group 2 and posterior implants in group 1 vs. posterior implants in group 2).

2.7 Sample size

The study was planned to be of a continuous response variable from matched pairs of study subjects. Previous data show that the difference in the response of matched pairs is distributed normally with standard deviation of 0.4 [10]. Suppose the true difference in the mean response of matched pairs is 0.2. To achieve a power of 0.8, 14 subjects are required in order to reject the null hypothesis that the response difference is zero. The test for this null hypothesis has a Type I error probability of 0.05. Sample size calculation was done using PS (Power and Sample size calculation) program version 3.1.2.

2.8 Statistical analysis of the data

The statistical description of the data included mean ± standard deviation (± SD), or median and range when suitable. The normal assumption of numerical data was assessed using the Shapiro-Wilk test. To compare the study groups, an independent samples Student t-test was employed. Comparison between anterior and posterior implants was done using paired *t*-test. Comparison over time points was done using repeated measures analysis of variance (ANOVA) test with Paired *t*-test as post hoc multiple 2-group comparisons after applying Bonferroni adjustment for multiple comparisons. Statistical significance was determined based on two-sided p-values below 0.05. All statistical computations were performed using IBM SPSS (Statistical Package for the Social Sciences; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

3 Results

The study was carried out on a total of twenty-eight completely edentulous patients, as no patients dropped out (16 males and 12 females). Their age ranged from 50-65 years, with a mean age of 56.62 ± 9.52 years. According to the placement of distal implants, patients were allocated into two equal groups with either axial or distally inclined dental implants.

At the end of the follow-up period, no implant loss was observed in both groups, representing a survival rate of 100%. Regarding marginal bone loss, a comparison between the study groups was done using a Student *t*-test for independent samples. The results of Student *t*-test for the comparison between tested groups, statistical data, mean, and standard deviation (SD), are represented in **Table 2**. When comparing the two groups, a non-statistically significant difference was revealed between anterior implants at 6, 12, and 24 months with *p*-value of 0.931, 0.684, and 0.846, respectively. In addition, there was no statistically significant difference between posterior implants at 6, 12, and 24 months with *p*-value of 0.834, 0.765, and 0.904, respectively.

Table 2. Comparisons between anterior and posterior implants of both groups

Item	Group 1			Group 2			Analysis assuming equal variance								
	Mean	SD	n	Mean	SD	n	df	SD-both	1/n1	1/n2	Sum	SE diff	t	Tails	*p*-value
Anterior-6m	0.707	0.230	14	0.714	0.199	14	26	0.22	0.07	0.07	0.14	0.081	0.09	2	0.931
Posterior-6m	0.707	0.159	14	0.724	0.243	14	26	0.21	0.07	0.07	0.14	0.078	0.21	2	0.834
Anterior-12m	1.114	0.211	14	1.149	0.230	14	26	0.22	0.07	0.07	0.14	0.083	0.41	2	0.684
Posterior-12m	1.107	0.198	14	1.133	0.251	14	26	0.23	0.07	0.07	0.14	0.085	0.30	2	0.765
Anterior-24m	1.300	0.188	14	1.318	0.283	14	26	0.24	0.07	0.07	0.14	0.091	0.20	2	0.846
Posterior-24m	1.300	0.188	14	1.290	0.254	14	26	0.22	0.07	0.07	0.14	0.084	0.12	2	0.904

n: number

df: degree of freedom

SE: Standard Error

Table 3. Comparison between anterior and posterior implants within each group

Item	Anterior			Posterior			Analysis assuming equal variance								
	Mean	SD	n	Mean	SD	n	df	SD-both	1/n1	1/n2	Sum	SE diff	t	Tails	*p*-value
6m - Group 1	0.707	0.23	14	0.707	0.159	14	26	0.20	0.07	0.07	0.14	0.075	0.00	1	0.500
12m - Group 1	1.114	0.211	14	1.107	0.198	14	26	0.20	0.07	0.07	0.14	0.077	0.09	1	0.464
24m - Group 1	1.3	0.188	14	1.3	0.188	14	26	0.19	0.07	0.07	0.14	0.071	0.00	1	0.500
6m - Group 2	0.714	0.199	14	0.724	0.243	14	26	0.22	0.07	0.07	0.14	0.084	0.11	1	0.456
12m - Group 2	1.149	0.23	14	1.133	0.251	14	26	0.24	0.07	0.07	0.14	0.091	0.17	1	0.433
24m - Group 2	1.318	0.283	14	1.29	0.254	14	26	0.27	0.07	0.07	0.14	0.102	0.28	1	0.392

n: number

df: degree of freedom

SE: Standard Error

Table 4. Comparison overtime points

Item	6m			12m			24m			One-Way Analysis of Variance												
	Mean	SD	n	Mean	SD	n	Mean	SD	n	N groups	T1	T2	T3	G	N	SS-between	df-between	df-within	MS-between	MS-within	F	p
Ant.-G1	0.71	0.23	14	1.11	0.21	14	1.3	0.19	14	3	9.9	15.6	18.2	43.7	42	2.57476	2	39	1.287381	0.044267	29.082	0.000
Post.-G1	0.71	0.16	14	1.1	0.2	14	1.3	0.2	14	3	9.9	15.5	18.2	43.6	42	2.56048	2	39	1.280238	0.033297	38.449	0.000
Ant.-G2	0.71	0.20	14	1.1	0.2	14	1.3	0.3	14	3	10	16.08	18.45	44.53	42	2.71395	2	39	1.356974	0.057674	23.528	0.000
Post.-G2	0.72	0.24	14	1.1	0.3	14	1.3	0.3	14	3	10.13	15.862	18.056	44.048	42	2.39264	2	39	1.196321	0.062198	19.234	0.000

The results of paired *t*-test for comparison between anterior and posterior implants within each group were done using paired *t-test* as shown in **Table 3**. Comparing anterior and posterior implants in group 1 at 6, 12, and 24 months showed no-significant difference with *p*-value of 0.500, 0.464, and 0.500, respectively. Additionally, a non-statistically significant difference was revealed in group 2 at 6, 12, and 24 months with *p*-value of 0.456, 0.433, and 0.392, respectively.

Comparison over time points proved a statistically significant difference for marginal bone loss in anterior and posterior implants, as shown in **Table 4** with *p*-value of zero.

4 Discussion

The purpose of this study was to examine and compare the survival rate and peri-implant bone loss of axially placed and tilted distal implants. Based on the findings of this study, no statistically significant difference was observed between the two methods of implant placement, suggesting that placing the implant in a straight or angulated position does not affect the outcome.

There is a biomechanical advantage of splinting implants using full arch fixed prosthesis and placing implants in a strategic position. A Finite Element Analysis (FEA) study found that there is a biomechanical benefit if two posterior tilted implants were used in conjunction with two anterior axial implants instead of inserting posterior axial implants supporting a high number of cantilever teeth [11].

In the present study, a survival rate of 100% was observed in both groups. This can be due to splinting of dental implants, which permits an even distribution of occlusal load, thus decreasing the stresses observed at bone-implant interface [12]. Another cause for high survival rates in tilted implants may be due to the high contact between angulated implants and cortical bone, increasing the initial stability [13].

In terms of marginal bone loss, there was no notable distinction observed between axial and tilted distal implants. This finding aligns with the outcomes of a systematic review that encompassed 44 publications, comparing a total of 5029 tilted dental implants and 5732 axially placed implants. [14]. The author suggested that this finding may be attributed to the fact that in most of the included studies, the most common rehabilitation was fixed full-arch prosthesis where the implants were splinted.

It is noted that some studies detected concentrated stresses around angulated implant necks which can result in greater bone resorption in comparison to axially placed implants [15-17]. Angulated implants may also be exposed to bending, leading to marginal bone stresses [18].

Nevertheless, other studies have shown that tilting the posterior implants can result in the reduction of the cantilever length and wider distribution of forces, and less stress at the neck of the implant [19,20], which leads to reduced marginal bone loss [21]. Additionally, studies showed an increase in stresses around single tilted implants [15-17], while more favorable results were detected in splinted full arch prosthesis owing to splinting effect [19,20].

5 Conclusion

The angulation of distal implants in an All-On-4 mandibular screw-retained prosthesis does not influence the implant survival nor the peri-implant marginal bone loss. These findings support the use of either axial or tilted distal implants, with considerations for implant splinting and biomechanical factors. Further research is needed to validate these findings and provide more comprehensive evidence.

Authors' Contributions

DE, WI and SM, principle investigators.
WI, SM and DE, managed manuscript writing and design.
AH managed the assessment of the outcomes.
All authors have read and approved the manuscript.

Informed consent

Patients accepted and signed a written informed consent to this treatment protocol

Conflicts of interests

The authors declare no conflict of interest.

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