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

Dina Elawady¹, Sarah Abouel Fetouh Mohamed², Ahmed Mohamed Hossam Eldin³, Wafaa Ibrahim Ibrahim⁴

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.

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 interforaminal 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 stress on the implant and surrounding bone tissue under dynamic loading.

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; however, when used in conjunction with a short cantilever, inclined implants to decrease stress on 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 randomized 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 Prosthodontic Department, Faculty of Dentistry, MSA University, 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 MSA University approved the trial. 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 interforaminal 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 (Fig 1A). CBCT scanning was performed for all patients using a tray with ready-made extraoral radiopaque markers (Fig 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 (Fig 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 (Fig 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 (Fig 1C). The parallelism between all implants was checked in group 1 and between anterior implants in group 2. CAM surgical guide was digitally designed (Fig 1D) and constructed in order to perform a prosthetic-driven implant placement using a flapless technique (Fig 1E).

<table>
<thead>
<tr>
<th>Group</th>
<th>Tooth Region</th>
<th>Implant Type</th>
<th>Angulation</th>
<th>Size</th>
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</thead>
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<tr>
<td>Group 1</td>
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<td>Implant Direct</td>
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<tr>
<td></td>
<td>35 &amp; 45</td>
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<td>Implant Direct</td>
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<td>Width: 3.75mm Length: 11.5mm</td>
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<tr>
<td></td>
<td>35 &amp; 45</td>
<td>Implant Direct</td>
<td>30 degrees</td>
<td>Width: 4.7mm Length: 13mm</td>
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</tbody>
</table>

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

Fig 1. (A) complete denture. (B) Ready-made extraoral RO
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 (Fig 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 (Fig 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 (Fig 7).

Postoperative CBCT was performed for the patients of the two groups (Fig 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.

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 (Fig 3A). The final open tray impression was carried out using a rubber base (Putty and light consistency addition silicone, elite HD+, Zhermack, Italy) (Fig 3B, C). Artificial soft tissue material was placed around the implant analog (Gingifast rigid consistency addition silicone, Zhermack, Italy) (Fig 3C) prior to pouring the final impression (Fig 3D). A verification jig was used to verify the master casts for accuracy (Fig 3E).

Plastic burnout cylinders (Legacy temporary plastic non-engaging abutment) were fixed to the implant analogues and were joined together using duralay resin. Over the duralay frame structure, a wax pattern was constructed (Fig 4) and tried in the patient’s mouth, then cast into chrome cobalt alloy (Fig 5).

Occlusion blocks were constructed for new bite registration records. Setting up of teeth was carried out and try-in was done. The final prosthesis was constructed and then finished and polished. A torque wrench was then used to tighten the prosthetic screws to 25 Ncm.
Fig 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.

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

Fig 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 (Fig 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 (Fig 6B), and the final prosthesis was delivered (Fig 7).

Fig 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).

Fig 7. Final prosthesis in occlusion.
2.6 Follow-up

A follow-up period of 2 years was decided, after which implant survival was evaluated. Bone loss was measured after 6 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 6 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. Prior data indicate that the difference in the response of matched pairs is normally distributed with a standard deviation of $0.4^{(10)}$. Suppose the true difference in the mean response of matched pairs is 0.2. In that case, we need to study 14 subjects to be able to reject the null hypothesis that this response difference is zero with a probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 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 data were statistically described in terms of mean±standard deviation (± SD), or median and range when appropriate. Numerical data were tested for the normal assumption using Shapiro Wilk test. Comparison between the study groups was done using Student $t$-test for independent samples. 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. Two-sided $p$-values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program IBM SPSS (Statistical Package for the Social Science; 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 $56.62 \pm 9.52$ 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.

<table>
<thead>
<tr>
<th>Item</th>
<th>Group 1</th>
<th>Group 2</th>
<th>Analysis assuming equal variance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>SD</td>
<td>n</td>
</tr>
<tr>
<td>Anterior-6m</td>
<td>0.707</td>
<td>0.23</td>
<td>1</td>
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<tr>
<td>Posterior-6m</td>
<td>0.707</td>
<td>0.15</td>
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<tr>
<td>Anterior-12m</td>
<td>1.114</td>
<td>0.21</td>
<td>1</td>
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<tr>
<td>Posterior-12m</td>
<td>1.107</td>
<td>0.19</td>
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<tr>
<td>Anterior-24m</td>
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<td>0.18</td>
<td>8</td>
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<tr>
<td>Posterior-24m</td>
<td>1.300</td>
<td>0.18</td>
<td>8</td>
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</table>

n: number  
df: degree of freedom  
SE: Standard Error

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Anterior</th>
<th>Posterior</th>
<th>Analysis assuming equal variance</th>
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<td></td>
<td>Mean</td>
<td>SD</td>
<td>n</td>
</tr>
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<td>6m - Group 1</td>
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<td>0.23</td>
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<tr>
<td>12m - Group 1</td>
<td>1.114</td>
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<td>24m - Group 1</td>
<td>1.300</td>
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<td>4</td>
</tr>
<tr>
<td>6m - Group 2</td>
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<td>4</td>
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<td>12m - Group 2</td>
<td>1.149</td>
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<td>4</td>
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<tr>
<td>24m - Group 2</td>
<td>1.318</td>
<td>0.28</td>
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</table>

n: number  
df: degree of freedom  
SE: Standard Error
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

This study was conducted to compare the survival rate and peri-implant bone loss between axially placed and tilted distal implants. According to the results of the present study, there was no statistically significant difference between both implant placement methods, 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 advantage if two posterior tilted implants were used in conjunction with two anterior axial implants rather than inserting posterior axial implants supporting a high number of cantilever teeth. (1)

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### Table 4. Comparison overtime points.

<table>
<thead>
<tr>
<th>Item</th>
<th>Mean 6m</th>
<th>S D</th>
<th>n</th>
<th>Mean 12m</th>
<th>S D</th>
<th>n</th>
<th>Mean 24m</th>
<th>S D</th>
<th>n</th>
<th>N groups</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>G</th>
<th>SS-between</th>
<th>df-between</th>
<th>df-within</th>
<th>MS-between</th>
<th>MS-within</th>
<th>F</th>
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<tbody>
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<td>An t.-G1</td>
<td>0.71</td>
<td>0.23</td>
<td>14</td>
<td>1.11</td>
<td>0.21</td>
<td>14</td>
<td>1.30</td>
<td>1.49</td>
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<td>9</td>
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<td>1.287</td>
<td>381</td>
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<tr>
<td>Post-G1</td>
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<td>0.16</td>
<td>14</td>
<td>1.02</td>
<td>0.32</td>
<td>14</td>
<td>1.30</td>
<td>1.44</td>
<td>14</td>
<td>3</td>
<td>9</td>
<td>15</td>
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<td>2</td>
<td>2.560</td>
<td>48</td>
<td>2</td>
<td>1.280</td>
<td>238</td>
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<td>0.24</td>
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<td>1.30</td>
<td>1.32</td>
<td>14</td>
<td>3</td>
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<td>18</td>
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<td>19</td>
<td>2.713</td>
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<td>Post-G2</td>
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<td>0.06</td>
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In the present study, a survival rate of 100% was observed in both groups. This can be due to splinting of implants, which allows an even distribution of occlusal load, thus decreasing stresses at the bone-implant interface (12). Another reason for the high survival rate in tilted implants may be due to the high contact between cortical bone and angulated implants, which increases the initial stability (13).

Regarding marginal bone loss, there was no significant difference between axial and tilted distal implants; this is similar to the results of a systematic review which included 44 publications comparing a total of 5029 dental implants which were tilted, and 5732 implants that were axially placed (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.

Authors’ Contributions
DE and SM, principle investigators.

6. References

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

FWI
10. Mandibular Full-Arch Fixed Prostheses Supported on 4 Implants with Either Axial Or Tilted Distal Implants: A 3-Year Prospective Study


