

## INFLUENCE OF CONICAL VERSUS TRILOBE IMPLANT ABUTMENT CONNECTION ON MARGINAL BONE LOSS, SOFT TISSUE HEALTH AND PROSTHETIC MAINTENANCE IN MANDIBULAR IMPLANT- ASSISTED OVERDENTURE: A 3-YEAR PROSPECTIVE SPLIT-MOUTH RANDOMIZED CLINICAL TRIAL

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### ABSTRACT

**Background:** An accurate fit at the implant-abutment connection is a key factor to preclude biological and mechanical complications.

**Purpose:** The aim of this study was to compare marginal bone level (MBL), modified sulcus bleeding index (mSBI), simplified gingival index (sGI), modified plaque index (mPI) and prosthetic maintenance in conical and trilobe implant-abutment connections (IACs) in mandibular implant assisted overdenture during 3 years in service.

**Materials and method:** new complete dentures were constructed for fourteen completely edentulous patients. After 3 months of use and adaption to their new denture, 28 implants were inserted such that 14 implants with conical implant-abutment connection (group I) and 14 implants with trilobe implant-abutment connection (group II). Split mouth design was used for all patients participated in this study. Statistical software was used to randomly assign which type of connection to be inserted intraorally in the two contralateral sides for each patient. The implants were inserted in the mandibular canine region using two-stage surgical technique and following conventional loading protocol. After 3 months, each patient received two ball and socket attachments; and pick up was done to the denture fitting surface. The MBL, mSBI, sGI, mPI, and prosthetic complications and maintenance requirements for each group of implants were evaluated at loading time, after 6, 12, 24, and 36 months follow up visits. Data were collected, organized, tabulated, and statistically analyzed.

**Results:** The implant survival rate at the end of follow up period in conical and trilobe IAC groups were 100% and 92.8% respectively. On comparing MBL in both groups, no significant difference was found at 0-6 months, while at the 0-12 and 0-36 follow up periods a significant

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difference was found ( $p < 0.05$ ). No significant difference was found on comparing the mSBI, sGI and mPI scores of both IAC groups at all follow up visits. The total prosthetic maintenance events were 50 in both groups together. In general, the technical complications and prosthetic maintenance requirements were fewer and less frequent in conical than in trilobe IAC in all categories and their sum and percentages were less in conical (12 (22%)) compared to trilobe (38 (78%)).

**Conclusion:** Within the limitations of this study, it was concluded that the implant abutment connection in mandibular implant assisted overdenture cases may influence marginal bone loss and prosthetic maintenance requirements. The conical implant-abutment connection can be associated with significantly less marginal bone loss and prosthetic maintenance requirements offering a more stable implant system compared to the trilobe Implant-abutment connection.

**KEYWORDS:** Implant assisted overdenture, implant-abutment connection, prosthetic maintenance, conical connection, trilobe connection

## INTRODUCTION

The inadequacy of conventional complete denture makes implant mandibular overdenture a better substitute providing significant improvement in stability, retention, and quality of life in denture-wearing patients<sup>1,2</sup>. The 2002 McGill Consensus stated that two implant supported overdenture is considered the standard of care for edentulous patients, mainly in mandibles, particularly in cases when alveolar bone preservation is desired<sup>3</sup>. The relative simplicity, minimal invasiveness, and affordability of mandibular two implant-supported overdentures<sup>4-6</sup>, compared to fixed implant prosthesis, makes it an adequate alternative. It can also provide better esthetics especially in patients with large vertical bone loss maintaining effective oral hygiene measures. In addition, concerning oral hygiene, a removable prosthesis demands less time and effort to maintain a proper plaque control level. This is an important issue for elderly patients having decreased visual capability and dexterity<sup>7</sup>

Dental implants' success depends on the manner stresses are transmitted to the surrounding bone. Load transfer depends on several factors among which, the type of loading, the bone-implant interface, the used implants' dimensions, shape and surface characteristics, the prosthesis form, and the properties of the surrounding bone. Implant design features are among the fundamental elements that

affect implant primary stability and the ability of implant to withstand loads during and after osseointegration<sup>8</sup>. Moreover, to assure long-term implant success, mechanical complications under loading must be minimized.

The implant-abutment connection (IAC) represents the weakest point of the dental implant fixtures and is considered as one of the key factors to success. It must resist and endure maximal masticatory forces together with preventing bacterial penetration. It was documented that fractures usually occur at the weakest point of the construction<sup>9-11</sup>.

The IAC is commonly described as internal or external connection that can be designated by whether there is an extension of a geometric figure above or within the implant fixture. When the connection is recessed into the body of the implant, it is called internal connection while in external connection; there is distinct projection external to the implant fixture<sup>12</sup>.

In addition, the IAC can be categorized as "Slip-fit" joint, where a slight space is found between the mating components accordingly the connection is passive, or as "Friction-fit" joint where no space and the parts are exactly forced together. The mating surfaces are additionally described as being "Butt" joint where two flat right-angled surfaces opposite each other or "Bevel" joint where the

surfaces are angled either internally or externally. Furthermore, the joined surfaces may incorporate rotational resistance and indexing structure and/or lateral stabilizing geometry that is designated as hexagonal, octagonal, conical, cylinder hex, etc.<sup>12</sup>.

Internal IACs were introduced to overcome some of the design limitations and the clinical complications such as bone loss related to the external hexagonal IACs through targeting new designs to enhance connection stability during the placement and functional intervals<sup>13, 14</sup>. Internal connections provide improved joint strength, additional long-term implant-abutment complex stability, better esthetics, enhanced microbial seal and better crestal bone levels in the short -medium intervals when compared to the external connection<sup>13, 15, 16</sup>.

The most widely used internal connections are internal hexagonal, internal octagonal, conical screw and Morse connections. Morse taper is a conical internal connection, in which friction takes place between the surfaces that generate cold-welding<sup>17, 18</sup>. This connection creates a good seal between its parts which consequently provides decreased microleakage. In addition, it produces greater joint stability and less marginal bone loss<sup>13, 18-20</sup>.

Two-piece implant inevitably presents microgap between the implant and the abutment. The presence of microgap allows the bacterial microleakage to persist adjacent to the implant-abutment boundary acting as a bacterial reservoir that affects peri-implant tissue health and nearby bone and further exaggerates the micromotion while in function. Both micromotion and microleakage cause wear, plastic deformation, and screw loosening. These mechanical impairments will increase the micromotion and microgap, leading to a closed vicious cycle. Hence, both microgap and microleakage influence and promote each other<sup>21, 22</sup>.

The identified possible causes for the development of microgaps: occlusal load during masticatory function, manufacturing tolerance and existence of

micromotion between implant-abutment interface. The presence of sharp angles and vertices at the abutment connection produce high stresses causing wear and consequently microgap formation. In a finite element analysis study, the conical and butt-joint (in three different forms: hexagonal, octagonal and trilobe) abutment connections the micromotion of the contacting components was evaluated. The internal conical abutment produced the highest magnitude of micromotion while the trilobe abutment showed the lowest magnitude, this was mainly attributed to its polygonal profile. Non-cylindrical abutments showed lower micromotion, however the possibility of stress concentration at the vertices increased the risk for microfracture and microgap formation<sup>23</sup>. On the other hand, in another in-vitro study, lower permeability to bacteria owing to the reduced gap found in the conical connection compared to trilobe connection was concluded<sup>24</sup>.

Microgaps in the implant-abutment interface ranges from 0.1-10  $\mu\text{m}$  and after cyclic loading this range may increase which may lead to microbial leakage. Most oral bacteria, having the size range within the width of 0.2-1.5  $\mu\text{m}$  and length of 2-10  $\mu\text{m}$ , thus they can penetrate across a 10  $\mu\text{m}$  gap resulting in bacterial colonization and plaque formation at the boundary leading to inflammation in peri-implant soft and hard tissues. Accordingly, causing gingivitis, marginal bone loss nearby the implant collar that if persisting for long time finally may lead to implant failure<sup>25, 26</sup>. Peri-implantitis is considered as a critical complication and one of the significant factors associated with late failure. Peri-implantitis is an outcome of the interaction between the implant-bearing tissues, bacteria, and the host immune response<sup>27</sup>.

Preservation of bone level is a very important aspect to be considered in implant prosthodontics hence post-operative evaluation of the marginal bone level is of great importance to prosthodontist. Accordingly radiographic assessment of bone is an

important and viable method for determining the health and stability of peri-implant bone. A decrease of marginal bone level indicates that the implant is losing its bony anchorage<sup>28</sup>. Smith and Zarb<sup>29</sup> suggested that one of the criteria of implant success was peri implant bone loss per year after the first year of service to be less than 0.2 mm.

Conical and non-conical connection designs have approximately same success and survival rates. However, conical connection showed lower marginal bone loss in most of the cases<sup>30</sup>. Besides it was found that IAC has impacts on the stresses and strains induced in marginal bone around the implant<sup>31</sup>.

Prosthetic complications are known as any mechanical damage of the implant and/or its supra-structures<sup>32</sup>. The accurate fit of IAC and abutment screw preload are mechanical considerations that affect the success of implant-assisted prosthesis. The preload loss during the occlusal load where the prosthesis is in use enhances misfit of the IAC subsequently stresses increase in the implant and connection components, and consequently in the adjacent bone. This could lead to screw fracture, abutment, and prosthesis damage, necessitating the replacement of the prosthesis<sup>33</sup>.

The possibility of screw loosening decreases when gaps between implant and abutment are minimized<sup>34</sup>. It has been assumed in laboratory studies that complications related to screw whether loosening or fracture are associated with IAC misfit<sup>34-36</sup>. Yet few clinical studies on conical connection designs concluded that there is a decrease in prosthetic complications incidence compared to other IACs<sup>37,38</sup>.

Evidence about the needed prosthetic maintenance procedures to maintain the efficiency of implant-assisted overdenture for long time in relation to implant-abutment connection is lacking. It is a critical outcome as when maintenance requirements increase the cost of the prosthesis increases affecting patient's satisfaction with it.

This feature is important for the practitioner as it may influence the selection of the implant type.

Currently no IAC is assumed as evidently superior to other connections in all features. Concerning rehabilitation with implant assisted overdentures, scientific evidence concerning the impact of various implant abutment connections on the clinical outcomes in is comparatively inadequate in the literature. Most of the studies performed, were concerned to evaluate of the mechanical performance of different IACs; they were in-vitro studies mainly. Although the mentioned features of conical connection might hypothetically provide improved clinical results, few clinical evidence is available. Furthermore, long follow-up results are not adequately provided.

This finding introduces a question about the clinical performance of two main IACs categories (the passive fit or slip-fit; the trilobe connection and the friction fit; the conical connection) for longer follow-up periods intraorally. Accordingly, this research work was performed as an attempt to answer this question.

## **MATERIALS AND METHOD**

### **Participant selection and treatment**

Fourteen completely edentulous patients (9 males and 5 females) were selected from the outpatient clinic of the Prosthodontics Department; Faculty of Dentistry, Ain Shams University, Egypt. The inclusion criteria of the participants were patients having well developed mandibular ridge with sufficient height and width that allows implant insertion with 16 mm length and 3.7 mm width, Class 1 Angle's classification with sufficient inter-arch distance. The exclusion criteria were patients with parafunctional habits as bruxism, smokers, have history of radiotherapy in the head and neck region, or having any disease that might affect osteointegration. The participants in this study

were all informed about the nature of the study and agreed to continue along the follow up period.

Intra-oral examination was done where the mucoperiosteum covering the edentulous ridge at the proposed implants sites was clinically evaluated and palpated to detect any flabby tissues, undercuts, ridge irregularities or sharp bony spicules.

All participants were informed about the purpose of the study and the treatment modality used, they accepted to take part in it and signed an informed consent. The study has the approval of the faculty research ethical committee. All required steps to protect the confidentiality of their personal information and privacy of the patient protected health were taken.

A new complete denture was constructed following conventional denture fabrication procedures. Upper and lower primary impression was taken using irreversible hydrocolloid material (Cavex CA37, Normal Set, Holland) to obtain the study casts. Self-cured acrylic special trays were constructed, border molding was done, and the final impression was taken in Zinc-oxide eugenol (S.S White Impression paste, S. S. White group, England) to obtain the master casts.

Upper and lower occlusion blocks were constructed and used to record the jaw relations. Face bow (Dentatus face bow. Type AEB. Jakobsdal Swagen 14-16.512653) record was used to mount the upper cast, and centric occluding relation record at the predetermined vertical dimension using interocclusal wax technique was used to mount the mandibular cast. Thus, mounting the master casts on a semi-adjustable articulator (Dentatus Articulator. Type ARH. Jakobsdal Swagen 14-16.512653) was performed. In addition, the condylar guidance of the articulator was adjusted using protrusive records.

Cross-linked semi-anatomic acrylic teeth Vitapan; (Vita Zahnfabrik, Badackingen, Germany) were arranged according to the medially lingualized

occlusal concept to achieve lever balance by elimination of the buccal cusp contact in centric and eccentric excursions.

Following the try-in visit, the waxed-up denture was processed using high impact strength acrylic resin with long cycle processing technique to give sufficient strength to the denture base when modified to receive the attachments. After denture processing, laboratory remounting was done, finishing and polishing, then clinical remount was done before the denture was delivered to the patient.

The patient was recalled a week following denture insertion for any needed occlusal adjustments and inspection. Patients were informed with proper denture hygiene instructions and the denture was regularly evaluated for at least 3 months before implants placement. The denture acted as an interim for confirming patient's adaptation, neuromuscular accommodation, and evaluation of occlusion.

The new mandibular complete denture was duplicated into clear acrylic denture to be used as radiographic stent where the radiographic record was taken while the patient wearing his denture with a radiopaque material (gutta percha rods were placed at the mandibular canine sites) that was used as scan markers.

### **Surgical and prosthetic phases**

A pre-operative radiograph using cone beam computed tomography (CBCT) (iCAT FLX series Imaging Sciences International, LLC 1910 N Penn Road, Hatfield, PA 19440, Pennsylvania, USA) was taken for each participant to examine the proposed implant sites, at the canine region bilateral, regarding the residual alveolar bone quality and quantity and to exclude the presence of any pathology.

The radiographic stent was transformed into surgical stent by making vertical holes in the predetermined implant position (in the canine position confirmed by the radiographic evaluation and the place of the markers).

### Patients grouping

Each patient received two implants (16 mm in length and 3.7 mm in diameter) from the same implant system as well as the same design except for the IAC. An implant with 12-degree conical internal hex IAC (implant direct: interactive™ no. 653716, USA) was inserted in the canine region of the mandible at one side and another implant with trilobe IAC (implant direct: Reactive® no.753716) was inserted in the canine region of contralateral side using two-stage surgical technique and delayed loading protocol. The Insertion for each implant type was randomly allocated between the two contralateral sides intraorally for each patient. Each patient was treated following **split mouth design**. Statistical software program (Minitab 17.0, Pennsylvania, USA) was used to randomly assign which type of connection to be inserted intraorally between the two contralateral sides in each patient. The grouping was according to the implant-abutment connection type where in **Group I** implants were with conical IAC and in **Group II** implants were with trilobe IAC. Fig (1a,b)

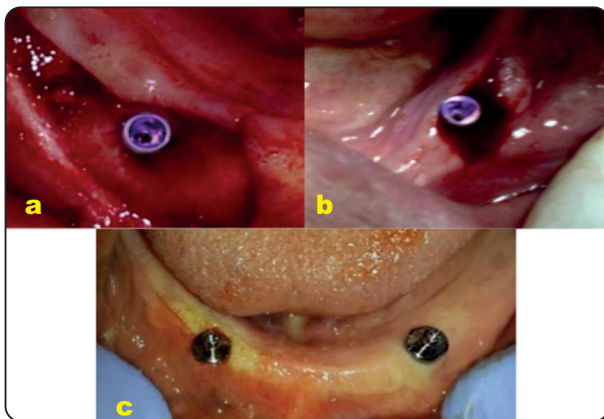


Fig (1): a) Group I implant (conical internal hex IAC), b) Group II implant (trilobe IAC), c) an occlusal view for the ball abutments intraorally

All patients were prepared for the first stage surgery following medication protocol typical for implant surgery; using antibiotic coverage (Augmentin 1gm) starting 24 hours before surgery

and continued for 5 days after surgery as 1 tablet every 12 hours, non-steroidal anti-inflammatory (Ibuprofen) one capsule twice daily and the patients were instructed to rinse with Chlorohexidine mouth wash 3 times daily starting 2 days before surgery.

Implants were inserted in the mandibular canine region using two-stage surgical technique following conventional loading protocol. The position of the two implants was determined as planned by using the surgical stent formerly prepared, the site of two canines were marked on the crest of the ridge using indelible pencil, then the stent was removed. Two separate crestal incisions were carried out reaching to the bone of the ridge crest at canine–premolar region, then two anterior vertical incisions were done.

Full thickness mucoperiosteal flaps maintaining an intact periosteal coverage was made. Pilot drill was used to prepare the two implant sites directed perpendicular to the occlusal plane. Then parallel pins were placed into the prepared sites to check implants angulation and position. Sequential drilling was continued following the checked direction furthermore the osteotomies' parallelism was checked again for correct alignment by the parallel pins. Fig (2a)

The implants were inserted according to the grouping plan where the cone connection in one side and the trilobe connection on the other. Fig (2 b) Implants were manually inserted with the torque wrench till become flushed with the bone level. Then the cover screw was placed and the mucoperiosteal flap was repositioned, approximated, and sutured.

In the Post-surgical steps, the fitting surface of the lower denture was relieved about 2mm opposing the sutures. Soft liner (Acrostone, Anglo Egyptian lab, Egypt) was added to the fitting surface and was relieved over the implant sites to ensure there is no contact with the prosthesis. (Following delayed loading protocol) Then occlusion was checked and needed adjustments were done.

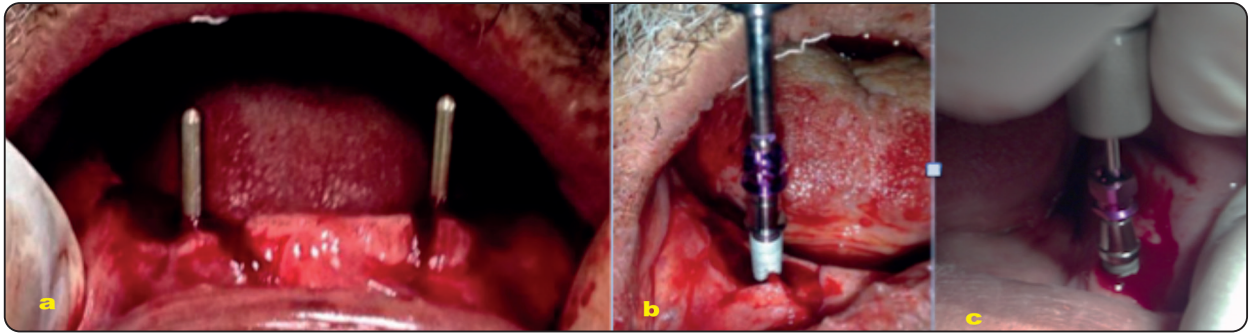


Fig (2): a) Parallel pins used to align the implant sites, b) conical connection and c) trilobe connection implants initial threading by screwdriver.

Implants were kept submerged for 3 months. Afterwards, the implants were exposed by making keyhole access excisions about 1 mm of soft tissue directly over the implant's head on both sides and retrieval of the cover screw was done. Then two ball abutments were screwed into position and hand tightened into the implants using 1.25 mm hex tool then using calibrated torque wrench to be tightened to 30 Ncm. The ball abutment whether with cone connection or with tri-lobe connection was screwed according to the planned grouping for each patient fig. (1c).

Three days after the second stage surgery, patients were recalled where the ball abutments and the surrounding mucosa were checked that there was no sign of inflammation. Rubber rings were glided around the ball abutments, then the metallic housings were placed, and Opaldam (Opaldam light cure barrier, Ultradent Products, Inc. South Jordan, UT 84095, United States) was put to protect the gingival sulcus surrounding the abutments. Fig (3a) Pressure indicating paste was painted on the fitting surface of the lower denture then seated in the patient's mouth to have marks corresponding to the location of the attachment housings in the fitting surface then these two marked areas were relieved.

Small amount of self-cured acrylic resin (UFI Gel hard, VOCO GmbH, Cuxhaven, Germany) was

placed on the two relieved areas. Then the upper and lower dentures were seated in the patient's mouth while biting in light centric occlusion till acrylic polymerize. The denture was carefully removed containing the attached housings, excess resin was removed, the denture was finished and polished. Occlusion was checked and any errors detected were adjusted. Fig.(3b)

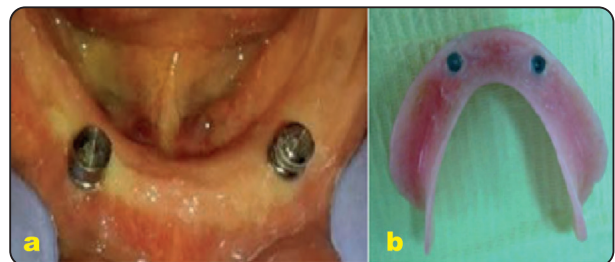


Fig (3): a) The metal housing is placed over the ball abutments, b) metal housing picked up in the mandibular denture fitting surface.

### Parameters of evaluation

#### *Marginal bone loss (MBL)*

After performing the needed post insertion adjustments, radiographic evaluation to assess the peri-implant marginal bone loss was done. The measurements of marginal bone height mesial and distal to the implants were assessed at implant loading (baseline or zero month), six, twelve, thirty-six months after implant loading by periapical

radiographs following the standardized long cone paralleling technique.

A Rinn periapical film holder (XCP Extension Cone Paralleling, DENTSPLY Rinn Corporation, USA) was used to get the radiographs, the x-ray tube was mounted by a long cone. Rinn technique was followed in every visit by means of the XCP instrument for extension cone paralleling technique and a phosphorus x-ray plate was utilized to receive the image. The duplicated clear denture of the patient was used in the follow up radiographs where cold cure acrylic resin was used to attach the bite blocks of the Rinn XCP to it. Thus provide a reproducible and steady positioning of the phosphorus x-ray plate in every follow-up visit.

All used films were exposed using the same x-ray machine (Fona XDC, Fona, Assago, Italy) (at 8 milliamperes and 70 kilovolts for 0.6 seconds with a focal film distance of 35 cm) these exposure parameters were fixed for all the patients in the follow-up visits for standardization of radiographs. To read the image data, a scanner was used to scan the plate to form a digital image. Image display was viewed and checked on the computer screen before it was saved to be analyzed by Viewer software (Romexis Viewer software, Planmeca, Helsinki, Finland) to get the linear measurements.

For Calibration, as an additional standardization technique for the measurements, and to avoid any human or procedural error; the visible radiographic implant length of each implant was measured on each image and matched to the actual known length of the implant (16 mm).

On the imported images, a horizontal line tangential to the implant apex and perpendicular to its long axis was drawn. Then two vertical lines were drawn tangential to the implant mesial and distal surfaces extending from the horizontal line to the highest bone-implant contact. The mesial and distal marginal bone height were measured fig. (4) The images were evaluated by a calibrated clinician

blinded by the nature of the study. The marginal bone loss was calculated by subtracting follow-up visits (6, 12, and 36 months) marginal bone height measures from the baseline measures (0 month - at loading).



Fig. (4): Software measuring the mesial and distal marginal bone height.

### **Soft tissue outcomes**

The Soft tissue health was assessed clinically using modified Sulcus Bleeding Index (mSBI), simplified Gingival Index (sGI) and modified Plaque Index (mPI). These indices were assessed at four possible areas labial, mesial, distal, and lingual. The sum of score were added together then divided by four to get the gingival score of each implant. This index is based on scale from 0 to 3 as follows:

- Assessment of bleeding tendency by a modified Sulcus Bleeding Index<sup>39</sup> (mSBI); score 0: no bleeding when a periodontal probe is passed along the gingival margin adjacent to the implant, score 1: isolated bleeding spots visible, score 2: blood forms a confluent red line on margin. score 3: heavy or profuse bleeding.
- Assessment of peri-implant gingival tissues with modified gingival index which was simplified by Apse et al.<sup>40</sup> to be the simplified Gingival index (sGI); score 0: normal gingival with no inflammation, score 1: mild inflammation, slight change in color, slight edema and no bleeding on probing, score 2: moderate inflammation, redness, edema, glazing and bleeding on



probing, score 3: severe inflammation, marked redness, edema, ulceration and exemplified by spontaneous bleeding.

- Assessment of plaque accumulation with a modified Plaque Index (mPI)<sup>39</sup>; score 0: no detection of plaque, score 1: plaque only recognized by running a probe across the smooth marginal surface of the implant. score 2: plaque can be seen by the naked eye and score 3: abundance of soft matter.

### ***Prosthetic maintenance***

Technical complications and prosthetic maintenance requirements were documented and compared between the two IAC groups (group I and II) for each patient along the whole study period (36 months); patients had planned visits every six months. Patients who had complications or problems during the study period came to the clinic, maintenance service was done and recorded.

Prosthetic complications and maintenances related to the implant/abutment/ attachment assembly were recorded and documented. The Prosthetic complications and maintenances' comparing aspects included abutment screw loosening and retightening, implant fracture and replacement, abutment screw fracture and retrieval, metal housing loss and replacement, metal housing deformation and replacement, metal housing worn out and replacement, reactivation of attachment retention (nylon cap replacement), worn ball (abutment) and replacement and fractured ball (abutment) and retrieval .

### **Statistical analysis**

The data were collected, organized, tabulated, and statistically analyzed. The statistical software program Minitab (Minitab 17.0, Pennsylvania, USA) was utilized to analyze the data. Data were expressed as mean  $\pm$  standard deviation (SD). The

Kolmogorov-Smirnov and Shapiro-Wilk tests were used to test normality of data. One-way analysis of variance (ANOVA), Tuckey post-hoc and paired t-test were used to analyze marginal bone loss (MBL) data. Wilcoxon signed rank and Friedman tests were used to analyze soft tissue outcomes. The prosthetic maintenance data was presented as total maintenance events in each category through the whole follow-up periods and their percentages from the maintenance requirements needed for each group. Any P-value  $\leq 0.05$  was considered significant.

## **RESULTS**

Fourteen completely edentulous patients (9 males and 5 females) with a mean age 59.5 years (range 49-70) were enrolled in this study. They all received new complete dentures. For each patient, two root form implants were inserted in the mandibular canine region following delayed implant-loading protocol (after 3 months).

This study used split mouth design where in each patient the two implant-abutment connections were used and were randomly allocated in the right or left sides. The grouping was assigned according to the implant-abutment connection used; Group I the implant with conical IAC in one side and group II received an implant with trilobe IAC in the contralateral side according to split mouth study design.

All implants were successful 12 months post loading, but in the 24th months (2 years) follow up visit an implant (with trilobe IAC) in the right side of a 68-year-old female patient showed signs of failure (peri-implantitis and looseness). The patient refused to have the implant substituted and to continue in the study. Accordingly, the implant survival rate in conical and trilobe IAC groups were 100% and 92.8% respectively.

## Peri-implant hard and soft tissues outcomes

### Marginal bone loss (MBL)

During each follow up period MBL was evaluated at the mesial and distal side of each implant in Group I and II. A paired t-test was done to compare the MBL at mesial and distal sides of each implant. No significant difference was found between mesial and distal MBL in all implants ( $P < 0.05$ ). Hence, the mean of the mesial and distal MBL for each implant was calculated.

The mean  $\pm$  SD of marginal bone loss in Group I (GpI) were  $0.61 \pm 0.10$ ,  $0.67 \pm 0.12$ , and  $0.74 \pm 0.18$  at 0-6, 0-12 and 0-36 months follow up visits respectively. The mean  $\pm$  SD of marginal bone loss in Group II (GpII) were  $0.63 \pm 0.11$ ,  $0.88 \pm 0.13$ , and  $1.05 \pm 0.22$  at 0-6, 0-12 and 0-36 months follow up visits respectively. (Table 1 and Fig. 5) On examining the MBL, two and three implants, in the 0-12 and 0-36 months follow up periods in group I respectively, showed a slight bone deposition.

To explore the effect of time on MBL in each group individually, One-way ANOVA test was conducted. In group I, no significant difference was found between MBL in follow up periods ( $P > 0.05$ ). On the contrary, there was significant difference in group II between MBL in follow up periods ( $P < 0.05$ ). Accordingly, a Tuckey post-hoc test was done to compare MBL in all follow up periods in group II, a significant difference was found between all follow up periods when compared individually to 0-6 follow up and to each other ( $P < 0.05$ ).

To investigate the effect of IAC on MBL, a paired t-test was done to compare MBL in group I to that in group II at each follow up record. On comparing MBL in 0-6 months in both groups, no significant difference was found ( $P > 0.05$ ). On the other hand, at 0-12 and 0-36 months follow up periods a significant difference was found ( $P < 0.05$ ).

TABLE. (1) Descriptive statistics of marginal bone loss (mm) for group I (conical IAC) and group II (trilobe IAC) in all follow up periods.

	Group I (mm) (Mean $\pm$ SD)	Group II (mm) (Mean $\pm$ SD)	t-test P-value
0-6 m Follow-up (n=14)	$0.61 \pm 0.10$	$0.63 \pm 0.11$	0.61
0-12 m Follow-up (n=14)	$0.67 \pm 0.12$	$0.88 \pm 0.13$	0.000
0-36 m Follow-up (n=13)	$0.74 \pm 0.18$	$1.05 \pm 0.22$	0.000
ANOVA P-value	0.13	0.000	

*P-value  $\leq 0.05$  is considered significant*

### II- Modified Sulcus Bleeding Index (mSBI), modified Gingival Index (sGI) and modified Plaque Index (mPI)

Mean  $\pm$  standard deviation (SD) of the modified Sulcus Bleeding Index (mSBI), modified gingival Index (sGI) and modified Plaque Index (mPI) for 0, 6, 12, 24, 36 months follow up visits was calculated (Table 2 and fig. 1b,a,c). To explore the effect of time on mSBI, sGI and mPI scores, Friedman test was done. There was a statistically significant difference between the scores in group I and II at 0, 6, 12, 24 and 36 months follow up visits.

The means of the mSBI and sGI scores showed an obvious increase at the 6 months follow up visit compared to that at the first follow up visit (baseline) in both groups. Afterwards, the means in both groups started to gradually decrease in the subsequent visits (12, 24 and 36 months). On the other hand, the means of the mPI scores in group I and II showed an obvious increase at the 6 and 12 months follow up visits compared to the first follow up visit (baseline) scores. Afterwards, the means of the mPI started to gradually decrease in the following visits (24 and 36 months).

Wilcoxon signed-rank test was conducted to explore the effect of IAC on the mSBI, sGI and mPI scores in the study follow up visits (0, 6, 12, 24 and 36 months). Although the means of mSBI, sGI and mPI scores in group I were lower than those of group II in 93.3% of the study follow up visits, Wilcoxon test showed no statistically significant difference between them.

**Prosthetic maintenance**

The technical complications and prosthetic maintenances performed according to their category throughout the whole study period (36 months) were recorded, tabulated and their percentages to the sum of prosthetic maintenances required for each group separately are shown in table 3. The technical complications and prosthetic maintenance

TABLE (2). Descriptive statistics of the modified Sulcus Bleeding Index (mSBI), simplified gingival Index (sGI) and modified Plaque Index (mPI) in group I and II in all follow up visits

Follow-up	Group I (Mean ± SD)	Group II (Mean ± SD)	Wilcoxon test P-value
<b>Modified Sulcus Bleeding Index (mSBI)</b>			
0 m (n=14)	0.22 ±0.0908	0.28 ±0.12	0.375
6 m (n=14)	0.69 ±0.47	0.77 ±0.45	0.727
12 m (n=14)	0.46 ±0.27	0.54 ±0.57	0.432
24 m (n=14)	0.39 ±0.18	0.51 ±0.22	0.06
36 m (n=13)	0.33 ±0.15	0.43 ±0.21	0.642
Friedman Test P-value	0.005	0.034	
<b>Simplified gingival Index (sGI)</b>			
0 m (n=14)	0.23 ±0.20	0.33 ±0.18	0.453
6 m (n=14)	0.76 ±0.52	0.89 ±0.60	0.125
12 m (n=14)	0.55 ±0.39	0.73 ±0.51	0.180
24 m (n=14)	0.46 ±0.19	0.60 ±0.28	0.289
36 m (n=13)	0.41 ±0.21	0.55 ±0.24	0.109
Friedman Test P-value	0.003	0.018	
<b>Modified Plaque Index (mPI)</b>			
0 m (n=14)	0.00 ±0.00	0.00 ±0.00	1.000
6 m (n=14)	0.45 ±0.24	0.53 ±0.31	0.125
12 m (n=14)	0.62 ±0.38	0.69 ±0.16	0.063
24 m (n=14)	0.51 ±0.20	0.56 ±0.27	0.083
36 m (n=13)	0.46 ±0.24	0.50 ±0.21	0.065
Friedman Test P-value	0.002	0.013	

*P-value ≤ 0.05 is considered significant*

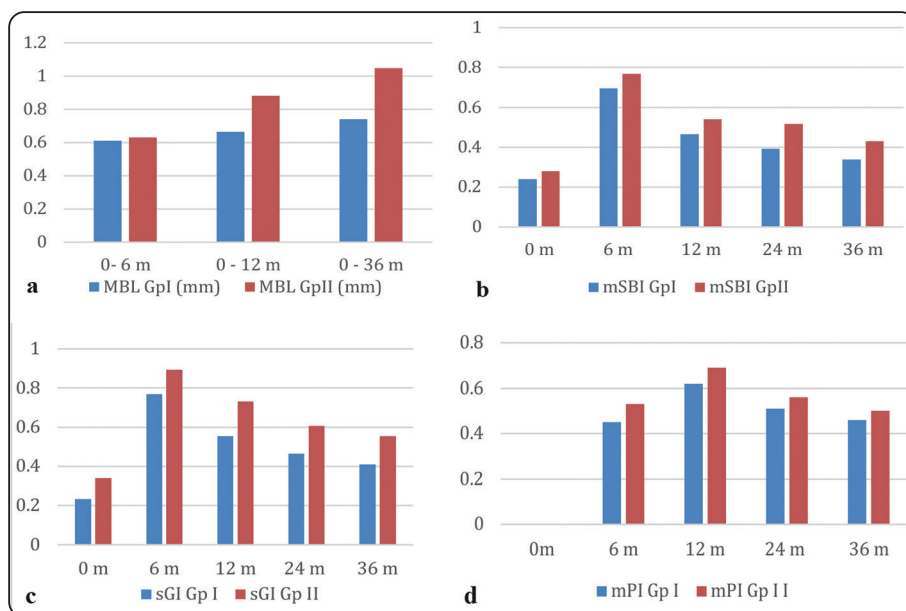


Fig. (5): a) Mean marginal bone loss (MBL), b) mean modified sulcus bleeding index (mSBI), c) mean simplified gingival index (sGI), d) mean modified plaque index (MPI) all calculated from 0 to 36 months follow up period.

requirements were lower and less frequent in group I than in group II in all categories and their sum and percentages were less in group I (12 (22%)) compared to group II (38 (78%)).

The most frequent technical complication and prosthetic maintenance requirement was reactivation of attachment retention in both groups which was 48% of the prosthetic maintenance requirements. In group I and II, 6 and 18 attachments needed replacement of the nylon cap. The second most frequent technical complication and prosthetic

maintenance requirement was abutment screw loosening and retightening in both groups which was 30% of the whole prosthetic maintenance requirements. In group I and II, 4 and 11 attachments needed retightening of the abutment screw. One abutment screw was fractured in group I and it was retrieved using an ultrasonic scaler while no abutment screw fracture occurred in group I. Two and three metal housings were lost and replaced in the dentures fitting surfaces in group I and II respectively.

TABLE (3) The prosthetic maintenance requirements along the whole study period (36 months) for group I and II

Prosthetic maintenance	Group I	Group II	Total
Abutment screw loosening and retightening	4 (33%)	11 (29%)	15 (30%)
Implant fracture and replacement	0 (0%)	0 (0%)	0 (0%)
Abutment screw fracture and retrieval	0 (0%)	1 (03%)	1 (2%)
Metal housing loss and replacement	2 (17%)	3 (08%)	5 (10%)
Metal housing deformation and replacement	0 (0%)	2 (05%)	2 (4%)
Metal housing worn out and replacement	0 (0%)	1 (03%)	1 (2%)
Metal housing fracture and replacement	0 (0%)	0 (0%)	0 (0%)
Reactivation of attachment retention (nylon cap replacement)	6 (50%)	18 (47%)	24 (48%)
Worn ball (abutment) and replacement	0 (0%)	2 (05%)	2 (4%)
Fractured ball (abutment) and retrieval	0 (0%)	0 (0%)	0 (0%)
<b>Total</b>	<b>12 (22%)</b>	<b>38 (78%)</b>	<b>50</b>

## DISCUSSION

Precision and Stability of the IAC must be achieved to provide for long-term success of implant therapy. Implant abutment connection is a principal factor of the stability of implant supported prostheses where it is the transition from the surgical to the prosthetic stage. The manufacturers provide modifications in the implant-abutment connection design to increase the prosthetic stability, decrease stress on the bone-implant interface and the implant-abutment gap that has been reported in several implant systems<sup>41</sup>.

Conical connection is considered one of the best IACs. Its main advantage is load transfer through two conical constructions that results in restricted abutment loading. This design makes separation of the interior of an implant from the surrounding tissues thus limiting microleakage<sup>42</sup>. This type of connection offers better resistance to abutment movement, fatigue loading, maximum bending, torque loss, superior bacterial seal compared to other connection systems<sup>20</sup>. Most of the research work comparing conical connection to other types, especially with trilobe connection, were in-vitro studies.<sup>43-45</sup>

Dental implants loading circumstances during function in the oral cavity is a complicated process that is affected by neuromuscular control and other intervening factors. Few studies evaluated clinically the effect of IAC on either marginal bone loss, peri-implant soft tissue or prosthetic maintenance.<sup>46-48</sup>

The conservation of the marginal bone height is controlled by the mechanical and microbiological characteristics of the IAC. In both groups, marginal bone loss did not exceed 1.5 mm in the first year follow up, which is agreed to be the standard range of any successful implant through the first year.<sup>49</sup> Survival rate of conical and trilobe IAC were 100 % and 92,8 % three years post implant loading. This high survival rate may be attributed to the strict patient inclusion criteria, precise implant planning,

implant-related factors, meticulous surgical technique, careful post-insertion loading follow-up.

In the current study, conical IAC group showed significantly lower MBL compared to the trilobe IAC group in the follow-up periods except at the first follow up period. In this period (0-6m), the peri-implant marginal bone loss is probably an adaptive response to healing not threatening implant anchorage and not essentially predictive for MBL in the following follow-up periods.

Furthermore, there was statistically insignificant difference in MBL, in conical IAC group, between the MBL in all follow up periods of the study. This may be attributed to its superior mechanical and biological performance compared to other systems.<sup>20,41,42,50</sup> Several in-vitro studies reported that conical IAC can be more stable than flat-to-flat connections because the implant abutment gap is reduced and subsequently the bacterial penetration is decreased<sup>41,43,50,51</sup>. Additionally, the stress concentration at abutments vertices is significantly less in conical compared to trilobe IAC<sup>23</sup>. Research concluded that the trilobe IAC has the greatest micro gap compared to other IACs and showed greater bacterial leakage than conical IAC<sup>24,52</sup>.

In a three- dimensional finite element analysis, it was found that the stress generated by tri-lobe IAC on bone was double the cone IAC generated stress<sup>53</sup>. This may be attributed to that fact that the frictional fit between components of the conical IAC absorbs more stress and dissipates less stress to the adjacent bone creating wedging effect and cold welding between IAC components improving IAC joint stability against lateral forces. This helps transmission of loading force lengthwise the conical surface, dispensing the stress on the implant and dramatically reducing biomechanical complications<sup>20,54</sup>. All these findings may explain the significant difference in MBL between conical and trilobe IAC groups in 0-12 m and 0-36 m follow up periods. Additionally, these outcomes also explain the

insignificant difference in MBL between follow up periods in the conical IAC group.

In conical IAC group, two and three implants showed a slight marginal bone gain in the 0-12 and 0-36 months follow up periods respectively. This may be explained by the fact that implant surface in the used system is soluble blast media of hydroxyapatite crystals with a medium rough surface which provides a superior implant bone contact in addition to the previously mentioned superior biomechanical characteristics of conical IAC; minimal micro-motions reduced microgap, and better dissipation of loading at the implant abutment interface and the peri-implant tissues<sup>15</sup>.

It is critical to detect the occurrence of inflammation at early stages, because early implant failure is an unnecessary financial load on the clinician and the patient. Peri-implant tissues' clinical evaluation is crucial to foresee early signs of disease and properly executing the suitable therapy. Early diagnosis of early phases of peri-implantitis is essential to lessen the need of treating an active peri-implantitis<sup>32</sup>.

In the current study, there was a statistically significant difference between the soft tissue outcomes scores (mSBI, sGI and mPI) at 0, 6, 12, 24 and 36 months follow up visits scores in conical and trilobe IAC groups compared with time in each group separately. At first in both groups, mSBI and sGI scores started to increase from the 0 month to the 6 months follow up, then started to decrease afterwards in the following visits. The same happened in the mPI scores in both groups but the decline in the scores started after the 12-month follow-up visit.

These outcomes may be due to effect of implant loading in the first six month and the fact that five patients did not strictly follow the oral hygiene instructions given to them which led to elevating their scores. These patients were asked firmly to precisely follow the oral hygiene instructions and

were needed to have review visits. They were also motivated to achieve success of their implant-assisted overdentures.

Additionally, this significant difference in soft tissue outcomes within the same group may be due to the relatively long follow-up period (3 years). This result is consistent with another study results that stated that statistically significant results may be attained by the longer research period<sup>55</sup>.

Although insignificantly different, the means of mSBI, sGI and mPI scores in conical IAC group at all follow up visits were lower than those of trilobe IAC group in 93.3% of the study follow up visits. This outcome might be due to the unique structure of the conical IAC with a matching taper shape and an equal angle between the abutment and implant wall creating an intimate contact and a considerable amount of mechanical friction locking. Consequently, this design is stable under static load, reduces microgap under dynamic load and prevents micromovement<sup>56</sup>.

The microgap in conical IAC (2-3  $\mu\text{m}$ ) is extremely reduced, thus providing a better bacterial seal compared to other IACs<sup>57</sup>. Microgap bacterial contamination causes an inflammatory response in the peri-implant soft tissue. The Satisfactory peri-implant soft tissue assessment results are likely to be related to the optimum marginal bone support owing to the low MBL. This result of the present study is consistent with a study which concluded that morse taper was more effective in preserving the stability of the peri-implant hard and soft tissue<sup>58</sup>. The lower mPI scores around implants with conical IAC were also reported in many studies<sup>56,58,59</sup>. On the contrary, a study failed to prove that conical IAC can significantly have lower mPI scores<sup>60</sup>.

The probability of complications development increases as the functional period of the prosthesis increases. Accordingly, the prosthetic complications and maintenance requirements that were specific to the IAC were recorded along three years follow

up period. The total prosthetic maintenance events were 50 in both groups together. The most frequent prosthetic maintenance requirement was the reactivation of retention and replacement of nylon cap in both groups. This may be due to wear of nylon cap due to repetitive removal and insertion every day which led to loss of retentive force of the attachment<sup>61</sup>.

In general, the technical complications and prosthetic maintenance requirements were lower and less frequent in conical IAC group than in trilobe IAC in all categories. This outcome is in accordance with other studies outcomes<sup>47,55</sup>, where conical IACs displayed the least prosthetic complications and maintenance services compared to other IACs. In the screw loosening category, 4 and 11 implants got slightly loose in conical and trilobe IAC. This may be attributed to the more stable design and superior biomechanical inherent properties of the conical IAC<sup>20,59</sup>.

In contrast to the conical IAC, cold welding does not occur in the trilobe connection leading to a greater microgap and micromotion at the interface during clinical loading. This may lead to stress on the abutment screw and therefore loss of preload and loosening of screw. Additionally, the larger contact area and deeper interface position inside the implant in conical IAC permitted broader stress distribution and better stability<sup>53</sup>.

Moreover, the self-locking mechanism of conical connections providing a tight contact pressure between the abutment and the implant reducing the microgap size significantly. Additionally, conical connections possess a frictional resistance stabilizing the abutment, changing a two-piece connection to function as a single piece. Subsequently, the conical IAC provides superior mechanical performance resulting in an extremely consistent implant-abutment connection stability<sup>50</sup>.

All these superior characteristics inherited in the conical implant connection may have motivated the

patients and encouraged them to bite more efficiently on the conical implant side. Consequently, this may have caused the four screw loosening incidences in the conical IAC due to patients' feeling more secured to bite more on the conical IAC implants sides thus increasing the bite force (load) in these groups. This finding is consistent with another split mouth study which concluded that maximum bite force is significantly greater in the conical compared to trilobe IACs<sup>47</sup>.

Furthermore, screw preload torque and abutment materials may influence the prosthetic maintenance outcomes<sup>62</sup>. Regarding the screw fracture incidence in trilobe group, it may be due to the frictional nature of conical IAC and the higher magnitude of Von Mises stresses concentrated at the edges of tri-lobe connection which might cause higher crack tendency leading to increased incidence of screw microfractures<sup>23,53</sup>. Future longer-term research should assess if this difference between the conical and trilobe IAC systems is validated.

## CONCLUSION

Within the limitations of this study, it was concluded that the implant abutment connection in mandibular implant assisted overdenture cases may influence marginal bone loss and prosthetic maintenance requirements. The conical implant-abutment connection can be associated with significantly less marginal bone loss and prosthetic maintenance requirements offering a more stable implant system compared to the trilobe Implant-abutment connection.

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