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INFLUENCE OF DISTAL EXTENSION BAR ON HARD AND SOFT TISSUE OUTCOMES AROUND TWO IMPLANTS SUPPORTING A MANDIBULAR OVERDENTURE: A 5-YEAR CLINICAL TRIAL

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ABSTRACT

Objectives: This randomized clinical trial aimed to investigate the potential influence of a short distal extension bar on marginal bone and soft tissues around a mandibular two-implant overdenture (2-IOD).

Patients and Methods: Thirty participants (18 males, 12 females) were randomly assigned to receive new maxillary complete denture, opposed by mandibular cast-bar-retained 2-IOD by using either a straight bar and a single clip as control group (SB) or bar with bilateral 7-mm distal extension and 3 nylon clips as intervention group (DBE). Peri-implant marginal Bone Loss (PiBL) and clinical soft tissue parameters were evaluated during a 5-year follow-up. Data were analyzed to detect differences between groups or time points.

Results: Study data were collected from 26 patients (9 females and 17 males) and were analyzed after considering 4 patients as dropouts. PiBL in both groups significantly occurred after the first year when compared with other time points, which showed a slower rate. Distal aspect in DBE showed statistically significant less bone loss when compared to the mesial aspect in the first two years. Both mesial and distal aspects recorded non-significant differences between SB and DBE groups when they were compared at any of the time points. DBE group registered improved clinical parameters compared to SB group during the evaluation periods. At the end of the study, there were no differences between groups for most indices.

Conclusions: Within the considered limitations, Mandibular 2-IOD supported by a bar with short distal extensions can provide predictable outcomes regarding peri-implant hard and soft tissues.

KEYWORDS: Edentulous mandible, two-implant overdenture, distal extension bar, peri-implant bone loss, peri-implant soft tissue

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INTRODUCTION

Conventional complete denture wearers still suffer from functional shortcomings such as impaired chewing capacity, reduced bite force, psychological impact, and difficult denture adaptation.[1-6] A variety of implant-supported prosthetic designs has emerged in response to these well-known clinical conditions, depending on the quality and quantity of remaining jaw bones.[7]

Implant overdenture (IOD) is generally considered a non-invasive, low-cost, and hygienic implant therapy that offers functional stability and retention compared to fixed prostheses for rehabilitation of edentulous mandibles.[7-9] The implant number required for IODs is based on clinical considerations including; the shape of the alveolar ridge, the present vertical dimension, the prosthetic restoration of the opposite jaw, and financial benefits.[10] Consequently, two-implant retained overdenture (2-IOD) is considered the "standard of care" for rehabilitation of edentulous mandibles.[1,3]

The commonly available attachment systems include splinted attachments (such as different bar designs), or individual attachments (such as ball studs, Locator, magnets, and telescopic crowns).[6,11] A Cochrane review on IODs concluded that there is too little evidence to support the effectiveness of one attachment system over the others on prosthodontic maintenance, prosthesis retention, patient satisfaction, patient preference, or costs.[11] A network meta-analysis, concluded that all types of attachments used for 2-IOD with different implant loading protocols showed a similar effect on peri-implant health.[6]

Bar attachments are most commonly used and have been reported to improve denture stability and retention with low incidence of complications.[6,12,13,14] Bars also contribute to load sharing and stress distribution onto the connected implants.[15] The divergent implants can be compensated and achieve a better insertion path of the prosthesis, however, space requirements for different bar designs can control the access for oral hygiene, plaque retention, and soft tissue proliferation that have been considered as the major drawbacks.[16-18] However; the different characteristics of bars lead to different biomechanical behaviors, clinical and prosthetic outcomes such as implant loading forces, retention forces, need for maintenance, and patient satisfaction.[2,8,9,12,13,18]

IODs supported by 2 implants connected by a bar inherently reduce cost and surgical morbidity where the anatomical or financial limitations preclude placing four implants. *Meijer et al.*[20] reported similar outcomes regarding clinical complications, radiographic bone loss, and patient satisfaction between IODs supported by 2 or 4 implants. A meta-analysis detected no significant difference in peri-implant marginal bone loss when 2 versus 4-implant supporting bar overdentures were compared.[21] *Meijer et al.*[22] studied marginal bone loss around different implant systems supporting mandibular 2-IODs. The authors found no statistically significant differences in clinical value between the three implant systems after a 5-year observation period.

The placement of additional implants in the posterior region of the mandible to support IOD presents a considerable challenge to the practitioner.[23] These additional surgical procedures imply a more invasive surgery, higher treatment costs, and risks of increased morbidity of the patient.[7,8] Mandibular implant splinting with a long bar might also interfere with mandibular flexure and jeopardize implant success.[24]

Distal cantilevers may be preferred to provide additional posterior support, create a more stable overdenture against lateral and rotational forces, and protect the denture-bearing area from overloading by functional forces.[2,7,15,25,26] This approach can contribute to improved chewing efficiency, enhanced

patient satisfaction, reduced ridge resorption, and stable occlusion over time.[2,23,27] However; the higher the distal extension length, the more stress it causes on the peri-implant bone.[27,28] Cantilevers may lead to high loading impact with frequent screw loosening, more prosthetic complications, and fracture of soldered bars.[16,19,26]

Controversies have been established to determine the maximum cantilever extension length in order to improve the predictability of this approach. Distal extension bars of less than 1.5 times of anteroposterior distance and supported 4-implant IODs showed no adverse serious effect on either the degree of distal bone loss or the implant survival rate.[7,16] Moreover, studies have reported that using 3 or more implants with distal cantilevers up to 12 mm long has no negative effect on marginal bone alterations around implants.[7,26,29] Implant overloading may be generated under mandibular 2-IODs via the hidden cantilever that occurs when a rigid bar design does not allow the free overdenture rotation at the first molar region, particularly with a lack of proper posterior soft tissue support.[16] In vivo force measurements and biomechanical studies reported that short distal cantilevers up to 7 mm could increase denture stability against non-axial loading and prevent generating the high strain around the two implants.[15, 24, 28] *Mericske-Stern et al*.[10] recommended that distal cantilevers should not exceed the area of the first premolar taking into account that their total lengths must be shorter than the central bar segment.

From a biological perspective, distal cantilever reconstructions may lead to a reduced accessibility to adequate oral hygiene, and subsequently, endanger peri-implant tissue health.[2,13,14] A 5-year prospective radiographic study observed that the IOD group retained by distal extension bars on two canine implants recorded peri-implant bone loss violating the acceptable range of success criteria after the first year of function.[23] Surprisingly, 1-year controlled trial found no significant changes in bone loss between CAD-CAM milled bar with 15-mm long distal extensions compared to the prefabricated stud attachment supporting mandibular 2-IODs.[27]

To date, the clinical impact of distal bar extension on the peri-implant tissues is still unknown, but mostly, no negative outcome has been reported in several published studies. [10, 15, 24, 28] Current systematic reviews recommended randomized clinical trials (RCTs) to compare different overdenture attachments in order to draw a clear conclusion from their results.[6,11] To the knowledge of the authors, RCTs investigating the effect of distal bar cantilevers on peri-implant tissue health under 2-IOD are scarce in the literature. The primary aim of the present randomized clinical trial was to investigate the potential influence of distal 7mm-bar extension on marginal bone loss around mandibular 2-IOD. The null hypothesis was that bar design with a distal cantilever (DBE as the intervention group) or straight bar without a cantilever (SSB as a control group) would have no significant difference on peri-implant bone loss after the first year of the 5-year observational period. Peri-implant mucosal conditions were also investigated as a secondary outcome measure.

MATERIALS AND METHODS

Patient selection

Forty-three subjects with conventional complete dentures were recruited for the study from the outpatient clinic of the Prosthodontics Department, Faculty of Dentistry, Mansoura University between December 2018 and March 2019. They were suffering from insufficient stability and retention of their existing mandibular dentures.

The inclusion criteria in this study were: 1) Fully edentulous patients wearing technically acceptable conventional dentures for at least 6 months and still complaining from lower denture instability

problems. 2) Adequate bone quantity and at least 15 mm mandibular vertical bone height as registered in initial screening of panoramic radiograph. 3) Classes 1-3 bone density according to *Lekholm & Zarb*[30] to receive implant size 13×4 mm as verified in the canine area by preoperative cone beam computerized tomography. 4) Class IV or Class V resorption pattern of posterior mandible according to *Cawood & Howell*[31] classification. (knife-edge ridge form, or flat ridge form assessed by clinical inspection. 5) class I restorative space according to *Ahuja & Cagna*[32] (at least 15 mm available space exists by measuring the distance between the fitting surfaces and incisal edges of the existing mandibular dentures. 6) agreement to receive a new set of full dentures and implant treatment at no cost.

Patients were excluded if they had one of the following criteria: parafunctional habit (e.g., bruxism or clenching), habits such as heavy smoking (>10 cigarettes per day) and alcoholism, history of periodontal diseases, systemic-related cause of bone diseases (e.g., uncontrolled diabetes, osteoporosis, and parathyroidism) that may affect implant osseointegration, history of congenital or acquired uncontrolled bleeding, history of radiation therapy in the head and neck region, and use of medications that might affect soft or hard tissue wound healing such as use of steroids or immunosuppressant drugs. Patients with history of previous implant failure, need for grafting procedures, or those unable to commit to the scheduled follow-up visits were also excluded.

Thirteen subjects were excluded for reasons reported in study flow chart **(Figure 1)**. Thirty participants (18 males; 12 females) were eligible for the study. All study participants were fully informed about treatment options, the purpose and method of the study as well. Each individual had signed

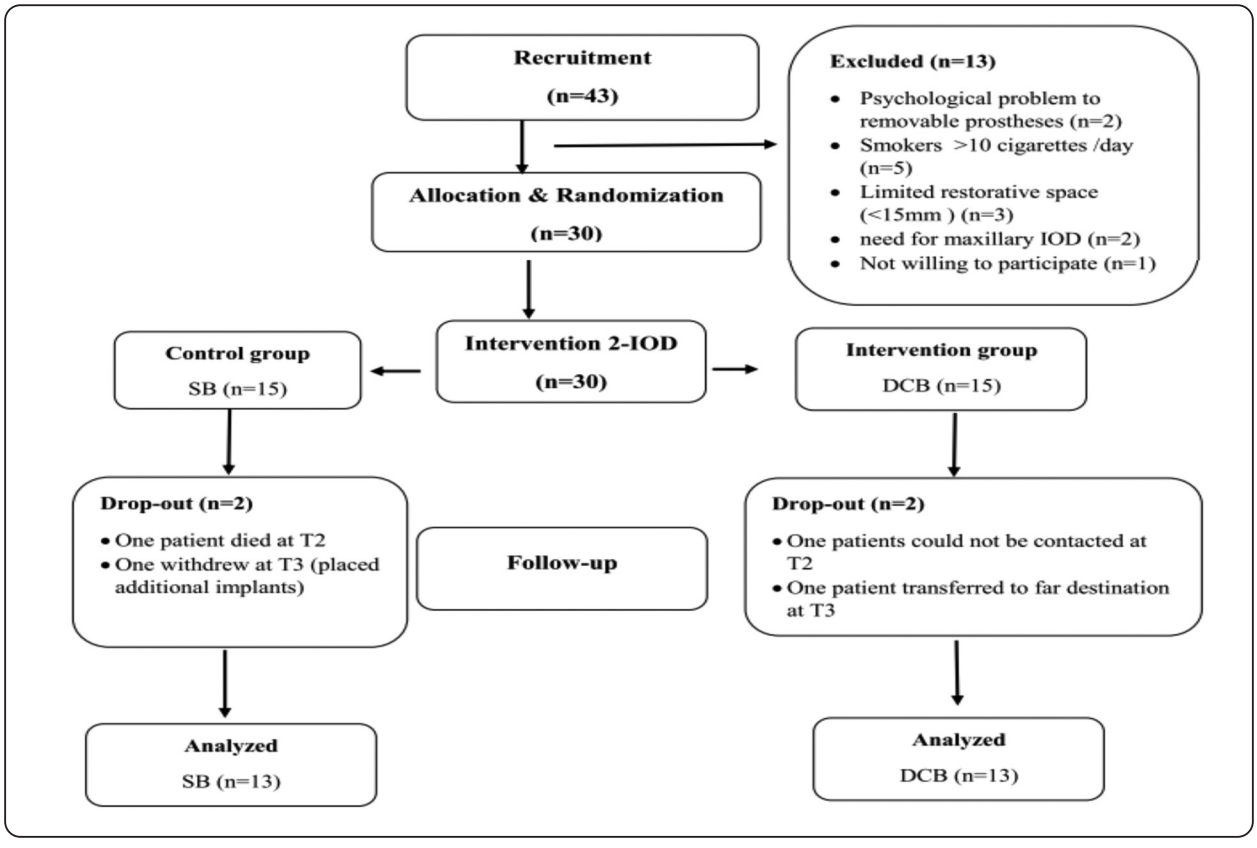

Fig (1) Flow chart of the study groups.

a consent form before receiving two inter-foraminal implants in the mandible, a new maxillary complete denture, and a new mandibular bar-retained IOD. Each patient was given a detailed description of the planned procedures and agreed for frequent recalls throughout the 5-year follow-up period of the study.

The study protocol was revised and approved by the Faculty Ethics Committee (No: A0107024RP). Clinical outcomes were reported following the revised CONSORT statement for reporting randomized trials.

Sample Size Calculation

Sample size was calculated for this trial assumed a confidence level of 95% and power of 80% (two-tailed and α was set at 0.05). The calculations were based on results from a previous study,[23] in which the authors found a clinical significant difference in marginal bone loss around implants supporting mandibular bar-retained overdentures between the base line and 1st year after loading. The power analysis was performed using free calculators available online "http://www.biomath.info". The calculated total sample size is 25 patients. If the allowance of 15% is assumed for the anticipated dropouts, the corrected sample is 30 subjects. A sample size of 15 patients per group was deemed necessary with allocation ratio 1:1. Two-tailed test was used to determine whether overdentures supported by two implants and cantilevered bar significantly change peri-implant bone loss after the 1st year.

Randomization and allocation

Balanced randomization procedure and stratification of confounders were performed to create equal distribution within the trial groups with respect to baseline criteria mentioned in Table 1. Allocation to one group of bar designs utilized sequentially numbered envelopes technique (SNOSE).[34]

Pre-surgical prosthetic and radiographic procedures

Fabrication of a new set of maxillary and mandibular conventional dentures was standardized according to prosthodontic principles. Semi-anatomical artificial teeth *(Vitapan, Vita Zahnfabrik, Germany*) were arranged in lingualized balanced occlusion with no anterior teeth contact in the maximal intercuspal position. Processed conventional dentures were inserted and allowed for settling at least two weeks post-insertion. The mandibular denture was modified at the canine position to act as a radiographic template. CBCT scans *(i-CAT device; Imaging Sciences Intl, Hatfield, PA, USA)* were performed for each patient with radio-opaque markers by using the dual-scan method.[35]

TABLE (1) Patient demographic data at the start of the study

Demographic	SB	DBE	Test of significance	df	*P*-value
Age (yrs)	63.35±9.45	62.66±8.51	t=0.196	24	0.846
Gender (Male/Female)	8/5	9/4	X^2=0.170	24	0.680
Being Edentulous (yrs)	4.8 (2.3-8.3)	6 (2-11.5)	Z=1.08	24	0.28
Posterior Mandibular Height (mm)	17.4 ±1.47	17.27±1.41	t=0.395	24	0.696
No. of Previous Dentures	1 (1-2)	1 (1-3)	Z=0.105	24	0.917
Bone Quality (D1-3)	2 (1-3)	2 (1-3)	Z=0.227	24	0.821

X^2=Chi-Square tetst , t :Student t test , Z:Mann Whitney U test df:degree of freedom

Pre-operative implant planning was made using software *(OnDemand3DApp Software; CyberMed Inc, Seoul, South Korea)* to place the virtual parallel implants at the proposed canine area bilaterally. A mucosally-supported stereolithographic surgical guide was fabricated by using rapid prototyping technology. Each patient received two NanoTite™ Tapered Certain implants® with internal connection *(BIOMET 3i, Palm Beach Gardens, FL, USA)* of 13 mm long and 4 mm diameter in the canine regions.

Surgical Procedure:

All surgical procedures were performed by the same blinded surgeon. All patients were under local anesthesia (lidocaine 2% with 1:100,000 epinephrine). Crestal incision with vertical releasing incision is made with slight flap reflection to allow for proper plateauing of the osteotomy site if needed before drilling. A standard two-stage surgical protocol using sequential drilling was followed. Drilling was made starting with the pilot drill and then sequential drilling with copious normal saline irrigation to complete the osteotomy. Guiding pin was placed in the first osteotomy site to aid in the preparation of the other osteotomy site, to insure parallelism during drilling. A manual torque wrench of at least 35 Ncm was applied at implant insertion. Countersink drill was used to seat the implant platform at the level of bone crest. Wound closure was performed with interrupted sutures *(Ethicon Inc, Johnson & Johnson co., USA)*. Postoperatively, patients were administered ibuprofen 600 mg TID, 1000 mg amoxicillin and clavulanic acid BID orally for one week after surgery. Clindamycin 300 mg TID was given orally for patients with a penicillin allergy. An antiseptic mouth rinse of chlorhexidine 0.12% TID was prescribed for rinse 15 to 30 seconds. Patients were not allowed to wear their dentures for 10 days, after which, sutures were removed and mandibular denture was relieved at the surgical site and refitted to the ridges using an autopolymerized silicone material *(softliner, Promedica, Germany)*, and then the occlusion was refined.

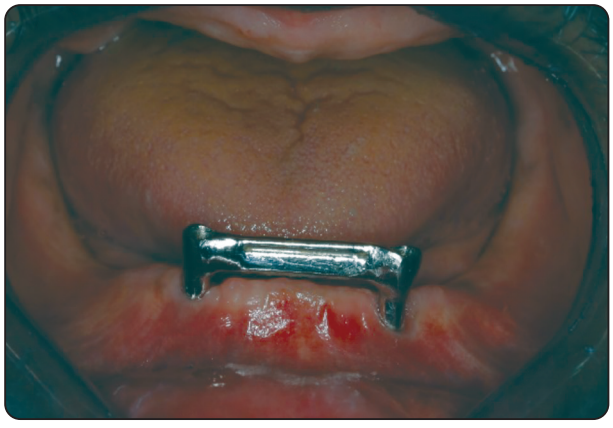

Fig (2) Control group with straight bar (SB)

Following an osseointegration period of 3 months, the stereolithographic surgical guide with a tissue punch were used to uncover the implants. Healing abutments of suitable gingival heights were fastened to the implants for 2 weeks during which, the mandibular dentures were relieved and refitted again using a soft relining material.

Fabrication of new mandibular 2-IODs were standardized opposing the existing maxillary dentures. A two-stage selective pressure impression technique on mandibular custom tray with two holes at implant sites was used as described by Jannesar et al.[36] Posterior ridge areas were recorded by using zinc- oxide non-eugenol paste (*Cavex outline, Holland*) while the anterior inter-implant area was recorded by injecting polyether impression material *(Impregum F, 3M ESPE, St. Paul, MN)* around the long-pin transfer copings.

Autopolymerized acrylic resin was used to splint the transfer copings to the outer surface of the tray while applying finger pressure steadily on its molar area in order to relate the supporting mucosa of the posterior residual ridge to the implants anteriorly. A smooth transition between the impression materials was mandatory before pouring with hard stone *(Elite Double 22; Zhermack S.p.A, Badio Polesine, Italy)*. Mandibular occlusal rim (supported by long healing abutments) was mounted against upper denture replica using mounting jig, centric, and protrusive inter-occlusal records. Occlusion and articulation of

the dentures were evaluated. A silicon putty index was constructed on the waxed trial denture to guide the labiolingual and occlusogingival placement of the bar as described by *Lee & Agar*.[37]

Assignment

Only after final impressions and fabrication of master casts were completed, a sealed envelope was opened and every subject was randomly assigned to receive a 2-IOD that was retained with either a straight bar and a single nylon clip (SB) as a control group **(Figure 2)**; or a bar with bilateral 7-mm distal extensions and 3 nylon clips (DBE) as intervention group **(Figure 3).**

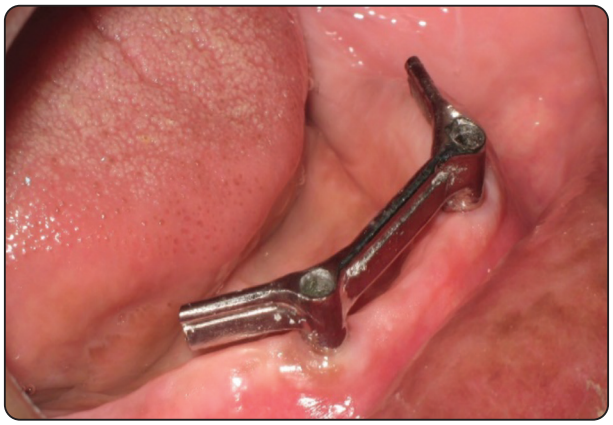

Fig (3) Intervention group with bar and short distal extensions (DBE)

Specifics of the prosthesis design for both groups involved non-hex castable-type UCLA abutments *(BIOMET 3i, Palm Beach Gardens, FL, USA)*, and a castable bar pattern *(VSP-GS, bredent, Senden, Germany)*. Median bar segment was aligned straight, parallel to incisal plane, perpendicular to sagittal plane. Short (7-mm) distal bar extensions were connected to the bar abutments and directed along the posterior ridge crest by using the paralleling mandrel tool supplied by the manufacturer and pattern resin *(GC Pattern Resin; GC Corp, Tokyo, Japan)*. Putty index was used to ensure accessible oral hygiene by providing at least 2-mm clearance space underneath the bar and to guide its positioning for sufficient bulk of acrylic denture base. The bar/abutments assembly pattern was sprued, invested, and cast into cobalt–chromium alloy *(Degussa, Germany),* finished, and polished. The metal bar assemblies were tried in the patient mouth and was verified with periapical radiographs for passive fit. The screws were tightened with a torque driver according to the manufacturer's recommendation. Bar assemblies were returned to their master casts and laboratory processing clips were snapped on bar segments with block-out and duplicated in stone casts before processing stage. Before delivery of 2-IOD, recess was created in fitting surface of the denture to accommodate yellow plastic clips (medium retention) by using direct pick up procedure and the patient closed in maximal intercuspal position while the autopolymerized acrylic resin was hardening. Lack of direct contact between denture base and the top or vertical walls of bar assembly was verified by using a silicone material *(Fit Checker II, GC Corp, Tokyo, Japan)* to avoid torsional forces and overloading of the implants. All mandibular overdentures were produced completely of acrylic resin without reinforcement and were processed by the same commercial laboratory using the same laboratory procedures, artificial teeth, and denture base materials under the supervision of the study prosthodontists. During the 1st week, the subjects were recalled for occlusal adjustment and prosthetic adaptation was reviewed.

Outcome Measures

Marginal bone level changes were collected as the primary outcome measures. While, peri-implant soft tissue conditions were monitored as secondary outcome measures.

Follow-up visits were scheduled as baseline assessment two weeks post-insertion (T0), thereafter, data collection was performed annually for 5 years (T1, T2, T3, T4, and T5) after prosthetic loading. At the recall sessions, occlusion was evaluated to ensure freedom of contact with uniformly distributed forces between attachment and supporting mandible.

Denture fitting to the underlying bearing tissues was checked using a pressure indicating paste. Changing the retentive clips or tightening the loose abutment screws were also carried out. In the case of denture fitting was not acceptable, a relining was performed and occlusion was accordingly adjusted. Additional urgent visits were performed when any patient had noticed an issue.

The same investigator recorded all peri-implant parameters. An implant was considered successful when it fulfilled the criteria of *Alberktson & Zarb*[38] which include; 1) absence of persistent subjective complains (pain, foreign body sensation, and/or dysesthesia), 2) absence of recurrent peri-implant infection with suppuration, 3) absence of implant mobility, 4) radiographic bone resorption less than 1.5mm in the first year. The annual recall program for evaluation of peri-implant conditions included peri-implant marginal bone loss (PiBL) and peri-implant soft tissue condition as well.

Peri-Implant Marginal Bone Loss (PiBL)

Peri-implant bone changes were assessed on standardized series of digital periapical radiographs (*Digora® Optime, Orion Corp./Soredex, Helsinki, Finland*) by using a film-aiming device (*Dentsply RINN, Rinn Cooperation, USA*) and long-cone paralleling technique assisted by custom acrylic template as a film-holding device.[39] The imaging software (*Scanora light version. 3.2.6*) analyzed each image by measuring the vertical distance from the implant shoulder to the marginal bone-implant contact (BIC) in mm at the mesial and distal aspects of each implant **(Figure 4)**. Differences in PiBL were analyzed by subtracting the measured bone height at each time point from the measurements of previous observation time. The recorded data were averaged at every mesial or distal aspect and then presented considering the patient as a unit.

Clinical Soft Tissue Evaluation

Modified Plaque Index (mPI) and modified Bleeding Index (mBI) were performed according to *Mombelli et al*.[40] The modified Gingival Index

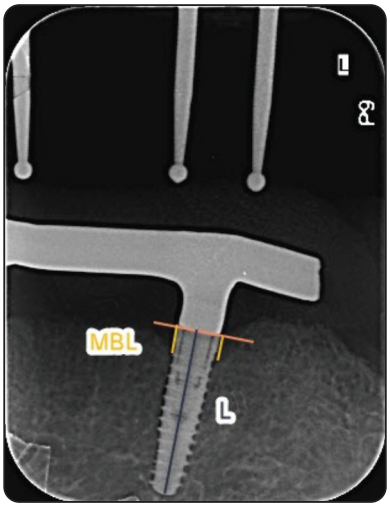

Fig (4) A standardized periapical radiograph traced for PiBL measurements

(mGI) was used to assess potential peri-implant inflammation according to the *Löe & Silness*.[41] All clinical parameters were recorded at four sites (mesial, buccal, distal, and lingual) of all implants using a calibrated pressure-sensitive plastic periodontal probe (*Hu-Friedy, Chicago, IL, USA*). Probing Depth (PD) was evaluated in mm by measuring the distance from the bottom of the peri-implant crevice to the mucosal margin **(Figure 5).** Measurement of the Gingival Crest Position (GCP) was performed by measuring the distance from the top of bar abutment, as a fixed reference point, to the highest mucosal margin around abutments. A Peri-implant Mucosal Level (PiML) was calculated by subtracting the measured GCP at each observation time from the baseline value. Negative values indicate mucosal recession while positive values indicate mucosal enlargement.

Dropouts:

Thirty patients attended the evaluation at the first year (T1) after placement of the overdentures (T0). There were missing data from two patients in DBE group because they could not attend T4 &T5 of observation (one female had lost contact and another male suffered severe illness). Their previous last observed values were used to impute missing values and they were included in the statistical

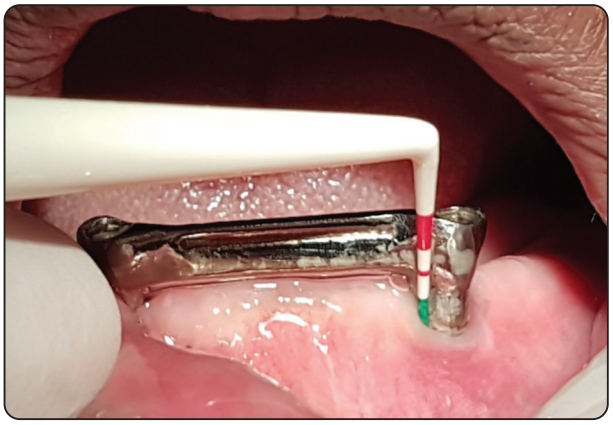

Fig (5) Measurement of pocket depth by using a graduated plastic probe.

analysis. Four patients were unavailable to complete follow-up observations; two female patients could not be contacted or attend at the time of recalls (DBE at T2, T3); one male patient withdrew and placed additional implants with augmentation in the mandible (SB at T3); another one female patient had died (SB at T2). Data sets of only 4 participants were ignored and they are considered missing (dropout rate: 4/30 = 13.3%).

Statistical analysis

The data were analyzed by SPSS® software version 26 (SPSS Inc.). Shapiro-Wilk test was used to determine the normal distribution of the data. Comparison between the observation periods was done by Friedman test with pairwise. Comparison between 2 follow up periods was done by Wilcoxon signed rank test. Comparison between the two groups was done by Mann-Whitney test (for non-normally distributed data) or Student t test (for normally distributed data)

RESULTS

All implants were successful according to the applied criteria with 5-survival rate of 100%.[38] Twenty-six (9 females and 17 males) were analyzed from the 30 patients, and their results were compared after 5 years. The intervention group (DBE) comprised 4 females and 9 males (mean age, 62.66±8.51yrs), while the control group (SB) consisted of 5 females and 8 males (mean age, 63.35±9.45 yrs). The features of study participants at the baseline are listed in Table 1 that showed no statistical difference between the trial groups ($p > 0.05$).

Tables 2 & 3 show comparisons of PiBL between mesial and distal aspect within group as well as comparisons between time points. Average PiBL after the 1st year T1 was 0.76 and 0.85 for mesial and distal aspects in SB; respectively while the average PiBL after T1 in DBE was 0.83 and 0.68 for mesial and distal; respectively. SB group showed slightly higher bone loss at the distal aspect in comparison to the mesial, but of no significant difference ($p > 0.05$). Distal aspect in DBE showed

Table (2) Comparing peri-implant bone loss (PiBL) between the mesial and distal aspects in SB group at different time points

	T1	T2	T3	T4	T5	X^2	Df	*P*-value
Mesial	0.76	0.14	0.12	0.08	0.04			
Median (min-max)	(0.46-1.41)	(0.07-0.22)	(0.02-0.18)	(0.02-0.15)	(0.0-0.16)	35.35	4	0.001*
Distal	0.85	0.14	0.12	0.08	0.06			
Median (min-max)	(0.43-1.35)[a]	(0.05-0.21) [b]	(0.03-0.17)[c]	(0.0-0.14)[d]	(0.0-0.16)[d]	39.81	4	0.001*
df	24	24	24	24	24			
Z	0.629	0.079	0.039	0.987	1.18			
***P*-value**	0.529	0.937	0.969	0.324	0.240			

Z:Mann Whitney U test (within group aspects) ***X^2= Chi-Square test value of Friedman test (between time points)***

****= Statistically significant if p<0.05*** ***df:degree of freedom***

Similar letters in same raw denote non-significant difference between follow-up readings.

statistically significant less bone loss when compared to mesial aspect at T1, T2 (p= 0.036 and p=0.001; respectively). Either mesial or distal aspects within each trial group showed high significant differences (p=0.001) over the time up to 5th year. The majority of bone loss occurred at T1 when compared with other observation times that showed slower rate. The distal aspect in DBE group recorded statistically non-significant bone loss neither between T2 and T3 nor between T4 and T5. The distal aspect in SB group recorded statistically non-significant bone loss between time points T3 and T4. Both mesial and distal aspects recorded non-significant differences between SB and DBE groups when they compared at any of the observation times (Table 4).

The data of soft tissue parameters are reported in Table 5. Baseline data showed no significant differences ($p > 0.05$) between the trial groups concerning the parameters PD, mPI, mBI, mGI, and PiML. DBE group registered a significant lower score with mPI compared to SB at T1, T2, T3 and T4 (p=0.013, p=0.013, and p=0.004, p=0.02 respectively).

TABLE (3) Comparing peri-implant bone loss (PiBL) between the mesial and distal aspects in DBE group at different time points

	T1	T2	T3	T4	T5	X^2	Df	*P*-value
Mesial								
Median (min-max)	0.83 (0.42-1.45)	0.12 (0.05-0.28)	0.09 (0.06-0.18)	0.06 (0.02-0.17)	0.04 (0.0-0.11)	42.25	4	0.001*
Distal								
Median (min-max)	0.68 (0.23-1.1)	0.08 (0.02-0.19)a	0.08 (0.03-0.16)a	0.06 (0.0-0.11)c	0.04 (0.0-0.08)c	35.17	4	0.001*
df	24	24	24	24	24			
Z	2.09	3.23	1.57	1.61	0.223			
***P*-value**	0.036*	0.001*	0.116	0.108	0.824			

Z:Mann Whitney U test (within group aspects) ***X^2= Chi-Square test value of Friedman test (between time points)***
****= Statistically significant if p<0.05*** ***df:degree of freedom***
Similar letters in same raw denote non-significant difference between follow-up readings.

TABLE (4) Comparing peri-implant bone loss (PiBL) between the mesial and distal aspects in the study groups at different time points

Time Points	SB Median (min-max)	DBE Median (min-max)	df	Z	*P*-value
Mesial					
T1	0.76(0.46-1.41)	0.83(0.42-1.45)	24	0.205	0.837
T2	0.14(0.07-0.22)	0.12(0.05-0.28)	24	0.283	0.777
T3	0.12(0.02-0.18)	0.09(0.06-0.18)	24	0.874	0.382
T4	0.08(0.02-0.15)	0.06(0.02-0.17)	24	1.01	0.314
T5	0.04(0.0-0.16)	0.04(0.0-0.11)	24	0.623	0.533
Total changes	1.18(0.76-2.02)	1.17(0.71-2.15)	24	0.437	0.662
Distal					**P-value**
T1	0.85(0.43-1.35)	0.68(0.23-1.1)	24	1.26	0.209
T2	0.14(0.05-0.21)	0.08(0.02-0.19)	24	1.88	0.06
T3	0.12(0.03-0.17)	0.08(0.03-0.16)	24	1.42	0.156
T4	0.08(0.0-0.14)	0.06(0.0-0.11)	24	1.42	0.156
T5	0.06(0.0-0.16)	0.04(0.0-0.08)	24	1.44	0.149
Total changes	1.27(0.75-1.83)	0.96(0.43-1.58)	24	1.87	0.061

Z:Mann Whitney U test ***df:degree of freedom***

TABLE (5) Comparing clinical parameters around implants between the study groups at different time points

Time points	**SB** Median [Min- Max.]	**DBE** Median [Min- Max.]	df	**Z**	***P*-value**
T0:					
mBI	1 [0.0-1]	0.0 [0.0-1]	24	1.15	0.249
mGI	0.0 [0.0-1]	0.0 [0.0-1]	24	0.0	1.0
mPI	0.25 [0.0 -0.5]	0.0 [0.0-0.75]	24	0.751	0.453
PD	2 [1.5-2.5]	2 [1.5-3]	24	1.33	0.185
PiML†	Baseline point	Baseline point	..	…	…
T1:					
mBI	1 [0.0-1]	0.0 [0.0-1]	24	1.67	0.092
mGI	1 [0.0-3]	0.0 [0.0-3]	24	0.920	0.356
mPI	0.25 [0.0-0.75]	0.0 [0.0-0.5]	24	2.49	0.013*
PD	2 [1.5-3]	3 [1.5-3.5]	24	1.29	0.194
PiML	-0.5[-2 , 0.5]	0[-1.5 , 1.5]	24	1.48	0.139
T2:					
mBI	1 [0.0-2]	0.0 [0.0-1]	24	1.72	0.086
mGI	1 [0.0-3]	0.0 [0.0-3]	24	0.928	0.353
mPI	0.5 [0.0 -1]	0.0 [0.0-0.5]	24	2.48	0.013*
PD	2 [1.5-3.5]	3 [2-4]	24	1.61	0.108
PiML	0[-2 , 0.5]	0[-2.0, 2.0]	24	0.691	0.489
T3:					
mBI	1 [0.0-1]	0.0 [0.0-1]	24	2.83	0.005*
mGI	0.0 [0.0-1]	0.0 [0.0-1]	24	0.434	0.665
mPI	0.25 [0.0-0.75]	0.0 [0.0-0.5]	24	2.89	0.004*
PD	2.5 [1.5-4]	3 [1.5-4]	24	2.06	0.04*
PiML	0[-2 , 0.5]	0[-2 , 1.5]	24	0.743	0.457
T4:					
mBI	1 [0.0-2]	0.0 [0.0-1]	24	2.77	0.004*
mGI	1 [0.0-2]	0.0 [0.0-1]	24	2.04	0.04*
mPI	0.25 [0.0-1]	0.0 [0.0-0.5]	24	2.19	0.02*
PD	2.5[1.5-3.5]	3 [2-4]	24	1.57	0.116
PiML	-0.5[-2, 0.5]	0[-2, 2]	24	1.13	0.259
T5:					
mBI	1 [0.0-1]	0.0[0.0-1]	24	1.16	0.243
mGI	1 [0.0-1]	0.0[0.0-1]	24	2.37	0.018*
mPI	0.25 [0.0 -0.5]	0.0[0.0-0.5]	24	1.63	0.104
PD	2.5 [1.5-3.5]	2[2- 4]	24	1.29	0.197
PiML	0[-2 , 1]	0[-2, 1.5]	24	0.244	0.808

To: Baseline after two weeks from ovedenture insertion.

mBI: modified Bleeding index [score 0-3), mGI: modified Gingival index [score 0-3), mPI: modified Plaque index [score 0-3), PD: Pocket Depth index [in mm), PiML: changes in Peri-Implant Mucosal Level [differences in measured values in mm).

†: initial measurement from the reference point ***Z:Mann Whitney U test*** ***Mann-Whitney test***

****= Statistically significant at p<0.05*** ***df: degree of freedom***

The average PD at T3, increased significantly (P=0.04) for DBE group (3 mm) compared to SB group (2.5 mm). The mBI and mPI were significantly higher in SB group than DBE. SB group recorded significantly higher scores for mBI, mGI, and mPI than DBE at T3 (p =0.004, p =0.04, and p =0.02, respectively). However; there was no statistically significant differences for PD between groups at T4 (Table 5). At the T5 recall period, there were no differences between groups with most indices. The only significant difference (p = 0.018) was the increase in mGI with SB group.

DISCUSSION

A bar connecting 2 implants supporting an overdenture can provide a feasible treatment option for edentulous mandibles, particularly with atrophied ridges.[22] The current study reported a high survival rate of up to 100% after 5 years in accordance with those reported in the literature. The explanation could be attributed to bone density and quality in the anterior mandible coupled with improvements in implant surface,[22, 33] even for bars with distal extensions.[25]

The resilient bar design should be straight and connect the implants in a line parallel to the mandibular hinge axis, therefore, the prosthesis rotates around the fulcrum axis in a hinging movement. Distal bar extensions are often added in order to improve prosthesis stability and limit the hinging mechanism around the bar, thus controlling the load ratio between the implant and mucosal support.[10,13,15]

The existing findings reported that most of PiBL occurred within the first year after abutment connection. A wide variability in study design and bar varieties make the results difficult to compare, however, these findings are in accordance with other studies describing bone level changes around implants.[13, 20, 23, 25, 29, 33] This may be attributed to the process of bone remodeling that mostly occur during the healing period or in response to functional load. PiBL in the present study approximated 1 mm after the first year and less than 0.2 mm in the years thereafter which is considered as an acceptable natural biological process for both groups.[38]

The current clinical findings agreed with a previous 3D in vivo study[15] that short distal cantilevers might transmit forces to the implants within the biologically tolerated range. Moreover; a recent 1-year RCT study found no significant differences in PiBL between 15-mm long distal extensions of CAD-CAM milled bar compared to the prefabricated stud attachment supporting mandibular 2-IODs.[27] Results of the present trial could be compared to the 2-IOD cantilever group in another clinical study conducted by *Elsyad et al*.[23] Their group with short cantilever reported a slightly higher bone loss in the first year (1.49 mm) and after 5 years (0.43 mm), however, that study lacked a control group. On the contrary, the present study found significantly less bone loss at the distal aspect of DBE group when compared to mesial aspect after T1.

Although PiBL in the present study was statistically significant from year to year within groups, the distal aspect in DBE group recorded statistically non-significant bone loss when comparing T2 and T3 or comparing T4 and T5. Additionally, the distal aspect with DBE group at T1 and T2 significantly recorded lower bone loss in comparison to the mesial aspect. These findings might confirm the effect of bar extensions in controlling the continued resorption of the crestal areas posterior to the distal implant the mandibles.[7] For the conventional SB group, the distal aspect recorded statistically non-significant bone loss between time points T3 and T4. These findings agree with the fact that bone level became more stable at 3rd year from loading.[33]

Non-significant values of PiBL between the mesial and distal aspects within trial groups at

different time points could be attributed to 2-mm cleaning space under bar segments that allow accessible hygienic areas and both group designs can provide good stress distribution to the implants.[8]

The variability in the amount of PiBL between studies could be attributed to different prosthetic parameters such as impression technique, bar geometry, clip material, and occlusal scheme that may influence the force patterns and contribute significantly to force distribution onto the implants and the residual ridges.[15] Different implant systems can affect PiBL but within the acceptable success range.[11,22]

The reason for reduced mPI values in DBE group compared to SB might be related to the presence of clips on the cantilevered bar segments without direct contact of acrylic resin and the load might be directed to the inner portion of the bar, limiting overdenture rotation at the posterior denture base.[23,29] Additionally; hinging overdenture around rotational axis could allow room for food stagnation and plaque accumulation around implants.[24,42] This explanation agrees with *Mericske-Stern & colleagues*[2] who observed that 40% of their study subjects complained of food impaction under bar retained 2-IODs with more hinging movements. The increased mPI observed in this study was concurrent with *Lehmann et al*.[13] who reported that mandibular bar-retained IODs showed more plaque accumulation, particularly in the cast bar groups either with or without extensions.

The significantly increased PD values (p =0.04) in DBE at T3 compared to SBB might be explained by the presence of slight soft tissue proliferation around abutments in response to the increased values in mPI during the same observation time. However; those statistical significances might be of no clinical importance because the recorded 3 mm PD in DBE group yielded healthy and successful implants and showed a lack of negative influence of an increase in the other clinical indices.[13,25,43] The present findings are concurrent with literature that reported similar plaque accumulation in bar-retained IOD over the years, while gingival trauma and occlusal loading changed over the years depending on the degree of denture rotation.[26, 42, 44]

Significantly higher mBI and mPI in SB group in comparison with DBE could be attributed to the free-hinging overdenture design that causes premature contact between acrylic denture base and distal portion of supporting implants. This biomechanical behavior emphasized the traumatizing effect and confirmed the need for creating more relief space in the lingual aspect around implants supporting 2-IODs, however, that space would facilitate more plaque retention.[44]

At T4, the higher mGI (degree of swelling and red color of the mucosa around implants) in SB group may be attributed to the higher plaque accumulation in conjugation with more denture rotation.[44] Moreover; reduced motivation for oral hygiene was reported in old patients wearing IODs.[25] The statistically significant higher indices between groups at T4 had no value of clinical significance because of the acceptable values of PD or PiBL reported in this study. The results of the current study, as demonstrated by higher mPl and mBI at T5 agree with the literature IODs are less accessible for cleaning by tongue, lip, cheeks, and saliva.[9]

A longitudinal study reported that the lower PD values result from gingival shrinkage and absence of soft tissue proliferation around abutments at the observation periods.[25] However, the dynamic changes in tissue response to 2-IOD are expected without any relevant signs of deterioration of implant success. The average scores of indices for plaque, gingiva, and bleeding were low and did not significantly differ between groups. A reasonable explanation of slightly higher indices with the control group may be SB hinging bar design that allows more denture rotation and might cause mechanical trauma to the underlying soft tissues represented as

mild signs of inflammation and mucosal redness around the implants.[44] In line with this explanation, *Katsoulis et al*.[26] reported that cantilever bar design reduces the impact of rotational movements on technical complications and clips wear. It could be considered that a vertical distance of 2 mm between soft tissue and increased inter-implant distance for a bar connecting mandibular IOD can provide enough access for oral hygiene aids.[8,17]

There is a lack of published studies investigating mucosal level changes around implants supporting 2-IODs. In the present study the independently investigated PiML showed insignificant statistical differences between trial groups at the 5th year. PiML measurement differs from other conducted studies that calculated the clinical attachment loss postulating that only the recession can occur around the abutments.[22, 33]

The current study did not investigate the correlation between PiBL and clinical parameters because the width of keratinized mucosa was not considered at the start of the study. The literature showed contradictory results among studies that reported a lack of relation[45,46] and those that reported a relationship[44]. A 5-year retrospective study conducted by *Ebadian et al*.[44] reported that higher PD was moderately associated with a higher rate of bone loss. The reasons of debate may involve; 1) PDs were reported as significantly higher in the thick maxillary mucoperiosteum than in the mandible.[46] 2) A significant relation between PD and PiBL over time might be found in cases with peri-implant diseases.[34] 3) Degree of keratinized mucosa is not usually concerned in most of studies, particularly narrower zones (< 2mm) that are prone to inflammation and its apical proliferation may occur. [30]

At the end of the study, the authors failed to find significant differences between groups in most of the clinical indices. The similar soft tissue responses to both 2-IOD designs might emerge from other factors such as the material incompatibilities (Ti vs. Cr-Co) and possible galvanic corrosion. The potential microgap at the implant-abutment interface might also contribute to increase mPI, harbor micoroorganism, tissue inflammation, and subsequent increased mBI in both groups at different observation times.[29]

The null hypothesis that distal 7-mm bar extensions would not influence the marginal bone loss, around implants supporting mandibular 2-IOD cannot be rejected. Additionally; the present study failed to prove any significant difference of clinical importance for peri-implant tissue conditions among the bar designs with or without distal extensions. The current data suggest that other prosthetic parameters such as available prosthetic space, bar/clip designing, proper impression protocol, and bar fabrication method might play an important role in controlling tissue changes around the implants.[10] Cantilevered bar supporting mandibular 2-IODs and opposed by maxillary conventional denture might have been subjected to occlusal load within the physiologic limit of bone.

The relatively small sample size and attrition are considered as limitations of the current study. Some confounders that might influence the results of the study such as width of keratinized mucosa around implants were not considered. Within the limitation of the present study, conclusions and generalizability of the results might be questionable. Further clinical trials are required to investigate the recommended cantilever lengths for 2-IODs. A larger sample size and a longer observation period should be conducted.

CONCLUSION

Mandibular 2-IODs supported by bar/clip attachment with short distal extensions can provide predictable outcomes regarding the peri-implant hard and soft tissues. However, future investigations on the influence of regular maintenance and long-term care are required for two-implant cantilevered bar overdentures in the mandible.

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