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MARGINAL BONE LOSS OF TWO IMMEDIATELY LOADED NARROW VERSUS STANDARD DIAMETER IMPLANTS RETAINING MANDIBULAR OVERDENTURES: A RANDOMIZED CONTROLLED PILOT STUDY

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ABSTRACT

Purpose: To evaluate peri-implant marginal bone loss in two immediately loaded narrow versus standard diameter implants retaining mandibular implant overdentures.

Material and methods: Twenty completely edentulous patients were collected from Outpatient Clinic of Prosthodontic Department, Faculty of Oral and Dental Medicine, Cairo University, for whom maxillary and mandibular dentures were constructed. Patients were randomly divided into two equal groups; N group which 10 received narrow (3x12 mm) and S group, 20 standard diameter implants (3.7x 12mm). Implants were immediately loaded using the previously constructed dentures, ball attachments for retention and silicone based resilient liner acting as female receptacle. Marginal bone loss was then assessed using standardized digital peri-apical radiographs at denture insertion, then 6 and 12 months later. Independent t test was used to study effect of group, while repeated measure ANOVA was used for studying effect of time on peri-implant marginal bone loss. Results were considered significant at $p \leq 0.05$.

Results: For both groups a significant difference was found among the different follow up intervals and between mesial and distal aspects of all implants at 0-6 and 0-12 months. N was associated with significantly higher bone loss if compared to S at all follow up intervals with the highest bone loss recorded at distal aspects of both groups after one year (N=1.485±0.215, S=1.062±0.125).

Conclusion: Despite of the 100% one year survival rate found in both groups of the study, immediately loaded conventional diameter implants retaining mandibular overdentures are associated with lesser marginal bone loss if compared to immediately loaded narrow diameter ones.

KEYWORDS: Narrow diameter implants, standard diameter implants, marginal bone loss, ball retained mandibular implant overdentures

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INTRODUCTION

Managing atrophic edentulous ridges has been always a challenge to prosthodontists, especially in the era of esthetics and immediate loading protocols. This problem is more obvious in mandibular ridges and is commonly associated with lack of keratinized or load bearing mucosa.[1] With the increased number of patients presenting with severely resorbed edentulous mandible and searching for implant prostheses in the last 2 decades, the problem became even bigger. Many surgical techniques involving hard and soft tissue augmentation, ridge splitting with immediate implant placement, distraction osteogenesis[2] and mini or narrow implants have been proposed to solve the problem.[3,4,5,6] Mini implants are single piece dental implants ranging in diameter from 1.8-2.9 mm, while narrow diameter implants are one or two piece implants with a diameter ranging from 3 to less than 3.7 mm.[7] Others state that mini implants with a diameter between 2.7 and 3mm are classified sometimes as hybrid implants with a two-piece design and could be used as narrow dental implants, where only two narrow implants are required to retain mandibular overdentures. Two piece narrow diameter implants are usually used with delayed loading protocols, while one piece ones are used with immediate loading protocols.[8] They have the advantage of expanding the bone while being placed, and minimizing the osteotomy size, thereby decreasing the risk of perforating the resorbed ridge.[9] Besides, it provides immediate stabilization and loading on the day of implant placement and hence requires less treatment visits[8,10,11] Moreover, flapless placement leads to minimal surgical trauma, bleeding, postoperative discomfort, and reduced healing time, in addition to easier removal and healing in case of failure.[12] Their cost is also significantly less than conventional implants.[13] Mini implants were mainly used as transitional implants to support immediately loaded prosthesis during the healing period of the standard diameter implants. However, the development that has been made in the implant shape, thread patterns and its surface treatments considerably improved the primary stability of mini implants, lead to faster osseointegration and to their recommendation by the United States Food and Drug Administration (FDA) for long term use to support and retain definitive prostheses,[14] not only for narrow ridges but also for cases with well-developed ridges and/or indicated for immediate loading.[15,16,17,18] Preoteasa et al reported a survival rate of mini implants between 88.5% and 96%, higher in the mandible than in the maxilla.[19]Worries about their use include the fact of being single piece and of small diameter, which makes them less forgiving when implants lack the required parallelism. Their small diameter jeopardized the belief in their long term survival, since it was said to be associated with higher marginal bone loss.[20,21,22] This made researchers recommend more than two mini implants to support a mandibular overdenture,[7] which might obviate their cost effectiveness and reduce the possibility of their parallel placement.[23] Overdentures retained by two mini implants have been, therefore, suggested by some authors.[23,24, 25] Occlusal loading could be reduced on the implants by using implant length not less than 10 mm[26] and by incorporating soft liners to act as female receptacles for the ball attachment-retained overdentures.[27] Soft liners are simple, inexpensive, and easy to replace. They provide a shock absorbing effect[28,29] which is highly required in immediate loading protocols, and overcome many treatment problems of number, location, size, or angulation of dental implants. Besides, they eliminate problems encountered with attachments, such as the narrow incorporation space within the denture, the low abrasion resistance of the male part, the difficulty in replacing or repairing the abraded male parts, and the time consuming manipulation technique.[30] In an attempt to reduce the number of placed implants, while still maintaining the advantage of low cost, placement of two narrow diameter implants to retain an overdenture, with

soft liners acting as female receptacles and shock absorber, was considered in this study and was set in comparison with two standard diameter implants also opposed by resilient liners as female receptacles. The question now is which of these treatment modalities will provides less marginal bone loss over a one year follow up period?

MATERIAL AND METHODS

In this randomized pilot study twenty patients were selected from the outpatient clinic of the Prosthodontic Department, Faculty of Oral and Dental Medicine, Cairo University consecutively (consecutive sampling). The study has a parallel design, an equivalence frame, and an allocation ratio of 1:1 for the narrow (N) and the standard (S) diameter implant groups. Eligibility of the patients was based on clinical and radiographic examinations. All patients fulfilled the following criteria: Eligible patients were completely edentulous patients, > 18 years in age, assuming normal maxillo-mandibular relationship (Class I Angle classification), and adequate mandibular bone width that allowed the placement of implant dimensions, 12 mm in length and 3.7 mm in diameter, as dictated by the larger diameter implant group (S). The mandibular ridge of the included patients should be covered by firm healthy mucosa. Before being included, patients received maxillary and mandibular conventional heat cured acrylic resin complete dentures, which were duplicated and provided by radio-opaque resin at the proposed implant sites to act as radiographic stents. Only patients with a D2 (375-750) or D3 (751-1250)[31] bone density were included in the study. This was confirmed by their cone beam computed tomographic (CBCT) scans of the mandible, while wearing radiographic stents. The CBCT was also used to ensure sufficient bone width at the proposed implant sites, namely canine regions and for subsequent planning of implant once the patient was included in the study. Diagnostic set ups for all patients were also prepared to ensure a crown height space of at least 12 mm to accommodate the ball attachments of the S group. Patients with para-functional habits (clenching or bruxism., etc.) or with systemic diseases that contraindicate implant placement and those who were heavy smokers (more than 10 cigarettes/day) or received chemotherapy or local radiotherapy were excluded.

All participants were informed about the nature of the trial and hence signed an informed written consent as recommended by the ethical committee. The included patients had an age range of 52-71 years with a mean age of 61.3. The baseline characteristics of the included patients are shown in table 1.

TABLE (1) Baseline characteristics of the included patients in groups N and S.

	Group N	Group S
Gender (Male/ female)	7/3	6/4
Mean age ± SD (years)	59.4± 6.4	63.2±5 5.2
Mean bone Density± SD (HU)	920±135	834±162
Mean anterior bone height±SD (mm)	18.4 ±1.9	18.6±2.01
Mean anterior bone thickness (mm)	6.9 ±0.7	7.1 ±0.4
Crown height space (mm)	13.3±0.8	12.7±0.8
Thickness of attached mucosa (mm)	2.5±0.4	2.1±0.8

Randomization and allocation concealment

Patients were randomly allocated to both treatment groups using simple randomization. The method required the preparation of twenty opaque sealed envelopes, 10 containing the letter “N” and 10 the letter “S” to represent the narrow and the standard diameter implant groups, respectively.

Surgical procedures

Participants of both groups were given a dose of 2g antibiotic (Amoxicillin, Caps, Teva Canadal

Limited, Toronto, Canada) one hour before surgery, in addition to an analgesic and anti-inflammatory medication (Ibuprofen 400mg, tabs, Shasun Chemicals and Drugs limited, Unit-II, Puducherry, India) prescribed every 8 hours for 2 days following the surgery and 0.2% Cholorohexidine mouth wash (Chlorhexidine, Kahira Pharm. and chem. Ind. Co. Cairo, Egypt) for one week after surgery. On the day of surgery, infiltration anesthesia was given bilaterally in the canine regions and a crestal incision was attempted, extending from canine premolar area of one side to that of the other side with bilateral small vertical releasing incisions. This was done in both groups to eliminate the effect of the flapless technique, recommended for the small diameter implants, on the bone loss pattern. The flap was then elevated and reflected using a periosteal elevator. The canine areas were identified by the aid of the surgical guide, which is actually the modified radiographic stent. Of the twenty patients, 8 required plateauing to level both attachments parallel to the occlusal plane and to achieve adequate bone width. Each patient was then allowed to pick up an opaque sealed envelope containing either the letter "S" or "N". According to the picked up envelope the patient was allocated to either the narrow or the standard diameter implant group. For both groups drilling was started using a cortical drill.

For the S group: (Fig. 1)

Drilling was continued using intermediate and final drills (3.5 x12 mm drill, Dentis, Korea). Implants (3.7 mm x10 mm, Cleanlant, S Clean tapered, Dentis, Daegu, Korea) were first hand threaded and then threaded using the torque wrench and hex tool 1.25. A minimum insertion torque of 30 Ncm is required to allow for immediate loading. The installed implants were all inserted with an insertion torque of 30-40 Ncm. Once the implant platform flushed with the crestal bone, ball abutment (Osteoseal, Irvine, California, USA) was attached to the implant.

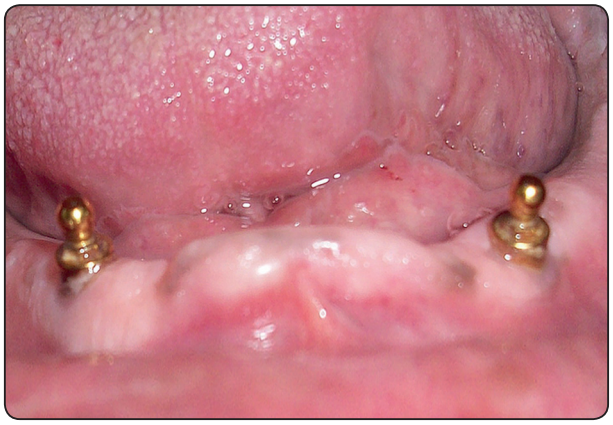

Fig. (1) The standard diameter implant after three months of healing (S group)

For the N group: (Fig. 2)

For the N group drilling was continued using just the final drill (2.3x12mm drill, Cowellmedi Co., Ltd., MiniPlus implant system, Seoul; Korea) and was stopped just short of the full implant length as recommended by Preoteasa et al.[8] Implants were then manually threaded using the implant mount. Threading was then continued by the torque wrench and ratchet driver. All narrow diameter implants were inserted at an insertion torque of 30- 35 Ncm. This is in accordance with Dilek et al , who recommended an insertion torque for small diameter implants lower than that of conventional diameter ones to avoid implant body fracture.

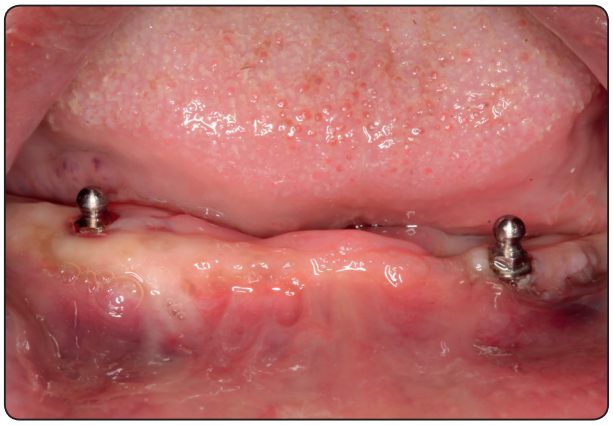

Fig. (2) The narrow diameter implant after one month of healing (N group)

For both groups

The flap was then sutured using interrupted suturing technique with a 000 black silk suture and a side and end cutting needle (000 black silk sutures, Aurolab, India).

Prosthetic insertion (Fig. 3a, b)

The previously constructed dentures, that were fabricated following the lingualized occlusal scheme, were used at this step. The mandibular denture was prepared for the relining procedures by creating sufficient space in the fitting surface of the denture opposite to the attachments. The sutures were lubricated using an oral gel (Kenalog in Orabase, 1% 10 mg Oral Gel, Squibb, Egypt) to prevent the subsequently applied rubber base and liner from sticking to the sutures. Clearance was insured by applying light bodied rubber base (Zehrmack, C-silicones, Badia Polesine, Italy) in the relieved areas. If denture base was apparent through the set rubber base, further relief was performed until only the layer of the rubber base was seen. Mollosil liner (long term condensation silicone based soft liner, DETAX GmbH & Co. KG, Germany) was used to act as the female receptacle of the ball attachments in both groups. Before applying the liner, the denture was prepared by first degreasing the fitting surface of the denture using medical alcohol. After the latter had dried, the manufacturer supplied adhesive was painted over the relieved areas and left for one minute to dry. A small mix of the liner was then prepared and applied to the relevant areas and the patient was asked to close in centric relation. The denture was then left intra-orally, while the patient maintained centric relation until the liner set. Excess liner was then trimmed using hot wax knife and the denture was polished and delivered to the patient. Patients were then given the following post-insertion instructions; In the first 72 hours it was recommended to remove the denture only during oral and denture hygiene procedures. Strict oral hygiene measures should be followed by the patients.

Radiographic assessment

For each patient, marginal bone loss around the implants was assessed at time of denture delivery, then six and twelve months later. Marginal bone loss, mesial and distal to the implants, was measured on standardized digital periapical radiographic images obtained by radiographing them using long cone paralleling technique, a customized radiographic template, (Dentsply, Ontario, Canada) and an x-ray sensor (Dentsply, Ontario, Canada). To enhance the

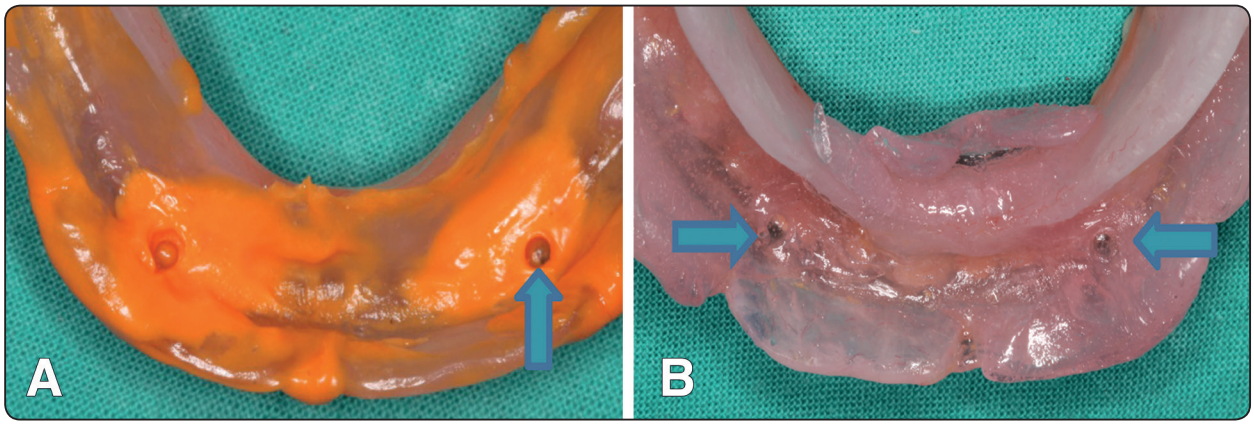

Fig. (3) a) Light body rubber base to ensure proper relief. Arrow points to a pressure area that requires relief b)The silicone based liner applied in the fitting surface of the denture. Blue arrows are pointing at the female receptacle liner.

standardization, exposure parameters for all patients were fixed. They were radiographed using Orix x-ray machine at 70 kilovolt, 10 milliampere and 0.06 seconds. The images were displayed on a computer screen and analyzed with the computer software (DIGORA Optime, Soredex, Tuusula, Finland) as shown in Figure 4. Two lines were drawn extending from the top of the ball attachment till the marginal bone mesial and distal to the implant. The lines ran parallel to the long axis of the implant. Vertical bone loss was calculated by subtracting the bone heights in the baseline radiographs from those in the follow-up visits. For each implant side, three measurements were made at three different times and the average of the three readings was taken to decrease the inter-observer error.

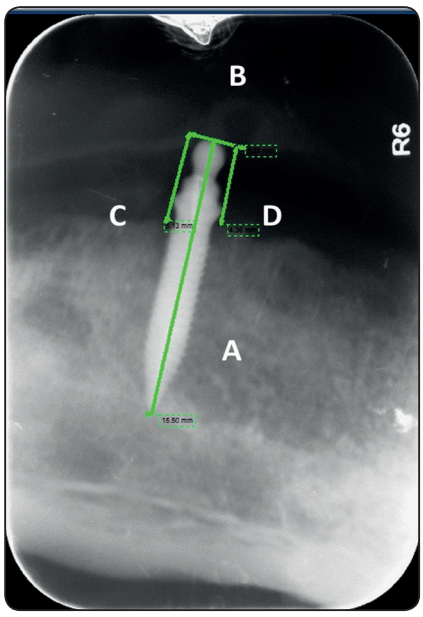

Fig. (4) Analysis of the vertical bone loss using the DIGORA software. A line "A" was drawn parallel to long axis of the implant. Then line "B" ran from the mesial to the distal sides of the attachment's occlusal edge perpendicular to line "A". Two lines "C" and "D" were then drawn to extend form line "B" to the marginal bone. These lines represented the bone height mesial and distal to the implant, respectively.

Statistical methods

The obtained data were collected, presented as means and standard deviations and tabulated using Microsoft Excel 2013 (Microsoft Cooperation). Statistical analysis of the obtained data was done using SPSS 21 for Windows statistical package (IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp). Normal distribution of data was checked using Shapiro-Wilk test. Paired t test was used to compare between the right and left implants of each group separately. For comparison between groups, independent t-test was used, while ANOVA with repeated measures followed by paired t test for pairwise comparison was used to analyze the within group changes along the different time intervals. Results were considered significant at a p value $\leq$ 0.05 for all statistical tests.

RESULTS

All patients attended the different follow up visits with no drop outs. Implants of both groups showed 100% one year survival. Statistical analysis of data showed no significant difference between marginal bone loss on right and left implants of each group. This required pooling of data recorded for both sides of each group. Further statistical analysis of the pooled data revealed significant bone loss for both groups of the study among all follow up intervals (0-6, 6-12 and 0-12 months following denture insertion) (table 2).

For each group, comparing marginal bone loss on mesial and distal aspects of implants revealed a statistically significant difference between them at all follow up intervals except at 6-12 months, where the difference became insignificant (table 3). On the other hand, the comparison between N and S groups on mesial and distal aspects at all follow up intervals showed a significant difference between them at all follow up intervals (table 4).

TABLE (2) The effect of time on mesial and distal marginal bone loss in N and S groups

Group	Aspect	0-6 months		6-12 months		0-12 months		F-value	P-value
		Mean	SD	Mean	SD	Mean	SD		
N group	Mesial	**0.636**	0.0981	**0.541**	0.157	**1.177**	0.226	272.105	<0.001*
	Distal	**0.841**	0.0826	**0.643**	0.167	**1.485**	0.215	398.248	<0.001*
S group	Mesial	**0.496**	0.0639	**0.357**	0.0889	**0.853**	0.134	433.539	<0.001*
	Distal	**0.579**	0.0643	**0.483**	0.0645	**1.062**	0.125	1246.717	<0.001*

**** : Significant difference at P-value ≤ 0.05*** ***SD: standard deviation***

TABLE (3) The effect of aspect (mesial versus distal) on marginal bone loss in N and S groups at the different follow up intervals

Aspect		0-6 months		6-12 months		0-12 months	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
N group	**Mesial**	0.636	0.098	0.541	0.157	1.177	0.226
	Distal	0.841	0.083	0.643	0.167	1.485	0.215
Difference		0.205		0.102		0.308	
P value		≤0.001*		0.054		≤0.001*	
95% confidence interval		-0.264 to -0.147		-0.206 to 0.00189		-0.449 to -0.166	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
S group	**Mesial**	0.496	0.064	0.357	0.089	0.853	0.134
	Distal	0.579	0.064	0.483	0.065	1.062	0.125
Difference		0.0825		0.127		0.209	
P value		≤0.001*		0.062		≤0.001*	
95% confidence interval		-0.124 to -0.0415		-0.176 to -0.0768		-0.292 to -0.126	

**** : Significant difference at P-value ≤ 0.05*** ***SD: standard deviation***

TABLE (4) The effect of implant diameter on marginal bone loss on mesial and distal sides at the different follow up intervals

Group		0-6 months		6-12 months		0-12 months	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Mesial	**N**	0.636	0.098	0.541	0.157	1.177	0.226
	S	0.496	0.064	0.357	0.089	0.853	0.134
Mean difference		0.140		0.185		0.324	
P value		≤0.001*		≤0.001*		≤0.001*	
95% confidence interval		0.0865 to 0.192		0.103 to 0.266		0.205 to 0.443	
		Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**
Distal	**N**	0.841	0.083	0.643	0.167	1.485	0.215
	S	0.579	0.064	0.483	0.065	1.062	0.125
Mean difference		0.262		0.160		0.423	
P value		≤0.001*		≤0.001*		≤0.001*	
95% confidence interval		0.215 to 0.310		0.0789 to 0.241		0.310 to 0.535	

**** : Significant difference at P-value ≤ 0.05*** ***SD: standard deviation***

DISCUSSION

Since they have proved successful in retaining definitive prostheses, small diameter implants could be considered an alternative to conventional implants not only in atrophic ridges but also in well developed ones. This is attributed to their reduced invasiveness, elimination of second stage surgery, possibility of immediate loading, decreased vertical space required, lower risk of denture base fracture and relatively low cost of the mini type.[8]

Concerns have been raised about possibility of overloading them because of their reduced diameter. Therefore, a minimum of 10 mm length has been recommended for these implants to produce good initial stability, which allows for immediate loading. Besides, a minimum number of 4 are recommended for mini and 2 for narrow diameter implants to retain an immediately loaded mandibular implant overdenture.[7,8] Soft liners as female receptacles have been also suggested to reduce the occlsual load.[28,29] However, randomized clinical trials comparing mini and/or narrow diameter implants to the conventional ones are scarce. Hence, this study was conducted to clarify the effect of immediately loaded narrow versus standard diameter implants on marginal bone loss, with soft liner as female receptacle in mandibular implant retained overdentures.

Studying the effect of time on marginal bone loss revealed significant differences among follow up intervals of both groups, N and S. The highest bone loss was recorded after one year at the distal aspect of N group, namely 1.485± 0.215. Reviewing data in table 1 shows that most of the bone changes have occurred during the first six months. This is in accordance with some studies who found that highest bone loss occurs during the first six months of implant insertion.[32,33] First year bone changes are usually in the range of 1- 1.5 mm, while subsequent ones are about 0.2mm.[34,35] Tatarakus et al[36] attributed this significant loss to healing process, biologic bone turn over, occlusal loading, establishment

of biological width and micromotion at prosthetic abutment interface.

The comparison between mesial and distal aspects of implants of both groups showed a significant difference between them at all follow up intervals except at 6-12 months, where the difference became statistically insignificant. This could be related to the rotational movement that is allowed by silicone caps of ball attachment and that is dependent on the resiliency and thickness of the mucosa.[23] This movement makes the denture encroach on the distal aspects of the implants and result in higher bone loss if compared to mesial sides. Disappearance of this difference at 6-12 months could be explained by the small bone changes that happened during this period and that was not big enough to reveal significant difference between distal and mesial aspects.

By studying the effect of implant diameter on marginal bone loss, significant difference was found between N and S groups on the mesial and distal sides and at all follow up intervals. This finding is consistent with many studies who found that conventional diameter implants were associated with less marginal bone loss if compared to narrow or mini implants.[20,21] They attributed their findings to the larger implant diameter which is associated with increased implant bone contact, and hence decreased implant displacement and periimplant stresses per unit area.[22]

Limitations of the study

This study was conducted over a one year follow up period, which is considered relatively short, especially with the periimplant osseous changes that are usually more pronounced during the first year. Besides, significant difference between narrow and standard diameter implants could be due to chance or α error. Further randomized clinical trials with longer follow up periods and sample size calculation are highly recommended.

CONCLUSION

Within the limitations of this study, immediately loaded conventional diameter implants retaining mandibular overdentures are associated with lesser marginal bone loss if compared to immediately loaded narrow diameter ones.

DISCLOSURE

The author declares no financial interest, either directly or indirectly, in the products or information listed in this article.

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