Effect of Splinting Mini-Implants on Marginal Bone Loss: A Biomechanical Model and Clinical Randomized Study with Mandibular Overdentures

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Purpose: *This aim of this study was to evaluate the effect of splinting mini-implants on marginal bone loss when used to retain mandibular overdentures.* ***Materials and Methods:*** *With mathematical models, a finite element analysis was performed to compare the bone stress distribution around two mini-implants, either splinted with a bar superstructure or not splinted. In the clinical portion of this study, 90 mini-implants were placed in the anterior mandibles of 45 completely edentulous patients selected from a public health center. Patients were randomly allocated into two groups. Group-ball (22 patients, n = 44) received two single ball-type mini-implants, and group-bar (23 patients, n = 46) received two mini-implants splinted with a prefabricated bar. All implants were placed using a flapless technique and loaded immediately. Marginal bone loss was assessed through standardized retroalveolar radiographs of each mini-implant and compared 5, 10, 15, and 24 months after implant placement.* ***Results:*** *The finite element analysis showed the highest minimum principal stress (−118 MPa) in bone surrounding the unsplinted mini-implant, while around the splinted implants the principal stresses were −56.8 MPa. After 2 years of follow-up in the clinical study, group-ball showed a trend toward greater marginal bone loss than group-bar (1.43 ± 1.26 mm and 0.92 ± 0.75 mm, respectively). Group-ball showed a significantly higher prevalence of vertical bone loss than group-bar (chi-square test, two-tailed).* ***Conclusion:*** *Splinted mini-implants with a rigid superstructure decrease the bone stress level in comparison with single mini-implants. The effects of bone stress magnitude may explain the clinical outcome, in which splinted mini-implants supporting a mandibular overdenture showed less marginal bone loss compared with nonsplinted mini-implants. Vertical bone resorption morphology was significantly more prevalent in the latter group.* INT J ORAL MAXILLOFAC IMPLANTS 2010;25:1137–1144

Key words: *biomechanics, marginal bone loss, mini-implant, overdentures, splinting*

Recent clinical case reports have encouraged the use of smaller-diameter mini-implants in situations where standard-sized implants cannot be used without grafting or bone reshaping.[1,2] Mini-implants do not require sophisticated procedures or extended traumatic surgeries. These are solid one-piece implants placed in a single-stage procedure using only one guiding drill. They have also become very popular for ongoing procedures, providing satisfactory outcomes for patients.[3] They are very easy to use and can be loaded immediately. However, the direct result of occlusal forces on the bone surrounding mini-implants has not been investigated in vivo. Although the loading conditions and implant designs of orthodontic and prosthetic mini-implants are not comparable, clinical studies that have used mini-implants for orthodontic anchorage have provided some information about the force effects at different magnitudes and times.[4–8] However, there are still controversies regarding these issues, and future studies that apply a standardized methodology are strongly recommended.[9]

Mathematical finite element analyses (FEAs) of narrow implants have shown high levels of risk as a result of stress on the bone, suggesting that narrow implants should not be used as definitive implants under masticatory loads.[10] An implant could be considered definitive if the bone around it remains stable after receiving a physiologic load. Thus, a physiologic load for conventional implants may be considered an overload for mini-implants if it produces excessive

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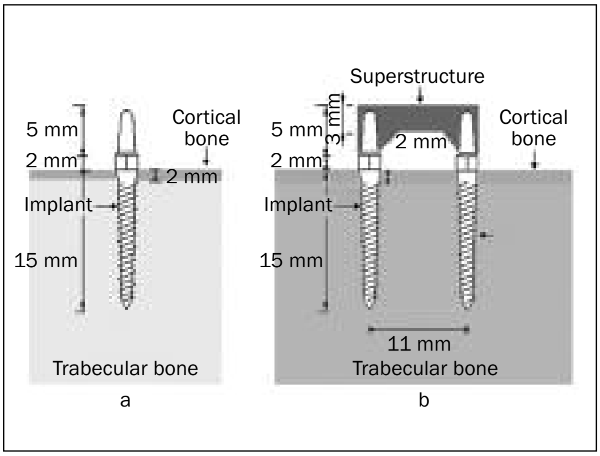

Fig 1 Diagrams of the two model implants. *(Left)* Isolated mini-implant; *(right)* two mini-implants combined with a rigid superstructure.

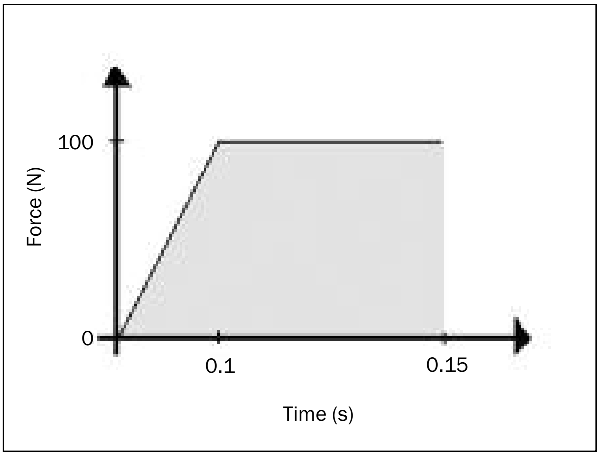

Fig 2 History of loading in masticatory cycle.

Table 1 Mechanical Properties of Modeled Materials

Material	Modulus of elasticity (N/mm^2)	Poisson coefficient	Density (kg/mm^3)
Implants and superstructure	110,000	0.35	4.5×10^{-6}
Cortical bone	13,700	0.3	4.5×10^{-7}
Trabecular bone	1,370	0.3	1.0×10^{-7}

bone loss.[11,12] An implant system is considered successful when bone loss is not more than 1.5 mm during the first year of function and not more than 0.2 mm annually in subsequent years.[13]

Although different types of attachments provide different degrees of horizontal and vertical resistance against dislodging forces that may transmit different loads to the implant-bone interface, these differences do not seem to evoke bone resorption around conventional implants.[14–16] However, this aspect of implant-prosthodontic treatment has not been evaluated for mini-implants with diameters less than 3 mm. The literature is lacking in scientific evidence to support or even reject the long-term use of small-diameter (1.8-mm) implants.[2]

To understand this clinical phenomenon, a two-dimensional FEA could be performed to develop numeric analysis models that would evaluate the behavior when a rigid structure is used to join two mini-implants. This phenomenon, at a macro level, was hypothesized to compensate for the small diameter of the implants and make the stresses comparable to those generated by unsplinted standard-diameter implants. To test the hypothesis that splinted mini-implants (1.8-mm-diameter) would produce lower stress in the bone than nonsplinted mini-implants, an FEA was carried out to determine the mini-implant biomechanical behavior. In addition, a clinical study was performed to compare the effect of splinting mini-implants on marginal bone loss.

MATERIALS AND METHODS

Finite Element Analysis

Two FE models were developed. The first involved a single mini-implant, and the second model consisted of a rigid superstructure and two mini-implants. Both the mini-implants and the rigid superstructure were made of a biocompatible titanium-aluminum-vanadium alloy. The model considered implants that were inserted 13 mm into trabecular bone and 2 mm into cortical bone (Fig 1).

It was considered that the properties of the cortical bone, trabecular bone, implants, and rigid superstructure were linearly elastic, and the internal structure was homogenous and isotropic (Table 1). For the purposes of numeric analysis using the FE method, the Cauchy equation for movement was adapted for a flat stress state and the osseous structure was assumed to have linearly elastic behavior with 100% osseointegration.

Numerically, the threads decrease the tension in the area of bone-implant contact. Thus, in this study, the implant walls were assumed to be smooth to simulate a higher-risk situation.

According to Brunski,[17] a dynamic load of 100 N applied at a 45-degree angle relative to the vertical axis was applied to the two systems. To characterize the dynamic effect of the masticatory cycle, it was assumed that this value would vary according to the law defined in Fig 2.

To evaluate the biomechanical behavior, the distribution of the maximum principal stress (S_1) and minimum principal stress (S_2) was analyzed at the bone-implant interface. By convention, tensile stresses were given positive values and compressive stresses were accorded negative values.

Clinical Study

At a public health center in Concepcion, Chile, 45 edentulous people were selected. Every participant received oral and written trial information prior to signing an informed consent document to participate. The study protocol was approved by the University of Concepcion Ethics Committee and the National Commission on Scientific and Technological Research of Chile.

Patient Population. Participants were recruited between December 2004 and July 2005. Edentulous men and women between 45 and 90 years of age who had a persistent loss of stability and retention of their conventional mandibular dentures were included. All patients were free from symptoms of temporomandibular disorders and had an Angle Class I occlusion. Patients with uncontrolled systemic disease (eg, hypertension, diabetes), with severe osteoporosis (bone mineral density > 2.5 SD below the young adult reference mean, plus 1 or more fragility fractures) and/or taking bisphosphonates, with mental disorders, or who had received radiotherapy in the 18 months prior to the trial were excluded.

All dentures were made with anatomical teeth (Marche). A specialist in prosthodontics standardized the entire sample, reestablishing the vertical dimension prior to participant allocation. Furthermore, this specialist improved the extension and prosthetic fit of the maxillary and mandibular prostheses using a low-exothermic acrylic resin (Tokuyama J. Morita) and created a balanced bilateral occlusal scheme with stable dental contacts.

Surgical Phase. Each patient received prophylactic antibiotics (2 g amoxicillin 1 hour before and 500 mg 6 hours after surgery) and a nonsteroidal anti-inflammatory 1 hour before and 24 hours after surgery.[18,19] An infiltrative technique was used for nerve blocking in the area, and an initial spiral drill of 1.1 mm was used to prepare the implant site with a transmucosal perforation. Allocation of the implants and the prosthetic system selection (ball or bar) was performed in a simple random fashion through an independent collaborator who allocated the patients into groups according to a list of random numbers. Neither the surgeon nor the prosthodontist participated in the patient assignment into groups.

Ninety mini-implants with treated surfaces (1.8 × 15 mm, Sendax MDI, IMTEC) were placed in the anterior mandibles of 45 completely edentulous patients selected from a public health center. In all cases, an electronic OsseoCare DEC600 motor (Nobel Biocare) and a flapless surgical protocol were used.

Group-ball patients received 44 single-standing ball-headed mini-implants in the canine regions; the implants were separated by 19 to 22 mm. Group-bar patients received 46 square-headed mini-implants set in the center of the bone tissue at a standardized parallel distance of 11 mm. For this group, a surgical guide was required for the standard protocol. Just after insertion, all implants were immediately loaded with mandibular overdentures.

Baseline participant characteristics (eg, gender, age, comorbidities) were recorded to assure comparability between groups. All patients received post-surgical implant care instructions. To minimize patient dropout, patients were transported free of charge from their homes to the university clinic and vice versa to attend each scheduled examination.

Assessment. Assessment of outcomes was performed at baseline (immediately after surgery) and 5, 10, 15, and 24 months later. The primary outcome in the clinical study was average marginal bone loss in the peri-implant zone. The secondary outcome was the morphology of the bone loss.

Marginal Bone Loss. For the prospective evaluation of marginal bone loss, standardized periapical radiographs of each mini-implant were taken immediately after surgery using a long-cone technique with a device that allowed a reproducible unidirectional focus. To measure the marginal bone loss, the distance from the first implant thread to the first bone-to-implant contact was measured by means of a digital caliper (ABS Digimatic caliper, Mitutoyo). Measurements were performed twice at the two proximal implant sites (mesial and distal) by an experienced radiologist at a 2-week interval, and the values were averaged.[20] According to Weber et al,[21] the first radiograph must be taken immediately after surgery so that it can be used to establish a baseline in terms of bone tissue contact with the mini-implant. Differences between this point and successive measurements (after 5, 10, 15, and 24 months) were calculated as the number of threads between baseline bone contact and the new bone contact location observed in the baseline radiograph. The known height of threads (0.5 mm) was used to translate this into millimetric values. The marginal bone loss corresponded to the average of the mesial and distal measurements at each recall appointment.

Morphology of Bone Loss. Two types of marginal bone loss were distinguished: vertical and horizontal.[22] Each implant was classified according to this morphology. Loss was classified as vertical when

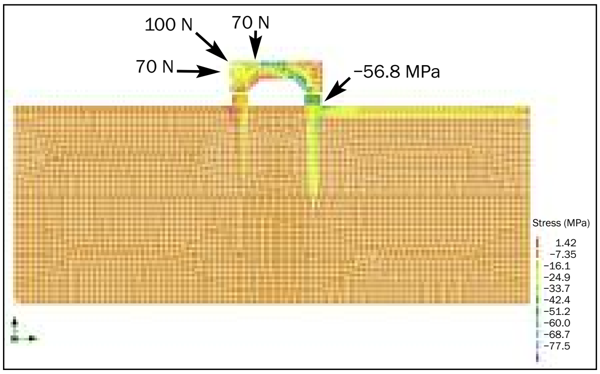

Fig 3 Distribution of principal stresses for two mini-implants splinted with a rigid superstructure.

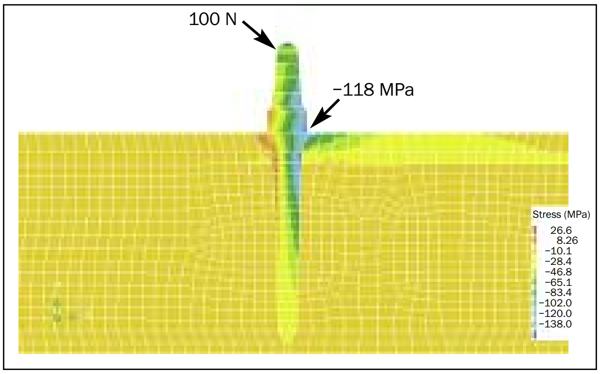

Fig 4 Distribution of principal stresses for a single mini-implant.

Table 2 Highest Maximum (S1) and Minimum (S2) Principal Stresses at the First Implant-Bone Contact

	S_1 (MPa)	S_2 (MPa)
Individual implant	74	−118
Splinted implants	25	−56.8

the angle between the implant axis and the alveolar crest of the bone destruction was less than 60 degrees; otherwise, when the angle was greater than 60 degrees, the loss was categorized as horizontal. Measurements were performed twice for each implant with a protractor by an experienced radiologist. Because of the small diameter of the mini-implants, the bone loss was quite similar at the two proximal implant sites (mesial and distal); therefore, the largest angle found between the two zones was considered to classify the bone loss morphology.

Statistical Analysis. Data were analyzed using SPSS version 15.0 (SPSS). Baseline characteristics of the patients were compared using the Fisher exact test and continuous variables were compared with the Student *t* test. The marginal bone loss and morphology were registered, evaluated, and tabulated using descriptive statistics on the implant level (bone loss value was calculated for each mini-implant). Continuous variables for the nonparametric data were compared using the Mann-Whitney *U* test, and categorical variables were compared by means of the Fisher exact or chi-square test. A difference between the groups was considered significant if $P \leq .05$.

RESULTS

Findings of the Finite Element Analysis

Table 2 shows the highest maximum and minimum principal stresses in both models. Overall, the principal stresses were higher in a single mini-implant than splinted one. Stress concentration areas were located at the cortical bone. The compressive stress over two mini-implants splinted by a rigid superstructure was observed in the area of the cortical bone at the implant side, opposite to the load and within the limit values of −70 to −50 MPa recommended in the literature[23,24] (Fig 3).

The stress around a single mini-implant showed a critical compressive stress in the area of the cortical bone. This value was greater than the critical limit recommended in the literature and could result in bone damage (Fig 4).

Clinical Study

Two hundred edentulous patients with difficulty retaining their conventional mandibular dentures were interviewed. Seventy-five were eligible for the study, 45 agreed to participate and were randomized (22 into the ball group and 23 into the bar group) (Fig 5). One patient did not return for the recall appointments and another died before the end of the study, reducing the number of participants in group-ball to 20. Baseline characteristics were similar between the two groups ($P > .05$) (Table 3).

Marginal Bone Loss. There was a trend toward increased bone loss in both groups over time. The average marginal bone loss at 24 months was 1.43 ± 1.26 mm for group-ball and 0.92 ± 0.75 mm for group-bar. However, this difference was not statistically significant (Mann-Whitney *U* test; two-tailed $P = .116$). During the follow-up period, there was no statistically significant difference in bone loss between group-ball and group-bar, except at the fifth month (Mann-Whitney *U* test; two-tailed $P = .03$) (Table 4, Fig 6).

Bone Loss Morphology. In group-ball, 51% of the mini-implants showed vertical bone loss and 49% showed horizontal bone loss. Figure 7 shows vertical bone loss in a nonsplinted mini-implant. In group-bar, 29% of the mini-implants showed vertical bone loss and 71% showed horizontal bone loss. Figure 8 shows

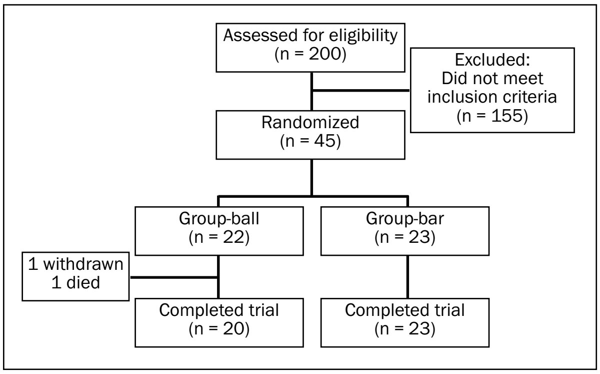

Fig 5 Flow of study participants.

Table 3 Baseline Patient Characteristics

Characteristic	Group-ball	Group-bar	Difference between groups
Sex (F/M)	13/9	14/9	ns
Age (y)	69 ± 8.7	73 ± 9.6	ns
Comorbidities			ns
Diabetes	2/22	3/23	ns
Osteoporosis	1/22	0/23	ns
Smoking	1/22	1/23	ns

ns = Statistically insignificant (Fisher exact test, $P > .05$).

Table 4 Comparison of Marginal Bone Loss After 2 Years

	Ball group		Bar group		
	No. of implants	Mean loss ± SD (mm)	No. of implants	Mean loss ± SD (mm)	*P*
Baseline	36	0.30 ± 0.30	34	0.21 ± 0.24	.306
5 mo	28	0.90 ± 0.75	38	0.55 ± 0.59	.030*
10 mo	35	1.09 ± 0.91	41	0.76 ± 0.55	.154
15 mo	37	1.34 ± 1.32	37	0.80 ± 0.58	.096
24 mo	33	1.43 ± 1.26	44	0.92 ± 0.75	.116

*Statistically significant.

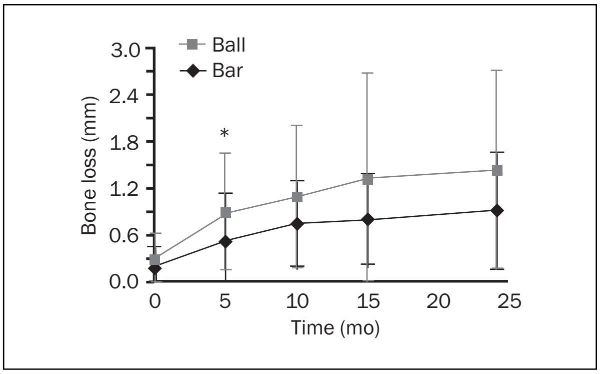

Fig 6 Comparison of overall bone loss between groups at 2 years follow-up (means and ranges shown). A statistically significant difference *(asterisk)* was observed at the fifth month (Mann-Whitney *U* test; $P = .030$).

horizontal bone loss around splinted mini-implants. A statistically significant difference was found between groups (chi-square test; two-tailed $P = .04$).

DISCUSSION

The response to increased mechanical stress beyond a certain threshold will be fatigue microdamage resulting in bone resorption.[25] In vitro biomechanical studies suggest that a decreased implant diameter will increase stress at the bone-implant interface, which could lead to bone resorption.[10,26–29] However, these studies cannot reproduce the dynamic biologic process of osseointegration, and they assume 100% bone-implant contact. This would be realistic only in cases of immediate loading, where the implant stability is not biologic but mechanical.

To the authors' knowledge, the direct result of force on the mini-implants surrounding bone has not been previously investigated in vivo. Considering the limitations of mathematical studies in representing the biologic interaction produced at the interface between implant material and live tissue, a simple simulation model that provides information about the system on the macro level was chosen. Although this model does not provide precise information, because it is a first step in observing whether a superstructure will affect stress concentration at the osseous level, it can help researchers understand the clinical results.

When the isolated implant was submitted to an oblique load, unacceptable compressive stress developed in the cortical bone, exceeding its physiologic threshold. On the other hand, when the mini-implant was splinted together with a rigid superstructure (prosthesis), it presented better behavior and the principal stresses that developed in the osseous structure were lower.

Primary stability is determined by the bone-implant stiffness, and this is dependent on bone quality, the geometry of the implant, and surgical technique.[30] If some of these factors are deficient, implant stability may be compromised, increasing the risk of micromovements and resulting in bone resorption around the implant.

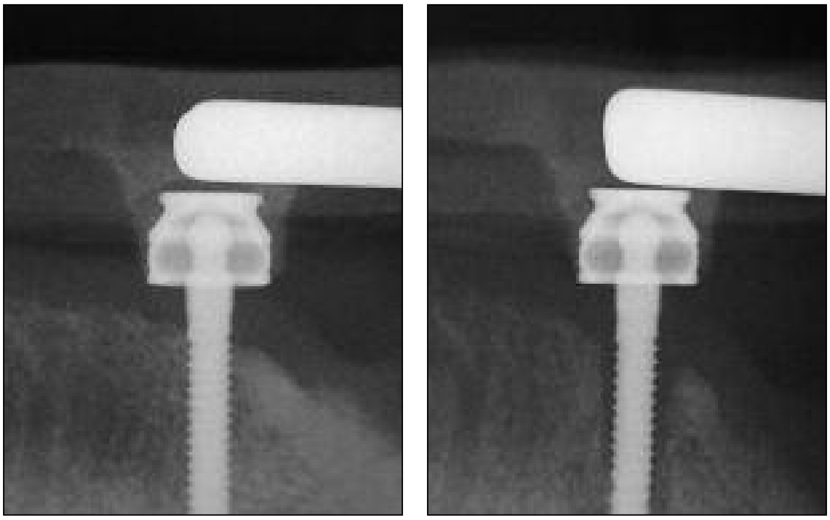

Fig 7 Example of vertical bone loss morphology. Marginal bone loss *(left)* at baseline and *(right)* at 24 months.

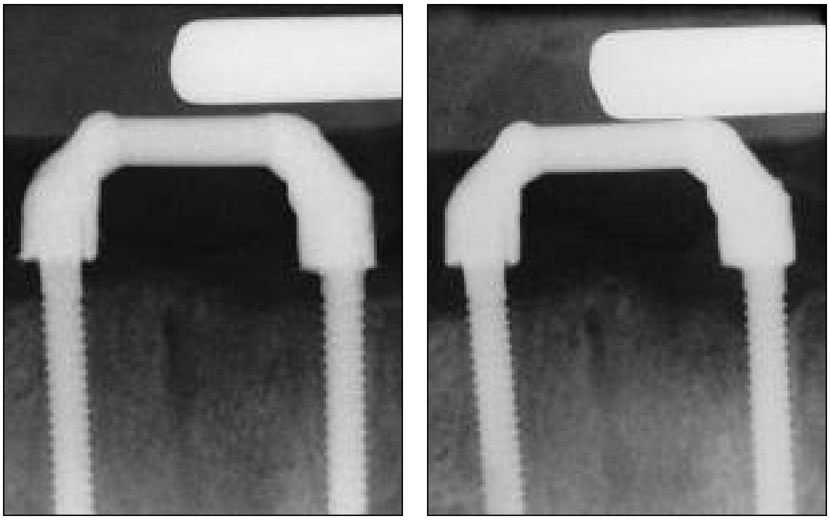

Fig 8 Example of horizontal bone loss morphology. Marginal bone loss at *(left)* baseline and *(right)* at 24 months.

Secondary stability is determined by the loading conditions and is dependent on the prosthetic design (eg, splinting, cantilever, cusp inclination); occlusal contacts; prosthetic connections (eg, rigid, semirigid); occlusal masticatory load (eg, parafunction, masticatory forces); and the implant's microgeometry. If the transmitted load produces a high stress on the bone-implant interface, implant stability can be affected at this stage.

When the load magnitude is increased over the physiologic threshold of bone adaptation, bone-implant anchorage may be lost, compromising implant success. Marginal bone loss is a major criterion in the success of dental implants. In fact, implant failure over the long term is caused by ongoing marginal bone loss.[31,32] Regarding marginal bone loss, Albrektsson et al[13] and Smith and Zarb[33] proposed that annual bone loss should not exceed 1.5 to 2 mm in the first year and 0.2 mm per year thereafter. Authors have reported that the greatest bone loss occurs during the first year.[34–37] Marginal bone loss around conventional implants supporting mandibular overdentures has been reported to range from 0.2 to 1.9 mm after the first year.[15,16,38] The results of this study showed bone loss similar to the published data for conventional-diameter implants; in fact, the bar group showed a much smaller bone loss compared with acceptable levels for conventional-width implants.

The type of implant attachment system used does not seem to influence bone resorption around conventional implants.[14,37] However, the high levels of stress on the bone exerted when single narrow implants are in place[10] can lead to mechanical overload, causing bone remodeling.[25] The present study found more bone loss in group-ball compared to group-bar; however, this difference was not statistically significant, except for the fifth month. This measurement was obtained during the healing period, and the significant difference observed was possibly a result of the fact that immediate loading of a single mini-implant could cause greater bone loss because the implant has less mechanical anchorage than a pair of splinted mini-implants.

A higher standard deviation was observed in group-ball than group-bar. Load magnitude over a ball-retained implant is dependent on the stability of the o-ring attachment and could change following deformation and loss. This probably is the reason for the data variability.

There are also in vitro studies that suggest that splinted implants could reduce bone stress.[26,39] This could be clinically relevant only in situations where the masticatory load is transmitted to the implant with high levels of risk, for example, immediate function with low primary stability or very small-diameter implants. In this sense, biomechanical factors that might reduce force magnification, such as the superstructure, would play an important role.

The percentage of bone loss was highest during the first 6 months, after which the rate of bone resorption tended to decrease until becoming stable. This behavior was observed in both groups and is similar to that observed around conventional implants.[21] The bone loss behavior around the mini-implants during this study was comparable to that of conventional implants; however, a longer observation period is needed to determine the long-term prognosis of this treatment approach.

The bone loss morphology in this study was characterized as horizontal or vertical. Horizontal bone loss is caused by inflammation, whereas vertical loss is usually associated with a combination of trauma and inflammation.[40–43]

In this study, the single unsplinted implants showed vertical and horizontal bone loss in similar proportions, whereas the splinted implants showed predominantly horizontal bone loss, suggesting that in this case bone loss could be a consequence mainly of a physiologic process and nonsplinted mini-implants could also have an overload component.

The small sample size in this study introduces the possibility of not detecting an actual difference between groups when it probably exists (type I error). Even so, this study provides an approach to the effect of splinting mini-implants on the marginal bone loss and suggests that the biomechanical behavior is improved by a superstructure, which increases the bone-implant anchorage area and decreases the bone loss under functional loading.

CONCLUSION

Splinting mini-implants with a rigid superstructure decreased bone stresses in comparison with single mini-implants. Splinted mini-implants supporting a mandibular overdenture showed less marginal bone loss than nonsplinted mini-implants. Bone loss morphology suggests an overload pattern associated with nonsplinted mini-implants working under functional load.

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