Bone Remodeling Around Implants with External Hexagon and Morse-Taper Connections: A Randomized, Controlled, Split-Mouth, Clinical Trial

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ABSTRACT

Objectives: To evaluate clinical, radiographic, microbiologic, and biomechanical parameters related to bone remodeling around implants with external hexagon (EH) and Morse-taper (MT) connections.

Materials and Methods: Twelve totally edentulous patients received four custom-made implants in the interforaminal region of the mandible. Two of those implants had the same macroscopic design, but different prosthetic connections. All patients received an immediate implant-supported prosthesis. Clinical parameters (periimplant probing pocket depth (PPD), modified gingival index (mGI), and mucosal thickness (MTh)) were evaluated at 12 months follow-up. The distance between the top of the implant and the first bone-to-implant contact (IT-FBIC) was evaluated on standardized digital peri-apical radiographs acquired at 1, 3, 6, and 12 months follow-up. Samples of the subgingival microbiota were collected 1, 3, and 6 months after implant loading and used for the quantification of *Tanerella forsythia*, *Porphyromonas gingivalis*, *Aggragatibacter actinomycetemcomitans*, *Prevotella intermedia*, and *Fusobacterium nucleatum*. Further, 36 computerized-tomography based finite element (FE) models were accomplished, simulating each patient under three loading conditions.

Results: The evaluated clinical parameters were equal for EH and MT implants. Mean IT-FBIC was significantly different between the tested connections (1.17 ± 0.44 mm for EH, and 0.17 ± 0.54 mm for MT, considering all evaluated time periods). No significant microbiological differences could be observed between tested connections. FE analysis showed a significantly higher peak of equivalent (EQV) strain ($p = 0.005$) for EH (mean 3,438.65 $\mu\varepsilon$) compared to MT (mean 840.98 $\mu\varepsilon$) connection.

Conclusions: Radiographic periimplant bone loss depends on the implant connection type. MT connections showed less periimplant bone loss, compared to EH connections.

KEY WORDS: clinical trials, crestal bone level changes, dental implant-abutment connection, marginal bone loss

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INTRODUCTION

The stability of hard tissues around dental implants directly affects its long-term success.[1] A dental implant can be considered successful if radiographic periimplant bone loss is less than 1.5 mm during the first year after implant placement, and less than 0.2 mm annually thereafter.[2] However, even mild marginal bone remodeling could influence soft tissue topography, jeopardizing the aesthetic outcomes of implant treatment over time.[1] In addition, the initial breakdown of the implant–tissue interface, which may lead to the failure of successfully osseointegrated implants, often begins at the crestal region.[3,4]

Several hypotheses have been proposed to explain periimplant bone loss. Some authors indicated a potential role for the implant–abutment interface microgap.[5–7] Bacterial leakage through this microgap and colonization of the connection's inner portion determine the formation of the periimplant chronic inflammatory infiltrate, thereby leading to bone resorption.[5–7] It has been also proposed that a minimum width of peri-implant mucosa is required to establish a proper epithelial–connective tissue attachment.[8–10] Additionally, the literature shows that the stress/strain concentration induced by an excessive dynamic loading can trigger bone resorption, by bone microdamage accumulation around osseointegrated implants, even in the absence of an oral biofilm.[11] This was confirmed by animal studies, in which complete or partial loss of osseointegration was found around excessively loaded implants.[3,4,12] In this way, the implant–abutment connection type has been considered to be one of the major factors affecting periimplant bone changes.[13–18]

The implant–abutment connection may have an impact on the amount of microbial penetration into the internal part of dental implants.[19,20] Besides, Morse-taper (MT) abutments emerging from the central region of the implant allow additional thickness in the horizontal soft-tissue component.[18] This might help reducing marginal bone remodeling during biological width formation.[21–23] Moreover, the literature indicates that the periimplant bone strain vary significantly with the type of implant–abutment connection.[24–26] The conical interface of MT connections helps dissipating the forces to the fixture.[24,25] Clinical trials evaluating periimplant bone remodeling corroborates these findings.[15–18]

However, diverse connection types have been evaluated using diverse implant- (e.g., diameter, length, macroscopic design, surface treatment, and clinical situation), and patient-related (e.g., clinical situation) parameters.[15–18] This makes it impossible to draw conclusions regarding bone loss differences.[15] Therefore, this study aimed at evaluating clinical, radiographic, microbiological, and biomechanical parameters related to bone remodeling around implants using external hexagon (EH) and MT connections, but equal on all other implant- and patient-related parameters.

MATERIAL AND METHODS

Study Population Definition

This study is a randomized, controlled, split-mouth, prospective clinical trial which was approved by the Ethics Committee for Human Research at Federal University of Uberlandia, Brazil (protocol n. 549.913).

A summary of study population can be found at Table 1. The 12 patients (three males and nine females, age range 18–75 years) included in this study presented with good general (physical and mental) health at the time of surgical section and provided a written informed consent. Patients with known alcohol, drug or medication abuse, smokers, or with known systemic diseases such as uncontrolled diabetes, coagulation disorders, allergy, serious cardiac vascular disorders, and other significant diseases that could influence the long-term follow-up or implant osseointegration were immediately excluded.

The recruited totally edentulous patients should also have adequate bone quantity for the placement of four 3.8 × 13 mm implants in the interforaminal region of the mandible, evaluated by means of clinical and radiographic/CBCT examination. No exclusion criteria were set for the opposing teeth (i.e., complete or partially removable dentures or natural teeth). In all recruited subjects, periodontally affected teeth were treated and stabilized before implant placement. Oral hygiene instruction was given/reinforced, and the oral prosthesis was cleaned in all follow-up visits. During the entire study period, all patients were scheduled for periodontal supportive recall visits, when necessary.

Surgical and Prosthetic Rehabilitation Procedures

A total of 48 customs made titanium implants (UNITITE®, SIN – Sistema de Implante, São Paulo, Brazil),

TABLE 1 Periimplant Radiographic Bone Loss and Mucosal Thickness, at 1 Year Follow-Up Evaluation, for all Evaluated Patients and Summary of Study Population

				Radiographic bone loss						Mucosal thickness					
				MT			EH			MT			EH		
Patient	Gender	Age	Maxillary antagonist	M	D	Mean	M	D	Mean	M	D	Mean	M	D	Mean
1	Male	66	NT	0.48	0.08	0.28	1.14	1.34	1.24	2.50	1.00	1.75	1.00	1.00	1.00
2	Female	55	IS-R	1.09	1.10	1.09	1.75	2.00	1.87	2.50	2.50	2.50	2.00	2.50	2.25
3	Female	54	IS-C	0.89	0.93	0.91	1.26	1.72	1.49	2.00	1.50	1.75	2.00	1.50	1.75
4	Female	54	RTP	0.53	0.05	0.29	1.15	0.95	1.05	1.50	2.00	1.75	1.00	2.00	1.50
5	Female	75	RTP	0.22	0.05	0.13	0.81	0.94	0.87	3.00	4.00	3.50	3.00	3.00	3.00
6	Male	71	RTP	−0.33	−0.05	−0.19	0.80	0.71	0.75	1.50	2.50	2.00	2.50	2.0	2.25
7	Female	67	RTP	0.25	0.25	0.25	0.69	0.34	0.51	2.00	3.00	2.50	2.50	2.0	2.25
8	Female	48	RTP	0.45	0.45	0.45	1.28	1.20	1.24	2.50	2.00	2.25	3.00	3.0	3.0
9	Female	75	RTP	−0.22	−0.56	−0.39	1.14	0.95	1.04	3.00	4.00	3.50	3.00	3.00	3.00
10	Female	69	NT	−0.84	−0.88	−0.86	0.88	1.11	0.99	3.50	3.00	3.25	3.00	2.50	2.75
11	Female	49	RTP	−0.33	−0.28	−0.30	1.07	0.93	1.00	1.50	1.50	1.50	2.50	2.50	2.50
12	Male	74	RTP	0.34	0.42	0.38	2.23	1.73	1.98	3.00	1.00	2.00	2.00	3.00	2.50

NT, Natural teeth; IS-R, Implant-supported, resin prosthesis; IS-C, Implant-supported, ceramic prosthesis; RTP, Removable total prosthesis.

four per patient, with a double acid-etched surface treatment, were used in the interforaminal region of the patient's mandible. Twenty-four of those implants (2 per patient) had the same macroscopic design, but a different prosthetic connection (12 were EH, and 12 were MT), as shown in Figure 1. Sample size calculation was made based on a continuous-outcome superiority trial design, to provide a minimum power of 80%. The main variable used for this calculation was the periimplantar bone loss measurements, since this is the variable in which the observed differences among the groups was expected to be of a minor range.

The implant positions would be the most right (1), center right (2), center left (3), and most left (4) positions in the arch. The implants were randomly placed based on a split-mouth design, in such a way that each implant occupied the same determined position in the arch the same number of times. This allowed the implants to be compared in a similar biological/biomechanical environment, and an acceptable repletion number to provide strong statistical inference regarding the studied parameters.

Surgical treatment was performed under local anesthesia with 3% mepivacaine (Epinefrine 1:100,000). All patients rinsed their mouths with 0.12% chlorhexidine solution preoperatively for 60 seconds. A crestal incision was made to raise a full-thickness muco-periosteal flap, allowing the installation of the four implants, according to the manufacturer's guidelines. The implants were placed to engage the full depth of a 13.5 mm osteotomy, thus resulting in the implant platform positioned 0.5 mm below the bone crest (IT-fBIC of -0.56 ± 0.30 mm and -0.54 ± 0.34 mm, for EH and MT, respectively, $p = 0.68$).

Definitive 2-mm tall mini-abutments (SIN – Sistema de Implantes, São Paulo, Brazil) were placed on the implants, and were never dis- and reconnected. Further, the flap was carefully repositioned using absorbable 4/0 sutures (Vicryl – Ethicon FS-2, St-Stevens-Woluwe, Belgium). Transfer copings were placed over the abutments and an impression was taken (Oralwash L®, Zhermack, Rovigo, Italy). An implant-supported full-arch prosthesis was installed within 48 hours after implant placement. Amoxicillin (1 g, three times, a day for four days) and paracetamol (500 mg, as needed) were prescribed post surgically. Patients were instructed to rinse their mouths twice daily with a 0.12% chlorhexidine solution, for 15 days. All surgeries have been done by one single experienced surgeon (RSP), as well as all prosthetic procedures were accomplished by one single prostodontist (RMS).

Clinical Assessments

At the 1 year follow-up visit, clinical assessments were conducted (six sites around each implant considered

Figure 1 Identical implant macrodesigns used in the study (left – external hexagon, right – Morse-taper). One should notice that the only difference between implants is the implant-abutment connection type.

for the study). mGI was recorded according to Mombeli et al. (1987): 0, no bleeding; 1, spot bleeding; 2, linear bleeding; and 3, spontaneous bleeding. Periimplant PPD and MTh were determined using a Hu-Friedy periodontal probe, and the mean value was calculated in millimeters for each implant. As all mini-abutments had 2-mm height, the thickness of the periimplant mucosa related to the implant shoulder could easily be found. Thus, the influence of periimplant MTh on the amount of periimplant bone loss could be evaluated. All clinical examinations were performed blindly, by on single periodontist (LPM).

Radiographic Evaluation

Periapical radiographs were taken at baseline (prosthetic device installation), and at 1, 3, 6, and 12 months after implant loading, using the paralleling technique and an intra-oral radiographic unit (70 kV, 8 mA, and 0.2 seconds). A digital sensor (Schick CDR Elite, Schick Technologies, EUA) was used to acquire the radiographic images. A custom made abutment-supported individualized sensor holder ensured image standardization for the radiographic follow-up. To compensate for possible blurring at the threads of the implants, and ensure the quality of the radiographic images for bone loss assessment, the method suggested by Schropp et al. was used.[27]

The acquired images were exported in the TIF (tagged image file) format, and evaluated using dedicated software (Image J, National Institutes of Health, Bethesda, MD, USA). The vertical distance from implant top to the first implant–bone contact (IT–fBIC) was measured. To calibrate for possible geometric distortion in the radiographic images, the known size of the implants was used.

Microbiological Evaluation

Samples of implants subgingival microbiota and unstimulated saliva (1 mL) (Sal), were collected 1, 3, and 6 months after implant loading. Before sampling, the supragingival plaque was removed with curettes. Each implant was sampled by eight paper swabs (Roeko®, Roeko, Langenau, Germany) that were left subgingivally for 20 seconds. These eight swabs were pooled (1 sample per implant). All samples were dispersed in reduced transport fluid, homogenized (vortex) for 30 seconds. Samples were dispersed using a vortex mixer and immediately frozen at −20°C until analysis (PMID 24164569). When the study was finished, the frozen samples were sent to the department of Periodontology of the KU Leuven (Belgium) on dry ice by express service and immediately frozen at 80°C on arrival. All samples of all subjects in a same group/period were processed at the same time. All microbiological evaluations were performed blindly.

DNA was extracted using InstaGene matrix (Bio-Rad Life Science Research, Hercules, CA, USA) according to the manufacturer instructions. A total of 5 μL of the purified DNA was used for the quantification of *Tanerella forsythia* (Tf), *Porphyromonas gingivalis* (Pg), *Aggragatibacter actinomycetemcomitans* (Aa), *Prevotella intermedia* (Pi), and *Fusobacterium nucleatum* (Fn).[28]

Finite Element Analysis

The computerized tomography of a totally edentulous mandible, acquired from one of the patients included in the study was taken by a helical scanner CT Brightspeed

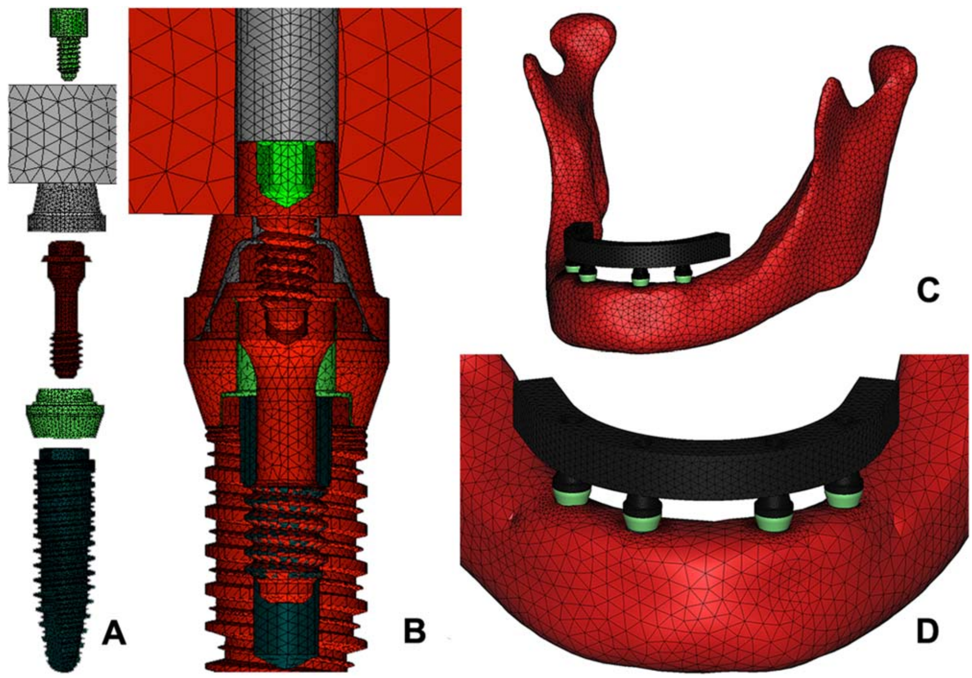

Figure 2 A – external hexagon implant system 3D meshes; B – final positioning of implant system (3D FE models are shown as sectional view); C – final finite element model, lateral view; D – final finite element model, frontal view.

Elite Select Multislice (GE Healthcare, NYSE: GE, United Kingdom) with a gantry tilt of 0°, at 120 kV acceleration voltage and 200 mA current. The projection data were exported using the DICOM (Digital Imaging and Communication in Medicine) file format. The data set had a voxel size of 0.35 mm and consisted of contiguous slices with respect to the Z-axis. The CT slices were reconstructed in a 3D solid model by thresholding within an image-processing software (Mimics 15.1, Materialise, Haasrode, Belgium). The implants and prosthetic components CAD (computer-aided design) of the implants used in study were provided by the implant producer (SIN Sistema de Implante, São Paulo, Brazil). The implant designs were imported into Mimics software (Materialise, Haasrode, Belgium) and positioned in the interforaminal region of the mandible, simulating the implant distribution of each patient included in the study. The implant insertion hole in the mandible model was obtained by means of Boolean subtraction between the bone and implant solids. The abutment and abutment screw models were subsequently aligned to the implants following the instructions from the implant manufacturer. A framework beam was designed as a geometric solid (6 × 5 mm), in a horseshoe configuration following the shape of the mandible, with 13 mm of cantilevers on both sides.

Bone, implant, abutments, abutment screws, and framework beam models were meshed separately in MSC.Patran 2010r2 (MSC.Software, Gouda, Netherlands). No simplifications were made regarding the implant systems macro-geometry (i.e., truly spiral threads were used) (Figure 2). In addition, the bone mesh was tested for convergence. The smallest elements in the constructed tetrahedral meshes were about 50 μm in size. The different levels of mesh refinement were used for feature recognition (i.e., at the threads).

The gray values of the CT images were used to assign the material properties of the elements contained in cortical and trabecular bone.[29] The values of the Young's modulus and Poisson ratio for the materials that used in this study can be found in relevant literature.[25,29]

Frictional contact elements, with a frictional coefficient (μ) of 0.5 were used to simulate the implant system component interfaces in contact. The implants were considered already osseointegrated by assuming the bone to implant interface as "glued." Three loading situations, 480N-loading (480N applied in 10 bilateral points), 640N-loading (640N applied in 10 bilateral points), and 480N-unilateral-loading (480N applied in five unilateral points), were applied by distributing point loadings on the top surface of the framework. Models were fully constrained in all directions at the nodes on inferior borders of the mandible. A total of 36 models simulating the 12 patients in the three loading situations were modeled.

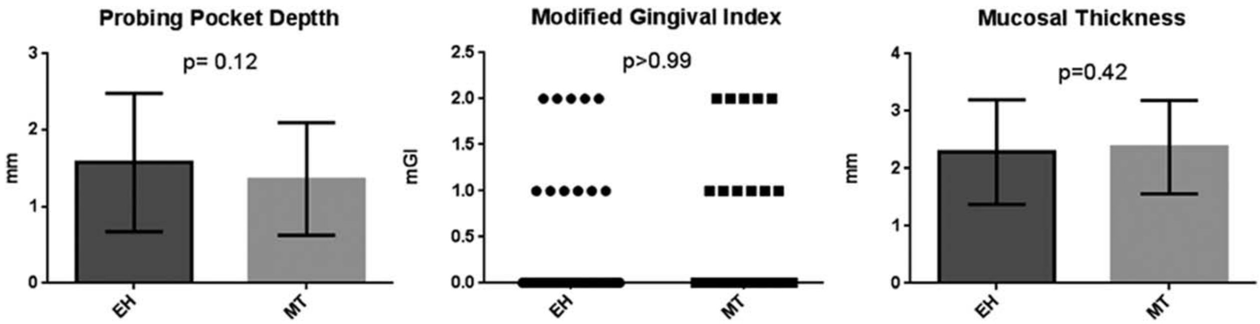

Figure 3 Clinical parameters (probing pocket depth, modified gingival index, and mucosal thickness) assessed at 12 months after implant placement.

The FE model analysis and post-processing were accomplished by means of the MSC.MARC/Mentat 2010r3 software (MSC.Software, Gouda, Netherlands).

Data Analysis

Commercially available software (GraphPad Prism 6.0 for Windows, GraphPad Software Inc., USA) was utilized to compare all assessed parameters and draw graphics. Data was subjected to D'Agostino & Pearson test and was defined to be normally distributed. For the clinical and radiographic evaluated parameters, comparisons among groups were done using paired *t*-test. Further, comparisons among the multiple periods of evaluation were done using Friedman test followed by Dunn's post-hoc test for multiple comparisons. Inferential statistical analysis regarding the microbiological evaluation was also performed by applying Friedman test followed by Dunn's post-hoc test for multiple comparisons. Pearson and Spearman correlation statistics were performed crossing all evaluated parameters.

Regarding FEM analysis, the results for the peak EQV strain in periimplant bone were interpreted by means of a general linear model Analysis of Variance (ANOVA).[30] In all instances, the level of significance was set at $p < 0.05$.

RESULTS

All the 12 participants accomplished the 1 year follow-up. Healing was uneventful at all implants. No implant was lost during that period. Clinically healthy periimplant mucosa with no signs of inflammation was observed for almost all implant sites at the 1 year follow-up examination. The evaluated clinical parameters are presented in Figure 3. All assessed clinical parameters, as PPD (1.57 ± 0.9 mm vs 1.36 ± 0.7 mm, for EH and MT, respectively, $p = 0.12$), mGI (median of 0 0 for both groups, $p > 0.99$), and MTh (2.16 ± 0.94 mm vs 2.27 ± 0.85 mm, for EH and MT, respectively, $p = 0.42$) were statistically equal.

Figure 4 presents the radiographic images of two implants in one of the included patients as an example, while Figure 5 presents the assessed periimplant bone loss for both the EH and MT groups, in all follow-up periods.

The variation in periimplant bone loss was significantly different between connection types, starting at the 1 month follow-up (IT-fBIC of 0.62 ± 0.65 mm and -0.82 ± 0.41 mm, for EH and MT, respectively, $p < 0.001$), and in all following examination periods. Differences in marginal bone remodeling were statistically significant comparing the measurements from baseline to those of 1 month follow-up for both MT ($p = 0.001$) and EH ($p < 0.001$). No additional marginal bone loss occurred for MT ($p = 0.302$), comparing 1 month and 1 year follow-ups, while EH still presented crestal bone loss ($p = 0.014$) when the same follow-up periods were compared. No direct relationship between periimplant bone loss and any of the other studied factors was found (low correlation coefficients, and $p > 0.05$), as presented in Table 1.

The results of the microbiologic assessments are shown in Figure 6. No significant microbiological differences could be observed between both connection types, after 6 months follow-up. Furthermore, no significant increase in any of the evaluated species could be observed comparing the assessed follow-up periods. Most of the collected samples had very few periimplant pathogens. The detection frequency, based on positive values, was low for Aa, while the highest concentration among the five analyzed species by qPCR was found for Fn.

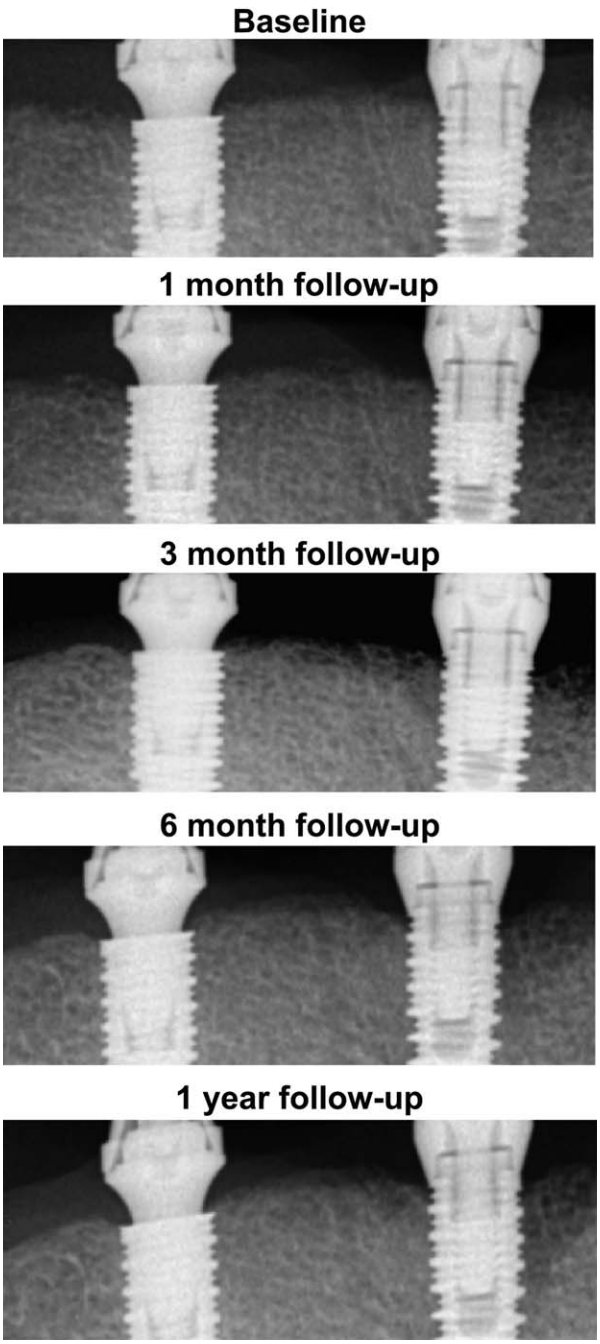

Figure 4 Representative radiographic evaluation of periimplant bone loss for MT (left implant) and EH (right implant), at all evaluated follow-up times.

In FE analysis, considering the three loading conditions and the 12 patients implant distribution, in a total of 36 models, a significantly higher peak of EQV strain ($p = 0.005$) was found for EH (mean of 3,438.65 με) compared to MT (mean of 840.98 με) connection (Table 2). Loading magnitude and implant position in the arch influenced greatly on the periimplant strain concentration, irrespective of connection type. Distal implants showed higher bone strain values, compared to medial implants, for all tested loading conditions.

Figure 7 shows both implant-abutment connections, in the same position. The model scale was set to range between 100 and 4,000 με to facilitate the visualization of the strain state in bone (Duyck et al. 2001). Considering the same loading condition, significantly higher bone strain levels were observed for EH, when compared MT connection.

DISCUSSION

This study was carried out to evaluate the influence of implant-abutment connection type (EH and MT) on clinical, radiographic, microbiologic, and biomechanical parameters related to bone remodeling (loss) around implants. The present results demonstrate that that the implant-abutment connection type will influence the bone loss around the implants. Further, the influence of clinical and microbiological conditions on early periimplant bone loss could not be demonstrated. Conversely, the singular loading transmission through implant-abutment connection designs led to significantly different bone strain magnitudes at implant vicinities. The tested MT connection showed less crestal bone changes, compared to an EH connection.

Implant-abutment connection designs have been shown to induce different degrees of periimplant crestal bone remodeling, after subjected to functional loading. Castro et al.,[13] in a histological and histomorphometrical evaluation of marginal bone resorption around implants in dogs, demonstrated smaller amount of bone loss for MT implants, both on the buccal and lingual sides, compared with larger bone loss for the EH implants. In a prospective randomized controlled split-mouth clinical trial, comparing two implant designs with different prosthetic interfaces and neck configurations, Pozzi et al.[15] also shown that marginal bone changes (loss) were statistically significantly different, with better results for the internal conical connection (0.51 ± 0.34 mm), comparing to EH (1.10 ± 0.52 mm). In another prospective clinical study, Koo et al.[18] compared epicrestally inserted root-form implants (acid-etched surface, microthreads in the neck area, length: 8.5–13 mm, outer diameter 4.3 mm) exhibiting either an external or internal

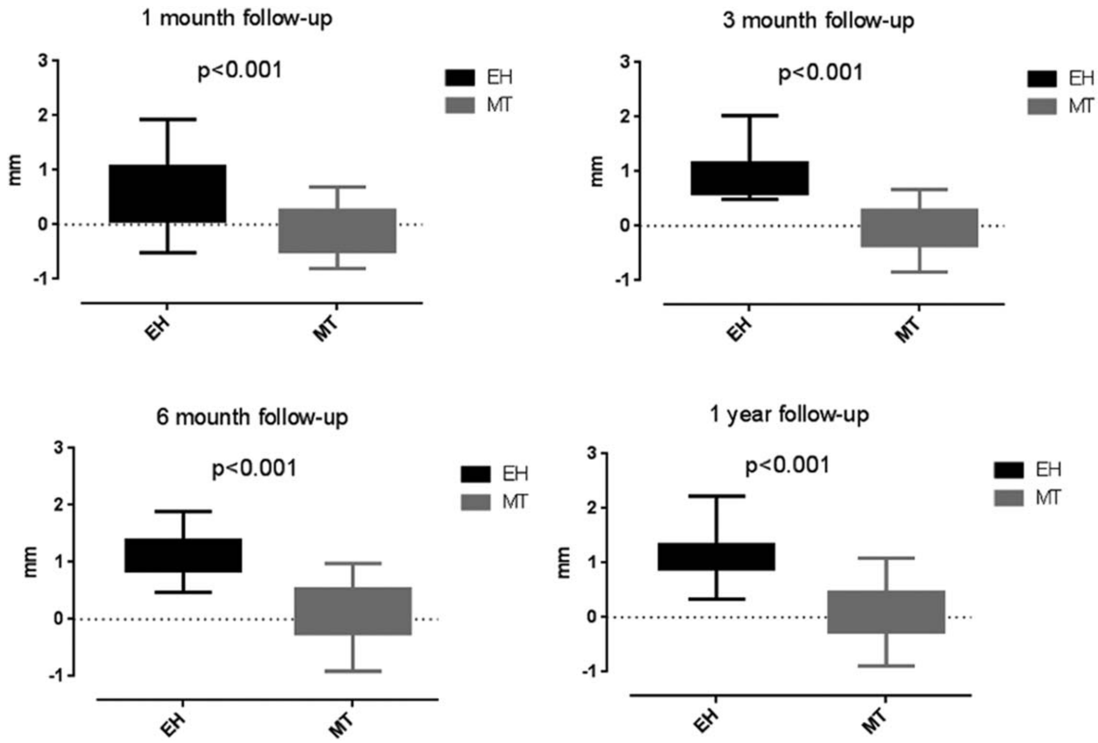

Figure 5 Radiographic periimplant bone loss assessed 1, 3, 6, and 12 months after implant placement.

implant–abutment connection. Radiographic evaluation after 1 year revealed significantly higher ($p < 0.05$) periimplant bone loss for the external (1.14 ± 0.54 mm), when compared with the internal (0.24 ± 0.29 mm) abutment connection. In previous studies, implant-abutment connection types have been compared between incongruous implant macrodesigns, surface treatments, and lengths in diverse clinical situations. As it was actually not only the implant-abutment connection type that varied, it is somewhat difficult to determine which factor had the highest contribution to the observed results. Opposing to such methodological pitfall, the present prospective randomized controlled split-mouth clinical trial have also shown, for the same implant macrodesign (including implant crestal module design, surface treatment, implant wide, and lenght), a significantly ($p < 0.001$) smaller periimplant bone loss for MT (0.17 ± 0.54 mm) comparing to EH (1.17 ± 0.44 mm) connection, after one year of implant loading. In addition, some confounding factors (i.e., patient biotype and/or life-style, genetic predisposition, clinical experience of the clinicians, dis- and reassembly of the abutment, interproximal bone height at neighboring teeth, prosthetic concepts, loading protocol) could also possible influence periimplant bone remodeling.[16] Several of these variables were excluded by the split-mouth design of this study. Some of the slight discrepancies in outcomes between clinical studies could be attributed to such differences in study designs.

Periimplant mucosal tissue thickness at the crest is considered to exert a significant influence on marginal bone stability around implants.[8,10] Some authors suggested that if the gingival thickness is 2.0 mm or less, there is a risk of losing up to 1.81 ± 0.06 mm of crestal bone, even if the implant-abutment interface is placed in a supracrestal position. Implants placed in naturally thick soft tissues (above 2 mm) experienced minor bone remodeling (0.34 ± 0.05 mm).[9] In the present clinical trial, similar periimplant MTh was reached for MT and EH implants after 1-year follow-up, although periimplant bone loss was significantly different between the connection types. In the same way, Koo et al.[18] found a weak association ($p = 0.291$) between soft-tissue thickness and periimplant bone changes 1 year after loading. Nevertheless, the authors argued that the differences in periimplant bone loss in their study might be explained in part because the abutment diameter is smaller than the implant diameter (platform-switching) for MT implants, allowing some additional

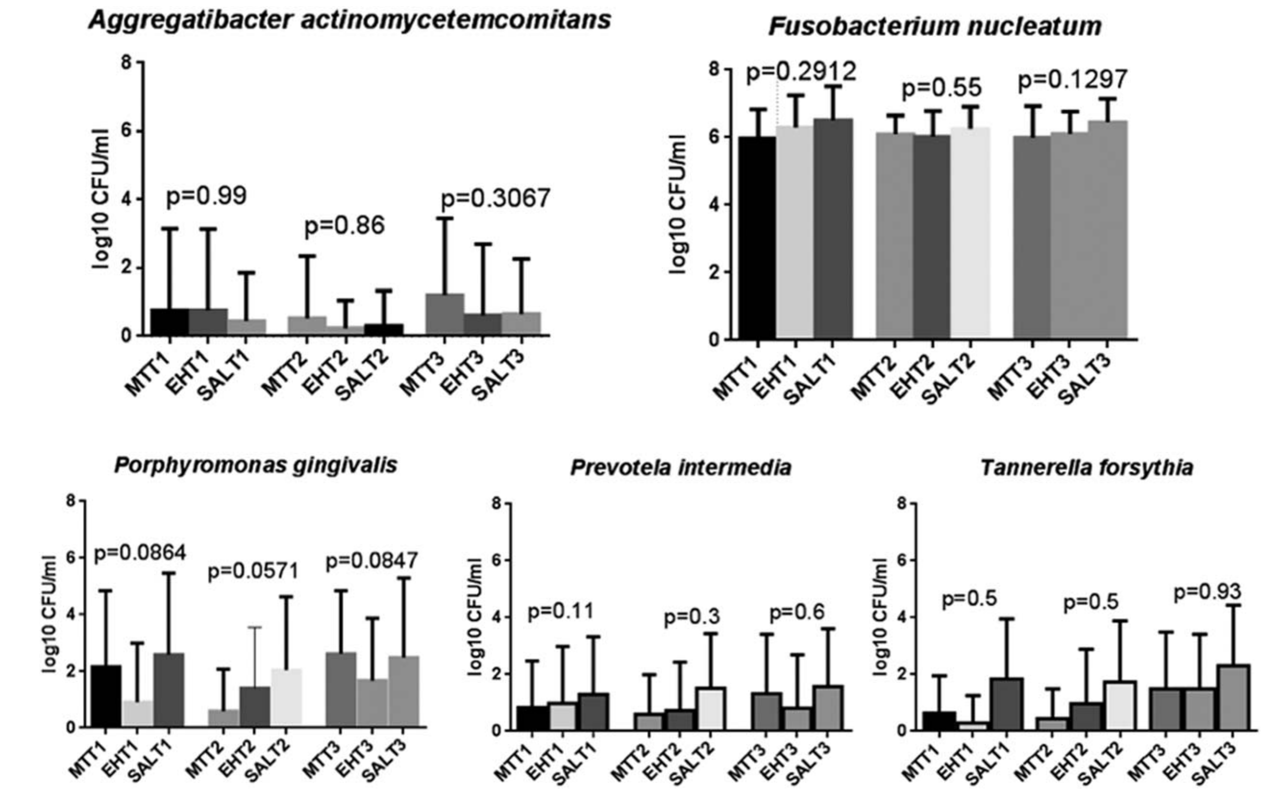

Figure 6 Logarithm of the bacterial load (Log10) for individual pathogens in the peri-implant sulcus and saliva. MT, Morse-taper; EH, external hexagon; Sal, saliva; T1, 1 month follow-up; T2, 3 months follow-up; T3, 6 months follow-up.

thickness in the horizontal soft-tissue component, whereas the abutment diameter is usually the same as the implant diameter for the external connection. On contrary, in the current study, periimplant bone remodeling up to 1.5 mm was frequently seen in thick soft tissues sites for EH implants. Moreover, thinner periimplant mucosal was not always associated to greater crestal bone changes, even for EH connections.

The concept of platform-switching, as introduced by Lazzara and Porter,[21] is based on the hypothesis that a narrower abutment can increase the distance between the implant-abutment microgap contamination and the crestal bone, and may allow the establishment of an adequately dimensioned biological width, thus reducing bone resorption. However, although the effects of the biological aspects (i.e., the formation of a biological width, implant-abutment

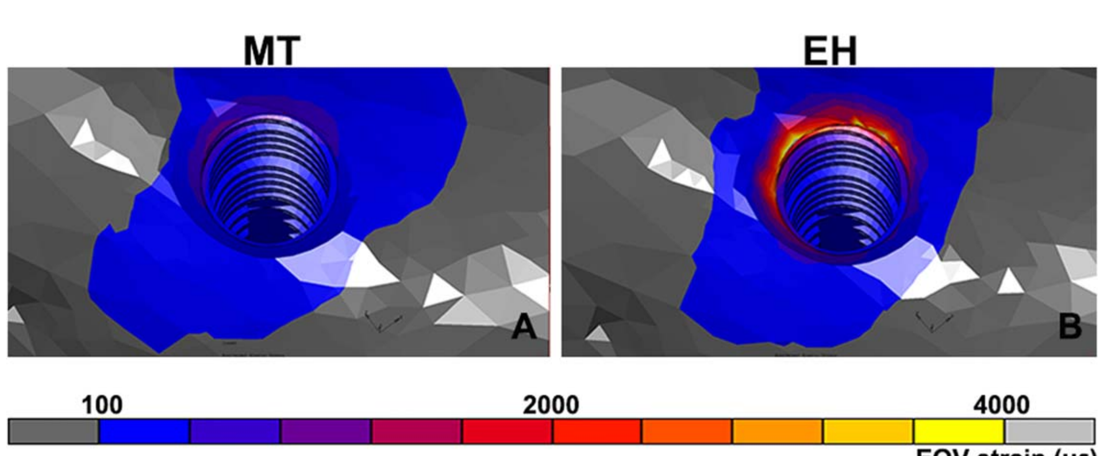

Figure 7 Occlusal view of EQV strain ($\mu\varepsilon$) distribution in bone for the Morse-taper (MT) and external hexagon (EH) models, for a 640N loading. The higher strain concentration for EH connection is visible.

TABLE 2 Mean Peak Equivalent (EQV) Strain in Bone, for all Simulated Models

		Mean EQV strain (με) in bone	
Implant position	Loading condition	Morse-taper	External hexagon
1	480 N	1,117.2	5,172.8
	480 N Uni	1,861.9	9,240.1
	640 N	1,332.5	6,245.6
2	480 N	623.2	491.0
	480 N Uni	756.6	711.9
	640 N	650.3	832.8
3	480 N	448.8	560.2
	480 N Uni	361.7	208.4
	640 N	462.2	790.1
4	480 N	894.0	6,964.0
	480 N Uni	427.5	1,532.4
	640 N	1,155.9	8,514.6

Implant positioning in the arch 1–4, considering positions from the right side to the left side.
Uni, Unilateral loading.

gap bacterial contamination) should not be ignored, these factors alone are not sufficient to entirely explain the crestal bone remodeling. Shin et al.[31], comparing different implant neck designs in a randomized clinical study, found the greatest amount of bone loss (1.32 ± 0.27 mm) for the group with platform-switching abutment and a machined neck. The smallest amount of bone loss (0.18 ± 0.16 mm) was found for the group with matching diameter abutment and a rough-surfaced microthreaded implant neck. Hence, it is important to consider all the possible factors that may exert an influence within the implant neck region such as, the presence of threads, surface roughness and the implant-abutment connection type. Moreover, the conclusions in some studies, in which less bone loss was observed for the platform-switching configuration, were made by comparing different implant diameters with different characteristics of implant neck designs.[21–23] As it was actually the implant design and not only the abutment diameter that varied, it is somewhat difficult to determine which factor had the highest contribution to the observed results.

Conversely, the presence of bacterial contamination at the implant-abutment gap could be responsible for inflammatory reaction in periimplant soft tissues, which may induce osteoclastic crestal bone resorption. Although no connection design has been able to provide a perfect sealing at the implant-abutment interface, conical connections seem to be superior in reducing bacterial leakage.[19,20] It has been speculated whether the microgap contamination could seriously affect the long term health of periimplant tissues. In this study, probing pocket depth (PPD) and mGI presented not significant differences, between connection types. In addition, the values of PPD were less than 2 mm and mGI scored very low, meaning that the evaluated regions were healthy from a clinical point of view. In the same way, Romanos et al.[19] found no clinical evidence of mucositis and/or peri-implantitis around internal butt joint connections and MT implants 2 years after loading. Similar results were also shown by Van Asscher et al.[28] Comparing EH and MT implants after 12 year of loading, the authors reported no differences in clinical parameters between both connection types.[28] As in this study, all patients were scheduled for periodontal supportive recall visits, during the entire study period.[28]

Accordingly, although Castro et al.[13] have shown significantly more bone remodeling for EH implants in a histometrical evaluation in dogs, as discussed above, no inflammatory cell infiltrate, foreign body reaction cells, or multinucleated giant cells were found in periimplant soft-tissue for both implant connection types.

Several studies have shown an association between the presence of certain periodontopathogens and periimplantitis-related pathogens, including *A. actinomycetemcomitans*, *P. gingivalis*, *P. intermedia*, *T. forsythia*, and *T. denticola*.[32–34] Peri-implant infections may also include *F. nucleatum* and *Actinomyces species*.[34] In this respect, however, Thöne-Muhling et al.[35] reported that the amount of micro-organisms at periimplant sites might be an important determinant for the development of disease. Thus, the main difference between mucositis and periimplant health may not be the prevalence but rather the amount of putative pathogens in the evaluated sites. In the present survey, most of the samples collected from periimplant sulcus, and also from unstimulated saliva, had very few periimplant pathogens, denoting a good microbiological condition at these regions (including saliva). Furthermore, no significant microbiological differences could be observed between both connection types, after 6 months follow-up. Van Assche et al.[28], comparing the microbiological outcome of two screw-shaped titanium implant systems (TiOblast™ – Astra Tech with MT connection vs Bra˚nemark – Nobel Biocare with EH connection) placed following a split-mouth randomized protocol, observed no significant microbiological differences (qualitative and quantitative) between both implant types. The authors argued that the implant–abutment connection did not seem to influence the microbiota sampled at periimplant sulcus, 12 years after loading.[28] In a recent study, Romanos et al.[19] evaluated in vivo bacterial composition of implant systems inner parts with two different prosthetic connections (Morse tapered vs internal polygonal butt-joint connections), loaded for 2 years. The authors found no statistical significance between the two connections. In addition, they reported no significant changes in the overall microbial profiles at the different time intervals. In other recent study, Canullo et al.[20] evaluated the bacterial microbiota present inside the implant connection and in the periimplant sulcus fluid of four different healthy implants systems. Even after 5 years of functional loading, the differences of total bacterial loading between different connection types neither inside implant connection nor in periimplant sulcus still did not reach statistical significance, although MT connection showed the lowest amount of red complex bacteria, for "total bacterial loading": considering together bacteria collected in sulcus and inside the implant.[20] In this study, differences in periimplant bone loss were statistical significant between connection types at 1-month follow-up and also comparing baseline and 1-month of implant loading, when most of the bone loss has already ocurred. In this way, it remains necessary to study the clinical relevance of such implant internal microbiota, and its possible influence in early periimplant bone loss.

A finite element analysis (FEA) has been often used to gain insight into the biomechanics of oral implants and to verify some of the hypotheses that relate mechanical loading to periimplant bone responses.[11,29,36,37] This can be achieved by a combination of the FEA and animal experiments. An individualized FE model, which incorporates specific bone geometry, implant position relative to the bone geometry and periimplant bone quality may be created, to calculate the bone stresses and strains resulting from a loading experiment, and then relate them to the observed bone response of a given implant. From this approach, important parameters for osteogenic, as well as for bone-resorptive mechanical stimulus were identified. Some criteria for adaptive bone modeling (bone gain and bone loss) have been proposed in relevant biomechanical literature, and might be used as reference for FEA results. In this way, Duyck et al.[11], in an experiment in rabbits' tibia, proved that the stress/strain concentration, as well as the bone-to-implant relative displacement, caused by an excessive dynamic loading, are capable to induce the marginal bone loss around well osseointegrated implants, without the presence of oral biofilm. Unloaded control implants showed no bone loss. Although, precise determination of the loading level that separates mechanical loading into acceptable, osteogenic or failure-inducing levels is difficult and until now unresolved, some authors focused on the bone strain amplitudes as the mechanical stimulus determinant to bone adaptive process. A possible threshold for pathological bone overload was considered by Frost[38] as 4,000 $\mu\varepsilon$. Also Duyck et al.[11], by FEA based on CT-images, estimated 4,200 $\mu\varepsilon$ as the value associated with overload-induced resorption.

Conversely, generic FE models, which intend to focus only on the relative influence of some implant parameter in a comparative analysis rather than to the absolute in vivo results could adopt some simplifications of complex reality (as the absence of implant and retaining screws preload, simplified loading direction, distribution, and boundary/interface conditions), assuming that proportions and relative effects would reflect the actual clinical situation with sufficient accuracy. As this study merely concentrated on the comparison of different conditions, the relative values were supposed to still lead to a better qualitative understanding of the biomechanics around implants. Furthermore, the present FE analysis showed peaks of bone strain much higher than 4,000 $\mu\varepsilon$ for EH connection. Nevertheless, rather than only strain amplitude, also loading frequency and number of loading cycles are parameters capable to greatly influence the cortical bone adaptive response.[37,39,40] Furthermore, the loading applied in the presented simulation was static, and one should consider that bone responds to dynamic (rather than to static) loads.[11,40,41] In this way, it must be kept in mind that the modeling of bone adaptive processes was not one of the aims of this study. The strain peaks were seen locally in a minor part of the marginal bone, where indeed some localized bone resorption is likely to occur for EH connection, as it has been shown by radiographic evaluation.

The present FEA simulating the randomized implant distribution of the 12 patients, in diverse loading conditions, showed higher peak bone strain levels for EH comparing to MT connection. Merz and coworkers[38] compared, by experimental and finite element methods, the stresses induced by off-axis loads on tapered and butt-joint connections. They concluded that the tapered interface distributed the stresses more evenly when compared to the butt-joint connection. In other finite element studies, Hansson[24] and also Pessoa et al.[25] observed that a MT implant-abutment at the level of the marginal bone substantially decreased bone stress peak and improved the stress distribution into the supporting bone.

Moreover, mechanical micromovements have been found to be extremely low in Morse tapered connections.[25] Basically, the external hex configuration and the taper connection have different mechanical principles of function.[38] EH connection determines the rotational position but does not absorb any lateral loading. There is no form lock or positive locking. On contrary, in a taper connection, lateral loading is resisted mainly by the taper interface, which prevents the abutment from tilting off.[25,42] Some authors suggested that microleakage occurs through these microgaps, and the degree of leakage is dependent on the type of abutment connection, the gap size, and the amount of micromovement.[43] A recent in vitro study has shown that implants with MT connection exhibited minimal bacterial penetration down to the threaded part of the implant-abutment interface subjected to dynamic loading,[43] which was in part supported by in vivo studies.[20] Some authors speculated that the stability of internal conical connection would minimize the pumping effect between the implant and the abutment, thus preventing periimplant bacterial colonization.[19,20] All of these hypotheses still lack definitive evidence.

CONCLUSION

Within the limitations of this study, it can be concluded that varying implant-abutment connection type will result in diverse early periimplant bone remodeling. The present findings suggest that MT connections are more efficient preventing early periimplant bone loss, compared to EH connections.

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