

CLINICAL RESEARCH

Three-year marginal bone loss associated with platform-switched versus platform-matched connections and Morse taper versus external hexagon implants: A split-mouth randomized clinical trial

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Peri-implant bone loss occurs around all types of implants, irrespective of macrogeometry, surface treatment, prosthetic connection type and design, or commercial brand.¹ Bone remodeling is a multifactorial physiological phenomenon primarily regulated by the epithelial growth factor (EGF) and is responsible for the formation of the peri-implant biological space.¹⁻⁵ Other factors reported to be involved include occlusal force transmission from abutment to implant,^{1,3,5-12} inflammatory cell infiltration caused by bacterial colonization of the implant-abutment microgap,^{1,5,6,10,13-17} micromovement of external hexagon connections,^{1,12,13,17} adaptive bone tissue response to the formation of the biological space,^{1,5,10,18-25} and the 3-dimensional position of the implant.¹⁴

The use of a platform-switched (PS) abutment, that is, with a smaller diameter than that of the implant platform,

ABSTRACT

Statement of problem. Whether the reduced peri-implant bone loss associated with platform-switched (PS) connections compared with platform-matched (PM) connections is consistent across different implant types remains unclear. Comparative clinical evidence is limited, highlighting the need for studies evaluating the interaction between connection design and implant type.

Purpose. The purpose of this split-mouth randomized clinical trial was to evaluate the influence of the interaction between connection design and connection type on vertical and horizontal marginal bone loss (vMBL and hMBL) associated with implant-supported prostheses in the posterior mandible after 3 years of follow-up.

Material and methods. Fourteen participants received 64 implants in the premolar and molar regions. Each side of the mouth received 2 implants—1 Morse taper (MT) and 1 external hexagon (EH)—with only 1 connection design, PS or PM, thus forming combinations MT+PS, MT+PM, EH+PS, and EH+PM. While each connection design was assigned to 1 side of the mouth, each implant type was assigned to 1 position on the hemiarch, either molar or premolar. Standardized digital periapical radiographs were obtained by using an acrylic resin device customized for each participant, and MBL was assessed immediately, at 3 months, and at 3 years after prosthesis installation. Three-way ANOVA for repeated measures and the Tukey HSD test were used to analyze vMBL, while the Mann-Whitney and Friedman tests were used for hMBL ($\alpha=.05$).

Results. vMBL was significantly higher for EH+PS than for MT+PS ($P<.05$) and higher for MT+PM than for MT+PS ($P<.05$). hMBL for MT+PS increased significantly over time ($P=.009$).

Conclusions. The MT+PS combination outperformed the EH+PS combination in terms of vMBL. Additionally, the PM connection design was ineffective in protecting the MT connection type against vMBL, and the hMBL associated with the MT+PS combination increased over time. (J Prosthet Dent xxxx;xxx:xxx-xxx)

as proposed by Lazzara and Porter,⁴ has been associated with reduced peri-implant bone loss compared with platform-matched (PM) abutments. Furthermore, changes in the emergence profile of abutments have been reported to

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Clinical Implications

Although horizontal bone loss associated with the MT+PS combination increased over time and equaled that of the other combinations tested, the vertical bone loss for this combination was lower than that for the EH+PM, EH+PS, and MT+PM combinations (the latter experimentally created in the present study). These findings confirmed that the determining factor for reduced vertical bone loss after 3 years was the connection design (PS) rather than the connection type (MT or EH).

have a more significant effect on peri-implant bone preservation than the type of implant-abutment connection.^{1,3,6,8,17,18,20–22,24–26} Clinical and radiographic follow-up of implants installed with a PS connection design has demonstrated reduced peri-implant bone remodeling. The initial justification for this technique was its biomechanical behavior, which directs the stresses generated in the implant-abutment connection toward the central axis of the implant, thereby promoting better dissipation of masticatory forces.^{1,3,4,6,8,10,20–22}

Thus, the aim of this study was to evaluate the influence of the interaction between connection design (either PS or PM) and connection type (either external hexagon [EH] or Morse taper [MT]) on the vertical and horizontal marginal bone loss (vMBL and hMBL) associated with implant-supported prostheses in the posterior region of partially edentulous mandibles. The null hypothesis was that no differences would be found between the connection designs and connection types studied regarding these radiographic variables associated with implant-supported prostheses at the end of a 3-year follow-up period.

MATERIAL AND METHODS

This randomized, controlled, split-mouth clinical study had been approved by the local research ethics

committee (no. 2 424 701), was conducted following the updated guidelines for reporting randomized parallel-group trials according to the 2010 CONSORT Statement,²⁷ and was registered in the Brazilian Clinical Trials Registry (ReBEC) (no. RBR-78JX54). All participants provided informed consent and did not incur any costs related to treatment.

Each side of the mouth received a minimum of 2 implants (SW line; S.I.N.)—1 with connection type MT and the other with EH—with only 1 connection design, either PS or PM. Thus, 4 combinations were tested: MT+PS, MT+PM, EH+PS, and EH+PM (Fig. 1). MT implants featured both a diameter and platform of 3.8 mm, while EH implants had a diameter of 3.75 mm and a platform of 4.1 mm. Both implant types shared the same macrogeometry,²⁸ identical surface treatment, and a minimum length of 8.5 mm. All implants were restored with single metal-ceramic crowns screwed onto a universal cast to long abutment (EUCLA 366-Q, EUCLA 406-Q, EUCLAM 3502-H, or EUCLAM 3502-H, depending on the requirement of each study group; S.I.N.).

The sample size was calculated by using ANOVA for repeated measures, with an effect size of 0.56—determined based on Caram et al¹⁹—a significance level of 5%, and a power of 80%. The calculation indicated a minimum requirement of 12 participants, and 14 were recruited to account for potential dropouts. One participant received 8 implants.

The enrolled individuals were over 18 years of age, bilaterally lacked posterior teeth in the mandibular arch (Kennedy Class I), and had a native bone volume of at least 5 mm in thickness and 10 mm in height, measured from the roof of the mandibular canal to the alveolar bone cortex. They had teeth or fixed prostheses in the opposing arch and no health conditions that could interfere with osseointegration or long-term follow-up. Pregnant women, minors, individuals with substance addiction, significant conditions that could compromise long-term follow-up, chronic periodontal disease in teeth adjacent to the implant sites, and those wearing

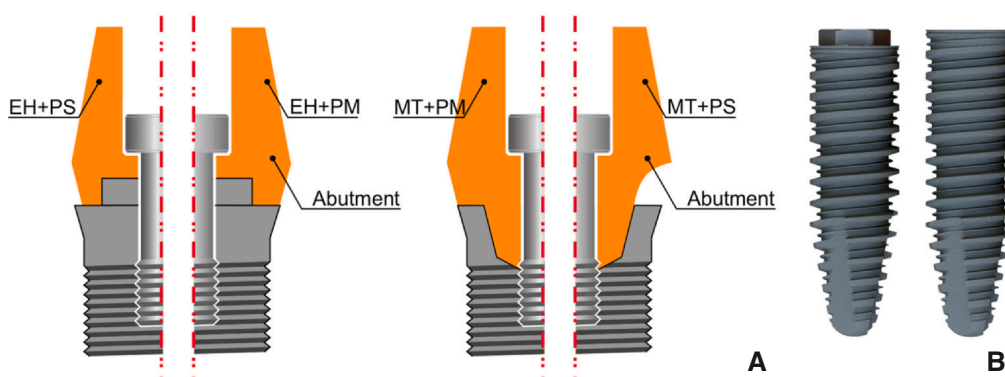


Figure 1. A, Connection types and connection designs tested in study groups. EH+PS, external hexagon type and platform-switched design; EH+PM, external hexagon type and platform-matched design; MT+PS, Morse taper type and platform-switched design; MT+PM, Morse taper type and platform-matched design. B, EH and MT implants used in study.

removable prostheses in the opposing arch were excluded from the study.

In each participant, an implant-abutment connection design (either PS or PM) was randomly assigned (www.randomizer.org) to 1 side of the mouth—left or right—while the opposite side received the other connection design. On each side of the mouth, a connection type (either MT or EH) was randomly assigned to 1 position on the hemiarch—either premolar or molar—while the other position received the alternative connection type. For the participant who received 8 implants, the connection type (MT or EH) was randomly assigned to 1 of the positions of each tooth type in the hemiarch—first or second premolar and first or second molar.

During the planning phase, panoramic and periapical radiographs, along with cone beam computed tomography, were used to assess bone availability. An irreversible hydrocolloid impression (Avagel; Dentsply Sirona) was made, and a cast was poured in Type III stone (Herodent; Vigodent), on which a 1-mm acetate surgical guide (Cristal; Bio-Art) was fabricated. The participants were prescribed 2 capsules of 1 g amoxicillin and 1 tablet of 4 mg dexamethasone preoperatively. All surgical procedures were performed by a single experienced operator (D.G.P.). Participants were anesthetized with 2% lidocaine hydrochloride combined with 1:100 000 epinephrine (Alphacaine; Nova DFL). A 15C scalpel blade (Solidor) was used to make an intrasulcular incision at the adjacent teeth and a linear incision on the edentulous space of the alveolar crest. Subsequently, a full-thickness mucoperiosteal flap was elevated.

The alveolar bone was cut by using a surgical kit (KCSW02; S.I.N. Implant System) under constant irrigation with a sterile 0.9% NaCl solution (Sanobiol). The surgical guide was used to guide the 3-dimensional positioning of the implants (Fig. 2). The bone cutting protocol recommended by the manufacturer was followed. The implants selected for each participant (SW line; S.I.N.) were installed, and primary stability was assessed with a surgical torque wrench (TMECC 02; S.I.N.). The implant platforms were kept at the level of

the bone crest (epicrestally) to standardize the reference for subsequent measurements of peri-implant bone loss (Fig. 2).²⁹ Continuous loop sutures were placed by using 5-0 monofilament nylon thread and a 1/2 CT needle (Technew).

Postoperatively, 1 capsule of 500 mg amoxicillin every 8 hours for 7 days, 1 tablet of 100 mg nimesulide every 12 hours for 3 days, 1 tablet of 750 mg paracetamol every 6 hours as needed for pain were prescribed, and, after 24 hours, daily mouth rinses with a 0.12% chlorhexidine gluconate solution (Periogard; Colgate Palmolive) were prescribed for 15 days. The sutures were removed 10 days after surgery. After 90 days, the surgical site was reopened under local anesthesia. A linear incision was made, and healing abutments were installed. Impressions were made with perforated complete arch impression trays (EI0099; S.I.N.) and addition silicone (Futura AD; Nova DFL). Casts with artificial gingiva (Gingifast Elastic; Zhermack) were poured in Type IV stone (Durone; Dentsply Sirona) and mounted in a semi-adjustable articulator (4000-S; Bio-Art).

The screw-retained metal-ceramic prostheses were fabricated by a single dental laboratory technician, with specific abutments (S.I.N.) for each of the connection type and connection design combinations: EH+PS, EUCLA 366-Q abutment; EH+PM, EUCLA 406-Q abutment; MT+PS, EUCLAM 3502-H abutment; and MT+PM, EUCLAM 3502-H abutment. In MT+PM, the abutment was modified by overcasting to create an experimental PM abutment for the MT implant¹⁹ (Fig. 3). A Ni-Cr alloy (Fit Cast 2; Talmax) was used for the overcasting, and a feldspathic ceramic (Super Porcelain Ex-3; Noritake) was applied to the abutments after casting to produce the metal-ceramic crowns. The prostheses were installed with the torque recommended by the manufacturer, and the screw access was sealed with composite resin (Z350; 3M). The occlusion was adjusted with 12- μ m articulating paper (Hanel; Coltène).

Once installed, the prostheses were not removed.^{19,26,30} Standardized digital periapical radiographs were made by using an acrylic resin device

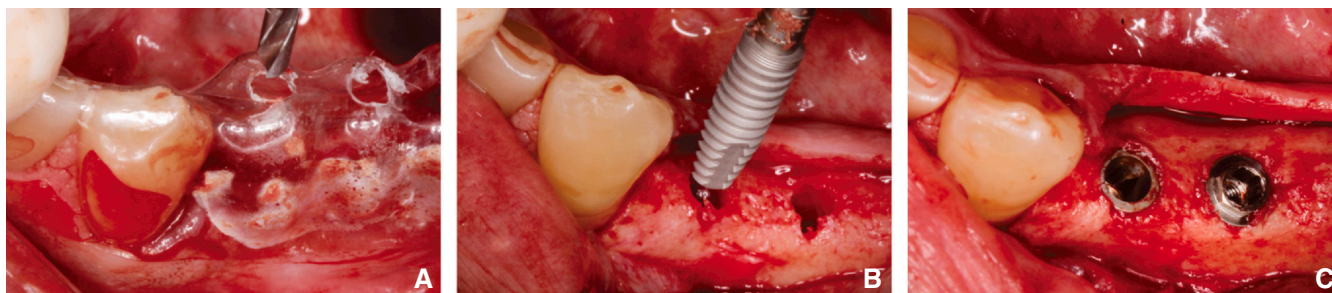


Figure 2. A, Surgical guided drilling to ensure optimal 3-dimensional positioning. B, Implant installation. C, MT and EH implants placed side-by-side and standardized at bone level. EH, external hexagon connection type; MT, Morse taper connection type.

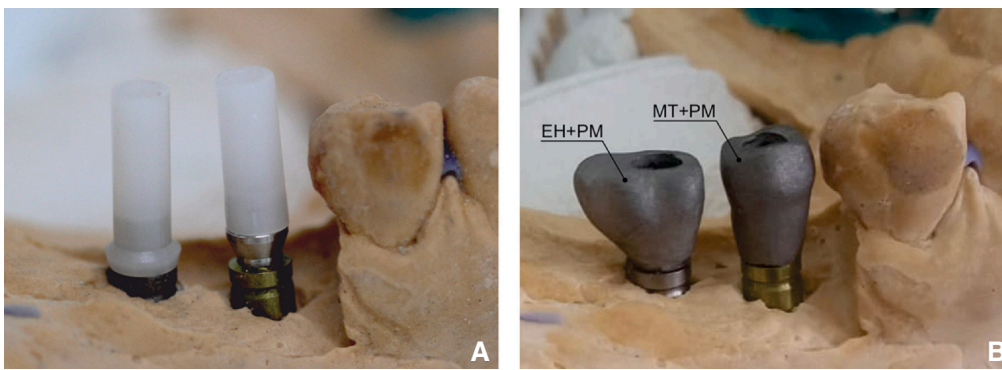


Figure 3. A, Abutments used for combinations EH+PM and MT+PM before casting. B, Abutments in place after casting. Note, in combination MT+PM, abutment modified by overcasting to produce experimental PM connection design for MT implant. EH, external hexagon connection type; MT, Morse taper connection type; PM, platform-matched connection design.

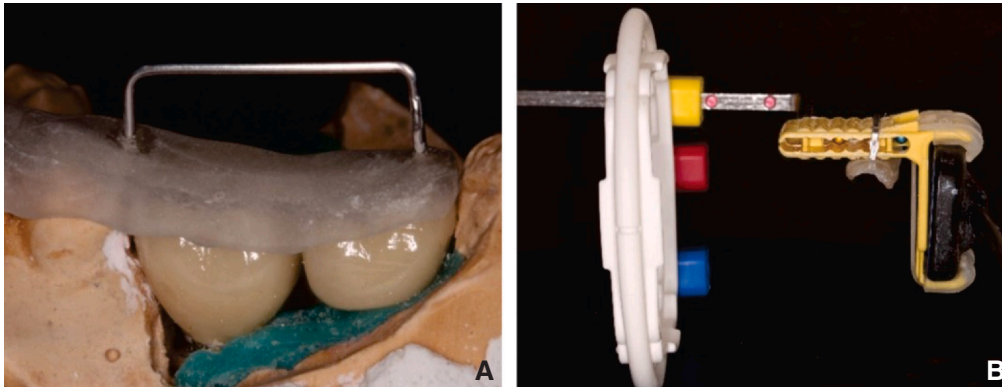


Figure 4. A, Acrylic resin occlusal device with metal handle developed to standardize radiographic images at different assessment timepoints (lateral view). B, Radiographic positioner holding digital sensor in selected position (periapical radiograph, yellow) inserted into device handle (frontal view).

customized for each participant (Figs. 4, 5). The device was used to stabilize the radiographic positioner, thereby ensuring that all follow-up radiographs were made from the same angle at each follow-up period: T1, at the moment of prosthesis installation; T2, 3 months after prosthesis installation; and T3, 3 years after prosthesis installation.^{10,25}

All digital radiographs were obtained by a single operator (D.G.P.) by using a periapical X-ray unit (765 DC; Gendex) at 0.01 seconds, 70 kVp, and 10 mA. The images were captured with a direct digital system (Visualix and HD; Gendex) with a CCD-type sensor and saved in JPG format at 100 dpi resolution. The images were analyzed on a computer equipped with a 2-MB

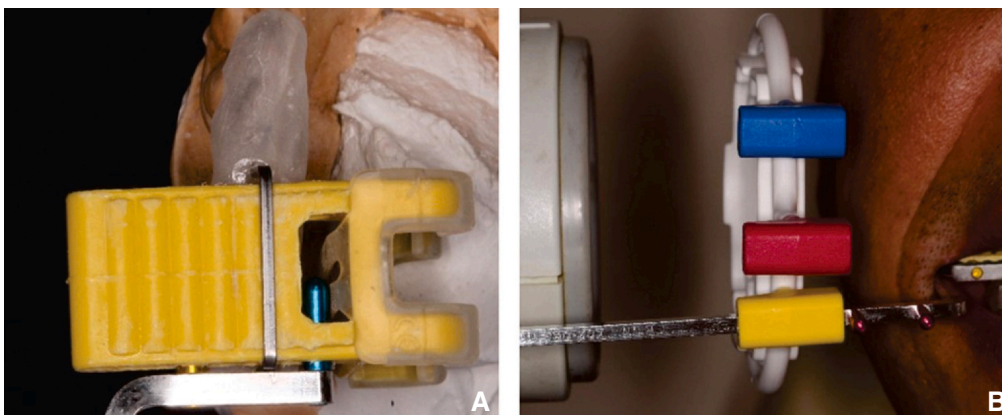


Figure 5. A, Device + positioner assembly adapted on cast (occlusal view). B, Device + positioner + sensor assembly positioned in participant's mouth (frontal view) and collimator of radiographic apparatus in position.

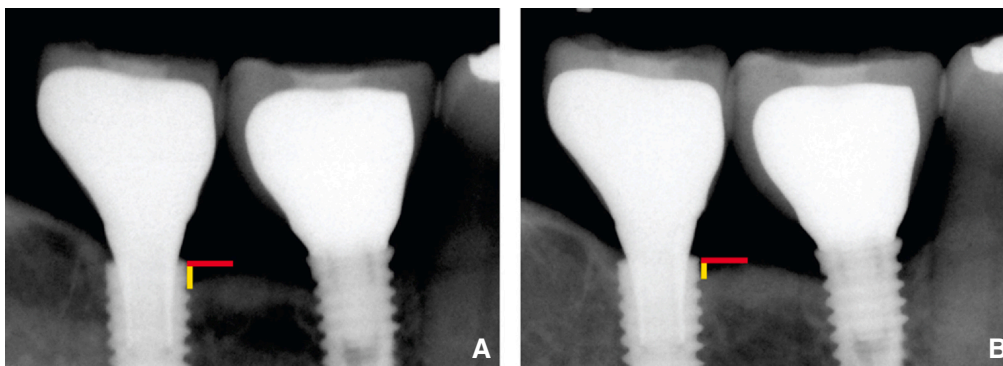


Figure 6. Measurement of vertical (yellow line) and horizontal (red line) bone loss. A, Radiograph made with radiographic device at prosthesis installation (T1). B, Radiograph made with radiographic device 90 days after prosthesis installation (T2).

video card and a calibrated monitor (ET1515L; Elo Touch Systems) under controlled lighting conditions.

Measurement of vMBL was based on the linear distance between the bone-to-implant contact point closest to the prosthetic platform, and the abutment-implant junction. hMBL was measured as the linear distance between the highest point of the bone crest and the abutment-implant junction. These measurements were made by a single, previously calibrated researcher (D.G.P.) and marked on the radiograph images in the mesial and distal regions of the implant^{3,19} (Fig. 6) by using a software program (ImageJ v. 1.52a; National Institutes of Health).

The assumptions of normality and homoscedasticity were met for vMBL, but not for hMBL. Therefore, 3-way ANOVA for repeated measures followed by the Tukey HSD test was used to analyze vMBL, while the Mann-Whitney and Friedman tests were applied to analyze hMBL. Statistical calculations were performed by using a statistical software program (IBM SPSS Statistics, v23; IBM Corp) ($\alpha=.05$).

RESULTS

The 14 participants received 64 implants, of which 21 (32.8%) were installed in the mandibular premolar region and 43 (67.2%) in the mandibular molar region. Early implant loss occurred twice in a single participant from Group MT+PS; however, the surgical procedure was repeated, and the participant remained in the study.

The values of vMBL and hMBL observed for the study groups are presented in Table 1. No interaction was found between connection type, connection design, and assessment timepoint regarding vMBL ($P=.798$), but an interaction was found between connection type and design regarding this variable ($P<.001$). Similarly, no significant interaction was found between connection type and timepoint ($P=.515$) or between connection design and timepoint ($P=.525$) regarding vMBL. Also, no significant differences were found among timepoints regarding this variable ($P=.847$). vMBL was significantly higher for EH+PS than for MT+PS ($P<.001$); however, no significant difference was found between EH+PM

Table 1. Mean \pm standard deviation values of vertical and horizontal marginal bone loss according to implant-abutment connection type, connection design, and assessment timepoint

Assessment Timepoint		EH		MT	
		PS	PM	PS	PM
vMBL (mm)	T1	1.37 \pm 0.47	1.40 \pm 0.26	0.73 \pm 0.47	1.13 \pm 0.73
	T2	1.37 \pm 0.43	1.45 \pm 0.33	0.63 \pm 0.39	1.27 \pm 0.67
	T3	1.22 \pm 0.54	1.33 \pm 0.43	0.64 \pm 0.42	1.34 \pm 0.52
	Mean (overall)	1.32 \pm 0.48 ^{A*}	1.39 \pm 0.34 ^{A**}	0.67 \pm 0.42 ^{B*}	1.25 \pm 0.64 ^{A**}
hMBL (mm)	T1	0.45 \pm 0.63	0.66 \pm 0.81	0.14 \pm 0.31 ^b	0.44 \pm 0.66
	T2	0.45 \pm 0.65	0.71 \pm 0.68	0.15 \pm 0.34 ^b	0.58 \pm 0.76
	T3	0.59 \pm 0.56	0.86 \pm 0.81	0.62 \pm 0.59 ^a	0.88 \pm 0.62

EH, external hexagon connection type; hMBL, horizontal marginal bone loss; MT, Morse taper connection type; PM, platform-matched connection design; PS, platform-switched connection design; T1, moment of crown installation; T2, 3-month follow-up; T3, 3-year follow-up; vMBL, vertical marginal bone loss.

Overall vMBL means followed by different uppercase letters indicate significant difference between the PS and PM connection designs, considering each implant type separately; * indicates significant difference between the EH+PS and MT+PS combinations; ** indicates lack of significant difference between the EH+PM and MT+PM combinations (3-way ANOVA for repeated measures and Tukey HSD test, $P<.05$); hMBL means followed by different lowercase letters indicate significant difference between assessment timepoints for the MT+PS combination (Mann-Whitney and Friedman tests, $P<.05$).

and MT+PM or between EH+PS and EH+PM regarding this variable ($P>.05$). In contrast, vMBL was significantly higher for MT+PM than for MT+PS ($P<.05$).

No significant difference was found between EH+PS and MT+PS regarding hMBL, whether at T1 ($P=.244$), T2 ($P=.191$), or T3 ($P=.969$). Likewise, no significant difference was found between EH+PM and MT+PM regarding this variable at either T1 ($P=.418$), T2 ($P=.471$), or T3 ($P=.666$). Also, no significant difference was found regarding hMBL, either between EH+PS and EH+PM, whether at T1 ($P=.509$), T2 ($P=.249$), or T3 ($P=.365$) or between MT+PS and MT+PM, whether at T1 ($P=.309$), T2 ($P=.158$), or T3 ($P=.200$). For MT+PS, hMBL values at T1 and T2 did not differ significantly but were significantly lower than those observed at T3 ($P=.009$). No other significant differences were observed over time regarding this variable, whether for the MT+PM ($P=.241$), EH+PS ($P=.705$), or EH+PM ($P=.433$) combinations.

DISCUSSION

No 3-way interaction (connection type \times connection design \times assessment timepoint) was observed for either vMBL or hMBL. However, separate analyses revealed significant 2-way interactions between connection type and design, leading to the partial rejection of the null hypothesis that no differences would be found between the connection designs and connection types studied regarding these radiographic variables associated with implant-supported prostheses at the end of a 3-year follow-up period.

These results contrast with those of Lin et al,¹⁰ who reported that the type and design of the implant-abutment connection had no significant impact on the peri-implant bone crest. However, Formoso et al³ conducted a clinical study with a 1-year follow-up and reported higher MBL values for PM connections, but the mean values they reported were lower than those found in the present study (0.01 mm for PS and 0.42 mm for PM connections). These values were also lower than those reported by Pozzi et al,¹ who compared PS and PM abutments in combination with MT and EH implants, respectively, in partially edentulous arches over 12 months, reporting a mean bone loss of 0.51 \pm 0.34 mm for MT+PS and 1.10 \pm 0.52 mm for EH+PM combinations. Sesma et al²⁵ and Pan et al³¹ also evaluated connection design in a 3-year study and concluded that PS connections were associated with lower vMBL compared with PM connections, consistent with the results of the present study.

However, as in the present study, Koo et al²⁹ standardized the positioning of the implants at bone level—a relevant differential factor that has been reported to significantly influence the biomechanics of the

implant, as demonstrated by Macedo et al³² in a finite element study, where implants positioned below the bone crest produced greater stress on the peri-implant bone than those positioned at bone level. Koo et al²⁹ conducted a 1-year follow-up and concluded that bone crest changes were significantly greater for the external connection, suggesting that the biological profile resulting from an internal connection allowed for better horizontal tissue adaptation. This was tested in the EH+PS and MT+PS combinations in the present study, which found a significant interaction between connection type and design regarding vMBL, showing that the bone crest was better preserved in MT+PS than in EH+PS combinations, even though both were installed at bone level.

Schwarz et al³³ conducted a systematic review and found that PS prevents or minimizes peri-implant MBL, suggesting that an increased distance between the implant-abutment interface (microgap) and the bone surface allows for thicker soft tissues in the horizontal plane, thus protecting the bone crest, consistent with Koo et al.²⁹ The role of the microgap was also examined by Cappiello et al,³⁴ who found mean bone loss values of 0.95 \pm 0.32 mm and 1.67 \pm 0.37 mm for PS and PM connections, respectively, confirming the impact of the microgap on bone crest remodeling. In the present study, the MT+PS combination was associated with lower vMBL compared with the MT+PM combination, an observation that may be linked to the microgap being closer to the bone crest.

Medeiros et al²⁴ conducted a systematic review and concluded that most studies reported lower MBL values for implants with internal connections compared with external connections. In another systematic review, Di Girolamo et al²⁰ reached a similar conclusion. In the present study, vMBL was higher in EH+PS than in MT+PS combinations, indicating that the external connection was less effective in preserving the peri-implant bone, even when combined with the PS design. This result, coupled with the finding that MT+PS performed better than MT+PM, confirmed the superiority of the MT implant when paired with the PS design in maintaining the vertical dimension of the bone. However, from T1 to T3, the PS design combined with the MT implant installed at bone level did not effectively prevent MBL. This observation might be linked to the action of EGF in forming a 3-dimensional peri-implant biological space and inducing the chamber effect, as described by Degidi et al.³⁰ Based on this rationale, some authors have suggested positioning MT implants in an infraosseous position to help prevent MBL and improve peri-implant tissue adaptation.^{14,30,35,36}

Medeiros et al²⁴ and Yamanishi et al¹² conducted finite element studies to evaluate external connection with straight abutment (EC+PM), internal connection

with straight abutment (IC+PM), and internal connection with tapered abutment (IC+PS). Both reported greater abutment micromovement for the EC+PM compared with IC+PS combinations, highlighting the lower mechanical stability of external connections. This finding was consistent with the higher vMBL observed in the present study for the EH+PS versus MT+PS combinations, confirming the superior performance of the MT implant. It also indicated that the PS design alone was insufficient to prevent bone remodeling in the EH+PS combination.

Hansson⁷ also conducted a finite element study and reported similar results to those of Yamanishi et al,¹² noting that an internal tapered connection combined with the PS design resulted in lower shear stress peaks between bone and implant compared with an external connection with the PM design. The present study examined MT implants with different designs and found higher vMBL in MT+PM compared with MT+PS combinations, indicating that the PM design did not adequately protect the MT implant against vMBL. In other words, even with an internal connection and mechanical stability, the lack of a narrower biological profile and the presence of a microgap positioned closer to the bone crest led to greater bone remodeling.

One key difference between the present study and previous research was the creation of an experimental abutment to form the MT+PM combination. Most of the existing literature supports the superiority of the MT implant when combined with the PS design regarding masticatory load distribution, gingival tissue adaptation, and prosthetic stability, and it has been argued that the biologically more favorable microgap positioning of this configuration helps in preserving peri-implant bone. Therefore, the creation of a PM abutment for the MT implant was intended to combine the mechanical benefits of the Morse connection with the biological condition characterized by the position of the microgap closer to the bone crest; this is considered less favorable, in principle, because of the reduced space available for the horizontal adaptation of gingival tissue. This approach enabled the evaluation of the individual effect of each factor involved.

Another methodological focus of this study was the installation of MT implants at bone level, ensuring an unbiased comparison between MT and EH implants in terms of bone remodeling.^{28,32} Nevertheless, this study was clinical in nature and, as such, inherently susceptible to the influence of uncontrolled and multifactorial variables. Therefore, studies with larger sample sizes and longer follow-up periods are needed to address these limitations.

CONCLUSIONS

Based on the findings of this split-mouth randomized clinical trial, the following conclusions were drawn:

1. Three years of radiographic follow-up of implant-supported prostheses in the posterior region of partially edentulous mandibles revealed that the MT+PS combination outperformed the EH+PS combination in terms of vMBL.
2. The PM connection design was ineffective in protecting the MT connection type against vMBL, and the hMBL associated with the MT+PS combination increased over time.

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