Clinical and Radiological Outcomes of Two Implants with Different Prosthetic Interfaces and Neck Configurations: Randomized, Controlled, Split-Mouth Clinical Trial

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ABSTRACT

Background: Peri-implant bone loss seems to occur following implant placement/loading regardless of all the efforts to eliminate it. Several factors, including surgical trauma, biologic width establishment, lack of passive fit of the superstructures, implant-abutment microgap, and occlusal overloading, may increase peri-implant bone loss. Over the years, new interface designs were introduced and clinical studies suggest that internal conical connection and platform shifting may be advantageous for marginal bone preservation.

Purpose: To compare clinical and radiological outcomes of two implant designs with different prosthetic interfaces and neck configurations in a randomized, controlled, split-mouth clinical trial.

Materials and Methods: Thirty-four partially edentate patients randomly received at least one internal conical connection with back-tapered collar and platform shifting design or external-hexagon implants with flat-to-flat implant-abutment interface. Primary end point was peri-implant bone level changes at different time points, failures of implants and/or prosthesis, any complications, implant stability quotient (ISQ) values, and periodontal parameters.

Results: No dropout occurred. Marginal bone changes were statistically significantly different with better results for the internal conical connection. No implants and prosthesis failures have been observed, yielding a cumulative survival rate of 100%. A high ISQ value was found for both implants, and no statistically significant difference was found for ISQ mean values between interventions at each time point ($p > .05$). All implants showed no bleeding on probing and a very slight amount of plaque at the 1-year-in-function visit.

Conclusions: Both implant designs investigated performed similarly in terms of failure rates, providing successful results up to 1 year after loading. The back-tapered neck configuration with conical connection and built-in platform shifting showed statistically lower marginal bone loss than straight neck configuration with flat-to-flat implant-abutment interface and external-hexagonal connection.

KEY WORDS: bone level, bone loss, dental implants, implant-abutment interface, platform shifting

INTRODUCTION

Marginal bone loss (MBL) at the implant-neck level seems to occur following implant placement/loading regardless of all the efforts to eliminate it.[1–4] During the first year of function, a certain amount of physiological MBL is often observed around a dental implant, both horizontally and vertically; thereafter, minimal further bone loss has been annually observed.[4,5] As described by Albrektsson and colleagues in 1986, the bone remodeling process is one of the critical factors in evaluating implant success.[4] The prerequisites for implant success are MBL up to 1 mm within the first year of implant

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loading and successive annual mean MBL 0.2 mm during the follow-up period.[6] However, maintaining and improving soft tissue and bone contours are prerequisites for a long-term aesthetic and function of implant-supported restoration.[7] Previous authors have proposed several factors that may increase MBL around dental implants, including surgical trauma, biologic width establishment, lack of passive fit of the superstructures, implant-abutment microgap, and occlusal overloading.[8–14] Microgap at the implant-abutment interface seems to play a significant role in bacterial colonization of the implant sulcus and may consequently lead to peri-implant inflammatory reactions and bone resorption. The peri-implant inflammatory reaction could be related to the bacterial contamination and micromovements at the implant-abutment interface.[14,15] The existence of bacterial leakages at the junction between abutment and implant, as well as along the abutment screw, has also been reported.[16] The microorganisms found inside the implants might be associated with the bone loss observed during the first year. Nevertheless, the microgap at the implant-abutment interface not always leads to bone loss. Bacterially induced bone infections often result in significant local inflammatory responses, which are coupled with loss of bone. However, the respective roles of the protective host response and of bacterial infection in the pathogenesis of bone loss around implant are not yet well understood. The bone loss may occur when the host response to infection makes the patient prone to it.[17] The size of this microgap could be significant, as well as the presence of movements between implants and abutments. Moreover, the presence of the microgap also results in micromovements occurring at the implant-abutment interface, influencing the stress distribution in the surrounding bone and enhancing crestal bone resorption.[18,19] Over the years, new interface designs were introduced in the attempt to overcome these possible drawbacks of the original external-hexagon (EH) implant-abutment connection. The conical connection (CC) is mechanically more stable and tighter than the flat-to-flat connection, sealing the implant-abutment interface and minimizing microleakage and micromovements.[20,21] Three-dimensional finite element analysis and clinical studies[22,23] showed that the highest loading stress distribution is located in the most coronal portion of the surrounding bone. If compared with a flat-to-flat connection, the stress distribution of the occlusal loading through the conical interface was reported to cause a substantial decrease of implant interfacial shear stress in the surrounding bone.[22] This could mean that the conical implant-abutment interface with an internal hexagonal interlocking is a more stable and reliable connection, which supports the maintenance of marginal bone and healthy soft tissues.[21–24] Furthermore, it has been suggested that the biological process resulting in loss of marginal bone may be limited when the outer edge of the implant-abutment interface is horizontally repositioned inwardly, away from the outer edge of the implant platform. This prosthetic concept has been defined as platform shifting. Moreover, crestal bone remodeling can be reduced through the use of an implant with a back-tapered collar instead of a straight or conical ones:[25] the advantage of this feature is a less outward pressure on the peri-implant bone after implant placement, which in turn may enhance bone relapsing and growing around implant neck. However, up to date, the literature still lacks providing evidence about the relative effectiveness of different implant-neck configurations in the preservation of marginal bone.[21] Hence, in order to minimize peri-implant inflammatory reactions and prevent MBL, the implant-abutment interface features and implant-neck configurations are a major challenge for the implants' manufacturers. The present study aimed to compare two implant designs with different prosthetic interfaces and neck configurations tested according to a split-mouth protocol. The null hypothesis was that there would be no difference between interventions. This research is reported according to the CONSORT statement[26] for improving the quality report of parallel-group randomized trial.

MATERIALS AND METHODS

This study was designed as a multicenter, randomized, controlled, split-mouth trial. Any partially edentate patient in the lower jaw, aged 25 years or more, requiring at least two single implant-supported crowns, and able to sign an informed consent form was eligible for this trial. Periapical radiographs were used for initial screening. Inclusion criteria were the following: Kennedy class I, II, and III in the mandible; teeth extracted at least 6 months before implant placement; and sufficient bone volumes to accommodate dental implants without augmentation procedure. Patients were not admitted to the study if any of the following exclusion criteria was present: general medical (such as stroke, recent cardiac

infarction, severe bleeding disorder, uncontrolled diabetes, or cancer) and/or psychiatric contraindications to implant surgery, pregnancy or nursing, absence of teeth/denture in the opposite jaw, untreated periodontitis, poor oral hygiene and motivation, heavy smoking (more than 10 cigarettes/day), patients who took or were taking bisphosphonates intravenously, an implant insertion torque ≤35 Ncm, and patients participating in other trials if the present protocol could not be properly followed. In addition, the minimum distance of an implant to the adjacent teeth had to be of at least 1.5 mm, and in case of two or more adjacent implants at least 3 mm between them. Eligible patients were asked to participate and were enrolled after detailed explanations of the study protocol. A written informed consent was obtained for each patient. Patients were recruited and treated in one center in Rome between January 2010 and July 2010. The investigation was conducted according to the principles embodied in the Helsinki Declaration of 1964 for biomedical research involving human subjects, as amended in 2008. Two experienced surgeon performed all interventions.

Patients were instructed to use chlorhexidine mouthwash 0.2% (Corsodyl, GlaxoSmithKline, Verona, Italy) for 1 minute, twice a day, starting 3 days prior to implant placement and thereafter for 1 week. A single 2-g dose of prophylactic antibiotic (amoxicillin 875 mg and clavulanic acid 125 mg, Augmentin, GlaxoSmithKline, Verona, Italy) was administered 1 hour before surgery.[27] When a patient presented a mandible Kennedy class I and needed to place one implant per side, by convention, it was decided to start from the left side first (site 1). In addition, when a patient with Kennedy class I needed to place two or more implants per side, by convention, it was decided to start mesially and to repeat the same procedure proceeding distally. Furthermore, when a patient presented a Kennedy class II or III, by convention, it was decided to place implant from the more mesial edentulous region first. Site number 1 of eligible patients was randomized to receive CC (NobelActive, Nobel Biocare AB, Göteborg, Sweden) or EH (NobelSpeedy Groovy, Nobel Biocare AB) dental implants. The NobelActive implant has a back-tapered collar with built-in platform shifting design and an internal 12° conical prosthetic interface with a hexagonal interlocking in the bottom. The NobelSpeedy Groovy implant features a straight neck configuration and a flat-to-flat implant-abutment interface with a 0.7-mm-tall external-hexagonal connection (Figure 1). Both implants had a moderately rough, highly crystalline, and phosphate-enriched titanium oxide surface (TiUnite, Nobel Biocare AB).

Local anesthesia was induced using 4% articaine solution with epinephrine 1:100,000 (Ubistein, 3M ESPE, Milan, Italy). Small flaps were elevated to reduce any kind of injury on the periosteum and maintain the blood supply during the healing period. All implants were 10 to 13 mm long, depending on the bone height available, and with regular-platform (RP) endosseous diameters of 4.3 (CC implants) and 4 mm (EH implants). All the implants were placed in the posterior mandible at bone crest level (BCL) (Figure 2) and the drill sequence was chosen according to manufacturer's information in relation to the bone quality (Nobel Biocare AB). The implants were placed in the prosthetically correct position by means of a surgical template in order to avoid any bias related to abnormal occlusal loading pattern and to unnatural emergence profile of the definitive prostheses that may affect the hygienic maintenance. The flaps were adapted to allow a submerged healing of the implants using an interrupted nonresorbable monofilament 4-0 sutures (Cytoplast, polytetrafluoroethylene suture, DeOre Biomaterials,

Figure 1 The two investigated implant designs with different prosthetic interfaces and neck configurations.

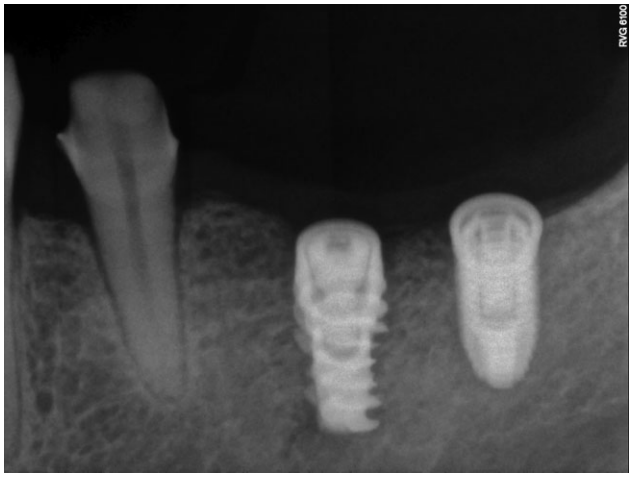

Figure 2 Periapical radiograph at implant placement in Kennedy Class II patient.

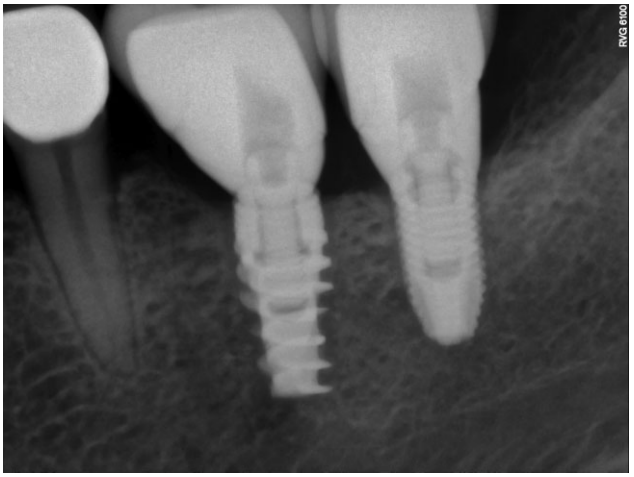

Figure 3 Periapical radiograph 1 year after loading.

Verona, Italy). After implant placement, all patients received oral and written recommendations: soft diet for 40 days and soft toothbrush. Moreover, ibuprofen 600 mg was prescribed to be taken every 6 to 8 hours if needed and mouth rinsing twice daily for 1 week with a solution of 0.2% chlorhexidine digluconate (Corsodyl, GlaxoSmithKline, Verona, Italy). No implant-supported temporary restoration was used during the first 16 weeks after implant placement (unloaded period). Implants were exposed 8 weeks after implant placement and healing abutments were connected. One week later, the sutures were removed and a preliminary impression was taken. Following, an open tray impression was taken using a polyether material (Impregum, 3M ESPE, Seefeld, Germany) with a custom open tray (Diatray Top, Dental Kontor GmbH, Stockelsdorf, Germany). Each patient received a single crown per implant (Figure 3). Titanium abutments and metal-ceramic restorations were fabricated by computer-aided design (CAD)/computer-aided manufacturing (CAM) technology (NobelProcera System, Nobel Biocare AB). At the time of prosthesis delivery, occlusion was adjusted. The abutments were screwed using the Torque Controller (Torq Control, Anthogyr, Sallanches, France) at the 35-Ncm setting. The definitive restorations were fixed, 4 months after implant placement, with a provisional cement (Temp Bond NE, Kerr Corporation, Orange, CA, USA). Patients were recalled every 3 months for maintenance and data collection for at least 1 year in function.

Primary outcome measure was peri-implant bone level changes, calculated using intraoral digital periapical radiographs at following time points: implant placement (baseline) (Figure 4, A and B), abutment connection (8 weeks), implant loading (4 months), and after 1 year in function (16 months) (Figure 5, A and B).

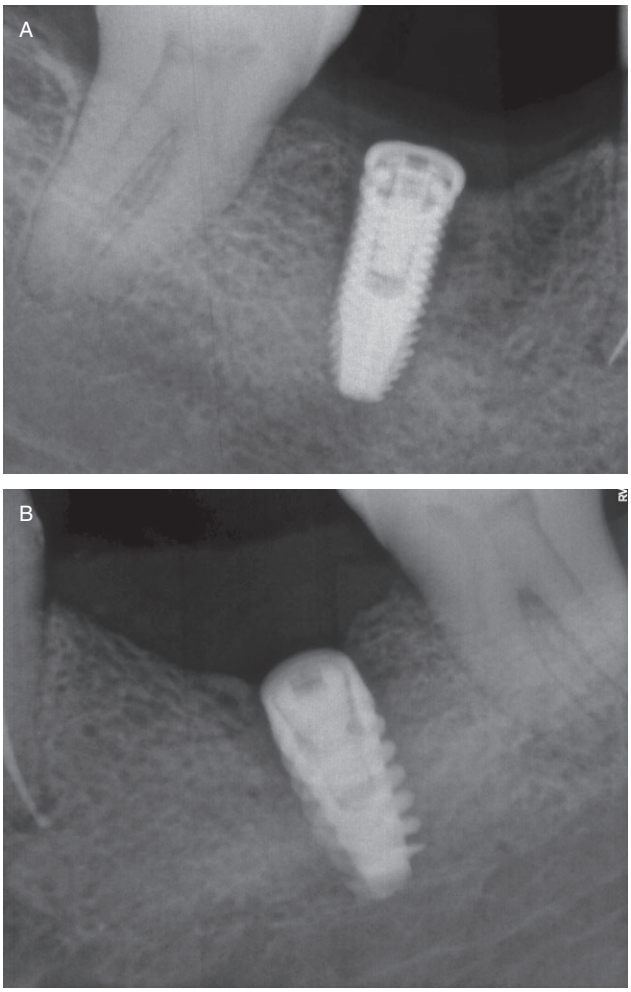

Figure 4 Periapical radiograph at implant placement in Kennedy Class III patient: *A*, Control group; *B*, Test group.

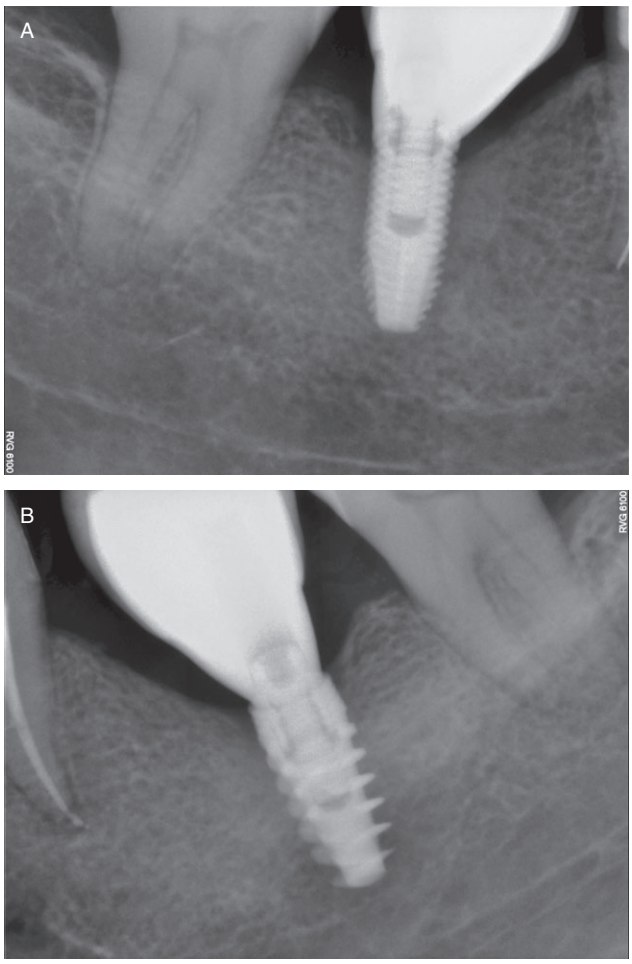

Figure 5 Periapical radiograph 1 year after loading in Kennedy Class III patient: *A*, Control group; *B*, Test group.

Secondary outcome measures were failures of the prostheses and the implants that required their removal,[28] any surgical and prosthetic complications occurred during the entire follow-up, and resonance frequency analysis values at implant placement and loading (4 months). Moreover, at the last follow-up visit, periodontal parameters (bleeding on probing [BoP] and plaque scores [PSs]) were recorded.

An independent assessor made intraoral radiographs by means of a custom radiograph holder and parallel technique. All readable radiographs were displayed in an image analysis program (Kodak Digital Imaging Software 6.11.7.0, Eastman Kodak, Rochester, NY, USA) on a 24-in. LCD (Liquid Crystal Display) screen (iMac, Apple, Cupertino, CA, USA) and evaluated under standardized conditions (SO 12646:2004). The software has been calibrated for every single image using the known distance of the implant diameter or length. The distance from the most coronal margin of the implant collar and the top of the bone crest was taken as BCL. The average radiographic values of mesial and distal measurements were taken for each implant at the time of implant placement, healing abutment connection (8 weeks), at definitive restoration delivery (4 months), and then at the 1-year-in-function examination. Measurements were made to the nearest 0.01 mm. The difference between BCL at various time points was taken as MBL. An independent radiologist, not previously involved in this study, performed all the bone height measurements (Department of Radiology, University of Rome Tor Vergata, Italy).

Implant stability quotient (ISQ) was recorded by means of resonance frequency analysis.[29] One blinded outcome assessor who was otherwise not involved in the study performed all resonance frequency measurements. The values were analyzed at implant placement (baseline), at implant-abutment connection, and at the definitive prosthesis delivery (4 months after implant placement) using the Osstell® Mentor device (Osstell, AB, Göteborg, Sweden). Two measurements were taken for each implant: one buccopalatal from the buccal side and one mesiodistal from the mesial side. The result was displayed by the device in ISQ units, which range from 1 to 100. The average of these measurements was used.

At the last follow-up visit, BoP and PSs were recorded using a Hu-Friedy periodontal probe. BoP was evaluated on four sites around each implant (mesial, distal, buccal, and lingual) according to the Mombelli Index[30]: 0, no bleeding; 1, spot bleeding; 2, linear bleeding; and 3, spontaneous bleeding. PS, defined as the presence of plaque (yes/no) on the abutment/restoration complex, was scored by running a periodontal probe (PCP15, Hu-Friedy, Chicago, IL, USA) around the implant, parallel to the abutment surfaces.

Since the study design was developed as a prospective observation, a priori sample size calculation was performed by means of G* Power 3.1.3 software for Mac OS X (version 10.7.2; University of Düsseldorf, Düsseldorf, Germany, http://www.psycho.uni-duesseldorf.de/abteilungen/aap/gpower3/) given effect size $dz = 0.5$, error probability $\alpha = 0.05$, and power = 0.80 (1-β error probability), resulting in a sample size of 34 patients. It was decided that the data would be collected 1, 3, and 5 years after loading.

For randomization of the implant type in the groups, a pregenerated random sequence was created (Random number generation pro 1.91 for Windows,

Segobit software; Segobit, Moscow, Russia, http://www.segobit.com). Opaque envelopes were sealed according to pregenerated list. An independent judge prepared all envelopes. Each edentulous site of each patient was randomly assigned to one of the two implant groups. Immediately after flap elevation, an assistant indicated which implant had to be placed first following the indications contained in the sequentially numbered envelope. The internal CC design was the test group and the EH with flat-to-flat implant-abutment interface was the control group.

The statistical analysis was performed for numeric parameters such as BCL, MBL, and ISQ values using SPSS for Windows release 18.0 (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed using mean ± standard deviation (median and 95% confidence interval). The patient was used as the statistical unit of the analysis. Comparisons between each time points were made for each group by paired *t*-test to detect any changes in marginal peri-implant bone levels during follow-up. Differences of means for continuous outcomes (radiographic BCLs and ISQ) between groups were then compared by paired *t*-test.

RESULTS

Thirty-four patients were checked for eligibility. All patients were considered eligible and were consecutively enrolled in the study between July 2009 and June 2010. The mean age was 52.20 ± 5.34 years (range 39–59 years). A total of 88 implants were placed in the posterior mandible, according to the split-mouth study design (44 implants with CC design and 44 EH implant/abutment complex). Fifty-two implants were placed in the molar and 36 implants were placed in the premolar area. The last follow-up was done in October 2011. Thirty out of 34 patients were nonsmokers, while four patients were smoking less than 10 cigarettes/day.

No dropouts occurred during the entire follow-up. All the data collected were included in the statistical analysis. No deviation from the original protocol occurred. All patients were treated according to the allocated interventions.

No implants were lost in any group, resulting in a cumulative survival rate of 100% at 1 year. No failure of the definitive prostheses occurred 1 year after implant loading.[26]

The mean BCL was not statistically significantly different at the moment of implant placement ($p = .061$) and at the abutment connection ($p = .011$). On the other hand, the mean BCL at the prosthesis delivery ($p = .000$) and 1 year after loading ($p = .000$) showed statistically significant difference between the investigated groups. The results of BCL at different time points are summarized in Table 1.

Both groups gradually lost a slight amount of marginal peri-implant bone. However, the CC design showed statistically better radiological results than the traditional EH one during the entire investigated period, with statistically significant difference when either implant placement or abutment connection was considered as baseline measurement ($p = .000$). On the other hand, the change in mean MBL during 1 year of function (between prosthesis delivery and the last follow-up) was not statistically significant between groups ($p = .776$). The results of the BCL changes for all time points are summarized in Table 2.

ISQ values were analyzed to compare test and control groups at baseline, at implant-abutment connection, and at prosthesis delivery. A high ISQ value was found in both groups at each time point. No statistically significant difference was found for ISQ mean values between groups at baseline (test group, 78.49 ± 2.35; control group, 78.53 ± 2.72; $p = .941$), at implant-abutment connection (test group, 80.46 ± 1.70; control group, 81.12 ± 2.58; $p = .454$), and at prosthesis delivery (test group, 81.50 ± 1.91; control group, 82.38 ± 2.37; $p = .120$). Statistically significant difference for ISQ mean values was found in each group between baseline and prosthesis delivery, with higher values at prosthesis delivery examination ($p = .000$).

BoP was not detected around any implant in both groups (score 0 according to the Mombelli Index), and only one patient (two implants, one per group) showed a very slight amount of plaque around implant/restoration complex.

DISCUSSION

The present prospective, randomized, controlled trial (RCT) aimed to investigate differences in marginal bone level changes between two implants with different prosthetic interfaces and neck configurations during submerged healing and up to 1 year in function. This RCT revealed statistically significant difference in peri-implant marginal bone level changes between the two investigated implants, with lower value for the CC implants (test group). Therefore, the null hypothesis

TABLE 1 Mean Radiographic Marginal Bone Crest Level (mm) between Groups and Time Periods

	Implant Placement (Baseline)			Abutment Connection (8 Weeks)			Prosthesis Delivery (4 Months)			After 1 Year in Function (16 Months)		
	Mean (SD)	Median	95% CI	Mean (SD)	Median	95% CI	Mean (SD)	Median	95% CI	Mean (SD)	Median	95% CI
Test group (CC) $n = 34$	0.16 (0.28)	0.10	0.07–0.25	0.13 (0.30)*	0.18	0.03–0.23	0.54 (0.28)†	0.40	0.45–0.63	0.68 (0.34)†§‡	0.53	0.57–0.79
Control group (EH) $n = 34$	0.05 (0.30)	0.05	−0.05 to 0.15	0.34 (0.28)†	0.40	0.25–0.43	0.99 (0.38)†	0.85	0.86–1.12	1.15 (0.34)†§‡	1.08	1.04–1.26
p Value	.061			.011			.000**			.000**		

*Changes from baseline, no statistically significantly different ($p = .634$).
†Changes from baseline, statistically significantly different ($p = .000$).
§Changes from abutment connection, statistically significantly different ($p = .000$).
‡Changes from prosthesis delivery, statistically significantly different ($p = .000$).
**Statistically significantly different.
CC = conical connection; CI = confidence interval; EH = external-hexagon.

TABLE 2 Comparison of Mean Marginal Bone Loss (mm) with Time

	Baseline to 8 Weeks (Submerged Healing) Mean (SD)	8–16 Weeks (Nonsubmerged Healing) Mean (SD)	Baseline to 16 Weeks (Unloaded Period) Mean (SD)	16 Weeks to 1 Year in Function (12 Months of Loaded Period) Mean (SD)	Baseline to 1 Year in Function (Entire Period) Mean (SD)
Test group (CC) $n = 34$	−0.03 (0.34)	0.40 (0.38)	0.37 (0.23)	0.14 (0.20)	0.51 (0.34)
Control group (EH) $n = 34$	0.29 (0.38)	0.65 (0.40)	0.95 (0.56)	0.16 (0.19)	1.10 (0.52)
p Value	.000**	.000**	.000**	.776	.000**

**Statistically significantly different.
CC = conical connection; EH = external-hexagon.

that radiological outcomes of a back-tapered collar with built-in platform shifting and conical prosthetic interface would not differ from those of a straight implant-neck configuration with an external flat-to-flat implant-abutment interface was rejected in favor of the alternative hypothesis.

The main limitation of the current trial was intrinsic in the main aim of the study itself. It is very difficult to compare implants highly different in terms of macrodesign and to draw conclusions regarding bone loss differences. However, both implants have a tapered shape with the same moderately rough, highly crystalline, and phosphate-enriched titanium oxide surface with microthreads all the way up to the platform interface. In the present trial, the newly developed neck configuration with back-tapered collar, variable thread design, and built-in platform shifting CC has been compared with the well-proven straight neck configuration with flat-to-flat implant-abutment interface and a 0.7-mm-tall external-hexagonal connection.

Up to now, there is lack of scientific evidence explaining the mechanisms concerning MBL around implants overall and their different types of connections and neck configurations. According to Bateli and colleagues,[21] the effort to preserve marginal bone around dental implants requires a multifactorial approach. In this study, possible influence of the patient biotype and/or lifestyle on the outcomes could be ruled out[25] due to the split-mouth design. Furthermore, in order to reduce bias, the same RP diameter[31–33] was adopted for all the implants of both groups; finally, all the implants were placed in the posterior mandible at BCL with the same drilling protocol and restored with the same type of CAD/CAM cemented retained single crown restorations.

The implants with built-in platform shifting feature significantly experienced in the present trial less MBL compared with implant-abutment matching diameter configuration. Canullo and colleagues[34] reported a MBL of 0.74 ± 0.39 mm in the platform shifting group (0.25 mm of mismatching between implant and abutment) and 1.23 ± 0.67 mm in the control group (perfect matching between components) after 9 months in function. However, in the aforementioned study, as well as in previous studies,[35] the baseline measurements were taken at the delivery of the definitive prostheses, nonconsidering the amount of bone remodeling occurring during healing period and biological width establishment after abutment connection. Differently, in order to discern the amount of bone resorption due to the surgical trauma and to the biological width establishment, we performed all interventions according to a split-mouth protocol design with BCL recorded at implant placement, abutment connection, definitive prosthesis delivery, and at 1-year-in-function follow-up. To date, no randomized, controlled clinical trial investigating the effect of different implant-neck configurations on peri-implant marginal bone preservation has been published. Our research found statistically significant differences in mean MBL between the two groups during the entire follow-up period ($p = .000$). The statistical analysis performed to compare mean MBL between implant placement and healing abutment connection found significantly lower MBL around CC implants ($p = .000$), with a mean reduction in bone loss of 0.32 mm. A possible explanation of the lower MBL around CC implants during the submerged period may be the different neck configurations. The back-tapered implant-neck design (4.3 mm body diameter and 3.9 mm platform diameter) of the NobelActive implants might have minimized the surgical injury on crestal bone allowing for maximum bone volume around the implant neck and reduction of bone strain at the same time. On the other hand, the NobelSpeedy implants with a straight neck configuration (4.0 mm–diameter body and a 4.1-mm platform) may have exerted a more strain on the surrounding crestal bone, potentially leading to a higher bone resorption.

The statistical analysis performed to compare the mean MBL between healing abutment connection and definitive prosthesis delivery found significantly lower MBL around CC implants ($p = .002$), with a mean reduction in bone loss of 0.25 mm. The reduction of MBL may be the result of the platform shifting design on the biological width establishment. It has been advocated that the platform shifting concept, throughout the use of smaller abutment diameter on wider-implant platform diameter, introduces a horizontal inward component to the establishment of the biological width (that otherwise is a vertical process),[36] contributing in preserving marginal bone level.[34,37,38] In two recently published prospective studies,[39,40] platform shifting has been advocated to move the inflammatory area existing at the implant-abutment interface away from the crestal bone, resulting in less bone resorption and highly satisfactory aesthetics.[41] Hence, the platform shifting concept may

result in significantly less radiographically detectable crestal bone loss in humans and better soft tissue support/maintenance in the aesthetic zone.[41,42] However, Vigolo and Givani[43] found, in a study with the currently longest follow-up period (5 years), that the effect of platform shifting is effective in preventing MBL only up to 1 year after abutment connection. In our research, the difference in MBL is statistically significant up to prosthesis delivery (4-month time point), while between prosthesis delivery and the 1-year-in-function time point is not statistically significant. These results may suggest that the greatest amount of bone changes occurred between surgery and abutment/crown connection. The reduction in MBL considered during the entire follow-up (16 months) is still statistically significant; nevertheless, further long-term randomized clinical trial is needed in order to confirm this preliminary result.

In recent years, greater biomechanical demands have been placed on restorative solutions as the use of implants for single-tooth replacement in posterior regions of the mouth has become more widespread; new restorative designs based on axial and tilted implants have also been introduced. These restorations require a stronger connection in order to withstand higher torque, lateral loading stress, and minimize forces on the retaining screw and prosthetic components. In order to improve the biomechanical characteristics of the implant-supported restoration, the internal connection design concept was introduced. Currently, there is a lack of evidence regarding the influence of implant-abutment connections on the peri-implant bone remodeling pattern.[44] The only randomized clinical trial[45] comparing implants with morse taper connection and built-in platform shifting feature and conventional implants with implant-abutment matching diameters, in the same clinical condition, showed results similar to those found in our research. The CC might decrease the micromovements at the implant–abutment prosthetic interface, reducing the stress and strain on the alveolar crest while the lack of firm stability and precision of the implant-abutment interface might allow biomechanical overloading and bacterial contamination of the implant/abutment complex. The microbial colonization of the prosthetic interface and internal cavity, as well as the spread of bacterial endotoxins into the surrounding tissue, can result in peri-implant inflammation and MBL.[46–48] The CC implant with tight seal implant-abutment interface showed higher sealing capability,[20,49] then EH implant with flat-to-flat interface.[48] The intended aim of a tight and precise CC is to preserve the marginal bone by minimizing micromovements and eventual microleakage and thus may lead to enhanced pink esthetics.

Regarding ISQ values, this research showed good results for both implants failing to find any statistically significant difference between them at the different time points. A possible explanation for the reported outcomes might be that the implants in both groups were placed in healed sites, prepared following strictly the manufacturer's instructions and according to a split-mouth study design.

CONCLUSIONS

Within the limitations of this study, the marginal bone level changes could be affected by the prosthetic interface and implant-neck configuration. Both implant designs investigated provided successful results; however, the MBL was statistically significantly lower in the back-tapered neck configuration with CC and built-in platform shifting compared with the straight neck configuration with flat-to-flat implant-abutment interface and external-hexagonal connection. Further long-term randomized clinical trials are needed to confirm these preliminary results.

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