KEY WORDS
Complication, Dental implant, Conical connection,
Internal hex, Peri-implant marginal bone levels

Randomized controlled trial

DENTAL IMPLANTS WITH CONICAL *VERSUS* INTERNAL HEX CONNECTIONS: A 5-YEAR REPORT FROM A MULTICENTRE RANDOMIZED CONTROLLED TRIAL

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PURPOSE. To compare implant failure and complication rates and radiographic bone level changes at dental implants with conical *versus* internal hex connections, 5 years after loading.

MATERIALS AND METHODS. A total of 90 patients with partial edentulism were selected and randomly allocated to two equal groups (n = 45) to be fitted with implants with either conical or internal hex connection at three dental surgeries. Patients were followed up for a period of 5 years. Outcomes considered were implant failures, any complications, and marginal bone level changes.

RESULTS. Three patients (6.7%) from the conical connection group and one patient (2.2%) from the internal hex group dropped out. One patient from the conical connection group lost one implant (1.5%) *versus* two implants (2.6%) in one patient from the internal hex group. There were no statistically significant differences in implant failures between the two groups (2.4% *vs.* 2.3% difference 0.1%; 95% CI: -0.9; 5.1; P = 0.584). Four patients from the conical connection group experienced four complications *versus* five patients with five complications in the internal hex group (9.5% *vs.* 11.4%, difference 1.9%; 95% CI: -0.7; 4.5; P = 0.781).
Five years after loading, patients in the conical connection group had lost an average of 1.41±0.94 mm of peri-implant bone *versus* 1.38±0.89 mm in the internal hex group, the difference not being statistically significant (difference: 0.03 mm; 95% CI -0.87; 0.96; P = 0.745). Both treatment groups had lost statistically significant marginal peri-implant bone at 5 years post-loading: P = 0.0001 for both conical and internal hex groups.

CONCLUSIONS. No statistically or clinically significant differences were observed in outcomes between implants with conical and internal hex connections 5 years after loading. Hence, clinicians are free to decide which type of connection to use, according to their preferences.

CONFLICT OF INTEREST STATEMENT. Tommaso Grandi serves as consultant for J Dental Care, Modena, Italy. This study was completely self-financed and no funding was sought or obtained, not even in the form of free material.

INTRODUCTION

Titanium dental implants are an effective and reliable solution for replacing missing teeth, yielding satisfying results in terms of rehabilitation of aesthetic and masticatory function. The osteointegration of dental implants in newly formed bone and the stability of hard/soft tissues around it are two important factors that directly influence long-term success[1]. Following implant placement, it is common to observe some marginal bone loss around implants, and peri-implant bone resorption of less than 1.5 mm during the first year after loading and less than 0.2 mm annually thereafter are considered acceptable values for successful placement[2]. Different hypotheses have been suggested to explain this phenomenon, including the microgap at the implant–abutment interface. Indeed, the tiny space between the two can provide a breeding ground for bacterial colonization: microorganisms can penetrate through a gap smaller than 10 μm, causing inflammation, bone resorption and influencing biological width establishment[3-5]. Other important factors which may influence the stability of peri-implant bone levels are surgical trauma, dental plaque, biological width, and occlusal overload[6].

The implant-abutment connection, however, is the point of transition from the surgical to the prosthetic phase[7], and therefore plays an important role in the outcome of implant therapy by influencing peri-implant crestal bone changes[8]. Historically, the first implant-abutment connection interface was the external hexagon connection, or "external hex", introduced by Branemark, initially with a height of 0.7 mm, and is still in use today[7,9].

However, the external hex connection has been reported as unfavourable because it forms a microgap at the abutment–implant interface; this promotes bacterial microleakage, and moreover, makes aesthetics more problematic, especially in the anterior areas[10]. That being said, data from a long term RCT by Esposito et al.[11] revealed no statistically significant differences between external and internal connections in terms of implant or prosthesis failures, complications or bone loss at 10 years post loading. In addition, external connections are more forgiving in the presence of multiple implants.

To address the limitations of external connections, which also include micromovement problems and screw loosening, and to provide a better aesthetic result, internal connections were developed. The supposed main advantage of this connection lies in the better stress distribution and greater stability of the prosthesis screw[5]. The most widely used connections are the internal hex and the conical, but there are many different types of internal connections, as the market for internal connections is growing rapidly, and almost every dental implant manufacturer has designed and developed their own connections. Each claims the superior efficacy and performance of their product with respect to their competitors', but despite their mechanical and clinical claims, no data has yet demonstrated the superiority of one type of connection over the others in terms of clinical outcomes. In fact, only a few randomized control trials (RCTs) have thus far investigated the relationship between the type of connection (internal or external) and the clinical and radiographic parameters related to marginal bone remodelling around implants[11-13]. There is as yet no reliable evidence-based clinical data about the relative performance of implant connections in terms of complications, peri-implant marginal bone loss, aesthetics or ease of use.

In this context, this RCT was designed to compare implant failure and complication rates and radiographic bone level changes at dental implants with conical *versus* internal hex connections, 5 years after loading. It is the continuation of the previously published study reporting results recorded 1 year after initial loading[13]. The null hypothesis of this trial is that there would be no difference in success rates, complications or peri-implant marginal bone level changes between the two connections.

The article is reported according to the CONSORT statement for improving the quality of reports of parallel-group randomized trials (http://www.consort-statement.org/).

MATERIALS AND METHODS

This multicentre randomized controlled trial of parallel-group design was conducted in Italy and Lebanon at three different private practices by three operators (MC, TG, RS), who performed all the surgical and prosthetic interventions. A total of 90 patients (30 for each clinician) with partial edentulism in the maxilla or mandible, requiring one implant-supported prothesis, were enrolled. All patients selected were 18 or older and able to provide informed consent. In patients requiring more than one prosthesis, the operator chose the site to include in the study after the screening visit.

The anatomical criterion considered as a requirement for inclusion in this trial was the presence of residual bone height of least 10 mm and thickness of at least 5 mm, as measured on computed tomography (CT) scans. A pre-operative periapical radiograph was performed for an initial screening, then a CT scan was taken to quantify the amount of bone. Broad inclusion criteria were used, including any type of bone quality, any jaw location, and smokers.

The criteria applied to patients for exclusion from the trial were:

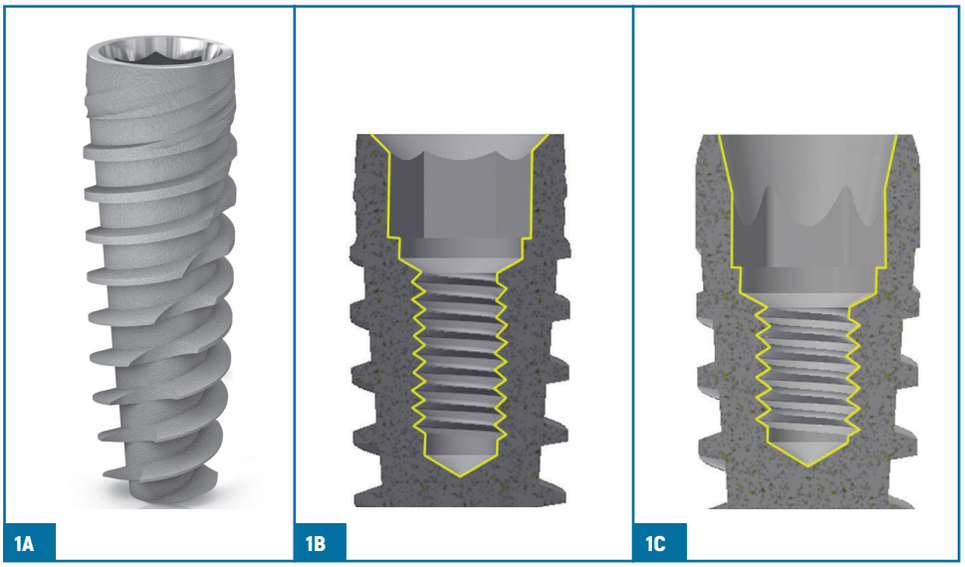
- General contraindications to implant surgery;
- Any irradiation of the head and neck area;
- Previous or ongoing treatment with intravenous aminobisphosphonates;
- Poor oral hygiene and motivation;
- Untreated periodontitis;
- Uncontrolled diabetes;
- Pregnancy or lactation;
- Substance abuse;
- A lack of opposing occluding dentition in the area scheduled for implant placement;
- Acute or chronic infection at the designated implant site;
- Patients referred only for implant placement who could not be monitored at the treating centre.

All patients received detailed information regarding the study and the treatment foreseen by the clinical protocol, and signed an informed written consent form prior to enrolment.

Patient were categorized into three groups depending on their declared smoking habits, namely non-smokers, moderate smokers (up to 10 cigarettes per day) or heavy smokers (more than 10 cigarettes per day). Surgeons were free to decide the operative procedures according to patients' needs (i.e., flapless implant placement, immediate post extractive implants, submerged or non-submerged technique).

Tapered titanium screw-shaped dental implants characterized by the same macro design and sand-blasting acid-etched surface up to the neck were used in this trial, the difference being the type of internal connection (JDIcon *vs.* JDEvolution system, J Dental Care, Modena, Italy). Specifically, the JDIcon implant is characterized by 12-degree internal conical connection with interlocking hexagon at the bottom, whereas the JDEvolution implant features a 2-mm deep internal hex and 45-degree internal bevel (**FIGS. 1A-C**).

Before the intervention, all patients underwent at least one session of oral hygiene training and, if needed, professional scaling. Antibiotic prophylaxis consisted of 1 g of amoxicillin and clavulanic acid (Augmentin Roche, Milan, Italy) every 12 hours from the day before surgery to the sixth post-surgical day. Clarithromycin (Klacid, Abbott, Rome, Italy) 500 mg was given the day before the intervention and 250 mg twice a day for one week to patients allergic to penicillin.

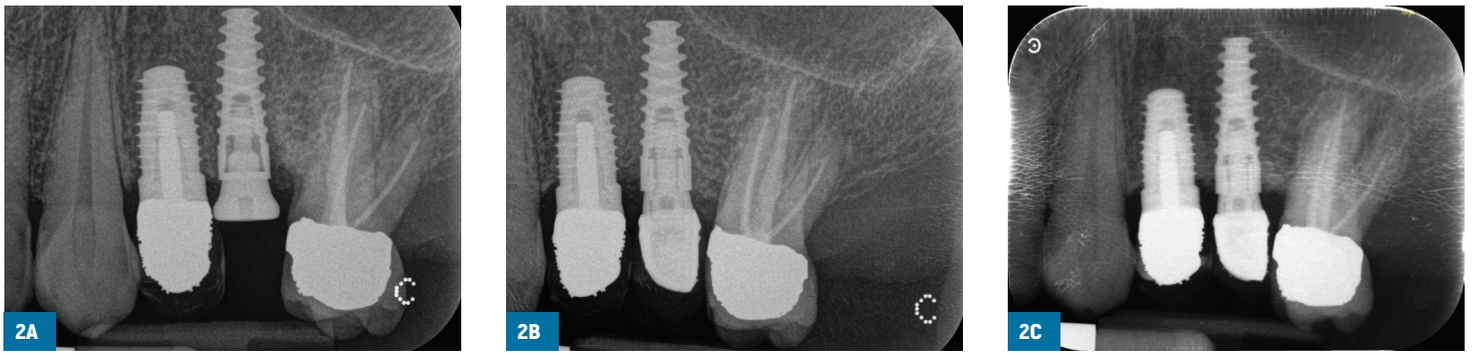


FIGS. 1A-C: *Characteristics of the implants used in the study: external macro-design of the implant (A); sagittal section showing the internal hex connection of JDEvolution implant (B); sagittal section showing the conical connection of JDIcon implant (C).*

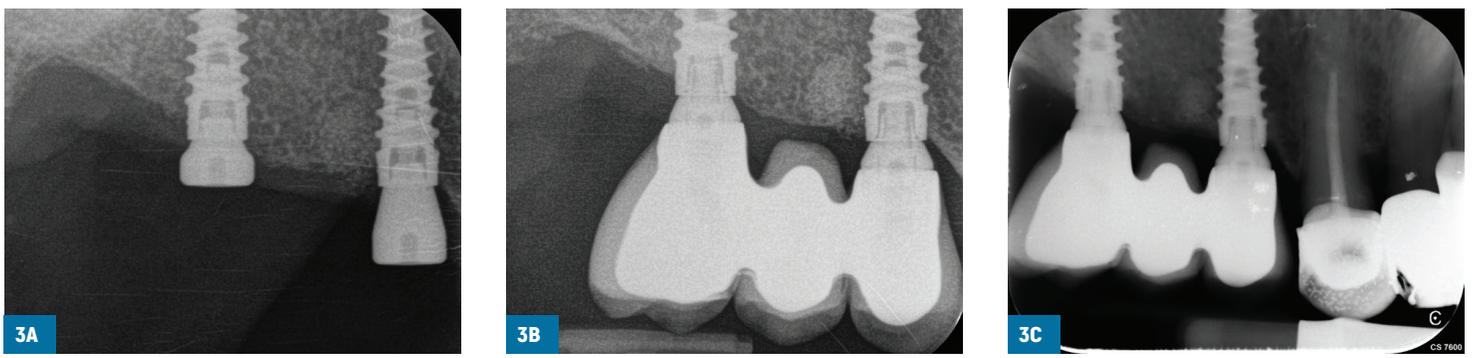
Surgical procedures were performed under local anaesthesia. When needed, tooth extractions were performed as atraumatically as possible, to preserve the alveolar buccal bone. Extraction sockets were carefully cleaned of any granulation tissue. Each clinician was free to decide whether to use a flap or flapless technique. The implant site was prepared as indicated by the implant manufacturer. Once the implant site preparation was completed, the operator was informed if the implants to be placed had to have conical or internal hex connection by opening a sequentially numbered sealed envelope corresponding to the patient recruitment number. Clinicians were free to decide to leave the implant submerged or not for the healing period. Baseline periapical radiographs were taken using the paralleling technique.
Patients were prescribed chlorhexidine digluconate 0.2% mouthwash twice daily for one week post-surgery. After three months, all the implants were loaded directly with definitive screw-retained or cemented restorations (**FIGS. 2, 3**). The three operators involved in the trial (MC, TG and RS) made all clinical assessments, therefore outcome assessors were not blinded.
The primary outcome measures were:

- Implant failures, i.e., implant mobility and removal of stable implants dictated by progressive marginal bone loss or infection. The stability of each implant was measured manually by tightening the abutment screw with a wrench delivering a torque of 30 Ncm. Spinning implants were recorded as failures;
- Complications, i.e., any biological or prosthetic complication occurring at the implant site during the entire follow-up period.

The secondary outcome measure was peri-implant marginal bone level changes, as evaluated on intraoral radiographs taken via the paralleling technique at implant placement, and at 1 year and 5 years after loading. Image J 1.42 software (National Institute of Mental Health, Maryland, USA) was used to measure peri-implant marginal bone levels on the digital radiographs, and was calibrated for each image using the known implant diameter. Measurements of the mesial and distal crestal bone levels adjacent to each implant were made to the nearest 0.01 mm and averaged at patient level and group level. All measurements were made



FIGS. 2A-C: *Sequence of periapical radiographs of one of the patients treated with JDIcon implant with conical connection included in this study: implant placement (A); 1 year after loading (B); 5 years after loading (C).*



FIGS. 3A-C: *Sequence of periapical radiographs of one of the patients treated with JDEvolution implants with internal hex connection included in this study: implant placement (A); 1 year after loading (B); 5 years after loading (C).*

parallel to the implant axis by an independent, blinded assessor (GG). The most coronal margin of the implant collar and the most coronal point of bone-to-implant contact were taken as reference for linear measurements.

No sample size calculation was performed. At the protocol definition stage, it was decided 30 patients should be enrolled by each of the three centres, and 45 of the 90 enrolled patients were randomised to each group using computer-generated random numbers, which were sealed in sequentially numbered, opaque envelopes. Envelopes were opened only after the implant site was prepared, to conceal allocation to the investigators in charge of enrolling and treating the patients.

For the data analysis, the patient was considered as the statistical unit of the analyses. A doctor with expertise in statistics analysed the data using the statistical package StatView (version 5.01.98, SAS Institute Inc, Cary, NC, USA), without knowing group allocation (GG).

The t-test was used for the following:

- Between-group comparison of differences in patient means for continuous outcomes;
- Within-group comparison (t-test for paired data);
- Between-group differences in resorption.

Comparisons among centres were performed via one-factor ANOVA. Differences in the proportion of patients with implant failures were compared among centres using the chi-squared test. Differences in crestal bone were compared among centres using ANOVA. Prevalence of patient characteristics was compared via contingency tables and the chi-squared test as appropriate. All statistical comparisons were conducted at the 0.05 level of significance.

RESULTS

The three centres screened 98 patients for eligibility, but eight patients were not included because they were referred only for implant placement. Ninety patients were then consecutively enrolled in the trial and randomized to the conical connection group or the internal hex group, 45 patients to each group according to a parallel-group design. All patients were treated according to the allocated interventions. Four patients (4.4%) dropped out before the 5-year post-loading follow-up.

Three dropouts (3/45, 6.7%) were recorded in the conical group:

- One patient died after 2 years (Dr. Grandi);
- One patient did not attend the 5-year follow-up visit because he had moved to another city (Dr Samarani);
- One patient declined to attend the 5-year follow-up (Dr. Grandi).

Only one dropout was recorded in the internal hex group (1/45, 2.2%), failing to return for the delivery of the definitive crowns (Dr Cannata).

Patients were recruited and operated on from February 2015 to July 2015. The follow-up for all patients was 5 years post-loading (last follow-up July 2020). The main baseline patient features, divided by treatment group, are reported in **TABLE 1**. There were no significant baseline imbalances between the two groups in terms of sex, age, smoking, opposing dentition or bone

TABLE 1 SUBJECT AND INTERVENTION CHARACTERISTICS

	Conical group (n = 45) (%)	Internal hex group (n = 45) (%)
Females	25 (55.6%)	22 (48.9%)
Mean age at implant insertion (range)	52.3 ± 16.8 (23-79)	51.2 ± 17.3 (25-75)
Smoking up to 10 cigarettes/day	9 (20.0%)	8 (17.8%)
Smoking more than 10 cigarettes/day	4 (8.9%)	6 (13.3%)
Implants inserted in mandibles	38/67 (57.8%)	40/72 (53.3%)
Implants inserted in incisor position	7 (10.4%)	8 (11.1%)
Implants inserted in canine position	4 (6%)	7 (9.7%)
Implants inserted in premolar position	31 (46.3%)	29 (40.3%)
Implants inserted in molar position	25 (37.3%)	28 (38.9%)
Mean implant length	10.4 ± 1.6	10.8 ± 1.8
Mean implant diameter	4.3 ± 0.8	4.1 ± 0.7
Hard bone quality at implant site	16 (23.9%)	14 (19.4%)
Medium bone quality at implant site	45 (67.1%)	47 (65.3%)
Soft bone quality at implant site	6 (9%)	11 (15.3%)
Post-extraction implants	22 (32.8%)	31 (43.1%)
Implants inserted flapless	25 (37.3%)	36 (50.0%)
Patients with submerged implants	2 (4.4%)	3 (6.7%)
Single crowns	32 (71.1%)	28 (62.2%)
Partial fixed prostheses	13 (28.9%)	17 (37.8%)

quality. In total 67 implants were inserted in the conical group and 72 implants were inserted in the internal hex group. More internal hex implants were placed flapless (36 *vs*. 25; **TABLE 1**). The following outcomes were recorded at 5 years post-loading.

Implant failures

One implant (1.5%) failed in the conical group *versus* two implants (2.6%) in the internal hex group. The failed implant in the conical group had been inserted as an immediate post-extraction implant in a maxillary premolar area in a male heavy smoker; it was mobile three weeks after placement and associated with postoperative pain, oedema and signs of infection with pus. It was successfully replaced after four months. Two implants failed in the internal hex group in a female non-smoker; they were affected by peri-implantitis and became mobile after 3 years. They were not replaced. There were no statistically significant differences between the two groups in terms of patients experiencing implant failures (patient level, 1/42 *vs*. 1/44, 2.4% *vs*. 2.3%, difference 0.1%; 95% CI: -0.9; 5.1; P = 0.584).

Complications

Four complications occurred in the conical group and five in the internal hex group. There was no statistically significant difference between groups in terms of patients experiencing complications (patient level, 4/42 *vs* 5/44, 9.5% *vs*. 11.4%, difference 1.9%; 95% CI: -0.7; 4.5; P = 0.781) or the three different centres (10.7% *vs*. 13.8% *vs*. 6.9%, P = 0.691; **TABLE 2**).

The following complications occurred in patients from the conical group:

- Post-operative pain and pus at one immediate post-extraction implant; it was removed 3 weeks after its placement;
- Loosening of one healing abutment after 3 weeks; it was retightened;
- One implant exhibited peri-implant mucositis at 8 months post-implantation; this was resolved by curettage and 0.2% chlorhexidine mouthwash;
- One metal-ceramic crown displayed chipping 3 years after loading. The prosthesis was unscrewed and repaired in the laboratory.

The following complications occurred in patients from the internal hex group:

- Screw loosening of one definitive crown 2 months after loading;
- One implant exhibited peri-implant mucositis at 10 months post-implantation; this was resolved by curettage and 0.2% chlorhexidine mouthwash;

TABLE 2 COMPARISON BETWEEN THE THREE DIFFERENT CENTRES; EACH CENTRE TREATED 30 SUBJECTS

	Grandi (n = 30)	Cannata (n = 30)	Samarani (n = 30)	P-value
Drop-out	2/30 (6.7%)	1/30 (3.3%)	1/30 (3.3%)	0.600
Patients with implant failure	1/28 (3.6%)	1/29 (3.4%)	0/29 (0%)	0.980
Patients with complications	3/28 (10.7%)	4/29 (13.8%)	2/29 (6.9%)	0.691
Bone loss after 1 year	0.32 ± 0.51	1.19 ± 0.75	0.35 ± 0.58	0.0001*
Bone loss after 5 years	1.28 ± 0.81	1.80 ± 0.75	1.20 ± 0.84	0.0001*

**Statistically significant difference*

- Two implants in the same patient were affected by mucositis 2 years after implantation; this was resolved by non-surgical debridement;
- Two implants in the same patient were affected by peri-implantitis and failed 3 years after loading;
- One patient experienced screw loosening of the final crown 4 years after loading.

Marginal bone level changes

At implant placement there was no statistically significant difference between the two different treatment groups (P = 0.393). Bone levels were 0.03±0.06 mm (95% CI -0.03; 0.09) in the conical group and 0.02±0.05 mm (95% CI -0.03; 0.07) in the internal hex group (**TABLE 3**). One year after loading there was no statistically significant difference between the two groups in terms of either peri-implant bone levels, which were 0.59±0.61 mm (95% CI -0.02; 1.20; P = 0.824) in the conical group and 0.62±0.65 mm (95% CI -0.03; 1.27) in the internal hex group (difference 0.03 mm; 95% CI -0.59; 0.65; P = 0.822), or bone loss, which was 0.56±0.53 mm (95% CI 0.03; 1.09) in the conical and 0.60±0.62 (95% CI 0.02; 1.22) in the internal hex group (difference 0.04 mm; 95% CI -0.51; 0.59; P = 0.534) (**TABLE 3**). There were also no significant differences between treatment groups (difference: 0.03 mm; 95% CI -0.87; 0.96; mm; P = 0.745) five years after loading, with patients in the conical group having lost an average of 1.41±0.94 peri-implant bone *versus* 1.38±0.89 mm in patients from the internal hex group. However, both treatment groups lost statistically significant marginal peri-implant bone at 5 years post-loading: P = 0.0001 for both conical and internal hex group (**TABLE 3**).

A comparison of the outcomes at the three different centres revealed no statistically significant differences in drop-out, failures or complications (**TABLE 2**). Nonetheless, at one centre (Cannata) there was significantly greater bone loss than at the other centres at both 1 year (0.87 mm, 95% CI 0.26; 1.48) and 5 years (0.56 mm, 95% CI 0.21; 0.91; P = 0.0001) (**TABLE 2**).

TABLE 3 MEAN RADIOGRAPHIC PERI-IMPLANT MARGINAL BONE LEVELS AND CHANGES BETWEEN GROUPS AND TIME PERIODS ACCORDING TO PER PROTOCOL ANALYSIS

	IMPLANT PLACEMENT	1 YEAR AFTER LOADING	5 YEARS AFTER LOADING	DIFFERENCE, PLACEMENT-5 YEARS	P-VALUE INTRAGROUP
	N Mean ± SD (95% CI)	N Mean ± SD (95% CI)	N Mean ± SD (95% CI)	N Mean ± SD (95% CI)	
Conical group	45 0.03 ± 0.06 (-0.03 to 0.09)	44 0.59 ± 0.61 (-0.02 to 1.20)	41 1.44 ± 0.81 (0.63 to 2.25)	41 1.41 ± 0.94 (0.47 to 2.35)	0.0001
Internal hex group	45 0.02 ± 0.05 (-0.03 to 0.07)	44 0.62 ± 0.65 (-0.03 to 1.27)	43 1.40 ± 0.79 (0.61 to 2.19)	43 1.38 ± 0.89 (0.49 to 2.27)	0.0001
Between groups mean difference	0.01 ± 0.05 (-0.04 to 0.06)	0.03 ± 0.62 (-0.59 to 0.65)	0.04 ± 0.80 (-0.76 to 0.84)	0.03 ± 0.93 (-0.87 to 0.96)	
P-value intergroup	0.393	0.822	0.657	0.745	

DISCUSSION

The main aim of this study was to compare identical implants with the same characteristics (implant material, surface characteristics and macrodesign) except for different abutment connection interfaces, specifically conical *versus* internal hex connection. Previously published data gathered at 1 year after loading[13], showed no statistically significant differences in outcomes between the two connections; the numbers of failures and complications were similarly low for both types. The same pattern is seen in the data recorded 5 years post-loading. Specifically, the average bone loss was 0.56 mm and 0.60 mm at conical and internal hex connection implants, respectively, 1 year after loading, and 1.41 mm and 1.38 mm for conical and internal hex connections, respectively, 5 years after loading. These results are in line with the 10-year data reported by Esposito et al.[11], who compared conical and external hex connections and found no differences. These findings suggest that the role of different connection types may not be as relevant as believed for the prognosis of implant-supported prostheses.

As similar bone loss was observed for the two types of connections 5 years after loading, clinicians are free to decide which type of connection to use, according to their preferences, bearing in mind the previously published data on bone resorption associated with conical and internal hex connections, specifically:

- In a 5-year study, Szyszkowski et al. observed lower bone resorption with the conical connection with respect to the internal hex group (0.68 ± 0.59 *versus* 0.99 ± 0.89 mm 1 year after loading, and 0.96 ± 1.02 *versus* 1.30 ± 1.15 mm 5 years after loading). The implants they compared were all made of the same medical-grade titanium, and all featured the same sandblasted and acid-etched surface. No implant failed[14];
- Pieri et al., in a randomized controlled clinical trial, also found a difference in average marginal bone loss (MBL) between conical and internal hex connection groups -0.31 mm in favour of the conical connection[15]. They compared the outcomes of immediately placed and restored single implants in 40 patients one year after the loading;
- Another randomised controlled trial, by Corvino et al., compared the clinical and radiographical outcomes in terms of success and survival rate, primary and secondary stability, and MBL for implants with the same micro- and macrotopography but with conical *versus* internal hex connection. In a total of 33 patients, the MBL values at 1 year after loading were 0.48 ± 0.18 mm for the conical connection and 0.57 ± 0.24 mm for the internal hex one. No implants failed. MBL was found to be influenced by different individual and clinical factors, but the conical connection appeared to yield better results than the internal hex one[16].

Meaningful comparison of our results with those in the literature is not possible, as only one other study[14] comparing conical *versus* internal hex connections for a period longer than one year has been published to date. That being said, the marginal bone loss values reported by both Corvino et al. and Pieri et al. are in line with those we recorded in the first part of the present study at the same time point, namely 1 year after loading.

The major limitations of this study were the small sample size and the fact that the outcome measurements, except for radiographic assessments, were made by operators aware of patient allocation and who treated the patients themselves. However, both implant types were tested under real clinical conditions and the patient inclusion criteria were rather broad, and therefore the results of the present trial can be generalized to patients having similar characteristics.

CONCLUSIONS

Five years after loading, no statistically or clinically significant differences in outcomes were observed between implants with conical *versus* internal hex connection. Both treatment groups lost statistically significant marginal peri-implant bone in the 5 years after loading, so clinicians are free to decide which type of connection to use, according to their preferences.

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