European **Rev**iew for **Med**ical and **Pharmacol**ogical **Sci**ences 2023; 27 (3 Suppl): 122-127

Microleakage and mechanical behavior of conical *vs.* internal hexagon implant-abutment connection under a cyclic load fatigue test

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Abstract. – OBJECTIVE: **The aim of the present investigation was to evaluate, by an *in vitro* simulation, the mechanical behavior of the conical *vs.* internal hexagon under cyclic load and the microleakage of the prosthetic connection of the fixture.**

MATERIALS AND METHODS: **A standardized cyclic loading was performed considering the implant with conical connection (diameter 4 mm - length 10 mm) (CS) and internal hexagon connection (diameter 4 mm - length 10 mm) (IH). The toluidine blue infiltration has been evaluated with the paper cone test.**

RESULTS: **After a total of 5x10^4 loads, the screw has been removed and the abutment appears solid and stable to the implant fixture for CS, while the IH was unstable. There was no infiltration of the toluidine marker in the connection interfaces of CS implants, while the IH was positive to the paper cone test.**

CONCLUSIONS: **The study data showed that the conical connection showed higher stability compared to the internal hexagon connection under the loading and it is able to prevent bacterial microleakage. This effectiveness should be considered for the long-term maintenance of the peri-implant soft and hard tissues around the fixture.**

Key Words:
Abutment, Micro gap, Crestal bone remodeling, Conical connection, Cyclic loading.

Introduction

Dental implants are medical devices, biocompatible and surgical inserted into the jawbone, mainly for prosthetic purposes, to replace one or more missing teeth[1-4]. Nowadays, the implant supported prostheses are extremely predictable. The success rate of dental implants, as shown by Papaspyridakos et al[5], exceeds 90% abundantly with 5 years follow-ups. However, crestal bone loss has been observed for decades around successfully integrated dental implants. Bone loss is significant in the first year while in the following years decreases dramatically[6,7], Adell et al[8] were the first to report and quantify a marginal bone loss that was around 1.5 mm in the first year with variability between 0 and 3 mm. In the following years, the bone loss was around 0.05 and 0.13[8]. This study about the causes of bone loss is fundamental because bone loss may influence aesthetic outcomes and can interfere with the long-term health of the peri-implant tissues and with the long-term prognosis of the implant[9-12]. The vast majority of implants consist of a fixture and an abutment that are coupled through connections[13-16]. However, a virtual micro gap space is produced at the level of the interface between the implant components. This

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which seems to be responsible for a peri-implant inflammatory infiltrate, a consequence of the fact that bacteria can proliferate precisely between the abutment and the fixture[6,9,17,18]. The majority of dental implants are composed by an abutment and a fixture coupled with connections screwed[19,20-23]. The micro gap can also lead to an altered distribution of the masticatory stresses with the danger of unscrewing and breakage for the components, and consequently it could produce a peri-implant bone resorption[19].

The bacterial infiltration between the implant and the abutment is called microleakage. It has been found to occur in static conditions and seems to increase when the assemblies are loaded[23]. Loading forces on the prosthetic restoration under function may cause bending of the components or movements inside the implant system, with the formation of a larger gap, determining a "pump" effect that probably increases the movement of the microorganisms[6,23]. The aim of this study is to evaluate *in vitro* two different types of implants connection under cyclic load and the possible microleakage of the prosthetic connection of the fixture.

Materials and Methods

In the present *in vitro* study a total of 30 implants were used: 15 Sirio implants 4 mm ×10 mm with a screw-retained internal hexagon (IH) and 15 Close BL implants 4 mm × 10 mm with a screw-retained conical abutment connection (CS); (Isomed, Due Carrare, Italy). All the samples were assessed after a cyclic load $5x10^4$ times. The load has been applied by an hemispherical cap positioned on the abutment. The implants and abutments were screwed at 30 N/cm as indicated by the manufacturer. To hold the implant into the desired position, a hole in a resin block was performed. The implants were inserted into the resin block with a 30° inclination to simulate masticatory forces. The implant-abutment connection was left out for about 3 mm from the resin block to simulate the worst bone condition. The resin blocks were designed by a 3D builder software (Microsoft, Redmond WA, USA) and the master model was printed by 3D resin printer (New Kinpo Group, New Taipei City, Taiwan). After that, the master model was used to realize all the resin blocks to reproduce all the experimental conditions required. All samples were loaded with a universal test machine Lloyd 30k (Lloyd, Instruments Segenswort, UK) managed by the Nexygen 4.0 software (Ametek, Berwyn, Pennsylvania, USA), to reproduce a load between 20 N/cm and 300 N/cm with a frequency of 4 Hz[23]. 0.7 μL of toluidine blue were placed into a cylinder on the resin block. At the end of the cyclic loads, the toluidine blue was eliminated, and the possible marker infiltration was evaluated by the "point test" with a paper cone put at the implant-abutment connection after the unscrewing of components. The possible toluidine blue on the paper cone was then misused.

Statistical Analysis

The power analysis has been conducted accordingly to the findings of a previous study[24]. The sample size calculation has been conducted by the Fisher's exact test [a err: 0.05; Power (1-b): 80%; p1: 0.6; p2: 0.1; allocation ratio: 1:1]. The minimum statistical sample size was 13 specimens for each experimental condition that was augmented to 15 samples for each study group as compensation for eventual test dropout. The study data were collected in a specially designed electronic database and analyzed by the statistical software package GraphPad 9 (La Jolla, CA, USA). The study data were analyzed by the Chi-square test and a $p<0.05$ was considered the reference for the statistical significance.

Results

Group CS (Conical Connection)

After one week and about $5x10^4$ loads, 15 samples with standard conical connections were unscrewed. All samples of this group had a stable abutment at the fixture. No marker of toluidine blue was found at the implant-abutment interface. The paper point test was negative (Figures 1-2) (Table I-II).

Group IH (Internal Hexagon)

After one week and about $5×10^4$ loads, 15 samples with internal hexagon connection were unscrewed and 5 sample was stable. All abutments of this group were unstable due to the loosening of the fixing screw. The marker toluidine blue was visible at the implant-abutment interface and the paper point test was positive (Figure 3-5) (Table I-II).

Figure 1. Preparation of the CS and IH implants specimens for the experimental tests. Both groups after submitted to 5x10^4 loads to evaluate the microleakage through toluidine blue infiltration.

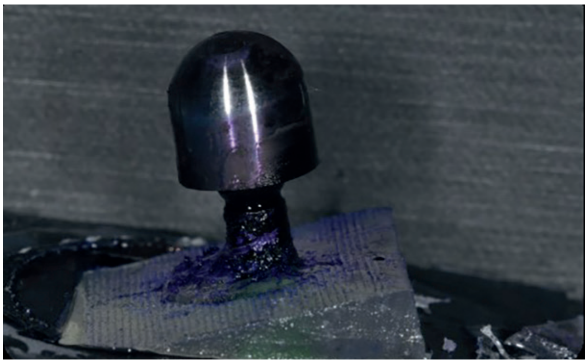

Figure 2. Specimen at the end of the loading test.

Discussion

Many authors[6,17,20,23] have studied the space at the implant-abutment junction. The problem of the micro gap is biological and mechanical. The biological problem relates to the presence of bacteria that, *in vivo*, can produce a bacterial reservoir that, in turn, interferes with the long-term health of the peri-implant tissues and with the long-term prognosis of the implant[10,25-33]. The mechanical problem relates to micromovement and possible loosening or fracturing of screw-retained abutments[17,34]. The precise mechanism responsible for the crestal bone remodeling in 2-piece implants is not known[11,34-39]. The existence of a bacterial leakage, both at the junction between the abutment and the implant, and along the abutment screw has been reported[23]. This crestal bone resorption has not been observed around sleeping implants, where both exposures to microbial colonization and loading were absent[40]. It has been shown that inflam-

Table I. Summary of the linear deformation (mm), average loading (N), minimum loading (N) and maximum loading (N) of the CS and IH implants.

Implant tested	Linear deformation (mm)	Average loading (N)	Minimum loading (N)	Maximum loading (N)
CS	0.609157991 ± 0.28	200 N ± 13.5	186.67 ± 10.2	216.86 ± 12.7
IH	0.887846462 ± 0.30	200 N ± 14.4	189.08 ± 11.3	213.17 ± 12.2
p-value	$p > 0.05$	$p > 0.05$	$p > 0.05$	$p > 0.05$

No significant difference was detected between the two groups after 5×10^4 loads ($p > 0.05$, Student *t*-test).

Table II. Summary of the Chi-square test of the study groups comparison.

Contingency: prospective data	
Test	Chi-square
Chi-square, df	6.000, 1
Z	2.449
p-value	0.0143
p-value summary	*
One- or two-sided?	Two-sided
Statistically significant ($p < 0.05$)?	Yes

*$p < 0.05$.

mation occurs if the abutment loosens on the implants placed in a submerged approach, with a possible fistula formation[41,42]. There is a physiological reaction to the presence of an interface; the reason for this reaction is unknown, but it may be related to bacterial contamination or micromovements of the interface[43,44]. Due to these problems, the manufacturers have proposed different implant-abutment connection designs to achieve a better reliability and better seal between the components[24,45]. In the present *in vitro* study, we have compared the internal hexagon connection (IH) and conical connection (CS). The samples were evaluated after cyclic loads to reproduce the masticatory loads inside the oral cavity. The effectiveness shows how the internal hexagon connections are less reliable in preventing microleakage, because in each sample of this group, the abutment screw was loosened, and toluidine blue was found inside the connection. Both conical connections, standard and narrow, have not shown a screw loosening, and no toluidine blue infiltration inside the implant-abutment junction with a negative paper point.

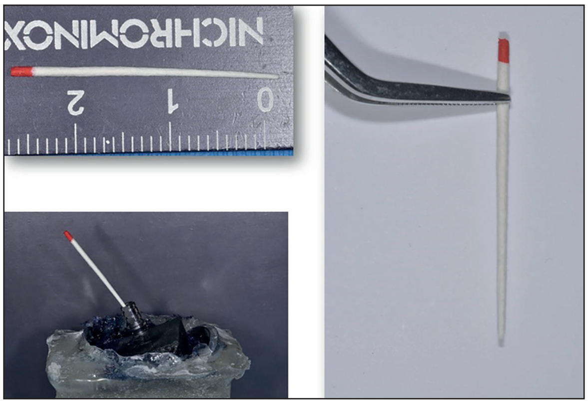

Figure 3. Toluidine blue infiltration measured by a paper cone. CS implant showed no marginal infiltration after the loading test.

Figure 4. Positivity to toluidine blue infiltration measured by a paper cone (IH group).

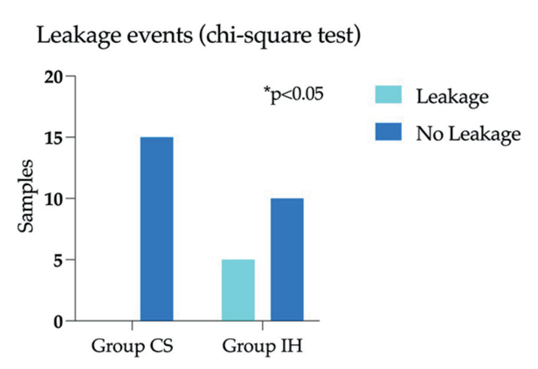

Figure 5. Chart of the leakage events associated to the study groups comparison after 5×10^4 times cycles.

Conclusions

In this *in vitro* study, both conical connections, standard and narrow diameter, seem more reliable than the internal hexagon in preventing bacterial microleakage and obtaining a more stable implant-abutment connection. These sealing capacities suggest that conical connection should be used, especially for the treatment of clinical cases with high aesthetic and functional value, where long-term stability of the peri-implant tissues is required.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Funding

This study did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Availability of Data and Materials

All data generated or analyzed during this study are included in this published article.

Authors' Contribution

All authors were involved in the literature review and performance of the investigation. All authors read and approved the final manuscript.

Ethics Approval

Not applicable.

Informed Consent

Not applicable.

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