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ORIGINAL ARTICLE

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Evaluation of internal and external hexagon connections in immediately loaded full-arch rehabilitations: A within-person randomized split-mouth controlled trial with a 3-year follow-up

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Abstract

Background: Although full-arch immediately loaded rehabilitations are widely used nowadays, little information is available on which implant/abutment connection is the most suitable in this type of treatment.

Purpose: The aim of the present multicentric split-mouth clinical trial was to compare the clinical outcomes of two different implant-abutment connections applied in full-arch immediate loading rehabilitations: external hexagon connection (EHC) versus internal hexagon connection (IHC).

Materials and methods: Twenty patients were rehabilitated with immediately loaded fixed full-arch rehabilitations. All the implants presented the same macro- and micro-topography but different implant/abutment connection. IHC were used in one randomly selected side of the jaw and EHC in the other side.

Outcome measures were implant survival rate, peri-implant marginal bone loss (MBL), plaque index (PI), probing depth (PD), and bleeding on probing (BoP) evaluated at 3, 6, 12, and 36-month post-loading. Any technical and biological complication was recorded. Kaplan–Meier procedure and linear mixed model were used to perform statistical analysis.

Results: Forty-three EHC and 40 IHC implants were inserted. No patients dropped out and two implants failed in the first 6 months. The CSR was 97.7% for EHC and 97.5% for IHC implants. No statistically significant differences were found among the two groups for any of the parameters at any time point. At the 36-month follow-up visit a slight difference was found in MBL with a mean value of 1.7 mm in the EHC and of 1.9 mm in the IHC group ($p = 0.355$).

No biologic complications were identified. Seven loosed abutment screws were identified in the entire follow-up period, two in the EHC, and five in the IHC group without a statistically significant difference ($p = 0.394$).

Francesco Pera and Maria Menini share the first authorship.

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Conclusions: After 36 months in function, both internal and external hexagon connections provided good clinical outcomes and were not associated with any significant difference.

KEYWORDS
abutment, bone resorption, connection, dental implants

What is known

External hexagon (EHC) has been the first implant/abutment connection introduced in implant dentistry.
EHC showed problems with microbial leaking, screw loosening, and force distribution.

What this study adds

This study compared over a 3-year period the EHC with an internal hexagon connection (IHC). Despite the fact that in vitro results showed more favorable outcome using IHC (lower microbial leaking, less screw loosening), no differences were available among the two groups.

1 | INTRODUCTION

Dental implants are increasingly popular for the rehabilitation of partially and totally edentulous patients, demonstrating optimal clinical outcomes and high levels of patients' satisfaction. Among the several factors that might affect their clinical outcomes, the type of implant-abutment connection is nowadays widely investigated. Implants are available on the market with many different connections design. However, the clinical advantages and indications of each specific connection are not clear.

The external hexagonal connection (EHC) has been the first connection proposed and has been extensively analyzed in many papers, demonstrating several advantages, especially in full-arch rehabilitations, such as the simplification of the prosthetic phase, with better passive-fit between prosthesis and implant and greater ease of management in the case of multiple implants.[1]

However, it has been reported that this connection might allow for micro-movements, resulting in abutment screw loosening or even fatigue fracture.[2] In addition, implants with an EHC have shown a worse distribution of forces on the peri-implant bone with greater concentration in some areas, affecting bone metabolism and therefore peri-implant bone resorption.[3,4]

Furthermore, EHC resulted to be the connection with the higher bacterial leakage and contamination.[5]

To overcome these problems, different implant/abutment connections have been introduced.[6–8] Among them, internal hexagonal connections (IHC) present a more homogeneous load distribution, lower bacterial microleakage, but in case of implant divergence exhibit a worst outcome in the impression accuracy and a greater difficulty in case of full-arch rehabilitations.[9]

IHC has demonstrated optimal results in partial implant rehabilitations[10]; however, few information is available regarding full arch implant rehabilitations.

In a recent publication, we reported the one-year outcomes of implants with internal versus external hexagon connections used in immediate loading full-arch rehabilitations. We did not find any difference in the clinical outcomes evaluated during the first year after loading.[7]

The aim of the present research was to update over a 3-year period differences in hard, soft peri-implant tissues, and complications among two different implant-abutment connections (EHC vs. IHC).

The null hypothesis was that there were no differences in the clinical outcomes using EHC versus IHC in full-arch immediate loading rehabilitations.

2 | MATERIALS AND METHODS

This multicenter, randomized, controlled, split-mouth trial was conducted in accordance with the Helsinki Declaration. The research was approved by the local Scientific Ethical Committee of the University of Genoa (protocol approval number: 527).

This research is reported according to the CONSORT statement for improving the quality of reports (www.consort-statement.org/).

All patients signed a written informed consent. Between September 2015 and July 2017, 10 patients referred to the Division of Implant and Prosthetic Dentistry (Department of Surgical Sciences) of the University of Genoa and 10 patients referred to the Prosthodontic Department of the Dental School, University of Turin were consecutively selected for the present research. Inclusion, exclusion criteria, and surgical and prosthodontic protocols are available in a previously published publication.[7]

Briefly, patients with terminal dentitions were rehabilitated with fixed full-arch rehabilitations supported by 4–5 immediately loaded implants according to the Columbus Bridge Protocol.[11–14] All the surgical and prosthodontic procedures were carried on by expert clinicians.

Implants with identical macro- and micro-topography but different connections were randomly inserted in each dental arch side.[7] In one

side implants with external hexagon connection were used (Syra, Sweden & Martina, Due Carrare, Padova, Italy); in the other side internal hexagon implants (Shelta, Sweden & Martina). Both implants presented a conical morphology and a ZirTi surface (sandblasted and etched).

After surgery, conical multi-unit abutments (0, 15, 30° PAD, Sweden & Martina) were immediately screwed on the implants and a plaster pick-up impression (BF-plaster Dental, Torino, Italy) was made. Fixed screw-retained prostheses with a metal framework and a composite resin veneering material were delivered within 48 h.

Follow-up visits for revaluation and removal of sutures were scheduled 7–10 days after surgery. The subjects were therefore recalled after 14 days, 1, 3, 6, 9 months and then yearly (Figure 1(A,B)).

2.1 | OUTCOME MEASURES

The main outcome evaluated was implant survival rate. Secondary outcome measures were peri-implant marginal bone loss (MBL) evaluated at 0, 3, 6, 12, and 36 months post-loading and plaque index (PI), probing depth (PD), and bleeding on probing (BoP) evaluated at 3, 6, 12 and 36 months post-loading.

MBL was evaluated using intraoral digital periapical radiographs taken with the parallel technique. Measurements were done using the implant-abutment interface as a reference point, mesially, and distally at each implant using a digital software (OrisWin DG, FONA, Assago, Italy).

Periodontal indexes (PI, PD, and BoP) were assessed in four points for each implant using a periodontal UNC 15 probe (Hu-Friedy, Chicago, IL, USA). To record indexes prostheses were unscrewed. BoP was evaluated as the presence of bleeding (yes/no); PI was defined as the presence of plaque (yes/no) on the multi-unit abutment using an erythrosine gel. All measurements were performed by two authors (PP and FB).

2.2 | STATISTICAL ANALYSIS

Mean with SD were reported for quantitative characteristics. For analysis on implant failure at patient level the Poisson regression model with number of failures as dependent variable was used to estimate confidence intervals and define statistical differences. Kaplan–Meier procedure was used to estimate the survival at a specified point on time and to compare the survival distributions of IHC and EHC implants.

Longitudinal assessment of bone resorption, PD, BOP, and PI during follow-up was performed using a linear mixed model with random intercept after visual inspection of their probability distribution. In all these regression models, the dependent variable was the outcome and the independent variables were the time indexes, the treatment group, and their interaction. Screw-loosed abutments were evaluated with the chi-square test. Nonparametric *U* Mann–Whitney test was used to assess the putative statistical difference between EHC and IHC techniques between Genoa and Turin groups.

A significance level of 5% was adopted in all tests and SPSS IBM (version 25) was used.

3 | RESULTS

Twenty patients were included in the present study (64 ± 9 years; range: 47 to 79 years; 14 males, 70%) and 83 implants (43 EHC and 40 IHC) were inserted. Three patients had five implants each, while all

FIGURE 1 (A,B) Clinical images at the last 3 years follow-up visit

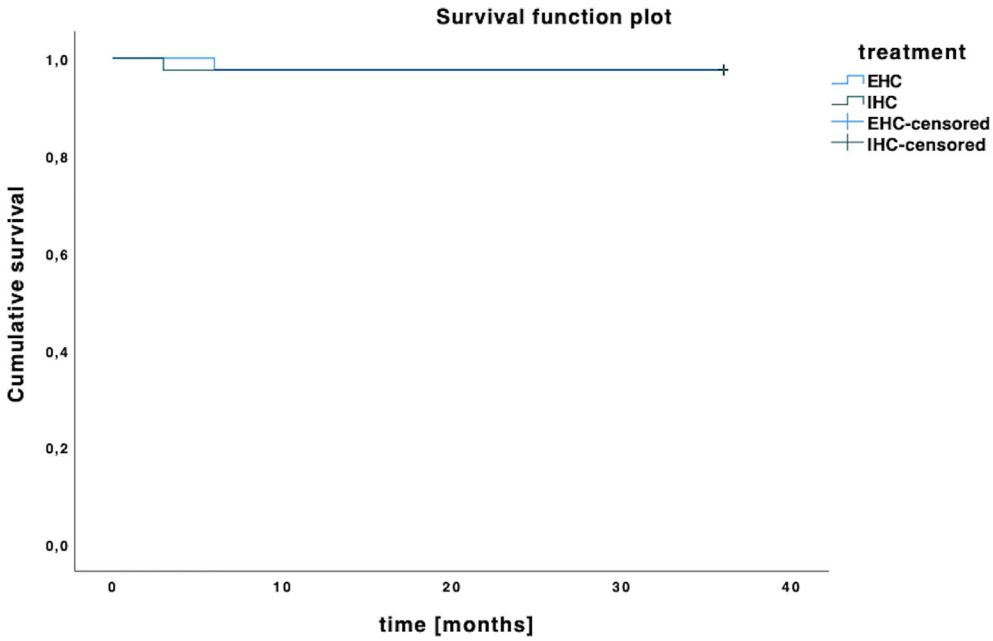

FIGURE 2 Survival function plot

TABLE 1 Peri-implant health parameters (BOP, MBL, PI, and PD) in the two groups. Mean (SD)

	EHC	IHC	*p*-value
MBL 3 m	−1.1 mm (0.7)	−1.1 mm (0.8)	0.868
MBL 6 m	−1.3 mm (0.8)	−1.4 mm (0.8)	0.541
MBL 12 m	−1.6 mm (0.8)	−1.7 mm (0.8)	0.565
MBL 36 m	−1.7 mm (0.7)	−1.9 mm (0.7)	0.355
PD 3 m	2.1 mm (0.8)	2.1 mm (0.7)	0.710
PD 6 m	2.2 mm(0.7)	2.2 mm (0.7)	0.914
PD 12 m	2.2 mm (0.5)	2.1 mm (0.3)	0.135
PD 36 m	2.2 mm (0.6)	2.3 mm (0.5)	0.304
BOP 3 m	1.0 (1.3)	0.9 (1.0)	0.681
BOP 6 m	1.1 (1.0)	0.9 (1.2)	0.494
BOP 12 m	0.8 (0.9)	1.0 (1.2)	0.416
BOP 36 m	1.3 (1.1)	1.1 (0.9)	0.255
PI 3 m	1.4 (1.7)	1.3 (1.5)	0.652
PI 6 m	1.7 (1.6)	1.9 (1.6)	0.611
PI 12 m	2.1 (1.5)	1.9 (1.6)	0.714
PI 36 m	2.5 (1.3)	2.0 (1.3)	0.095

Abbreviation: m, month.

the other patients received four implants. Eleven maxillae and nine mandibles were rehabilitated.

No patients dropped-out at the 36-months follow-up visit. Two posterior implants (one IHC and one EHC) failed respectively after 3 and 6 months in two different patients. Failed implants were immediately re-inserted, a new impression was taken, and the original framework was cut and welded with a new part including the replaced implant. Implant CSR was 97.7% and 97.5% respectively for EHC and IHC implants. No statistically significant difference was detected ($p = 0.952$) among the two groups regarding CSR.

Kaplan–Meier graph is reported in Figure 2.

Main periodontal indexes are reported in Table 1. No statistically significant differences were reported among the two groups at any time point.

At the 36-month follow-up visit, a slightly clinical difference was found in MBL with a resorption of 1.7 mm in the EHC and of 1.9 mm in the IHC group (Figure 3).

At the final follow-up visit a statistically significant difference among the two centers was identified regarding MBL in the IHC group ($p < 0.001$) with a higher Bone loss in the Genoa group and with BoP ($p = 0.008$) with higher index in the Turin group. No differences were identified for any other parameters.

3.1 | Complications

During the 36-month follow-up period, no biologic complications were identified. The composite resin veneering material was re-made on a prosthesis in a bruxist patient at 24 months post loading due to extensive chipping. Seven loosed abutment screws were identified in the entire follow-up period, two in the EHC and five in the IHC group without a statistically significant difference between the two groups ($p = 0.394$).

4 | DISCUSSION

Aim of the present trial was to compare implants with different implant/abutment connections used in full-arch immediate loading rehabilitations up to 36 months.

Data from the present study revealed no statistically significant differences between the two types of connections for any of the analyzed outcomes. Both implant types resulted clinically reliable; only two implants failed and were immediately re-inserted and loaded.

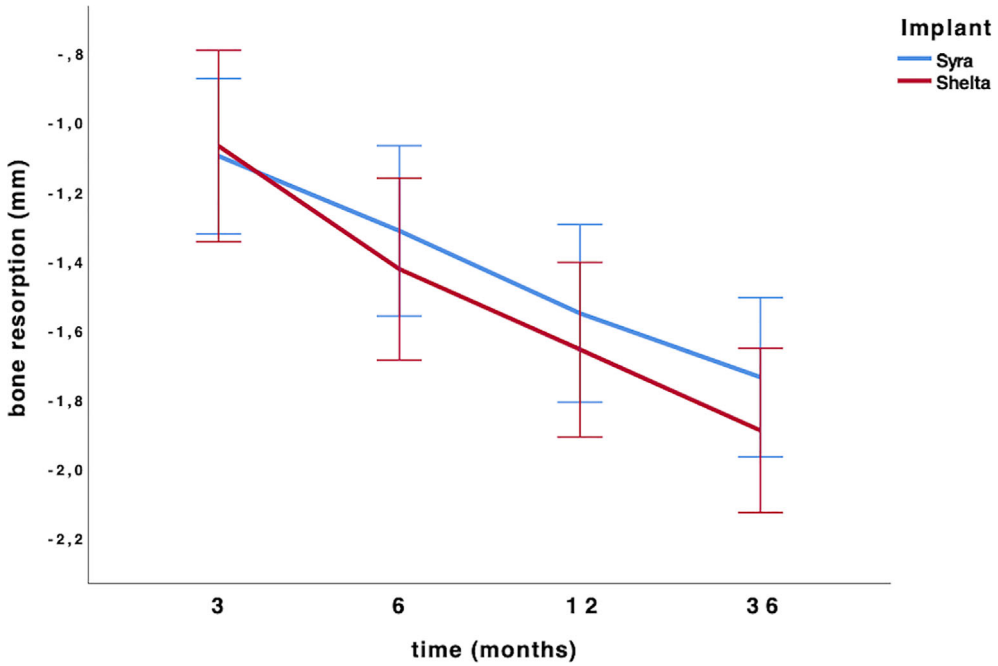

FIGURE 3 Graph reporting peri-implant bone loss over time. A non-statistically significant difference was detected. EHC implants exhibited lower mean values of bone loss compared with IHC implants from the 6-month follow-up appointment on

All the rehabilitations were clinically successful after the follow-up period of 36 months. MBL in the present research was lower in the EHC compared to the IHC group but without a statistically significant difference. The values of MBL were consistent with those recorded in other studies on full-arch implant rehabilitations. Tealdo and colleagues[15] found a MBL of 1.56 mm after 36 months of follow-up, using the same surgical and prosthetic protocol (Columbus Bridge Protocol) herein applied, but different types of external connection implants. Cannizzaro and colleagues[16] in a 3-year randomized controlled trial analyzed the outcomes of four implants in an immediate loading rehabilitation using the same EHC of the present study. The Authors found a MBL of 0.40 mm, which is less compared to the result of the present investigation. This may be due to the fact that in the above-mentioned study all the patients were already fully edentulous, while in the present research most of the implants were placed in post-extractive sites.

Koo and colleagues[17] analyzed the outcomes of implants with the same micro- and macro-morphology, but with different connections (external vs. internal). Their findings revealed that bone resorption was statistically significantly higher for the external connection, rather than for the internal one. However, the Authors[17] chose a platform switching approach,[18] which may have influenced the outcomes.

Seven mechanical complications were identified in the present research. Two screws were loosened for the external connection and five were loosened for the internal connection, without any statistically significant difference between the two groups. This finding is in accordance with a recent systematic review and meta-analysis by Lemons and colleagues[19] and in agreement with a 5-year randomized control trial on internal versus external connection by Esposito and colleagues,[20] who found no significant difference in the complication rate between the two groups.

The main limitations of the present research were the small sample size and the fact that the study was conducted in a single blind approach, where the clinician is aware of the implant type that he used or measured. Also, the examiners were aware of implant type.

This research was designed as a clinical study, which allows to observe implant's behavior under a real clinical situation, and with a split-mouth design, which is supposed to eliminate intra-patient variables. In addition, the study was designed as a multicenter research. The surgery and the prosthodontic rehabilitations were performed by expert operators and similar results were obtained from the two clinical centers, supporting the generalizability of the outcomes.

According to the present research, implant survival rate, peri-implant bone resorption, and clinical success do not seem to be affected by the implant/abutment connection. This result confirms the preliminary findings with a 1-year follow-up and the null hypothesis was not rejected.

In accordance with other research, which investigated differences between external and internal,[20] or conical and external connections,[21] finding no differences among them, the present outcomes suggest that the connection type can be chosen based on the clinician's experience and preferences.

In the present, research must be underlined that straight or angled abutments were screwed on each implant at the recommended manufacturer torque. Prostheses were, therefore, not directly connected to the implant. The abutment was connected at the surgery time and used to "protect" the soft tissue attachment according to the principle of the one-abutment-one-time technique.[22,23]

5 | CONCLUSIONS

Within the limitations of the present study, clinical outcomes of full-arch immediate loading rehabilitations were not significantly affected by different implant-abutment connections.

CONFLICT OF INTEREST

The authors declare that this study was partly funded by Sweden & Martina.

AUTHORS CONTRIBUTIONS

Paolo Pesce, Francesco Pera, and **Maria Menini**: contributed to conception, design, data acquisition and interpretation, performed all statistical analyses, drafted, and critically revised the article. **Francesco Bagnasco** and **Federico Mussano**: contributed to conception, design, data acquisition and interpretation, drafted, and critically revised the article. All authors approved the final version of this article.

DATA AVAILABILITY STATEMENT

Data source available upon request from authors

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