Clinical Outcomes of Dental Implants with Two Different Internal Connection Configurations—A RCT

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Abstract: Background: The aim of the present study was to highlight clinical and radiographical differences among implants sharing the same macro-geometry but with two different prosthodontic connections. Methods: Patients requiring at least 2 implants in the posterior area of the jaw were randomly divided into two groups (Conical (CS) and Internal Hexagonal (IH) connection). At implant surgery (T0), insertion torque, implant stability quotient (ISQ values recorded by resonance frequency analysis, RFA), and soft tissue thickness (STH) were assessed. A 1-abutment/1-time protocol was applied, and the prosthesis was realized following a fully digital workflow. At the 36-month follow-up periapical x-rays were taken. In order to statistically analyse differences among the two groups and the different variables, paired T-test was used. Linear regression analysis was conducted to analyze how marginal bone loss (MBL) was affected by other independent variables. A neural network created to predict the success (good or not good) of the implant itself was implemented. Results: 30 out of 33 patients (14 males, 16 females, mean age: 68.94 ± 13.01 years) (32 CS and 32 IH) were analyzed. No implants failed. Marginal bone loss at the 3-year time-point was 0.33 ± 0.34 mm and 0.43 ± 0.37 mm respectively for CS and IH with a significant difference between the two groups (p = 0.004). The presence of keratinized gingiva (p = 0.034) significantly influenced MBL. Conclusions: Both the implant connections investigated presented optimal clinical outcomes with minimal marginal bone loss; however, CS implants and implants with the presence of a greater width of keratinized tissue presented significantly lower MBL.

Keywords: dental implant; dental abutment; clinical trial; alveolar bone loss

1. Introduction

Long-term success of dental and implant-supported restorations is determined by the interaction of hard and soft tissues with the dental and implant-abutment complex [1,2]. Research has shown its predictability even in patients with orofacial disorders [3,4]. The contour and the shape of soft tissues around implants are important for long-term treatment success and are influenced by the quality and quantity of underlying bone [5]. Marginal bone loss (MBL) is commonly observed around dental implants following years of function and most of it is observed during the first year after implant insertion [6,7]. In this period, bone remodeling takes place after surgical trauma and several surgical and prosthetic procedures occur that might affect the interface between the implant and peri-implant tissues, such as: second-stage surgery, multiple healing abutment connections and disconnections, impressions, crown/bridge try-in, and final prosthetic delivery. The quantity of MBL which is tolerable during the first and the following years has been a topic for research and discussion over the years [8]. Several factors have been studied to evaluate their roles in MBL onset and these are: surgical procedure, implant type [9,10], abutment morphology and surfaces [11–17], implant-abutment connection [18–22], prosthetic procedure [23–27], and peri-implantitis [28,29]. The type of implant-abutment connection
plays a key role and has been demonstrated to affect peri-implant bone loss [5]. In fact, the micro-gap between implant and abutment may be colonized by bacteria [30] resulting in a bacterial reservoir close to the bone crest with possible contamination and inflammation of peri-implant tissues [31–33]. Moreover, the micro-movement of the abutments has been demonstrated to increase the risk of MBL in a canine model [34].

The relationship between the designs of implant-abutment connection and marginal bone loss (MBL) has been a topic of interest over the last decade and several types of implant-abutment connections have been developed by different manufacturers with the aim of reducing biological and mechanical complications; however, all of them have shown micro-gaps and bacterial micro-leakage [35] in in vitro [36–38] and in vivo studies [39–41]. Implants with internal conical connections demonstrated lower levels of bacterial contamination when compared with implants with external and internal clearance-fit connections. In addition, longitudinal studies found a clear difference regarding bacterial patterns related to conical and internal clearance-fit connections [5], which might affect peri-implant tissue health and bone maintenance over time. In the traditional restorative workflow, the healing abutment or provisional restoration is connected to the implant after implant exposure during second-stage surgery. Before the final prosthodontic connection, the healing or provisional abutment is connected and disconnected several times for impression taking and prosthodontic try-in. These multiple abutments connections and disconnections during the healing phase [42] disrupt the connective sealing and may lead to tissue downgrowth [24,43]. In 1997, it was demonstrated in an animal model that multiple abutment connections and disconnections increase MBL [44]. To overcome this issue, tissue-level implants can be used instead of bone-level implants [9,45]. As an alternative, when using bone-level implants, a prosthodontic strategy, referred to as “one abutment-one time”, was developed, and it focused on minimizing possible abutment disconnections and reconnections, and improving hard- and soft-tissue stability over time [46]. The one abutment-one time protocol has been the subject of clinical studies [46–49], narrative [50], and systematic reviews [24,51], leading to the conclusion that this procedure is associated with reduced MBL and reduced gingival recession.

Titanium abutments have shown high survival rates, but, especially in patients with thin phenotype, they could result in grayish discoloration of peri-implant mucosa [52]. In order to avoid this negative effect, ceramic abutments were introduced. Zirconia showed better mechanical characteristics compared with other non-metallic abutments, such as alumina [53,54]; therefore, zirconia abutments were introduced into clinical practice, such as prefabricated abutments, CAD–CAM all-zirconia abutments, and CAD–CAM zirconia abutments luted to a titanium base [55]. Zirconia abutments have demonstrated excellent biocompatibility in vitro [56,57] and the formation of a significantly thinner and less structured microbial biofilm on the surface compared to titanium and hydroxyapatite surfaces [58]. Zirconia abutments with a titanium base have better mechanical properties than all zirconia abutments [59] and showed no differences in survival rate after five years of function compared to titanium abutments [60].

The aim of the present study was to compare, over a three-year period, the clinical outcomes of implants sharing the same micro- and macro-design but with different connections. The tested hypothesis was that there were no differences in MBL and in implant survival among the two groups.

2. Materials and Methods

This is a three-year follow-up report of a randomized, controlled, split-mouth trial conducted according to the principles of the Helsinki Declaration. Patients signed a consent form and the study was approved by the local ethics committee of the University of Genova. The randomization process, inclusion and exclusion criteria, and surgical and prosthodontic procedures were reported in Corvino et al. 2021 [61].

Briefly, 33 patients were treated by an experienced surgeon (LC) between January and October 2018. Preoperative antibiotic therapy was prescribed [62,63] and surgical templates,
opening a small flap, were used and implants were inserted according to the manufacturer’s instruction. Patients were randomly divided into conical connection group (two or more implants with Conical Connection, NeO CS, Alpha Bio Tec Ltd. Modi’in-Maccabim-Re’ut, Israel—CS) or internal hexagon connection group (two or more implants with Internal Hexagon, NEO HEX, Alpha Bio Tec Ltd. Modi’in-Maccabim-Re’ut, Israel—IH). All implants were inserted 0.5 mm subcrestally and were 10 mm long and 3.75 mm in diameter. Insertion torque and primary stability (implant stability quotient, ISQ, recorded by resonance frequency analysis, RFA) were registered using SA-310 (W&H Elcomed implant unit W&H, Burmoos, Austria) and Osstell (AB, Göteborg, Sweden), respectively.

Eight to 12 weeks after surgery, second surgery was performed, and the prosthodontic phase carried out. CAD–CAM zirconia abutments were screwed on the implants following the platform-switching concept and a one abutment-one time protocol on the basis of digital impressions taken immediately after implant insertion. Monolitic zirconia crowns were realized following a fully digital workflow and then cemented (Temp Bond, Kerr, CA, USA).

Patients were recalled every six months for hygienic maintenance.

2.1. Study Outcomes

The study outcomes were:

Mean peri-implant bone-level change, calculated using intraoral digital periapical radiographs using a custom radiograph holder and the long-cone parallel technique at implant placement (baseline, T0); six months of function (T1); one year of function (T2); and three years of function (T3). Measurements were collected by an external assessor. All radiographs were displayed in an image-analysis program (AutoCAD 2019 23.0, Autodesk Inc., San Francisco, CA, USA) on a 24-in. LCD (Liquid Crystal Display) screen (iMac, Apple, Cupertino, CA, USA), and evaluated under standardized conditions (ISO 12646:2004). The software was calibrated using the known distance of the implant pitch (1.2 mm) as reference measurement. Bone crestal level (BCL) was defined as the distance from the implant collar to the bone crest and was measured for each implant at its mesial and distal sides. Marginal bone loss (MBL) was defined as the difference between BCL at various time points and BCL at T0.

Implant failure was defined as implant loss.

Prosthesis failure was defined as need to fabricate a new prosthesis.

Additionally, ISQ was recorded by RFA (Osstell, AB, Göteborg, Sweden) at implant insertion and at the second-surgery phase. Torque curve values recorded at 10 s intervals were registered during implant insertion.

At the time of implant insertion, soft tissue vertical thickness (STH) was measured with a periodontal probe, while attached keratinized tissue (KT) was recorded with a periodontal probe buccally from the prosthesis buccal margin to the mucogingival junction at the time of definitive prosthesis cementation.

2.2. Statistical Analysis

The statistical analysis was created for numeric parameters such as BCL, MBL, and ISQ values with SPSS for Windows release 18.0 (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed using mean and standard deviation. The statistical unit of the analysis was the patient. Comparisons between each time point were made for each group by paired t-test to detect any changes in MBL during different follow-up. The linear regression analysis, using the least squares method, was conducted in order to analyze how “MBL at three-year time point” (dependent variable) is affected by the values of the independent variables considered in the study.

2.3. Neural Network

In the previous publication a supervised neural network based on the torque curve values recorded at 10 s intervals was developed [61]. The aim of this work was to build
an algorithm that, when analysing the torque curve of a new implant, it could predict the success (good or not good) of the implant itself.

The results of the three-year data on MBL were used to fix and improve the neural network. The training set was used to adjust the parameters of the neural network, and the test set was used to assess the performance of the model. The neural network’s ability to classify was measured with a confusion matrix that was formed from the four outcomes produced as a result of binary classification.

3. Results

From the original 33 patients (17 males, 16 females, mean age: 67.4 y ±14.5 years) rehabilitated with 68 implants (34 CS and 34 IH), 3 patients with 4 implants (2 CS and 2 IH) dropped out due to the COVID-19 pandemic Figure 1.

Table 1. Demographic data of patients analysed at the three-year follow-up visit.

<table>
<thead>
<tr>
<th>Total Patients</th>
<th>Sex</th>
<th>Mean Age</th>
<th>Light Smokers</th>
<th>History of Periodontal Disease</th>
<th>Total Implants</th>
<th>Connection Type</th>
<th>Attached Keratinized Tissue</th>
<th>Soft Tissue Vertical Thickness</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>14</td>
<td>16</td>
<td>69.2 ± 12.6</td>
<td>5 25</td>
<td>64</td>
<td>32 CS</td>
<td>2.5 ± 0.9</td>
<td>2.8 ± 1.1</td>
</tr>
</tbody>
</table>

No implants failed during the three-year follow-up and all the prostheses were stable and in function at the last follow-up appointment. Clinical outcomes are presented in Table 2.
Table 2. Clinical Outcomes ISQ (implant-stability quotient) MBL (mean bone loss).

<table>
<thead>
<tr>
<th></th>
<th>CS</th>
<th>IH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marginal bone loss, six months</td>
<td>0.33 ± 0.34</td>
<td>0.43 ± 0.37</td>
</tr>
<tr>
<td>Marginal bone loss, one year</td>
<td>0.48 ± 0.18</td>
<td>0.57 ± 0.24</td>
</tr>
<tr>
<td>Marginal bone loss, three years</td>
<td>0.31 ± 0.10</td>
<td>0.44 ± 0.20</td>
</tr>
<tr>
<td>ISQ t0</td>
<td>68.6 ± 9.1</td>
<td>73 ± 9.8</td>
</tr>
<tr>
<td>ISQ t3</td>
<td>72.9 ± 7.5</td>
<td>79.3 ± 5.2</td>
</tr>
</tbody>
</table>

3.1. Marginal Bone Loss

Marginal bone loss after one year was 0.48 ± 0.18 mm for CS and 0.57 ± 0.24 mm for IH, with a statistically significant difference ($p = 0.043$). After three years, marginal bone loss was 0.31 ± 0.10 mm for CS and 0.44 ± 0.20 mm for IH with a statistically significant difference between the groups ($p = 0.002$). The intragroup differences between time points are reported in Table 3.

Table 3. Intragroup differences in mean bone loss. (* statistically significant).

<table>
<thead>
<tr>
<th></th>
<th>CS (6 months)</th>
<th>CS (1 year)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS (6 months)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS (1 year)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>p: 0.014 *</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The regression model built to determine how the variables recorded (sex, age, reason for extraction, site, phenotype, soft tissue height, keratinized gingiva, connection, highest insertion torque value, and area under the insertion torque curve) influence MBL returned the outcomes $p = 0.023$ and $R^2 = 31\%$ (Table 4); thus, it can be concluded that the regression model is quite a good fit.

Table 4. Results of the regression model * Signed area bounded by the x-axis (time) and the torque curve. ** Statistically significant.

<table>
<thead>
<tr>
<th>Regression Statistics</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple R</td>
<td>0.553</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R²</td>
<td>0.306</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adjusted R²</td>
<td>0.154</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard error</td>
<td>0.154</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observations</td>
<td>64</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ANOVA</th>
<th>df</th>
<th>SS</th>
<th>MS</th>
<th>F</th>
<th>Significance F</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regression</td>
<td>10</td>
<td>0.554</td>
<td>0.055</td>
<td>2.336</td>
<td>0.023 **</td>
</tr>
<tr>
<td>Residual</td>
<td>53</td>
<td>1.257</td>
<td>0.024</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>63</td>
<td>1.811</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Coefficients</th>
<th>Standard Error</th>
<th>t-Statistic</th>
<th>p Value</th>
<th>Lower 95%</th>
<th>Upper 95%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>0.086</td>
<td>0.251</td>
<td>0.342</td>
<td>0.734</td>
<td>−0.418</td>
</tr>
<tr>
<td>Gender</td>
<td>0.024</td>
<td>0.050</td>
<td>0.491</td>
<td>0.625</td>
<td>−0.075</td>
</tr>
<tr>
<td>Age</td>
<td>0.004</td>
<td>0.002</td>
<td>1.948</td>
<td>0.057</td>
<td>0.000</td>
</tr>
<tr>
<td>Reason for extraction</td>
<td>−0.034</td>
<td>0.034</td>
<td>−0.989</td>
<td>0.327</td>
<td>−0.102</td>
</tr>
<tr>
<td>Site</td>
<td>0.001</td>
<td>0.002</td>
<td>0.322</td>
<td>0.749</td>
<td>−0.004</td>
</tr>
<tr>
<td>Phenotype</td>
<td>0.006</td>
<td>0.062</td>
<td>0.090</td>
<td>0.929</td>
<td>−0.119</td>
</tr>
<tr>
<td>Connection</td>
<td>0.127</td>
<td>0.042</td>
<td>3.040</td>
<td>0.004 **</td>
<td>0.043</td>
</tr>
<tr>
<td>Thickness</td>
<td>0.011</td>
<td>0.020</td>
<td>0.529</td>
<td>0.599</td>
<td>−0.030</td>
</tr>
<tr>
<td>Keratinized gingiva</td>
<td>−0.064</td>
<td>0.029</td>
<td>−2.177</td>
<td>0.034 **</td>
<td>−0.123</td>
</tr>
</tbody>
</table>

highest insertion torque value (<70; ≥70)
| −0.034          | 0.048          | −0.694   | 0.491   | −0.130    | 0.063     |
| Area *          | 0.000          | 0.000     | 0.775   | 0.442     | 0.000     | 0.000     |

* Signed area bounded by the x-axis (time) and the torque curve.
The interpretation of regression coefficients confirms that keratinized gingiva ($p = 0.034$) and connection ($p = 0.004$) could significantly influence MBL, with CS connections and implants with presence of a greater width of keratinized tissue presenting a significantly lower MBL, while the other variables did not play a statistically significant role (Table 4).

### 3.2. Neural Network

The classification of confusion matrix produced four outcomes—true positive, true negative, false positive, and false negative:
- True positive (TP): correct positive prediction (12 implants);
- False positive (FP): incorrect positive prediction (3 implants);
- True negative (TN): correct negative prediction (7 implants);
- False negative (FN): incorrect negative prediction (2 implant).

The confusion matrix was used to calculate the performance metrics.

- **Accuracy** is a ratio of correctly predicted observation to the total observations. For our model, we achieved an accuracy of 0.792, which means our model is approximately 80% accurate.

- **Precision** is the ratio of correctly predicted positive observations to the total predicted positive observations. The model achieved a 0.800 precision, which is considered good.

- **Sensitivity** is the ratio of correctly predicted positive observations to all observations in actual class. We achieved a sensitivity of 0.857, which is very good for this model.

- **Specificity** is calculated as the number of correct negative predictions divided by the total number of negatives. The model obtained a specificity of 0.700.

A graphical representation of the model is shown in Figure 2.

**Figure 2.** Graphical representation of the neural network. Graphical representation of the model with the weights on each connection. The black lines show the connections between each layer and the weights on each connection while the blue lines show the bias term added at each step.
4. Discussion

The present study reported no differences in implant failure rate for dental implants with two different types of internal connections, while a statistically significant effect of implant connection on MBL was found. Results at the three-year follow-up showed a significant difference among the two groups, with higher bone loss in the IH group; however, the amount of bone loss in both groups was within normal limits (mean: 0.31 mm for CS and 0.44 mm for IH) and may be considered of minimal clinical relevance. In fact, a physiological bone remodelling has to be expected during the first year as a consequence of implant surgery and occlusal load.

Additionally, it is interesting to note that at the three-year follow-up visit the average MBL was less than the one registered at the one-year follow-up. The difference is around 0.10 mm, and it cannot be excluded that it was due to the intrinsic error of the radiographic measurement. It must be emphasized that to reduce this problem, all measurements were collected by the same assessor and that customized radiograph holders were used; however, it is necessary to emphasize the great bone stability that was registered in the three years. This outcome confirms the efficacy of the clinical procedures adopted, including the use of internal connection implants, the one abutment-one time approach, and platform switching. It might be suggested that following this strict protocol, the type of internal connection has limited influence on clinical outcomes, although the difference was statistically significant.

Results of the present study confirm recent systematic reviews of data reporting better results for internal connections and, in particular, conical connections [64,65]. Camps-Font et al. in a network meta-analysis comparing external, internal flat-to-flat, and conical implant abutment connections reported significantly less peri-implant MBL in conical connections when compared with external (MD: $-0.25$ mm; 95% CI: $-0.43$ to $-0.05$; $p = 0.01$; I$^2$: 81%) and internal flat-to-flat (MD: $-0.27$ mm; 95% CI: $-0.53$ to $-0.02$; $p = 0.04$; I$^2$: 95%) interfaces. Additionally, they reported that, according to the SUCRA ranking, conical implant abutments provide the best outcomes for implant survival (82.9%), peri-implant MBL (96.3%), and prosthodontic complications (93.9%) [64]. These performances of conical connections may be due the reduced implant-abutment gap and subsequent minor bacterial leakage [38].

Another interesting aspect of the present outcomes is the relationship between MBL and the quantity of keratinized tissue (KT). Several researches have tried to identify the influence of KT on implant survival and biological complications [66]. The 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions identified the lack of KT as one of the principal factors associated with recession of peri-implant mucosa [67]; however, the evidence is not unanimous and the studies on this topic are divergent [68–70]. In the present investigation, KT width was measured at the definitive prosthesis cementation from the prosthesis buccal margin to the mucogingival junction, and the clinical results confirmed a significant correlation between KT width value and MBL at three years post implant placement.

One last interesting aspect of the present study is the development of a neural network to predict the success of a dental implant on the basis of the insertion torque values recorded at 10 s intervals during implant insertion. Several factors, such as those mentioned above, affect dental implant success over time; however, the torque curve used in the development of our neural network has proven to be a valid instrument to predict MBL.

Recently, a systematic review by Insua et al. [71] histologically demonstrated the critical damages occurring to cortical bone due to implant site under preparation. This outcome can be due to the mechanical fragility of cortical bone and to the minimal number of cells and vessels present. From a clinical standpoint, fracture of the cortical bone may reflect a possible bone resorption.

Although controversial outcomes have been reported by animal studies [72,73], a very recent systematic review and meta-analysis highlighted a direct correlation between the osteotomy/implant body diameters mismatching and MBL in the case of corticalized bone [53].
This behavior appeared to be even more evident in the case of the implant being exposed early to the oral environment.

All this background might explain outcomes of the neuronal network herein presented: a picky torque curve, in fact, is representative of a torque pick reached quickly which implies it has an important impact on the cortical area and, then, results in a higher marginal bone loss. On the other hand, a smooth torque curve is characteristic of a torque pick reached slowly and obtained with minimal stress on the crestal bone.

5. Conclusions

Within the limitations of the present study, MBL seems to be influenced by the type of internal connection and the quantity of keratinized tissue, with better outcomes in the case of conical internal connection and in the presence of a greater width of keratinized tissue, although both implant connections reported optimal clinical outcomes at the three-year follow-up. Future studies with longer follow-ups are needed to confirm these results.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: Data available on request.

Conflicts of Interest: The authors declare no conflict of interest.

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