Abstract: Background: Dental implant abutment screw loosening is an increasingly common problem, as evidenced by multiple studies that have investigated its causes. The objective of this study was to compare the screw loosening torque values before and after cyclic loading and to determine whether they are affected by the CAD/CAM abutment manufacturing technique (machined or laser-sintered) and abutment angulation. Materials and Methods: Ninety implants were used and divided into two groups: 45 implants received machined abutments (group A) and 45 implants received laser-sintered abutments (group B). Each group was further divided into three subgroups, with 15 implants each, based on the abutment angulation involved (0°, 15° and 20°). The abutments were tightened to the torque recommended by the manufacturer, and the reverse torque value was measured before and after cyclic loading (300,000 cycles). Data analysis was performed using one-way ANOVA and Wilcoxon signed-rank tests. Results: Statistically significant differences were observed between the laser-sintered and machined groups (\(p<0.01\)). Additionally, differences were observed between subgroups with different angulations for both machined (16.2 ± 1.75, 14.7 ± 1.74 and 13.4 ± 1.08 Ncm) and laser-sintered abutments (14.6 ± 1.25, 12.7 ± 1.2 and 11.1 ± 1.35 Ncm) (0°, 15° and 20°, respectively). Conclusions: The final screw loosening torque after cyclic loading was lower than the initial loosening torque. Both abutment angulation and the CAD/CAM manufacturing method exerted a statistically significant influence on the final loosening torque. The abutment angulation factor was estimated to have an influence of 34.5%, while the abutment manufacturing method was estimated to have an influence of 21%.

Keywords: screw loosening; implant single crowns; machined abutments; laser sintered; abutment angulation

1 Introduction

Humans have long sought to replace lost teeth, due to aesthetic and functional reasons. In this regard, dental implants have become the treatment of choice for missing teeth, satisfying the patient needs and affording a success rate of over 90% in the first three years after placement [1].

It has been demonstrated that screw loosening in screw-retained prostheses is the most recurrent complication [2], and different authors have reported that abutment mobility secondary to loosening could place the survival of the restoration at risk [3–5]. One reason for this problem could be related to the use of angled abutments. In effect, in some cases, the implant cannot be placed in the ideal position, as in patients with limited
bone volume resulting from the reabsorption process that follows tooth loss, and in such situations, angled abutments must be used [6,7]. However, an inconvenience of angled abutments is that they have an extra metal band that increases their thickness; this in turn can increase the risk of tissue retraction, and the angulation of the abutment generates loading forces outside the axis that increase the risk of screw loosening.

A great variety of angled abutments are currently available, thanks to the existence of numerous commercial brands and implant systems. Thus, in general terms, it can be affirmed that the use of angled abutments (whether premanufactured or customized) allows clinicians to offer successful prosthetic restorations even in the least optimal situations [8,9].

Due to the limitations of the conventional techniques, technological advances and changes have been introduced, with the industrialization and automation of the melting techniques and the rapid creation of prototypes [10]. Digital dentistry has emerged as a result of these advances and refers to a range of digital technologies (computed-aided design and computed-aided manufacturing [CAD/CAM]) that increase efficiency compared to the conventional techniques. Among the different digital technologies, subtractive procedures and additive procedures must be mentioned. The additive technologies, also referred to as rapid prototyping techniques, are based on the addition of material layers to obtain a personalized solid structure. Their advantages include the creation of complex structures and the fact that they can be used in zones that would be difficult to treat with the subtractive techniques [11].

Metal abutments that have been manufactured using laser sintering (LS) technology are composed of a chromium–cobalt alloy and, as added components, may also contain tungsten, molybdenum, iron, silica, cerium, manganese and carbon. The structure is characterized by a particle size of 3–14 µm and, in combination with the laser technology affords greater density, by stronger abutments [12]. Different studies comparing prostheses manufactured with conventional techniques versus LS concluded that the marginal space for LS prostheses was 65 µm in comparison to 150–125 µm in the case of conventionally manufactured crowns [13].

Each component of this alloy contributes key features for the success of the material. Cobalt increases the elastic modulus, resistance, rigidity and hardness. Likewise, it is reactive and creates a transparent and passive layer that protects the metal from exposure to the environment, avoiding corrosion and pigmentation phenomena [14].

Among the main characteristics of this alloy, mention must be made of its high biocompatibility, its strength and increased resistance to wear compared with titanium alloys. Its widespread use in biomedical areas is due to the fact that it contains no elements that prove harmful to the human body [15].

The present in vitro study analyzes the influence of the abutment angulation and manufacturing method (machined or laser-sintered) on screw loosening with external connection implants following cyclic loading equivalent to one year of chewing function. The abutment angulation factor was estimated to have an influence of 34.5%, while the abutment manufacturing method was estimated to have an influence of 21%.

To carry out this work, we start from the following null hypothesis: there are no statistically significant differences between the initial loosening and the final loosening of the different pillars (machined or laser sintered) and angulations (0°, 15° and 20°) after being subjected to 300,000 cycles.

2. Materials and Methods

The study involved a total of 90 titanium alloy (Ti-6Al-4V) (6% aluminum and 4% vanadium) internal connection implants (MG-Osseous® STD 3.75 × 10 mm; platform 4.1 mm, Mozo-Grau S.L., Valladolid, Spain). The implants in turn were connected to 90 abutments: 45 abutments (MG-Osseous® STD) measuring 4.1 mm in diameter and 10 mm in height, with a hexagonal platform measuring 4.1 mm in diameter; and 45 laboratory-made laser-sintered chromium–cobalt abutments measuring 4.1 mm in diameter and 10 mm in height, with a 1.1 mm platform (Figures 1–5). Ninety external metric thread screws (thread
diameter 2 mm and thread pitch 0.4 mm) were also used. The standardized internal implant threading design presented a crest angulation of 60° (MG-Osseous® STD M 2 × 0.4, thread diameter 2 mm and thread pitch 0.4 mm).

The 90 implants were divided into two groups according to the abutment type involved: 45 implants with machined titanium abutments (group A) and 45 implants with laser-sintered chromium–cobalt abutments (group B). These groups in turn were each subdivided into three subgroups according to the type of abutment angle involved: group A (machined titanium abutments) consisted of three subgroups each comprising 15 samples with an angulation of 0°, 15° and 20°, respectively; and group B (laser-sintered chromium–cobalt abutments) likewise consisted of three subgroups each comprising 15 samples with an angulation of 0°, 15° and 20°, respectively.
The torque and reverse torque values were measured with a 1.25 mm hexagonal driver connected to an implant motor (iChiroPro®, BienAir, Bienne, Switzerland) that was used as a digital torque meter.

On the other hand, a customized aluminum test tube (manufactured by Euroortondoncia®, Madrid, Spain) was required, with three perforations angled at 0°, 15° and 20° corresponding to the angulations of the abutments (Figure 6). This tube was used as a retention base for the implant and abutment and moreover also served to align the implants and abutments subjected to cyclic loading (Figure 7). The angled perforations were designed to facilitate the correct positioning of the implant to ensure that the abutment received cyclic loading vertically (Figure 8).
The study was carried using an Instron® fatigue test machine (Instron, Norwood, MA, USA). Before cyclic loading, the machine was calibrated to produce a load of 200 N with a frequency of 2 Hz, and 300,000 cycles were programmed to simulate the chewing function of a person over approximately one year [16].

Then, the abutments were manually adjusted using the implant motor as the torque meter, applying a torque of 3000 Ncm to all the samples. Once the screws were tightened, a first measurement of screw loosening was made with the implant motor, without exposing the abutments to any loading (initial loosening). This was carried out to have a reference for a comparison of the results and to determine whether there was any screw loosening before and after cyclic loading. After obtaining the first tightening and initial loosening results, the screws were tightened again for the application of the 300,000 loading cycles (Figure 9).

Once the cycles were completed, the implant motor was used for the final screw measurements (Figure 10), and comparisons were made with the initial screw loosening results. The abutments, screws and implants were manually and visually examined to discard any type of problem.

In relation to the data of the 6 subgroups (n = 15 each), the Neyman-Pearson lemma was used to standardize the sample size assuming a risk factor of 0.2 and a statistical power of 80%. The calculated size was 14.84 samples per subgroup. Normal data distribution was assessed using the Kolmogorov–Smirnov test and Shapiro–Wilk test. One-way analysis of variance (ANOVA) was used to compare the loosening torque values. The contribution of angulation and abutment type to the loosening effect was calculated by obtaining the adjusted $R^2$ value. The SPSS version 26 statistical package (SPSS®, Chicago, IL, USA) was used throughout. Statistical significance was considered for $p < 0.05$. 
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exposing the abutments to any loading (initial loosening). This was carried out to have a reference for a comparison of the results and to determine whether there was any screw loosening before and after cyclic loading. After obtaining the first tightening and initial loosening results, the screws were tightened again for the application of the 300,000 loading cycles (Figure 9).

Figure 9. Cyclic loading fatigue test machine.

Once the cycles were completed, the implant motor was used for the final screw measurements (Figure 10), and comparisons were made with the initial screw loosening results. The abutments, screws and implants were manually and visually examined to discard any type of problem.

Figure 10. Final loosening.

In relation to the data of the 6 subgroups (n = 15 each), the Neyman-Pearson lemma was used to standardize the sample size assuming a risk factor of 0.2 and a statistical power of 80%. The calculated size was 14.84 samples per subgroup. Normal data distribution was assessed using the Kolmogorov–Smirnov test and Shapiro–Wilk test. One-way analysis of variance (ANOVA) was used to compare the loosening torque values. The contribution of angulation and abutment type to the loosening effect was calculated by

3. Results

The Kolmogorov–Smirnov test and Shapiro–Wilk test confirmed normal data distribution in the two groups, with values of over 0.05 in both cases (group A, \( p = 0.200 \) and \( p = 0.150 \); and group B, \( p = 0.200 \) and \( p = 0.937 \), respectively).

3.1. Machined Abutments with an Angulation of 0°

The mean of the machined abutments with an angulation of 0° (± standard deviation [SD]) initial loosening torque was 19.96 ± 1.64 Ncm, and the final loosening torque was 16.22 ± 1.75 Ncm (Figure 11; boxplot 1).

3.2. Machined Abutments with an Angulation of 15°

The mean of the machined abutments with an angulation of 15° initial loosening torque was 19.30 ± 1.51 Ncm, and the final loosening torque was 14.71 ± 1.75 Ncm (Figure 11; boxplot 2).
Figure 11. The initial and final loosening torque values of the machined abutments and laser-sintered abutments with an angulation of 0°, 15° and 20°.

3.3. Machined Abutments with an Angulation of 20°

The mean of the machined abutments with an angulation of 20° initial loosening torque was 19.40 ± 1.05 Ncm, and the final loosening torque was 13.45 ± 1.08 Ncm (Figure 11; boxplot 3).
3.4. Laser-Sintered Abutments with an Angulation of 0°

The mean of the laser-sintered abutments with an angulation of 0° initial loosening torque was 19.91 ± 0.98 Ncm, and the final loosening torque was 14.58 ± 1.26 Ncm (Figure 11; boxplot 4).

3.5. Laser-Sintered Abutments with an Angulation of 15°

The mean of the laser-sintered abutments with an angulation of 15° initial loosening torque was 19.93 ± 1.44 Ncm, and the final loosening torque was 12.71 ± 1.20 Ncm (Figure 11; boxplot 5).

3.6. Laser-Sintered Abutments with an Angulation of 20°

The mean of the laser-sintered abutments with an angulation of 20° initial loosening torque was 19.30 ± 1.25 Ncm, and the final loosening torque was 11.11 ± 1.36 Ncm (Figure 11; boxplot 6).

Figure 11 in turn shows the first, second and third boxplots corresponding to the initial and final loosening torque values of the machined abutments with an angulation of 0°, 15° and 20°, respectively, where the final values at 0° (between 15 and 17 Ncm) are seen to be lower than the initial values (between 19 and 20 Ncm). At 15°, the median final value (between 12 and 13 Ncm) is seen to be lower than the initial value (between 18 and 21 Ncm). And, at 20°, the final values (between 13 and 14 Ncm) are seen to be clearly lower than the initial values (between 18 and 20 Ncm).

The fourth, fifth and sixth boxplots correspond to the initial and final loosening torque values of the laser-sintered abutments with an angulation of 0°, 15° and 20°, where the final values at 01° (about 14 Ncm) are seen to be lower than the initial values (between 19 and 21 Ncm). At 15°, the final values (between 13 and 14 Ncm) are seen to be lower than the initial values (between 18 and 19 Ncm). And, at 20°, the final values (about 11 Ncm) are seen to be lower than the initial values (between 18 and 19 Ncm).

3.7. Machined Abutments with Angulations of 0°, 15° and 20°

Table 1 shows the mean values of the grouped descriptive statistics corresponding to the machined abutments with angulations of 0°, 15° and 20°, showing a global mean final loosening torque of 14.80 ± 1.91 Ncm.

Table 1. Pooled descriptive statistics of final loosening of the machined abutments (angulations of 0°, 15° and 20°) in group A.

<table>
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<th>Standard Deviation</th>
<th>Minimum</th>
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<td>1.9075</td>
<td>11.2</td>
<td>18.7</td>
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<td>group A</td>
<td></td>
<td>2.00</td>
<td>0.826</td>
<td>1</td>
<td>3</td>
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</tbody>
</table>

3.8. Laser-Sintered Abutments with Angulations of 0°, 15° and 20°

Table 2 shows the mean values of the grouped descriptive statistics corresponding to the laser-sintered abutments with angulations of 0°, 15° and 20°, showing a global mean final loosening torque of 12.80 ± 1.90 Ncm.

Table 2. Pooled descriptive statistics of final loosening of the laser-sintered abutments (angulations of 0°, 15° and 20°) in group B.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Minimum</th>
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<td>1</td>
<td>3</td>
</tr>
</tbody>
</table>
3.9. Influence of Angulation (0°, 15° and 20°) on the Machined Abutments and Laser-Sintered Abutments

Angulation (0°, 15° and 20°) had a significant impact on the final loosening torque of both the machined abutments and the laser-sintered abutments after being subjected to 300,000 loading cycles. The adjusted $R^2$ value of 0.345 indicates that abutment angulation had an influence of 34.5% on the final loosening torque value.

Figure 12 shows the boxplot corresponding to the final loosening torque values of the machined abutments and the laser-sintered abutments according to the degree of angulation. The greatest stability is seen to correspond to the abutments with an angulation of 0°, followed in descending order by 15° and 20°.

![Boxplot of final loosening torque values](image)

Figure 12. The final loosening torque values of the machined abutments and the laser-sintered abutments.

3.10. Influence of the Manufacturing Technique of the Machined Abutments and Laser-Sintered Abutments on Final Loosening Torque

The manufacturing technique was seen to have a significant influence on the final loosening torque of the machined abutments and laser-sintered abutments after being subjected to 300,000 loading cycles. The adjusted $R^2$ value of 0.210 indicates that the abutment manufacturing technique had an influence of 21% on the decrease in the final loosening torque value. It should be noted that in total, the global abutment groups accounted for 55.5% of the final loosening torque, which was the approximate sum of the angulation factor (34.5%) and the manufacturing technique (21%).

Figure 13 shows the boxplot corresponding to the final loosening torque according to the manufacturing technique involved. The machined abutments were seen to be more stable than the laser-sintered abutments. For that boxplot, all the abutments of the different angles were merged.
4. Discussion

The present study has focused on screw loosening because it is one of the most frequent mechanical complications in implantology, and as a result, a number of authors have evaluated the factors that influence loosening, such as the inadequate positioning of the implant, the inadequate tightening of the screw, the deficient seating of the components, inadequate prostheses, the type of implant abutment connection involved, abutment angulation, cyclic forces, etc. [17–22].

Different studies have used methods similar to our own in relation to cyclic loading, with forces of between 20 and 420 N, frequencies in the range of 1–30 Hz [18], chewing forces between 140 and 350 N [20,23,24], and the number of loading cycles of between 16,000 and 5,000,000 [25–27].

Félix et al. [22] also used external connection hexagonal implants. In the same way as in our study, they operated at the same frequency of 2 Hz and with the same cyclic loading force (200 N). Upon comparing our results with those reported by Félix et al. (specifically referring to an angulation of 20° since they did not take the angulation factor into account), the mean initial loosening torque values were found to be similar in both studies.

Pinheiro et al. [28] explored whether the type of internal or external connection influences screw loosening as evaluated before and after loading. In contrast to our study, these authors operated at higher frequency and loading force settings (8 Hz and 400 N, respectively). Significant differences in loosening torque were observed upon comparing their results with external connection implants versus our own data, 12.80 Ncm versus 19.4 Ncm and 15 Ncm versus 10.4 Ncm, respectively, on average, though a decrease in loosening torque was recorded after cyclic loading in all the studied groups.

On the other hand, Kanneganti et al. [19] studied the loosening of the screw considering its size (long or short), angulation (0° and 25°), the connection (conical or hexagonal) and the use of straight or angled abutments. They found angled abutments experienced greater loosening than straight abutments with both vertical and oblique loading forces. This is consistent with our own observations.

In our study, we used machined titanium and laser-sintered chromium–cobalt abutments. In this respect, Camós-Tena et al. [29] carried out a study to determine which manufacturing method was best for minimizing disadjustment between the implant and...
abutment, and in alignment with our own data, they found the results to be less favorable with the laser-sintered abutments.

Authors such as Yau et al. [30] have shown that the machined manufacturing technique offers greater precision than the sintering technique, though in contrast Kasparova et al. [31], they recorded similar precision with both methods.

External connections were employed in the present study in the same way as in the publication of Solá-Ruíz et al. [32], who analyzed the vertical disadjustment between the external hexagons of the implants and the abutments, with and without the application of mechanical torque. The results evidenced the advantages of the external connections, with improved results on applying mechanical torque, and compatibility was demonstrated between the implants and abutments of different manufacturers.

Ahmed et al. [33] used machined titanium abutments and customized chromium–cobalt abutments for measuring the reverse torque values before and after cyclic loading, with an abutment angulation of 25°. The abutments were screwed to titanium implants with an internal hexagonal connection, applying a torque of 35 N. The authors recorded a significantly greater loss of preload with the customized abutments versus the machined abutments, in alignment with our own observations. Such losses are indicative of the loosening of the abutment screw.

On the other hand, Mulla et al. [34] used the same angulation as Ahmed et al. [33] to compare the capacity of different systems, with an angulation of 25° versus straight abutments (unlike in our study, where three angulations were used); they found the reverse torque values to be lower in all groups after cyclic loading, in alignment with our own observations.

El-Sheikh et al. [35], in the same way as in our study, evaluated different angulations (0°, 15° and 25°) and moreover analyzed abutment length and its influence on screw loosening before and after cyclic loading. The screws were tightened to 30 N, and the torque values were measured before and after loading. The results of the mentioned authors were consistent with our own, since screw loosening was seen to increase upon increasing the abutment angle, with greater dynamic stability being observed with the straight abutments.

5. Conclusions

Based on the results obtained and considering the limitations of the present in vitro study, it can be concluded that the comparison between the two groups (A and B) showed statistically significant differences in the initial and final loosening torque values of the screws in all the cases. Regarding the manufacturing technique used, it was observed that the loosening of the screws was significantly greater in the laser-sintered group than in the machined group ($p < 0.05$). On the other hand, the comparison between the different angulations (0°, 15° and 20°) with each manufacturing method showed statistically significant differences in all cases ($p < 0.05$), and the maximum stability was achieved with 0°, followed by 15° and 20°.

Both factors (angulation and manufacturing technique) influenced the final loosening of the screw that fixed the connection of the implant to the transepithelial abutment with the clinical crown.

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