In vitro integrity of implant external hexagon after application of surgical placement torque simulating implant locking

Abstract: The aim of this study was to evaluate the integrity of the external hexagon of an implant system with internal and external hexagons but with prosthetic connection through the external hexagon (Internal Torque, IT) in comparison with that of an implant system with external hexagon with mount (External Hexagon, EH). A device was made to measure the rotational freedom angles between implant and abutment hexagons in 10 implants from each group after the application of surgical placement torques of 45, 60 and 80 Ncm simulating implant locking. The distances between the vertices of the external hexagon were also obtained. Rotational freedom data were subjected to ANOVA and Tukey’s test \((P < .05)\) showing no significant difference between the angles of the intact implants (EH – 3.31 ± 0.41° and IT – 3.30 ± 0.17°) and after application of a 45 Ncm torque (EH – 3.27 ± 0.38° and IT – 3.31 ± 0.22°). However, after application of a 60 Ncm torque there were significant differences (IT – 3.40 ± 0.20° and EH – 4.03 ± 0.54°). After application of a 80 Ncm torque, the IT implant presented values of 3.39 ± 0.21° whereas the EH did not support the torque, suffering deformation of its external hexagon. Within the limits of this study, it can be concluded that the IT implant system may be preferable in clinical situations where implant placement within a certain bone density could generate torques higher than 60 Ncm.

Descriptors: Biomechanics; Dental implants; Torque; Dental prosthesis.
Introduction

Over the last few decades, the use of dental implants in partially edentulous patients, including single tooth replacements, has revolutionized esthetic and functional rehabilitation. Brånemark et al. (1977) reported the principles of osseointegration of titanium implants in bone tissue and their clinical application in rehabilitating edentulous patients, thus reestablishing masticatory function.

The initial purpose of external hexagon implants was to transmit torque during surgical placement. Afterwards, the external hexagon was also shown to work as an antirotational mechanism and to orient the abutment in single tooth prostheses. Although these implants have been the ones most commonly used, and are designed by several companies all over the world, possible fatigue or overload failures could occur due to different manufacturing tolerances. The biomechanical complications reported are loosening or fracturing of the abutment and prostheses screws. Therefore, the external hexagon connection continues to be comprehensively studied with the aim of improving the dimensional machining tolerances of the components, and making this screwed junction more stable.

The rotational freedom between implant and abutment depends on the hexagon dimensions that are in connection. These dimensions can be compromised during surgical placement, depending on the torque applied, and after connection of the prosthesis, when the masticatory load could generate micromovements and deform the implant hexagon.

In the last few years, the surgical process was changed to a single stage, with immediate loading using the prosthesis connected to the implant. The advantages of immediate loading include less chair time and simplification of the dental replacement process. However, implants submitted to immediate loading need primary stability to prevent failure of osseointegration. This primary stability is obtained by attaching the implant to the bone and is normally checked by the value of the torque applied.

Recently, some internal implant connections have appeared on the market, which are able to receive higher torques during surgical placement, with effective screw joint stability. Sometimes these internal geometries make the prosthetic procedure more difficult and reduce the number of implant manufacturing companies with compatible systems.

Considering the hypothesis that implant systems with external hexagon devices for prosthesis connection and internal torque can improve the stability of the system, it could also speed up and facilitate surgical placement. Therefore, this in vitro study evaluated the integrity of the external hexagon of an implant system with internal and external hexagons, but with prosthetic connection through the external hexagon, in comparison with that of a conventional external hexagon implant with mount, by means of different levels of surgical placement torque applied simulating implant locking.

Material and Methods

Ten implants with external hexagon (Titamax Pores with mount – EH; 3.75 mm-wide, Neodent Implante Osteointegrável, Curitiba, PR, Brazil) and ten implants with internal and external hexagons but with prosthetic connection through the external hexagon (Cortical Titamax – IT; 3.75 mm-wide, Neodent Implante Osteointegrável, Curitiba, PR, Brazil), both with 4.1 mm-wide platform size, were used in this study.

An experimental device was designed and made to apply surgical placement torque on the dental implants and to measure rotational freedom angles between the abutment and the implant. The device consists of an apparatus to lock the implant using two side screws with nuts, a graduated scale with precision of 0.025°, a rod to measure the rotational freedom angle, and a steel device fitted to the abutment under pressure, as shown in Figure 1.

Each implant was placed in the device and fitted to the abutment and the rod, without requiring the abutment screw. Initially, the rotational freedom angle readings were taken with the intact implants positioned in the device.

The graduated scale can be moved to locate the initial point of the rotational angle reading at the reference mark of 0 degree, and is then fixed by a lateral screw. This initial point is marked when...
one of the vertices of the implant external hexagon touches one of the sides of the abutment internal hexagon. To obtain the initial point, the rod was turned by hand in a counterclockwise direction until it encountered slight resistance from the connection. Next, the rod was moved in a clockwise direction, again until there was slight resistance from the connection. At this moment, the values of the angles read on the scale were recorded. In order to minimize the errors in the measurements, each reading was repeated twice by two operators and the mean average of the four measurements was obtained. The operators were trained by measuring together two implants of each type and by analyzing how to obtain the angles on the graduated scale.

The implants were submitted to three levels of surgical placement torques: 45, 60 and 80 Ncm. The torque of 45 Ncm was applied in the groups with the aid of an electronic torque controller handpiece (DEA 020, Bränemark System, Nobelpharma AB, Gothenburg, Sweden) at low-speed rotation. The values of the rotational freedom angles were taken in a similar manner to that in which the rotational freedom values for the intact implants were recorded. After the readings, the same analysis was made, successively, for the torques of 60 and 80 Ncm, with the aid of a surgical torquemeter ratchet (Neodent Implante Osteointegrável, Curitiba, PR, Brazil).

The distances between the vertices of the external hexagon were also used to evaluate the integrity of the external hexagon of the two groups of implants. These measurements were obtained for all intact implants, before any mechanical contact, and after each torque applied. Two operators measured the three distances between the vertices of each external hexagon and the mean value was determined. The measurements were carried out using an optical microscope (Carl Zeiss, Jena, TH, Germany), with a 20 times magnification. Each implant was placed in a device with a handle to turn the implant and place the vertex of the hexagon at the initial point of measurement.

The rotational freedom angles and the distances between the vertices of the external hexagons of the implants after different levels of torque were submitted to statistical analysis by ANOVA and Tukey’s test ($P < .05$), with the aid of the statistical program SPSS 12.0 (SPSS Inc., Chicago, IL, USA).
Results

Mean values of rotational freedom angles are presented in Table 1. Statistical analysis by ANOVA and Tukey’s test showed that there was no significant difference between the angles of the intact EH and IT implants and after application of the torque of 45 Ncm. After application of the torque of 60 Ncm, significant difference (P < .05) was found between the EH and IT systems. After application of the torque of 80 Ncm, the vertices of the EH implants became deformed, annulling their antirotational effect, and making it impossible to measure the respective angles (Figure 2).

The mean distances between the hexagon vertices of the samples measured in the microscope, under different levels of torque, are shown in Graph 1.

The statistical analysis showed that there was no significant difference between the distances between the vertices of intact EH and IT implants and after application of the torques of 45 and 60 Ncm. After application of the torque of 80 Ncm, the vertices of the EH implants became deformed, and Tukey’s test showed significant difference between the values for the EH and IT implants (Table 2).

Discussion

Dental implants are placed by means of external or internal connections and by the application of a certain level of torque. The connection could therefore become deformed and result in biomechanical complications over time. The Internal Torque implant that requires an implant driver to connect

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Table 1 - Mean ± SD values of the rotational freedom angles (*) for the EH and IT implants.

<table>
<thead>
<tr>
<th>Torque</th>
<th>EH Implants*</th>
<th>IT Implants</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3.308 ± 0.406° A</td>
<td>3.298 ± 0.168° A</td>
</tr>
<tr>
<td>45 Ncm</td>
<td>3.274 ± 0.380° A</td>
<td>3.309 ± 0.220° A</td>
</tr>
<tr>
<td>60 Ncm</td>
<td>4.029 ± 0.544° B</td>
<td>3.405 ± 0.197° A</td>
</tr>
<tr>
<td>80 Ncm</td>
<td>–</td>
<td>3.387 ± 0.215° A</td>
</tr>
</tbody>
</table>

*After application of the torque of 80 Ncm the vertices of the EH implants became deformed, annulling their antirotational effect. Groups that are significantly different (P < .05) are marked with different letters.

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Figure 2 - EH and IT implants after application of 45, 60 and 80 Ncm torques.
it to the internal hexagon and transmit torque for implant placement showed improved mechanical properties, confirming the hypothesis proposed in this study.

The fragility of the external hexagon of some systems can compromise the future dental prostheses if deformation of the hexagon vertices occurs due to the torque applied in the implant mount when the implant is placed. In these situations, the angles of rotational freedom between abutment and implant are increased, and this is especially critical in single prostheses. Greater rotation at the interface implant-abutment transfers stress to the implant components and to the bone, which could lead to screw loosening or fracturing, microfractures of bone, and loss of osseointegration.2,10

The integrity of the external hexagon was evaluated in all implants before torque application, and both the rotational freedom measurements and the distances of the hexagon vertices showed no significant differences between values for the EH and IT implants, because of the same machining tolerances. This result proves that the industrial production of the analyzed implants was standardized, and eliminates the possibility of initial failings.

Considering the technique of implant placement with immediate loading, there is a single-stage surgical procedure that has the advantage of immediate rehabilitation by means of fixed prostheses. In these cases, primary stability into the bone is very important, and this depends on the value of the torque applied during surgical placement.11,16,17 Misch14 (2004) established a minimum torque of 30 Ncm so that the implants could obtain primary stability for immediate loading. In other words, to be considered stable, the implant could not turn or show any mobility after the torque of 30 Ncm was reached. Bahat18 (2000) evaluated the long-term success of implants placed in the posterior area of the maxilla, under a condition of primary stability with a minimum torque of 40 Ncm. Both authors referred to a minimum torque for immediate loading, but there was no evidence about the maximum torque that could be applied on the implants without deforming the external hexagon.

Until the year of 1995, the electronic torque controllers available from Nobelpharma for implant placement were DEC 100 and DEA 020 (Nobelpharma AB, Gothenburg, Sweden), which allowed a maximum torque of 45 Ncm. They were used in the majority of the long-term studies published in the literature.1,2,6 Some of the implants, however, still required the manual torque wrench (DIA 250; Nobelpharma AB, Gothenburg, Sweden) to complete the implant seating, with uncontrolled torque but higher than 45 Ncm. Degidi, Piattelli16 (2005), in a study with 702 implants, reported torques higher than 76 Ncm. In vitro studies showed that placement torques above 100 Ncm increase the primary stability of different implant systems by reducing

### Table 2 - Mean ± SD values of the distances (mm) between the vertices of the EH and IT implants.

<table>
<thead>
<tr>
<th>Implants</th>
<th>Torque</th>
<th>Mean ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>External Torque</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hexagon</td>
</tr>
<tr>
<td>0</td>
<td>3.084 ± 0.009 mm A</td>
<td></td>
</tr>
<tr>
<td>45 Ncm</td>
<td>3.078 ± 0.015 mm A</td>
<td></td>
</tr>
<tr>
<td>60 Ncm</td>
<td>3.063 ± 0.020 mm A</td>
<td></td>
</tr>
<tr>
<td>80 Ncm</td>
<td>2.861 ± 0.073 mm B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Internal Torque</td>
</tr>
<tr>
<td>0</td>
<td>3.088 ± 0.006 mm A</td>
<td></td>
</tr>
<tr>
<td>45 Ncm</td>
<td>3.087 ± 0.006 mm A</td>
<td></td>
</tr>
<tr>
<td>60 Ncm</td>
<td>3.074 ± 0.009 mm A</td>
<td></td>
</tr>
<tr>
<td>80 Ncm</td>
<td>3.073 ± 0.009 mm A</td>
<td></td>
</tr>
</tbody>
</table>

Values with different letters are significantly different (P < .05).
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the amount of micromotion. Moreover, local bone density varies according to each surgical site, and the same drilling protocol could lead the implant to receive different levels of torque during placement until complete seating. The surgical torquemeter ratchets available in the market are graduated with the minimum torque (32 Ncm) (28839 – Nobel Biocare, TMEC – SIN Sistema de Implante) and allow higher measurements, achieving 80 Ncm (104027 – Neodent Implante Osteointegrável, 401000 – Conexão Sistemas de Prótese).

With the application of surgical placement torques it was possible to evaluate the deformations of the conventional external hexagon vertices and consequent changes in the system rotation. Different levels of torque were applied to the samples and the accumulative effects, although having small influence, were the same for the IT and EH implants. Thus, the load effect and possible deformation were equal for the implants. The torque of 60 Ncm caused a significant increase of the rotational freedom of the EH implants and the torque of 80 Ncm deformed the hexagon completely. Such deformations were not found in the IT implants because it uses the internal hexagon to transmit the torque for implant placement.

The junction between the abutment and the external hexagon of the EH and IT implants needs to be reliable for appropriate functioning and stability of implant-supported prostheses. For this to occur, the differences between the dimensions of the abutment hexagons and the respective implant must be minimal to favor the passive fit of the components and prevent stress from emerging in the screw due to rotational misfit.

According to Binon (1996), joint stiffness and preload are compromised when the rotational angles exceed 5 degrees, leading to failure of the screwed junction by screw loosening and movement of the abutment. In the present study, it was observed that the EH and IT implants maintained angles of rotational freedom below 5 degrees under the different levels of torque. But under the torque of 80 Ncm, it was impossible to measure the angles of the EH implants, due to deformation of the external hexagon.

It is important to emphasize that the EH implants may be indicated for cases where the applied torque does not exceed 60 Ncm. In this case, predictability may be achieved for implant-supported prostheses.

Conclusions

According to the methodology used in this study and based on the data analysis, it was possible to conclude that:

- Before and after application of a torque of 45 Ncm, the IT and EH implants presented similar rotational freedom. After application of a torque of 60 Ncm, although the IT implant obtained statistically better results, the EH implants did not present rotational freedom over 5 degrees, which is suggested as optimal for screw joint stability, justifying the clinical success of these implants.
- The use of the IT implant may be preferable in clinical situations where implant placement within a certain bone density could generate torques higher than 60 Ncm.

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References