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FAILURE TORQUE OF A NOVEL CERAMIC-NECK TITANIUM IMPLANT

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ABSTRACT

Statement of problem: Dental implants are typically made of titanium. However, with the current systems in the market, it is common for the implant neck to show through the gingival tissues as a black or dark grey line and/or as a grayish discoloration of the periimplant soft tissue.

Purpose: The purpose of this study was to test a new implant design; the ceramic neck implant is a novel implant design for tooth replacement. The key component of this novel design is the ceramic shell that covers the polished collar of the tissue level titanium implant and masks its dark color, which gives an appearance that mimics natural dentition. The main aim was to determine the maximum torque for fracturing the ceramic shell and compare it to clinical implant insertion torque value.

Material and Methods: Thirty type 4 commercially pure titanium endosseous implants of three different diameters (3.3, 4.1, 4.8 mm) were used in this study. Porcelain was applied in 0.5 mm thickness on the polished collar of each implant as determined in a previous article. Axial-torsional universal testing machine was used to twist the implants at X N.cm/s until failure. The data (n=10) were statistically analyzed by ANOVA/Tukey test with a significant level $\alpha = .05$. The maximum torque for each diameter group was also compared to optimum clinical implant insertion torque value of 35 Ncm (control) using one sample T-test ($P<.001$).

Results. None of the tested groups had a fractured ceramic shell at all. Instead, the implants carriers have fractured at certain torque levels. Therefore, the fracture of the implants carriers was selected as the maximum (failure) torque value. There was statistical difference for the failure torque (Mean ± SD) between 3.3 mm diameter and the other two diameters ($P<.001$) (F=15.6) while no statistical difference was found between the 4.1 mm and 4.8 mm diameters (p=.106). A statistically significant difference was found between failure torque of any one of the tested groups and the clinical insertion torque ($P<.001$).

Conclusions: Ceramic shells did not fracture. Instead, implants carriers have fractured at certain torque levels. These levels were sufficiently higher than the clinical torque values. This means that there are fewer chances that a fracture might happen while inserting the novel ceramic neck implant and/or the abutment.

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INTRODUCTION

Dental implants today are one of the most successful dental treatments offered to patients with a 95 percent success rate. Both high success rate and reduced cost of implants are the main reasons that have increased the number of patients being treated with implant supported prosthesis nowadays.[1]

However, placing dental implants in the esthetic anterior zone is considered to be the ultimate challenge for many dentists. The dental surgeons and restorative specialists are challenged with esthetic as well as functional success.[2,3] Any impairment in the esthetic outcome may be considered to be a failure of the whole reconstruction.[4]

Dental implants are typically made of titanium, a biocompatible material that is accepted by the body and serves as a strong and sturdy foundation for teeth replacement. Titanium also has good fatigue resistance, high elastic limit and low elastic modulus.[5] However, with the current systems in the market, it is common for the implant neck to show through the gingival tissues as a black or dark grey line and/or as a grayish discoloration of the periimplant soft tissue.[6] This main implant esthetic problem occurs when unfavorable soft tissue conditions exist such as thin periimplant mucosa and soft tissue recessions. A vertical bone loss of 1 mm is usually observed at the alveolar crest during the first year of function of an endosseous implant, followed by an additional 0.1 mm for every subsequent year.[7-9]Recession will result in progressive exposure of the implant with the unsightly exposure of the dark metal surface.

Tissue augmentation and grafting could be done by the surgeon or periodontist in an attempt to solve this esthetic problem, increase the tissue thickness and cover the metal exposure or showing through. However, this is very costly to the patient and the immediate and long term esthetic results are unpredictable. It is also common for the tissue graft to fail or to have a different color and texture from the surrounding tissue resulting in compromised esthetics.[10]

Another solution to this problem was the development of implant abutments made of esthetic materials such as alumina and zirconia ceramics. Clinical studies using spectrophotometric analysis showed lesser periimplant mucosal discoloration with zirconia abutments, but there was no evidence for difference in patient's esthetic satisfaction between ceramic and metal abutments. Moreover, more fractures have been reported for ceramic implant abutments in the anterior region.[11]

A new solution is suggested by the investigators of the current study. The top 1.0-3.0 mm of the neck of the titanium tissue level implant could be covered with a ceramic shell. This ceramic shell is the key component that will mask the dark color of the implant metal and give the whitish color (similar to a natural tooth color) underneath the soft tissues, which closely mimics nature and gives the patient a more pleasing result. The added ceramic coating will also help with achieving a favorable tissue response due to the proven track record of positive soft tissue response to ceramic surfaces[12-20]

The ceramic neck implant is a novel design of an endosseous dental implant for tooth replacement. This design is aimed at improving the esthetic outcome of the implant treatment and offering a more natural looking dental prosthesis that will optimally blend-in with surrounding dentition and oral structures.

However, it still needs to be determined if the novel design will meet its proposed advantages. Therefore, the investigators of the current study are aiming to test the torque failure. The clinical perception of implant primary stability is commonly related to rotational resistance (insertion torque) during implant placement.[21]Moreover, inadequate tightening of the abutment with insufficient torque has been cited as a possible reason for screw loosening.[22] Abutment screw loosening is one of the most frequent complications in single-tooth implant restoration. According to a systematic review conducted by Pjetursson et al[23], abutment screw loosening was found in 5.3% of implants in a one year follow-up. A systematic review by Jung el al of the literature revealed the incidence of screw loosening to be 5.8% - 12.7% after five years.[24] Screw loosening may cause implant or screw fracture, inadequate occlusal force distribution and possible osseointegration failure.[25]

The purpose of the study was to determine whether any significant difference exists between the clinical implant insertion torque value and failure torques for ceramic neck implants. The null hypothesis was "the ceramic shell of the ceramic neck implant cannot withstand the clinical implant insertion torque value of 35 Ncm (control)". The resulting information should provide insight into the question of whether structural problems within the implant might lead to the ceramic shell failure.

The correlation between implant diameter and insertion torque was investigated by Maiorana et al.[26] The authors observed that smaller diameter implants had lower insertion torque values and a lower implant primary stability. Thus, a secondary objective for this study was to test three different implants diameters representing implants in different clinical situations and investigate the effect of implant diameter on failure torque.

MATERIAL AND METHODS

Three different implant diameters (3.3 mm, 4.1 mm, 4.8 mm) were used in the study to represent implants in different clinical situations. Ten implants per diameter group were coated with a ceramic shell at the neck part of the implant. This resulted in a total of 30 implants (three groups of ten implants for each diameter).

Tissue-level endosseous, titanium implants (Straumann Standard Plus Implant, Straumann USA LLC) were used. Based on previous studyresults[27], the ceramic thickness was determined to be 0.5 mm based on the findings from the first study in this research series which determined the minimum thickness of porcelain to mask the color of underlying titanium. This thickness is sufficient to mask the dark titanium color of the implant. A lathe was used to mill out 0.5 mm from the neck of the implant. The surface where the titanium was to be covered with porcelain was also airborne-particle abraded using 250 μm Alumina particles. The ceramic shell was fabricated by hand. A thin coating of titanium bonder (GC Initial Titanium Bonder; GC America Inc.) was applied and fired. Properly fired bonder had very slight sheen under lighting. The titanium opaque (GC Initial Titanium Opaque; GC America Inc.) was then applied and fired according to manufacturer's instructions. The porcelain (GC Initial Titanium; GC America Inc.) was then applied to the neck part of the implant and fired at 780ºC.

The upper (superior surface) of implants is made of both metal and ceramic. The ceramic titanium junction has a scalloped contour to represent higher metal in the interproximal areas and lower metal and longer porcelain surface in the facial areas (Fig. 1).

To test for failure, the distal one-third of each implant was clamped in a table vice. An axial-torsional universal testing machine (ElectroForce 3300-AT; Bose Corporation) was used to twist the implants at X N.cm/s until failure. Torque was applied on the implants carriers. Failure torque was

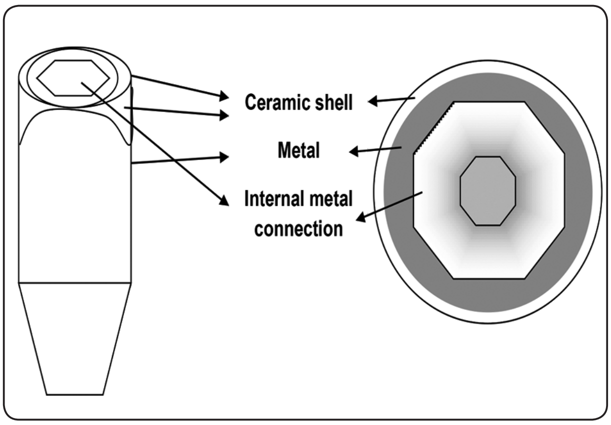

Fig. (1) Illustration of ceramic shell on implant neck.

defined as the maximum torque that the ceramic shell withstood before breaking (any visible fracture in the porcelain or when the implant carrier fractured). This test was intended to screen out implant designs that have a possibility of fracture during placement. The measured maximum torque was compared to clinical insertion torque value of 35 Ncm (as a control) using one sample T-test (*P*<.001). The measured average maximum torque for each implant diameter was also compared to those of other implant diameters. The statistical analysis was conducted by ANOVA/Tukey HSD post hoc test with a significant level $\alpha = .05$

RESULTS

This study aimed to determine the maximum torque for fracturing the ceramic shell. The results showed that none of the tested groups had a fractured ceramic shell at all. Instead, the implants carriers have fractured at certain torque levels. Therefore, the fracture of the implants carriers was selected as the landmark of maximum torque or as the end point for torque application (failure torque).

The results of the failure torque for the three tested groups are presented in Figure 2. The average maximum torque that led to carrier fracture for the 3.3 mm-diameter implants was 219 ±8.8 Ncm. Implants of 4.1 mm diameter withstood average torque application of 232 ± 8.4 Ncm before carrier fracture. The average failure torque for implants with 4.8 mm diameter was 240 ±8.1 Ncm.

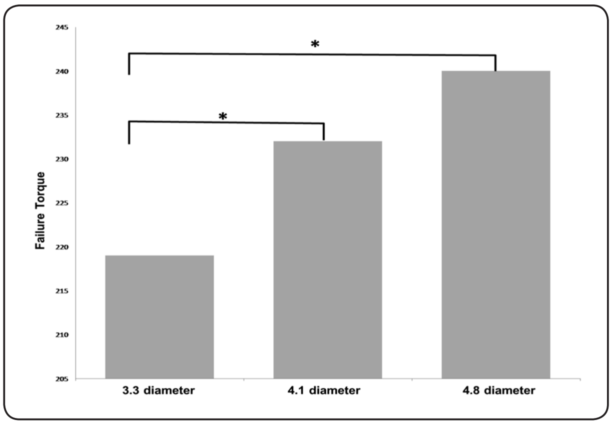

Fig. (2) Comparison of average torque failure of tested implants with different diameters. * indicates statistical significant difference.

The results also showed that the failure torque value increased with increasing implant diameter with the highest failure torque value (240 ±8.1 Ncm) for 4.8-mm implant diameter while the lowest implant diameter (3.3 mm) recorded the lowest failure torque value (219 ±8.8 Ncm). The 4.1 mm-diameter implant recorded a mean failure torque value (232 ± 8.4 Ncm). In other words, increasing the implant diameter results in higher resistance to torque failure.

The one-way ANOVA test revealed statistical significant difference (*P*<.001) between the three tested groups (F=15.6). Tukey's test revealed significant statistical difference (*P*= .005) between the 3.3 mm group and 4.1 mm group, and also showed statistical significant difference (*P*<.001) between the 3.3 mm group and 4.8 mm group. There was no statistical significant difference (*P*= .106) between the 4.1 mm group and 4.8 mm group. In addition, the results showed that the failure torque of any one of the tested groups was statistically higher than the clinical insertion torque value.

DISCUSSION

The dark metal color showing through the periimplant soft tissue as a result of poor implant placement or thin gingiva and progressive bone resorption is a common esthetic problem in implant dentistry.[6] The ceramic neck implant is a novel design of an endosseous dental implant which aims to solve this problem and improve the esthetic appearance of the dental implants by offering a more natural looking dental prosthesis that is in a harmony with surrounding dentition and oral structures. The key design feature of this novel design is the ceramic shell that covers the polished collar of the tissue level titanium implant and masks the color of the implant neck and gives a color that mimics natural dentition. Based on the results of the study, the authors can reject the null hypotheses and accept the alternative hypothesis which is “the ceramic shell of the ceramic neck implant can withstand the clinical implant insertion torque value of 35 Ncm”.

Another proposed advantage of this novel design is that the ceramic surface of the shell will provide a smooth surface that will help reduce the accumulation of pathogens on the implant surface as it will be less harboring to bacteria and other pathogens in the mouth and their by-products, which results in less periimplant tissue inflammation and recession.[28] This improves the gingival and periodontal health and reduces the chance of infection, which is detrimental to the life of the implant in many cases.

Another feature of this novel design is the higher metal in the interproximal areas that is anticipated to preserve the interdental bone height which will ultimately result in improved gingival esthetics. This could also preserve the natural bony architecture or even enhance the bone level in the interproximal areas for better osseointegration.

The current study aimed to test and optimize prototypes of a ceramic neck implant novel design for future use in humans in anticipation for commercialization of this product line. This study investigated the torque failure of the ceramic shell.

In protocols of early and immediate loading, the forces of mastication and other oral functions such as phonation, deglutition are transmitted through the implant to surrounding healing tissue. They are then transmitted to bone tissue.[29]These forces, when excessive, can lead to fibrointegration during the healing stage, rather than osseointegration. Such healing would be considered an implant failure. The only useful protection for the healing bone tissue from heavy occlusal forces is a reduction of micromovement that occurs at the bone-implant interface. Ensuring good primary stability for the implant fixture was found to make the micromovements not detrimental and does not interfere with healing.[30] A simple and immediate way to evaluate primary stability of an implant is through the recording of final insertion torque. Insertion torque is expressed in Newton centimeters (Ncm), a measurement of the strength needed to insert the implant. The higher the measurement of insertion torque, the higher the primary stability of the implant.[31] It is generally accepted that implants with a torque of at least 20 Ncm display a survival rate higher than ones with lower insertion torques.[32,33] To achieve good primary stability, it has been suggested that implants have to be inserted with a torque of at least 35 Ncm for an immediate loading protocol.[21,34] Some authors believe that insertion of implants with a high torque might cause excessive compression on the surrounding bone. If compression exceeds capillary pressure, temporary osteonecrosis will occur.[35] This is why the present study investigated the maximum torque for fracturing the ceramic shell and compared it to optimum clinical insertion torque values of 35 Ncm.

For all implant diameter groups tested, the ceramic shell did not fracture after reaching the maximum torque. Instead, fracture of the implant carrier was the end point of the maximum torque applied. It is advantageous that the mechanical failure test, even for implants with a smaller diameter, showed high torque requirements to cause failure of the ceramic shell. The larger the magnitude of difference between the failure torque (219, 232 and 240 Ncm for 3.3, 4.1 and 4.8 mm implant diameter) and the determined clinical insertion torque value (35 Ncm) means less chances that a ceramic shell fracture might happen while inserting the implant and/or the abutment.

Higher recorded peak insertion torque values generally ranging from 50 up to 176 Ncm have reported in the literature.[36,37] Even if those high insertion torque values were selected as controls, the ceramic shell still surpassed these levels before the implant carrier fractured.

It should be noted that in the present study the autors have chosen the worst possible scenario with the distal one-third of each implant was clamped in a table vice and torque force applied to the implants until failure. This scenario increased the torque impact on the implant rather than would be expected in a clinical situation where bone will absorb some of the torque force while the implant is being inserted. Nevertheless, Ceramic shells did not fracture. Instead, implants carriers have fractured at the maximum torque levels. These levels were sufficiently higher than the clinical torque values. This means that there are fewer chances that a fracture might happen while inserting the novel ceramic neck implant and/or the abutment.

The encouraging results of this torque test can be attributed to fact that the internal connection was made of metal titanium of sufficient thickness so that there are minimal stresses on the ceramic shell when the implant is torqued. It is also important to note that the use of a ceramic system with a high fracture resistance and the favorable physical properties of the titanium metal, and finally excellent titanium to ceramic bond strength may have played a role.

The results of this study have also demonstrated that implant diameter affected the failure torque. Implants of wider diameter sustained higher failure torque values. This is in accordance with other study[26] in which smaller diameter implants had lower insertion torque values and a lower implant primary stability.

The current study provided data ensuring the safe insertion of this novel design of ceramic neck implant without fracturing the ceramic shell. This promotes performing a future study for testing the performance of the novel design using fatigue fracture tests. The current study will also provide feasibility data for a large clinical study to test this product in humans to assess the esthetic outcome, improved tissue response and bone preservation, and improved patient satisfaction with the new implant design. The clinical study will also assess the dentists' impression of the complexity/simplicity of placement and restorative procedures.

CONCLUSIONS

The ceramic shell of the novel ceramic neck implant did not fracture during torque application, instead, the implant carriers fractured at torque levels that were significantly higher than optimal clinical torque values. Thus the authors can conclude that there are fewer chances that a fracture might happen while inserting the implant and/or the abutment. Within the limitations of this study we can conclude that the novel implant design will withstand high insertion torque values significantly beyond what is normally expected in clinical situations.

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