



The Effect of Tissue Entrapment on Screw Loosening at the Implant/Abutment Interface of External-and Internal-Connection Implants: An In Vitro Study

Helios A. Zeno, DMD,¹ Renan L. Buitrago, DDS,¹ Sidney S. Sternberger, DMD,¹ Marisa E. Patt, DMD,¹ Nick Tovar, PhD,² Paulo Coelho, DDS PhD,² Kenneth S. Kurtz, DDS, FACP,^{1,3} & Frank J. Tuminelli, DMD, FACP⁴

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Keywords

Tissue entrapment; gingival entrapment; preload; screw loosening.

Correspondence

Frank J. Tuminelli, Director, Graduate Prosthodontics, New York Hospital Queens, 23 Bond St., Great Neck, NY 11021. E-mail: Prosthodoc@aol.com

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Abstract

Purpose: To compare the removal of torque values of machined implant abutment connections (internal and external) with and without soft tissue entrapment using an in vitro model.

Materials and Methods: Thirty external- and 30 internal-connection implants were embedded in urethane dimethacrylate. Porcine tissue was prepared and measured to thicknesses of 0.5 and 1.0 mm. Six groups (n = 10) were studied: External- and internal-connection implants with no tissue (control), 0.5, and 1.0 mm of tissue were entrapped at the implant/abutment interface. Abutments were inserted to 20 Ncm for all six groups. Insertion torque values were recorded using a digital torque gauge. All groups were then immersed in 1 M NaOH for 48 hours to dissolve tissue. Subsequent reverse torque measurements were recorded. Mean and standard deviation were determined for each group, and one-way ANOVA and Bonferroni test were used for statistical analysis.

Results: All 60 specimens achieved a 20-Ncm insertion torque, despite tissue entrapment. Reverse torque measurements for external connection displayed a statistically significant difference (p < 0.05) between all groups with mean reverse torque values for the control (13.71 \pm 1.4 Ncm), 0.5 mm (7.83 \pm 2.4 Ncm), and 1.0 mm tissue entrapment (2.29 \pm 1.4 Ncm) groups. Some statistically significant differences (p < 0.05) were found between internal-connection groups. In all specimens, tissue did not completely dissolve after 48 hours.

Conclusions: External-connection implants were significantly affected by tissue entrapment; the thicker the tissue, the lower the reverse torque values noted. Internal-connection implants were less affected by tissue entrapment.

Abutment screw loosening is a common prosthetic complication when restoring dental implants. It can cause the prosthesis to become mobile, create a need to regain access to the access hole to retrieve screws, and place increased forces on splinted implants with engaging components. Potential consequences of abutment screw loosening include gingival inflammation, implant failure, and screw fracture.¹⁻⁴

Several clinical studies completed in the 1990s followed failures and complications of inserted implant-supported fixed dental prostheses (FDPs). Jemt found, after insertion of 271 FDPs, that 31% of the prosthetic screws were loose at the first

checkup appointment (approximately 2 weeks post-insertion) but almost all of the retightened screws were stable at the second checkup (approximately 3 months post-insertion).⁵ In another publication Jemt also reported a higher incidence of loosening for prosthetic screws in the premolar region than for those in incisor region.⁶ Naert et al, in a 6-year study including 509 implants, found that the most common mechanical complication for the prostheses was abutment screw loosening (6%).⁷A recent systematic review of the literature reported screw loosening as a frequent complication, occurring 5.3% of the time in a 5-year observation period. Other frequent

¹Department of Graduate Prosthodontics, New York Presbyterian, Queens, NY

²Department of Biomaterials and Biomimetics, New York University College of Dentistry, New York, NY

³Department of Graduate Prosthodontics, New York University College of Dentistry, New York, NY

⁴Director of Graduate Prosthodontics, New York Presbyterian, Queens, NY

prosthetic complications reported were fractures of the veneering material (13.5%), peri-implantitis and soft tissue complications (8.5%), loss of access hole restoration (5.4%), and loss of retention of cemented FDPs (4.7%).

The phenomenon of abutment screw loosening has been correlated with a decrease in preload between the implantabutment connections by various authors. 1-3,9 In implant dentistry, preload is defined as the tension created in a screw when tightened. 10 The preload induces the clamping force that acts at the interface between the abutment and the implant platform, maintaining the joint connection and counteracting any load applied to the prosthesis¹¹ by keeping the screw threads tightly secured to the mating counterpart. Preload depends on the applied torque, presence of lubricants, the physical properties of the materials in contact, and the settling of the screw. 12 As rotational force is applied to the abutment screw during insertion, the screw elongates, placing the screw body in tension. The elastic recovery of the screw creates the clamping force that pulls the prosthesis and implant together. 13,14 When functional loads are applied to the implant crown, the screw head is systematically compressed, reducing the frictional forces in the system. When the threads disengage and the preload declines, screw loosening may occur. 15,16

Studies have demonstrated that inadequate preload (undertightened) abutments showed significantly greater micromotion in the implant/abutment interface, ¹⁷ resulting in joint failure and loss of prosthesis function. The same sequela can theoretically occur with implant/abutment joints that do not achieve target preload values due to soft tissue interference. It has been suggested that micromotion between implant components may cause peri-implant irritation, including gingival tenderness, inflammation, and hyperplasia.4 Siamos et al studied whether varying the preload on the implant/abutment complex would affect screw loosening when prosthetically loaded. They found that (1) retorquing abutment screws 10 minutes after initial insertion should be done routinely and (2) increasing the insertion torque value above 30 Ncm resulted in a decrease of screw loosening, because a greater preload is achieved with higher initial torque values.18

Preload is an important concept for understanding abutment screw behavior as it relates to implant dentistry. Achieving implant/abutment joint success is accomplished by optimum preload of the interface that will maximize the fatigue life of the abutment screw while offering a reasonable degree of protection against loosening. ¹³ Upon connection of a dental abutment to a dental implant it is recommended to follow the manufacturer's insertion torque value to generate a preload between the abutment screw and internal threading of the dental implant. Depending on the manufacturer, recommended insertion torque values range from 10 to 35 Ncm. The abutment screws are engineered to result in a preload of between 100 and 400 N, as measured at the joint of the abutment screw and internal threading of the dental implant.

Many studies have been conducted to elucidate the relationship between implant design, preload, and screw loosening. Some variables are abutment screw body material, abutment screw surface treatment, implant/abutment interface design, and insertion torque values. Martin et al looked at implant/abutment screw rotations and preloads for four screw materials and surfaces and found that certain surface treatments helped reduce the coefficient of fiction and generated greater preload values when compared to conventional screws.⁹

Fatigue testing studies have been conducted on implant/abutment systems to better understand if lowered reverse torque values can lead to screw loosening. Cibirka et al found that changing the implant/abutment interface design did not produce a significant effect on the reverse torque values of the abutment screws. Variations of the interface studied by this group included increasing the vertical height, changing the degree of fit tolerance between the implant external hexagon and the abutment internal hexagon, or completely eliminating the implant external hexagon. ¹⁹ Khraisat et al tested lateral cyclic loading on implant/abutment complexes for abutment screw loosening of an external-hexagon system. They found that reverse torque values of the screw joint were preserved under eccentric lateral loading, as compared with centric loading. ²⁰

Kim et al studied the effect of using variable abutment compositions as related to screw loosening by fatigue testing⁴ internal-connection abutments. They found mechanical failures when using interchangeable abutment components that had differing physical and chemical composition and advised using abutments and implants manufactured by the same company to prevent the loosening of the abutment screw.²¹ Ha et al studied the influence of abutment angulation and screw loosening in anterior maxillary implants under cyclic loading. They discovered significant differences in reverse torque measurements for external-connection implants but not for internal-connection implants.²²

To maintain suitable preload, a stable implant/abutment joint consisting of an accurate interface, free of irregularities on the contacting surfaces, is necessary. 13,23 The maintenance of a clean implant/abutment interface during clinical procedures such as metal trial and final delivery is essential to ensuring accurate seat of the restoration. The entrapment of gingival tissue during final insertion at the abutment/implant connection could have a potentially detrimental effect to the seating and insertion of the abutment into the dental implant. In theory, tissue entrapped at the abutment/implant interface could create a space between the components due to tissue ischemia and subsequent tissue necrosis. This space at the abutment/implant connection could lead to decreased clamping force of the abutment screw that correlates with a lowering of preload values. 11,13,24

There is a consensus that there are limited guidelines available for gingival retraction for implant restoration. The use of the wide emergence profile and standard and custom healing abutments are all current methods employed to achieve gingival tissue retraction at implant restoration. Other methods described in the literature include the use of gingival retraction cord, injectable chemical retractants, electrosurgery, and lasers.²⁵

Presently no studies address gingival tissue entrapment at the abutment/implant interface and its possible effect on abutment screw loosening. Our null hypothesis was that (1) tissue entrapment does not have an effect on preload/screw loosening at the abutment/implant interface and (2) there are no differences in reverse torque values after entrapped tissue dissolution in external- versus internal-connection implant groups. This in vitro study was designed to gain understanding



Figure 1 Clinical photo of tissue entrapment following removal of implant abutment.

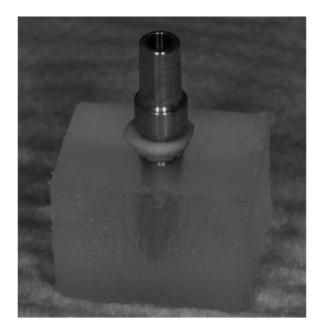


Figure 2 Implant mounted in UDMA block, with tissue entrapped following abutment insertion.

of how tissue entrapment, as it relates to both external- and internal-connection implant systems, can contribute to reduced reverse torque values and lead to screw loosening (Fig 1).

Materials and methods

Dental implant system

Thirty 4.0×13 -mm external-connection implants (Certain; Biomet 3i, Warsaw, IN) and 304.0×13 -mm internal-connection implants (Certain) were vertically embedded in urethane dimethacrylate (UDMA) (Triad Gel; Dentsply, York, PA) blocks with the use of a dental surveyor to ensure parallelism of the implants (Fig 2), exposing the implant/abutment interface $1.0 \, \text{mm}$ above the UDMA blocks. Implant abutments (Gingihue

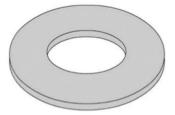


Figure 3 Example of tissue specimen. Internal diameter (2 mm), external diameter (4 mm) thickness (0.5 mm or 1 mm).

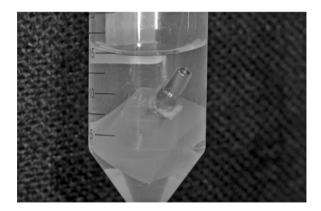


Figure 4 Immersion in NaOH.

abutments with Gold-Tite screws for internal connection [IU-NIHG] and Gold-Tite hexed screws for external connection [UNIHG]; Biomet 3i) were inserted at 20 Ncm as per manufacturer's instruction for all groups with the use of a calibrated digital torque gauge (Tohnichi, Tokyo, Japan).

Soft tissue preparation

To standardize tissue thickness, two aluminum alloy (6061) blocks were (CAD/CAM) fabricated using indentations with depths (0.5 mm or 1.0 mm) of the desired tissue thickness. A 4-mm diameter punch biopsy was excised from porcine palatal tissue (n = 40). Specimens were placed inside the block indentation and polished to either a 0.5-mm or 1.0-mm thickness using a tissue polishing system (MetaServ 250; Buehler, Lake Bluff, IL) with a 1200-grit sandpaper. Precise measurements of tissue thickness were recorded using a digital caliper (Mitutoyo, Kawasaki, Japan) to ensure consistency. Finally, a 2-mm punch biopsy of the internal aspect of the specimen was performed to allow space for the insertion of that abutment and screw (Fig 3).

Test groups

Six implant groups (n=10) were studied: External-connection and internal-connection with 10 of each variable: (a) 0.5 mm tissue (b) 1.0 mm tissue, or (c) control group, without tissue. All abutments were inserted and torqued to 20 Ncm using a digital torque gauge (Tohnichi).

Tissue and abutment/implant complex specimens were immersed in 1 M NaOH for 48 hours to dissolve tissue (Fig 4) to simulate salivary breakdown in the oral cavity. Subsequent reverse torque measurements were recorded. The presence or

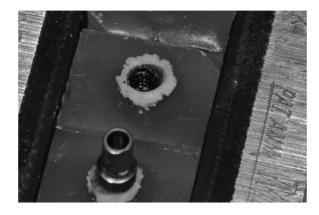


Figure 5 Tissue present after 48 hours.

absence of tissue at the implant/abutment interface was grossly evaluated by visual inspection.

Half the abutments and screws in each group were then disconnected from the implant bodies, and the specimens were manually cleaned. A second insertion torque was measured on all specimens using the digital torque gauge to assess the clinical significance of reinsertion of both control and tissue entrapped screws.

Statistical analysis

Mean and standard deviations were calculated for all tissue thickness measurements (0.5 mm, 1.0 mm, and no tissue) for both insertion and reverse torque values. Mean and standard deviations were determined for each group, and one-way ANOVA and Bonferroni's test were used for statistical analysis of reverse torque of the six groups (n = 10) to a 95%-confidence interval (p < 0.05).

Results

There were no complications in achieving the insertion-torque values of 20 Ncm in the 60 abutment specimens, whether or not they had tissue entrapped. No statistically significant differences (p < 0.05) were found between groups for insertion-torque (N = 40 for tissue groups, N = 20 for control). Consistency within groups was observed.

Following tissue dissolution in 1M NaOH, entrapped tissue was macroscopically visible for all specimens inserted initially with tissue, regardless of the initial 0.5- or 1.0-mm tissue, after the 48-hour immersion (Fig 5). There was no noted looseness of the implant/abutment joint for any of the test groups.

For the external-connection abutment/implant complex, the reverse torque findings displayed statistically significant differences between all three external-connection groups (p < 0.0001) (Figs 6 and 7, Table 1). Mean reverse torque measurements for the control, 0.5-mm and 1.0-mm tissue groups were 13.7 ± 1.4 , 7.8 ± 2.4 , and 2.3 ± 1.4 Ncm, respectively (mean of clean and not-clean as reported in Fig 7).

For the internal-connection abutment-screw complex (Table 2), the reverse torque findings demonstrated a statistically significant difference only between the control group and the 0.5-mm group (p < 0.005). No other significant differ-

 Table 1 Pairwise comparison:
 Statistical analysis for external-connection groups

Tissue (I)	Tissue (J)	Mean difference	Std. error	df	Sig	95% confidence Lower bound
0.0	0.5	5.875ª	0.798	27	< 0.0001	3.839
	1.0	11.415 ^a	0.798	27	< 0.0001	9.379
0.5	0.0	-5.875^{a}	0.798	27	< 0.0001	-7.911
	1.0	5.540 ^a	0.798	27	< 0.0001	3.504
1	0.0	-11.415 ^a	0.798	27	< 0.0001	-13.451
	0.5	-5.540^{a}	0.798	27	< 0.0001	-7.576

^aThe mean difference is significant at the 0.05 level.

Table 2 Bonferroni method: Statistical analysis for internal connection groups

Bonferroni									
Dependent variable: Reverse torque									
Tissue (I)	Tissue (J)	Mean difference	Std. error	Sig	95% confidence Lower bound				
0.0	0.5 1.0	-1.9800 ^a -0.9400	0.56044 0.56044	0.005 0.315	-3.4105 -2.3705				
0.5	0.0	1.9800 ^a 1.0400	0.56044 0.56044	0.005 0.223	0.5495 -0.3905				
1.0	0.0 0.5	0.9400 -1.0400	0.56044 0.56044	0.315 0.223	-0.4905 -2.4705				

^aThe mean difference is significant at the 0.05 level.

ences were observed for the other groups (p > 0.05) regardless of tissue thickness (Fig 6). Mean reverse torque measurements for the control, 0.5-mm and 1.0-mm tissue groups were 11.4 \pm 1.8, 9.4 \pm 1.1, and 10.4 \pm 0.6 Ncm, respectively (mean of clean and not-clean as reported in Fig 7).

Second insertion torque measurements were recorded after half the specimens were manually cleaned. All the specimens in the internal- and external-connection groups with 0.5-mm tissue entrapment were able to achieve 20 Ncm at the second insertion. It was noted that half the specimens of the internal-and external-connection groups with 1.0-mm tissue entrapment appeared to "spin" at the second insertion of the abutment, meaning they took additional revolutions to insert compared to other groups. Some groups were not able to achieve the desired insertion torque of 20 Ncm. These groups were the internal-connection with 1.0 mm of tissue entrapment that had been cleaned and the external-connection with 1.0 mm of tissue entrapment that was not cleaned.

Discussion

The present study focused on answering a relevant clinical question of the effect of tissue entrapment at the abutment/implant interface in external- and internal-connection implants. To gain understanding of how tissue entrapment can affect the preload values, insertion torque values were recorded and, following immersion in NaOH, reverse torque values were recorded. In recording insertion versus reverse torque values, our goal was

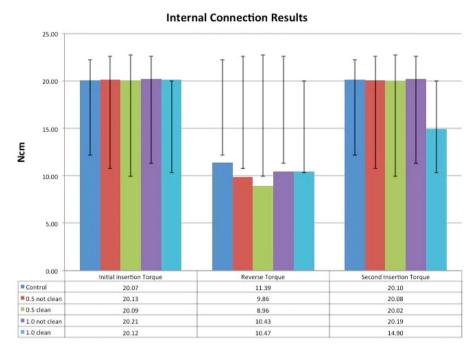


Figure 6 Internal connection results.

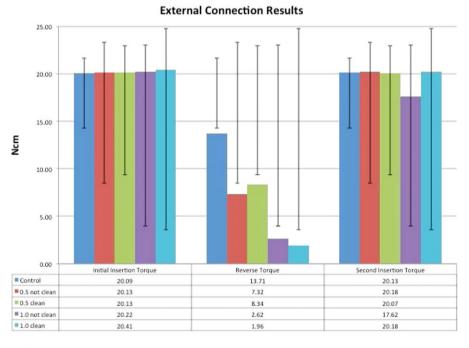


Figure 7 External connection results.

to observe if lower preload would be achieved in specimens with (1) external- versus internal-connection groups and (2) in groups with the abutment inserted with either 0.5 mm or 1.0 mm of tissue.

The data in this study revealed decreased reverse torque values following insertion for both internal- and external-

connection control groups, similar to the findings of previous authors. 9,18 In the literature, a high incidence of screw loosening has been reported in external-connection implants, 27 which is consistent with our findings. In this study, a decreased reverse torque value for the external- versus internal-connection control groups was recorded, 13.71 + -1.4 and 11.39 + -1.8,

respectively, a significant drop off from both group's insertion torques of 20 Ncm.

Despite lower reverse torque values for both implant configurations, only the external-connection reverse torque data versus the control was statistically significant. (p < 0.05) In the internal-connection groups, the abutments inserted with 0.5 mm of tissue recorded a lower reverse torque (9.41 +/- 1.1) compared to the control (11.39 +/- 1.8). This may be the function of a statistical test displaying a clinically trivial difference as statistically significant.

The external-connection has a lower contact area between abutment and implant and has a short (0.64 mm) engaging component. The tissue entrapped may act as a "spacer" because of the diminished contact area and increased difficulty for the entrapped tissue to displace. Internal-connection implants have a greater contact area with the longer engaging component (1.0 mm) and the design of the implant may help "funnel" the tissue out of the implant. A comparison of external-versus internal-connection reverse torques may be made despite geometric differences between the implant and abutment design; however, the statistical analysis of the reverse torque measurements of all groups would suggest that when it comes to tissue entrapment at the implant/abutment interface, internal-connection abutments are far less susceptible to screw loosening than external-connection abutments.

All specimens (n = 60) were able to achieve the manufacturer's recommended insertion torque of 20 Ncm regardless of whether there was tissue present at the implant/abutment interface. Following dissolution of the tissue in NaOH, visual inspection did not reveal any gross movement of the implant/abutment joint connection. Reverse torque data for the groups (0.5 mm, 1.0 mm tissue, and control) were analyzed and revealed reduced reverse torque values in both external- and internal-connection groups with inserted tissue. A statistically significant difference was observed between the external-connection abutments inserted with 1.0 mm of tissue versus the control external-connection implants.

Binon et al describe factors such as decreased preload, settling, and elongation as variables in an implant/abutment complex that can contribute to undesirable screw loosening.²⁴ Tissue entrapment may be another variable to consider. Tissue entrapment, with subsequent necrosis, may lead to contamination of the implant/abutment interface with debris. Theoretically, this debris must exist either in (1) the gap-junction, or (2) extrude out of the implant/abutment interface into the oral cavity or internally into the implant/abutment screw interface.

This study demonstrated that tissue entrapment at the abutment screw implant interface created lowered reverse torques that we believe were caused by a decreased preload at the abutment screw-implant joint. Despite placing a 20-Ncm torque to the head of the abutment screw, tissue entrapment may create a lowered initial preload than the optimal manufacturer recommendation at the screw joint. ¹¹

The implant/abutment complex specimens were inspected visually after all specimens had been immersed in the NaOH solvent. No obvious movement of the implant/abutment joint was noted, nor did the specimens have an apparent open gap junction. All specimens were then submitted to reverse torque testing, with subsequent removal and visual inspection of the

abutment screws. Macroscopically, the abutment screws appeared to be grossly clean when removed from the implant specimen. Future studies will be conducted to evaluate these abutment screws using a scanning electron microscope to confirm the presence of tissue debris on the abutment screw bodies for specimens that were inserted with tissue. In the future, an analysis of the abutment screws and implant connections would be useful to quantitatively assess tissue debris and/or possible screw deformation. In this in vitro study it was difficult to clinically assess cleanliness and amount or absence of deformation of abutment screws.

It is interesting to note how easily tissue is displaced at the implant/abutment interface. In practice, tissue may be entrapped at final impression, abutment insertion, or try-in, and it would be a challenge to evaluate clinically. During initial insertion, none of these abutment screws "spun." No additional revolutions were needed, and all abutment screws had a definitive stop. According to manufacturer's instructions, a quarter turn test may be performed to ensure passive seating of any abutment screw. This test alone may not indicate whether the abutment/implant complex achieves the desired preload engineered into the system. The results of this study suggest that a reduced preload is probable in cases of tissue entrapment. Future investigations may focus on understanding how this lower preload contributes to long-term function (with cyclic testing) or how splinted abutments in multiple-unit fixed partial dentures can affect the survival and success of the overall prosthesis.

Porcine palatal tissue was used for tissue entrapment and NaOH solution was used for tissue dissolution. Both materials were economical, readily available, and had comparable characteristics to human gingival tissue and collagenase, respectively. The authors acknowledge that these experimental materials may act differently than would human tissue in the saliva-rich oral cavity. Inherent in the design of this study, tissue was entrapped circumferentially around the implants. In a clinical setting, tissue entrapment may have a more unilateral presentation. It remains unclear how an asymmetry of tissue entrapment behaves during abutment insertion and what effect that would have on preload.

A second insertion of all screws with a digital torque gauge was performed to evaluate whether tissue-entrapped abutment screws could be reinserted and achieve the manufacturer's recommended 20-Ncm torque. Future studies replacing abutment screws that have been entrapped with tissue would be useful to assess the effect of tissue entrapment on the internal threading of implants with new abutment screws.

All of the screws in two of the groups (external connection with 1.0 mm of tissue entrapment after 48 hours and not cleaned at the interface and the internal connection with 1.0 mm of tissue entrapped and cleaned after 48 hours) were unable to achieve 20 Ncm and were considered malfunctioning screws. This was a significant finding, and all abutment screws in these groups demonstrated a "spinning" phenomenon. Statistical analysis demonstrated that these two groups were statistically different from the other external- and internal-connection groups, respectively.

After the finding that tissue did not completely dissolve in the NaOH solution, methods of cleaning the implant/abutment interface were evaluated, and a manual method was selected. Future studies may look at other methods of cleaning entrapped tissue, such as irrigation and ultrasonic immersion of the abutment screws.

This research project was conducted using regular platform implants. Tissue entrapment may affect the abutments of narrow platform, wide platform, or platform switching in a similar or dissimilar way. Future studies should consider what effect fatigue testing would have on abutments with tissue entrapped at the abutment/implant interface.

Biomet 3i Gold-Tite screws were used in this study. Its composition is 80% Pd, 10% Ga, 10% Cu, Au, and Zn with a 0.76- μ m pure gold coating.⁷ Future studies should evaluate what effect tissue entrapment would have on different screw alloys. Also, in the Gold-Tite screw, the gold coating helps to lubricate the screw threading and effectively achieve a higher preload but reduces friction during insertion.¹³ Tzenakis et al found that lubricants such as saliva may also help to achieve higher preload.²⁶ The finding that at the second insertion some of the specimens in the internal-connection group took additional revolutions to achieve desired insertion torque, or in some specimens did not reach the goal torque value, remains unclear. The authors believe that once the tissue has extruded down the length of the abutment screw, it affects the insertion process. Rather than acting as a lubricant, tissue debris binds at mating surfaces. In this case, manual removal of macroscopic debris may not be sufficient to prevent insertion interference. Additional studies may be designed to better understand this finding.

It is clear that methods of gingival retraction for dental implants need to be further studied. Tissue entrapment is possible, if not probable, during surgical and prosthetic phases of implant restoration. Additionally, the effect that tissue entrapment has on healing abutments is unknown. Future studies should also assess different methods of cleaning abutments and screws, such as irrigation, ultrasonic cleaning, or removal of debris with a brush. Moreover, an attempt should be made to evaluate what effect tissue entrapment has on the internal threading of dental implants, and whether tissue entrapment can be assessed at try-in and insertion of abutments.

Of particular interest to the investigators was an observation made when original abutment screws were reinserted. Some abutment screws inserted in the groups with 1.0 mm of tissue were not able to achieve the manufacturer's recommendation of 20-Ncm torque value at this second insertion. This phenomenon presents a clinical concern for practitioners. Future studies should explore the possibility of permanent screw surface damage, exceeded tensile limits, and/or damage to the internal aspect of the implants.

Conclusions

If tissue becomes entrapped at the implant/abutment interface it remains at the implant/abutment interface. External-connection implants were significantly affected by tissue entrapment. The thicker the tissue, the lower the reverse torque noted. Internal-connection implants were somewhat affected by tissue entrapment but not to the level of external-connection implants.

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