J Dent Mater Tech 2024; 13 (4): 169- 174
https:// 10.22038/jdmt.2024.79955.1640

J Dent Mater Tech

Original Article

Open Access

Effect of a silicon-based sealing agent (GapSeal) on the reverse torque value of the abutment–implant screw

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Abstract

Objective: One major cause of dental implant failure is screw loosening. Silicone sealants have been introduced to reduce the gap between abutments and implants, potentially reducing screw loosening. This study aimed to investigate the effect of using a sealing agent on the reverse torque value (RTV) of abutment–implant screws.

Methods: Sixteen implants were divided into experimental and control groups (N=8). GapSeal gel was injected into the fixture's intaglio cavity in the experimental group, while the control group received no injection. The abutments were tightened to the fixtures with a torque of 30 N.cm for all samples. Additionally, full-metal crowns were cemented onto each abutment. The implants underwent axial cyclic loading, with 500,000 cycles at a force of 75 N and a frequency of 2 Hz applied along the longitudinal axis of each sample. The detorque value was measured for all samples using a digital torque meter. Data were analyzed using an independent samples t-test, with significance set at $P < 0.05$.

Results: The mean reversed torque of the study group (18.50 ± 0.71 N.cm) was significantly higher than the control group (11.375 ± 0.43 N.cm; $P < 0.001$). The difference between the initial tightening torque value (TTV) and RTV (11.50 ± 0.56 N.cm) in the study group was significantly lower than that in the control group (18.62 ± 034 N.cm; P=0.001).

Conclusions: The GapSeal gel reduced the torque loss value of the abutment–implant screw and may be recommended in clinical settings to reduce the risk of screw loosening.

Keywords: Dental abutments, Dental implants, Implant–abutment connection, Torque, Silicones, Sealing agents

Introduction

The long-term success of dental implants is influenced by various factors including the microgap and microleakage at the implant-abutment interface, crestal bone loss, and the loosening of screws or prostheses. Among these, screw loosening is the most prevalent mechanical failure observed in implant-supported restorations, particularly in single-tooth implants (1). A study by Lee et al. (1) found that the prevalence of screw loosening is 7.2%, which increases to 14% in single implants. This issue can lead to a loss of stability between the implant and abutment, and ultimately, implant failure. Additionally, screw loosening may cause discomfort in the soft tissue surrounding the implant and result in inflammation (2).

The initial preload value refers to the energy transferred to a screw when torque is applied during the initial tightening. Factors contributing to the loosening of screws can be categorized into two groups: those affecting the initial preload value and those affecting the maintenance of preload over time (3). The first group of factors includes the initial tightening torque value (TTV), the friction coefficient between implant components, and the mechanical properties of the screw (4). The second group factors are related to the type and intensity of loads applied over time. This includes aspects like the restoration's design and dimensions, the abutment's angle, and the patient's bite force. These elements can lead to screw micromotion, causing reverse torque and screw loosening (5).

Various techniques have been suggested to reduce screw loosening. These techniques include minimizing the settling effect by retightening the screw within 10 minutes of the initial torque application, using a digital torque meter instead of a manual tool to enhance the

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Accepted: 10 September 2024. Submitted: 15 May 2024.

measurement accuracy, and applying a sealing agent to fill the gap between the screw and fixture threads to decrease frictional resistance (5-8).

Different materials have been recommended as sealing agents, including polytetrafluoroethylene-based materials (PTFE) (9, 10), Vaseline (11), gutta-percha (12), chlorhexidine, fluoride gel (13, 14), bonding agents and sealing gels (15-17). Theoretically, these materials reduce the friction coefficient between two mating surfaces and increase preload value, thus decreasing screw loosening. There are controversial reports about the effectiveness of PTFE (9, 10, 18), fluoride and chlorhexidine (13, 14, 19) in different studies on preload value, but Vaseline showed no beneficial effect (11, 20). Some studies reported that bonding agents increased reverse torque values (RTV) (15, 16); however, their use is contraindicated in clinical settings due to concerns about cytotoxicity and biocompatibility (15).

Specialized silicone-based materials have been developed for sealing implant-abutment connections. GapSeal gel, produced by HagerWerken Co. in Cologne, Germany, is a highly viscous silicone matrix sealer with thymol antiseptic. It contains antibacterial components and demonstrates excellent efficacy in preventing microleakage (21-23). The silicone composition of the GapSeal sealant contributes to its flexibility and durability, allowing it to fill effectively the microgaps present at the implant interface. Additionally, it is compatible with biological tissues, which lowers the risk of adverse reactions (24).

Previous studies on gap-sealing agents have mainly focused on evaluating microleakage (25, 26). Fernandes et al. (23) observed that GapSeal was effective in preventing bacterial microleakage and had an adequate cytocompatibility profile. Smojver et al. (21) reported that microleakage in the GapSeal group was significantly lower than in the control group. Other studies showed that GapSeal effectively reduced the micro-gap between the implant and the abutment (22, 23). Naser et al. (22) reported that the use of GapSeal reduces the microgap size from 3.04 microns in the control group to 0.99 microns in the experimental group.

The application of GapSeal gel is easy and cost-effective, while also providing favorable sealing properties. However, only a few studies have assessed the impact of this material on the reverse torque values (RTV) of the screw (5, 20), and these studies had limitations, such as minimal or no cyclic loading applied to the screw. Therefore, the present study aimed to investigate the effect of GapSeal gel injection at the implant-abutment interface on screw loosening under cyclic loading. The null hypothesis for this study was that GapSeal does not influence the RTV of the abutment screw.

Materials and methods

Ethical approval

The protocol of the present *in vitro* study was approved by the ethics committee of Qazvin University of Medical Sciences under the code IR.QUMS.REC.1398.259.

Sample Size Calculation

The sample size was calculated according to the results of Yu et al. (5), considering the significance level of 0.05 and a power of 0.80, using the following formula:

$$N = \frac{([Z1 - \alpha/2 + Z\,1 - \beta])^2 (s1 * s1) + (s2 * s2)}{(d)^2}$$

In this formula, the following values are used: Z1-α/2 = 1.96, d = 10.5, s1 = 7.76, s2 = 7.11, and Z1-β = 0.84. The sample size was calculated to be 8 samples in each group.

Implant characteristics

Sixteen tapered implant fixtures (DENTIS; Daegu, South Korea), specifically designed for the molar region were utilized in this study. The dimensions of these implants were as follows: a diameter of 4.1 mm, a length of 10 mm, and a platform diameter of 0.4 mm. This implant design incorporates an internal octagonal structure combined with a Morse taper connection. Additionally, 16 stock titanium abutments were chosen to correspond with the implants, featuring the following dimensions: a height of 7 mm, a diameter of 4.5 mm, and a gingival height of 1 mm.

Experimental design

The implants were mounted in self-polymerizing acrylic resin and positioned up to 1 mm below the abutment-fixture interface. A surveyor device was used to ensure that the fixture's longitudinal axis was perpendicular to the horizontal axis.

The samples were divided into two groups (N=8). In the study group, silicone-based GapSeal gel (HagerWerken Co., Cologne, Germany) was injected into the fixture’s intaglio cavity (Figure 1). In the control group, no sealant was applied. Following this, titanium abutments were placed onto the fixtures. The samples were fixed in place using a bench vise (YAS, Tehran, Iran) and secured to the initial TTV of 30 N.cm. The abutment

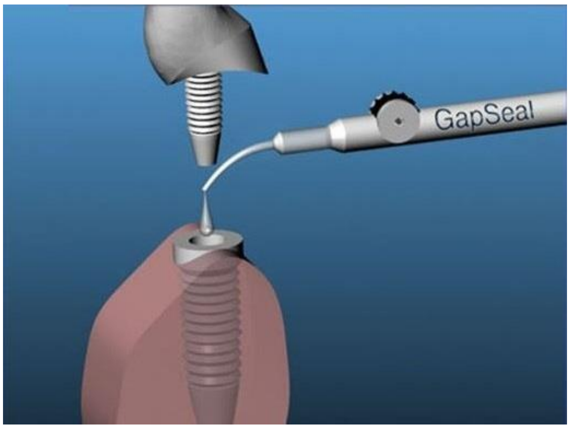

Figure 1. Injecting GapSeal gel into the fixture's intaglio cavity

screws were tightened with a calibrated digital torque meter (Lutron Electronic Enterprise Co., Taipei, Taiwan). To account for any settling effect, the screws were retorqued within ten minutes of the initial tightening. As mentioned in the ISO standard (14801:2016 - Dentistry - Implants), the loading center should be positioned at a distance of 11 mm from the implant support level. This point was considered in the test setup.

Subsequently, 16 nickel-chromium dental crowns were fabricated and cemented using temporary eugenol-free zinc-oxide cement (GC Co., Tokyo, Japan).

Mechanical cycling

The samples were transferred to a chewing simulator (CS-4SD Mechatronik GMBH, Feldkirchen, Germany). They were exposed to 500,000 cycles of loading with an axial force of 75 N at a frequency of 2 Hz. This number of loading cycles and force was approximately equal to the single implant loading in the mandibular molar area over one year (27). Forces were applied on the lingual slope of the buccal cusp of crowns to simulate the horizontal vector of oblique masticatory forces.

RTV measurement

The crowns were removed, and the samples were then fixed in a bench vise. The detorque force required to open the abutment screw was measured as the reverse torque (RTV) value of each sample using a digital torque meter (Lutron Electronic Enterprise Co., Taipei, Taiwan).

Statistical analysis

Data were analyzed using SPSS 26.0 (IBM Inc., NY, USA). The mean RTV for both groups was calculated and compared using an independent samples t-test. Statistical significance was set at P<0.05.

Results

Table 1 shows descriptive statistics and confidence intervals of RTV in the study and control groups. The mean RTV of the study group (18.50 ± 0.71 N.cm) was significantly higher than the control group (11.37 ± 0.43 N.cm; P<0.001). The lost torque, calculated as the difference between TTV and RTV, was significantly lower in the GapSeal group (11.50 ± 0.56 N.cm) compared to the control group (18.62 ± 0.34 N.cm; P=0.001).

Discussion

In the present study, the required torque needed for screw loosening in the GapSeal group was significantly higher than in the control group. Furthermore, the torque loss was significantly lower when GapSeal was used compared to using no sealer. Therefore, the null thesis was rejected.

The friction between screw surfaces with the fixture causes surface roughness and initial torque loss (5, 28). The present study showed that GapSeal decreased the torque loss value compared to the control group. The favorable result in the GapSeal group is probably related to its high viscosity, which could act as a protection layer. The gel forms a smooth layer on the fixture surface and reduces the wear effect. Yu et al. (5) found that GapSeal gel decreased the friction coefficient in the screw connection area from 0.24 to 0.17. Moreover, the silicone gel layer could buffer the impact of external cyclic load and protect the threads from abrasion (29). By absorbing the vibration and reducing micromotion, the probability of screw loosening is decreased.

In the present study, 500,000 cycles were applied to the crowns. After cyclic loading, the reverse torque value

Table 1. Mean ± standard deviation (SD) of RTV and the difference between RTV and TTV in the study and control groups

Variables	GapSeal group	Control group	P value
	Mean ± SD	Mean ± SD	
TTV (N.cm)	30	30	-
RTV (N.cm)	18.50 ± 0.71	11.37 ± 0.43	<0.001
Difference between RTV & TTV (N.cm)	11.50 ± 0.56	18.62 ± 034	0.001

SD: standard deviation; TTV: tightening torque value; RTV: reverse torque value
*Values lower than 0.05 represent a significant difference between the study groups according to independent samples t-test.

was lower than the initial TTV of the abutment screws in both groups. The mastication load and cyclic loading have been reported to cause micromotion of the abutment screw, leading to screw loosening (7, 17, 30). Several investigations have shown that using GapSeal gel decreases the abutment–implement microgap size and microleakage (22, 23). A study showed that GapSeal significantly decreases the microgap at the implant-abutment interface, with a reduction from 3.04 µm in the control group to 0.99 µm in the experimental group (29). Microgap size correlates with microleakage. Infection and inflammation following microleakage can lead to screw loosening and implant failure (31). GapSeal seals the interface and maintains a sterile environment around the implant, reducing the risk of infection.

Yu et al. (5) studied torque loss following GapSeal application versus using no sealing materials in three implant systems (Nobel, Straumann, and WEGO) exposed to 1800 cyclic loads. Similar to the present study, torque loss was lower in the GapSeal group than in the control group. However, more load cycles (500,000 cycles) were used in the present study to provide more reliable findings. In another study by Coelho et al. (20), the effect of GapSeal and a PTFE tape on the preload and RTV was evaluated. Similar to the present findings, GapSeal increased the RTV values. However, Coelho et al. (20) did not expose the abutments to cyclic loading.

One of the advantages of GapSeal, among other silicon sealers, is that it does not have a setting reaction. Therefore, the time of torquing does not affect its properties. In contrast, studies that investigated another common silicone sealer, Kiero Seal gel (Kuss Dental, Madrid, Spain), reported controversial reports. Ozdiler et al. (27) reported that Kiero Seal may cause screw loosening under functional loads. Rathe et al. (19) and Biscoping et al. (30) showed that the Kiero Seal did not have any significant effect on preload and RTV values of the abutment screw. It should be noted that Kiero Seal sets chemically, and thus its working time is important. If the initial torque is applied during the final stages of setting, the screw will go through plastic changes, which could reduce RTV and even cause the screw to break. This also stops the screw from sitting completely (27). Therefore, the mechanism of action and the setting reaction are important factors that need to be considered when selecting sealing materials.

This study had some limitations, the most significant being its in vitro design. Nonetheless, RTV was measured to simulate clinical situations, as it serves as a valid indicator of torque loss and is directly influenced by preload (18, 20). In addition, 500000 cyclic loads were applied. A crown was created for each sample and cemented to mimic masticatory loads in the mouth.

Another limitation of the study was that it focused on only one type of single-crown restoration and one type of abutment-implant connection. Examining other types of implant-supported prostheses, connections, and implant systems is warranted in future research. Moreover, GapSeal is a viscoelastic material, and the rate of force application influences its properties. Therefore, GapSeal's impact on retention at different rates of screw tightening also warrants further studies. Comparing the efficacy of GapSeal with other sealing materials is also recommended.

Conclusions

Based on the findings of this study:

1. After cyclic loading, the reverse torque value was lower than the initial tightening torque value of the abutment screws in both groups.
2. GapSeal gel demonstrated a significantly higher reverse torque value for the abutment–implant screw following cyclic loading.
3. Using GapSeal gel significantly reduced the torque loss value from 18.62 ± 0.34 N·cm in the control group to 11.50 ± 0.56 N·cm in the experimental group. Therefore, the GapSeal gel may be recommended in clinical settings to help prevent screw loosening.

Acknowledgements

We would like to acknowledge the support and coordination provided by the Dental School of Qazvin University of Medical Sciences.

Conflict of interest

The authors declare no conflict of interest.

Authors contributions

K.T. contributed to the research design and implementation; H.S. contributed to the research implementation and writing of the manuscript, and A.S. contributed to the research supervision and writing of the manuscript. All authors read and approved the final manuscript.

Ethical approval

The protocol of the present in vitro study was approved by the ethics committee of Qazvin University of Medical Sciences under the code IR.QUMS.REC.1398.259.

Funding

The research reported in this article was self-funded, and no external financial support was received for its conduct.

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