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Evaluation of Torque Maintenance in Implant abutment interface using a Novel Sealant: An In Vitro Study

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ABSTRACT:

Aim and Objective: Implant abutment microgap being one of the major problem leading to screw loosening. The aim of this study was to evaluate the effect of chitosan-based sealant on the implant abutment interface by evaluating the abutment screw torque loss.

Materials and Methods: CH/GP (chitosan β glycerophosphate) hydrogel was fabricated. Two experimental groups with thirty implant abutment internal connections (ADIN, Isreal) were used. Each system was divided into two groups with and without sealant (N=30). The sealant group was loaded with hydrogel while the control were bare implants. The abutments were tightened to the fixtures with a torque of 30 N.cm for all samples. Additionally, metal ceramic crowns were cemented onto each abutment. The implants underwent cyclic loading in chewing simulator, 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 analysed using an independent samples t-test, with significance set at $P < 0.05$.

Results: The mean reversed torque of the study group (23.64 ± 1.69 N.cm) was significantly higher than the control group (17.34 ± 1.57 N.cm; $P < 0.0001$). The difference between the initial tightening torque value (ITV) and RTV in the study group was significantly lower than that in the control group.

Conclusion: The application of the hydrogel was found to minimize torque loss at the implant–abutment interface, suggesting its potential use in clinical practice to decrease the likelihood of screw loosening.

Clinical Implication: The chitosan hydrogel tested shows a potential to reduce the risk

of mechanical complication for implant system and may extend their longevity.

1. INTRODUCTION

Dental implants have become a mainstream treatment approach in daily practice, and because of their high survival rates over time, they have become the preferred treatment option for prosthetic rehabilitation in many situations¹. Implant-supported prosthesis requires adequate protection of implant abutment interface to ensure long term success. Huynh-Ba et al² reported that the 5-year prosthetic survival rate of implant-supported prosthesis was as high as 95.8%. However, in spite of high success rate, occurrence of implants failure has been reported.

Abutment screw loosening is the second most common cause of failure of implant-supported restoration³. From 4.3% after five years to 26.4% after 10 years, the frequency of connection-related problems (screw loosening or fracture) increased. Of the 9% of restorations that were cemented, loss of retention of the restorations occurred in 6.2% within five years and 24.9% within 10 years. Ironically, the “prevention” of these problems from happening is the “therapy” for the issue of an increasing incidence of complications⁴.

The main causes include improper application of force, improper occlusal force, improper screw diameter, stress deformation, and screw corrosion due to microleakage of salivary bacteria, all of which result in insufficient pre-tightening force between the implant and abutment.⁵ In this regard, on the one hand, liquid or solid lubricants can be used to reduce friction between the implant and the abutment to improve the pre-tightening force and stability of the abutment^{6,7}.

The preload, also called clamping force, is induced by the compression between implant and abutment when abutment is tightened into implant with a certain torque.⁸⁻¹⁰ The preload is crucial for the stability of abutment, and the greater resistance to screw loosening relies on greater preload.¹¹ However, it has been reported that the percentage of the tightening torque transformed to preload is only 10%, while 90% is utilized to overcome the friction between implant and abutment.¹² An effective method to increase preload is decreasing the friction.¹³ Thus, liquid or solid lubricant has been utilized to decrease the friction so that the preload and stability of abutment should be improved.^{14,15} However, it is also detrimental for the stability of abutment if the friction is too low. Therefore, both friction and pre load between implant and abutment are pivotal to the stability of abutment.¹⁶ It is desirable that the friction be relatively low during the process of tightening abutment into implant to improve the preload then become greater to a suitable level after abutment has been tightened into the implant so that the improved preload and suitable friction could improve the stability of abutment when it functions in the oral cavity. Therefore, a friction-changeable material is required to achieve this purpose.¹⁷

In addition, a microgap ranging from 2 to 49 μm exists between implant and abutment.^{18,19} Bacteria can easily penetrate into the microgap, aggregate, and breed to form biofilms, which are difficult to be cleared.²⁰ Some tissue diseases around implant, such as mucositis, peri-implantitis, and marginal bone loss, would be caused by bacteria and their harmful metabolites.²¹ Currently, Gapseal gel, silicone O-ring washer, chlorhexidine-thymol varnish and other sealing materials have been used to solve this problem in clinic.^{22,23}

Over the past 50 years, chitosan and its derivatives have been incorporated in mouthrinse, toothpaste, varnish, denture adhesive gel, pulp capping agent, glass ionomer restorative material, and root canal sealer. With excellent biodegradability and biocompatibility, chitosan (CS) is widely used in biomedical and cosmetic fields.²⁴ β -glycerophosphate pentahydrate (β -GP) is able to catalyse the phase transition of CS solution at physiological temperature.²⁵

Therefore, we prepared a CS/ β -GP hydrogel in this study and evaluated its feasibility as a sealant between the implant and the abutment. In the present study aimed to investigate the effect of gel injection at the implant-abutment interface on screw loosening, later cyclic loading was performed to simulate masticatory forces between the implant and abutment. The null hypothesis for this study was that chitosan composite does not influence the RTV (removal torque value) of the abutment screw.

METHODS:

1. Sample size calculation

The sample size was calculated according to the results of T Katebi et al (5), considering a significance level of 0.05 and a

statistical power of 0.80, using the following formula:

$$N = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (s_1^2 + s_2^2)}{d^2}$$

In this formula, the applied values were:

$Z_{1-\alpha/2} = 1.96$, $Z_{1-\beta} = 0.84$, $d = 10.5$, $s_1 = 7.76$, and $s_2 = 7.11$. Based on these parameters, the estimated sample size was calculated to be 8 specimens per group, and was rounded to 15.

2. MATERIALS AND METHODS

2.1 Materials

Experimental materials such as CS (molecular weight=179.17 kDa; deacetylation degree $\geq 95\%$) from SISCO Lab and β -GP (molecular weight = 306.11 gmol⁻¹) were purchased from Sigmaldrich Co, Ltd. As for the implants (ADIN Dental Implant Systems Ltd., Israel), internal hex implants measuring 3.5 mm $\times$ 13 mm were mounted at the center of thirty autopolymerizing acrylic (DPI Cold Cure, Denture Base Material, Dental Products of India, Mumbai) blocks of approximately one inch each with a straight abutment.

2.2 Methods

For the preparation of chitosan beta -glycerophosphate hydrogel ,Firstly Chitosan (CS) powder was dissolved in acetic acid (0.1 M) under agitation at room temperature. Sterile formulation was obtained by regular liquid autoclaving(120 c for 15 min). Beta glycerophosphate solution was prepared by dissolving powder with deionized water to make up for the required volume and concentration. After sterilization through a 0.25 μ m filter, Beta glycerophosphate solution was added to prepared chitosan solution inside the ice bath at a volume ratio of 5:1, with constant stirring, the CH/GP mixture was transferred to 37 C for 15 minutes, and CH/GP hydrogel was formed.

The implants were then mounted in self-polymerizing acrylic resin (DPI Cold Cure, Denture Base Material, Dental Products of India, Mumbai) blocks of approximately one inch each 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.

These models were divided into two groups: with and without sealant, with 30 samples. Commercially disposable 2.5ml syringe was used with an opening of 2mm were used. Then 1ml of CH/GP hydrogel was added into the syringe. and the mixture was extruded from the syringe by hand into the internal recess. The gel group were injected into the screw access holes of the implant fixtures until they were filled, then the screw was fixed and tightened in place, and bare implant without any sealant was used as control.

The samples were secured in a table with clamps and the initial TTV of 30 N.cm, tightened with a calibrated digital torque meter(Digital torque gauge with adapter SP Series, Eclatorq, 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 centre should be positioned at a distance of 11 mm from the implant support level. This point was considered in the test setup. Subsequently, 30 metal ceramic dental crowns were fabricated and cemented using temporary eugenol-free zinc-oxide cement (3MTM RelyXTM Temp NE Zinc Oxide Non-Eugenol Temporary Cement Refill).

All samples were subjected to cyclic loading (Chewing simulator, S-D mechatronic, Feldkirchen-Westerham, Germany) for 500,000 cycles with a frequency of 2 Hz and force of 75 N. This number of loading cycles and force was approximately equal to the single implant loading in the mandibular molar area over one year 26 . Forces were applied on the lingual slope of the buccal cusp of crowns to simulate the horizontal vector of oblique masticatory forces.

The crowns were removed, and the samples were then secured back in table with clamps. 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 (Digital torque gauge with adapter SP Series, Eclatorq, 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 $P < 0.05$.

3. RESULTS

Experimental data were expressed as mean $\pm$ standard deviation (SD). Table 1 summarizes the descriptive statistics and confidence intervals for RTV in both groups. The chitosan hydrogel group exhibited a significantly higher mean RTV (23.64 ± 1.69 Ncm) compared with the control group (17.34 ± 1.57 Ncm; $P < 0.0001$). Torque loss, defined as the difference between TTV and RTV, was markedly lower in the chitosan hydrogel group (23.64 ± 1.69 Ncm) than in the control group (17.34 ± 1.57 Ncm).

4. DISCUSSION

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

The implant-abutment connection stability is closely related to the friction force and pre-tightening force. Currently, most studies aim to increase pre-tightening force as well as to reduce the friction between the abutment and the implant by using a liquid lubricant or a solid lubricant coating.²⁷⁻²⁹ On the other hand, low friction is not conducive to the stability of the abutment. Therefore, it is

particularly important to select materials with variable friction in implant. However, the influence of abutment stability on the implant system is ignored. In this study, removal torque test was utilized to indirectly reflect the stability of the abutment. Therefore, the hydrogel in the present experiment remained liquid when added to the implant and converted into gel before tightening the abutment. Under this condition, the friction coefficient would be relatively low, and the pre-tightening force would be enhanced. However, when it was converted to the gel state, the friction coefficient increased correspondingly. As a result, the variation of friction coefficient provided a large pre-tightening force and less friction.

Apart from pre-tightening force and friction between the implant and the abutment, the successful factors about dental implants are also related to the effect of normal mastication on the implant in clinical practice. In this study, the dynamic cyclic loading experiment was applied to simulate the situation that the implant had worked for 6 months under the normal chewing conditions and to observe different groups. The results found that the hydrogel could significantly improve the removal torque between the implant and the abutment. Besides, the hydrogel in this group was able to increase masticatory function load, thereby increasing its possibility of clinical application.

Dincer Kose *et al*³⁰ in a study reported that abutment screw with a 20 Ncm preload force can function for 2–3 months and those with a 30 Ncm preload force can function for 2–3 years without any complications. The participants in our study had clinically realistic limited access to simulate the oral cavity environment. Therefore the use of chitosan hydrogel has considerably reduced the removal torque value than the control. Thereby the use of such gel formulations can be beneficial for maintaining the torque even after loading.

Further studies in a more clinical similarities need to assessing the hydrogel effect in its biomechanical considerations for use as an implant abutment sealant. Therefore, hydrogel impact on retention at different rates of screw tightening also warrants further studies. Comparing the efficacy of hydrogel with other sealing materials is also recommended.

5. CONCLUSION

The chitosan hydrogel group exhibited a significantly higher reverse torque value compared to the control group after cyclic loading. Following cyclic loading, the reverse torque values of abutment screws were lower than their initial tightening torque values in both groups.

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Table 1 Mean $\pm$ standard deviation (SD) of RTV and the difference between RTV and TTV in the study and control groups

Variables	Tightening torque value (TTV)	Mean $\pm$ SD	Standard Error of Mean	T value	p Value
Post torque values with sealant (N/cm) (RTV)	30	23.64 $\pm$ 1.69	0.436	10.599	<0.0001
Post torque values without sealant (N/cm) (RTV)	30	17.34 $\pm$ 1.57	0.404		

*p value ≤ 0.05 statistically significant, RTV (removal torque value), TTV(tightening torque value)