



## Effect of GapSeal® as a Sealing Material on Microgap and Microleakage at External Hexagon Implant Connections Following Cyclic Loading: An In Vitro Study

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### ABSTRACT

**Background and Aim:** The mismatch of the implant-abutment connection can produce instant stress and microleakage which result in mechanical and biological complications. This study aimed to investigate the influence of GapSeal® as a sealing material on the extent of microgap and microleakage at the external hexagon implant platform following cyclic loading.

**Materials and Methods:** Sixteen implants with an external-hexagon connection (BioHorizons External dental implant) were employed in this in-vitro experimental study. All implant-abutment sets were assigned to two groups and were molded in acrylic resins. GapSeal® was injected into the implants in the experimental (test) group. Then, implant assemblies were tightened with the torque of 30 N/cm, and 1200,000 loading cycles with the force of 100 N and the frequency of 1 Hz were applied. Every sample was immersed in a methylene blue dye to evaluate microleakage. Microgap was measured in six regions randomly using a scanning electron microscope (SEM). The data were entered into SPSS 22 and were analyzed using t-test.

**Results:** The mean±SD microgap was 0.87±0.35 µm and 3.43±1.61 µm in the test and control groups, respectively. Methylene blue dye was observed in all of the specimens of the control group, while no liquid was seen in the test group. A significant statistical difference was found between the groups regarding the microgap and microleakage (P<0.0001).

**Conclusion:** Application of GapSeal® reduced the dimension of the microgap and decreased microleakage at the implant-abutment interface.

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## Introduction:

The most documented complications in implant dentistry are peri-implant mucositis and peri-implantitis which typically lead to inflammation of the peri-implant tissues and eventually the loss of the supporting crestal bone if left untreated.<sup>(1)</sup> Several factors have been stated to trigger peri-implantitis, one of the most frequent of which is microleakage at the implant-abutment interface (IAI).<sup>(2)</sup> The IAI may play a substantial role in the crestal bone loss which has been ascribed to the microgap between the implant and the abutment in two-piece implant systems.<sup>(3,4)</sup> The inadequate fitting might initiate microleakage of fluids and conceal bacteria, which may lead to peri-implantitis.<sup>(5)</sup>

Moreover, the implant connection design is a crucial feature associated with microleakage.<sup>(6)</sup> In all types of connections, the size of the microgap increases during loading, which results in a pumping effect. In both internal- and external-hex implants, the number of microorganisms in loading conditions is higher than that in non-loading conditions.<sup>(7)</sup> Owing to the widespread use of external-hex implants, studies are necessary to acquire sufficient knowledge about the biological and biomechanical effects of this type of connection.<sup>(8)</sup>

Numerous efforts have been made to strengthen the connection between the implant and the abutment, and several methods have been suggested for preventing or reducing bacterial contamination at the IAIs, such as the use of sealant materials, i.e. GapSeal®, decontamination of the internal cavity of the implant, the use of shape memory alloys and various geometries.<sup>(9)</sup> In order to seal the gap, O-ring, a polysiloxane ring, and GapSeal®, an antibacterial sealing gel, have been proposed.<sup>(10)</sup> Several studies have investigated the influence of microleakage and microgap on bacterial colonization and the effects of cyclic loading on microleakage in dental implants<sup>(7,8,10-16)</sup>. However, there is no information on the effect of GapSeal® on microleakage under cyclic loading. Therefore, this study aimed to investigate the effect of GapSeal® on microgap and microleakage in external-hex implants under cyclic loading.

## Materials and Methods

### Study design:

In this in-vitro experimental study, 16 implants with the length of 10.5 mm and the diameter of 4 mm (BioHorizons External dental implant, RBT body, AL 35244, Birmingham, England) were employed to check the efficacy of GapSeal® as a sealing agent at the IAI. The implants were divided into two groups of eight implants each: a group that used no sealing agent at the IAI and a group that used GapSeal® (Hager & Werken GmbH & Co. KG, Duisburg, Germany) at the IAI. GapSeal® is a silicon matrix with 5% weight of thymol, which has adequate viscosity and bactericidal properties. Due to high viscosity, it is very stable and highly resistant to washing-out from the oral cavity.<sup>(17)</sup>

Direct abutments of 6-mm length with collar height of 1 mm were tightened on the fixtures (Figure 1), and then, the assemblies were mounted in a block of translucent auto-polymerizing acrylic resin (Moravia, Boyman Boya, Tokyo, Japan) with a cross-section diameter of 34 mm and a height of 19 mm by a parallelometer (Hahnenkratt, Berlin, Germany).<sup>(18)</sup>



**Figure 1- BioHorizons External dental implant (4 mm × 10.5 mm) and abutment with the external-hex connection.**

To prepare the acrylic resin, the proper ratio of powder and liquid was used according to the factory instructions. In order to mount the fixture inside the acrylic mold in a completely perpendicular position (90° angle relative to the horizon), a surveyor (J. M. Ney Co., Bloomfield, CT, USA) was used. Accordingly, after the comple-

tion of resin polymerization, all samples were ready for the experiment.

In the experimental group, according to the manufacturer's instructions, the interior of the implant was entirely cleaned with alcohol, and then, GapSeal® was applied into the abutments to the maximum capacity to avoid air trapping. Afterward, the abutment screw was tightened on all samples using a digital torque meter (Lutron Electronic Enterprise Co. Ltd., Taipei, Taiwan) by a torque of 30 N/cm.<sup>(19)</sup> In order to compensate for the settling effect, five minutes later, the abutment screw was once more tightened by the 30-Ncm torque meter (Figure 2)<sup>(18,19)</sup>



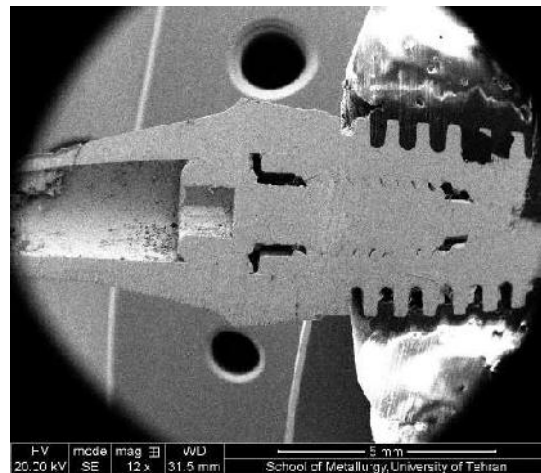
**Figure 2. Implant-abutment assemblies mounted in a block of acrylic resin.**

All samples were placed inside a chewing simulator CS4 (SD Mechatronic, Feldkirchen, Westerham, Germany) for cyclic loading, and 120,000 cycles (equivalent to 48 months of chewing force inside the mouth) were applied with a force of 100 N and a frequency of 1 Hz in the axial direction (perpendicular to the abutment's occlusal surface).<sup>(7)</sup>

Evaluation of microleakage:

A methylene blue dye (Sigma-Aldrich, USA) was used to evaluate microleakage. A hydrophilic silicone pellet was placed inside the upper end of the abutment component to eliminate any dye residues inside the abutment connection and to avoid inaccurate measurements.<sup>(8)</sup> The methylene blue dye was prepared according to the manufacturer's instructions, and all specimens were then immersed in the dye and were incubated for 24 hours at 37°C.<sup>(8)</sup>

The implant-abutment assembly was cut by a cutting machine (Mecatome T-201A, Presi, France) along its longitudinal axis with a high precision diamond wheel (Minitom Struers, Copenhagen, Denmark; Figure 3), and the penetration rate of the dye into the IAI was reported qualitatively at magnification levels of  $\times 200$  and  $\times 2000$  by scanning electron microscopy (SEM; Neon 40 with Gemini® column, Zeiss, Oberkochen, Germany).



**Figure 3-Axial view of an implant-abutment assembly under scanning electron microscopy (SEM) at  $\times 12$  magnification.**

Observation of microgap:

SEM was used for the implant-abutment microgap assessment under conditions of 20 kilovoltage (kV) potential. The microgap was measured in six regions randomly in the microphotographs, and the calculated mean  $\pm$  standard deviation (SD) was recorded for each specimen.

Statistical Analysis:

Statistical analysis was performed using SPSS 22.0 software (SPSS Inc., Chicago, IL, USA). Data were analyzed by student's t-test with a confidence interval of 95%. For the description of the data, mean  $\pm$  SD values ( $\mu\text{m}$ ) were calculated.  $P < 0.05$  was considered statistically significant.

**Results:**

The microgap measurements for each IAI are presented in Table 1.

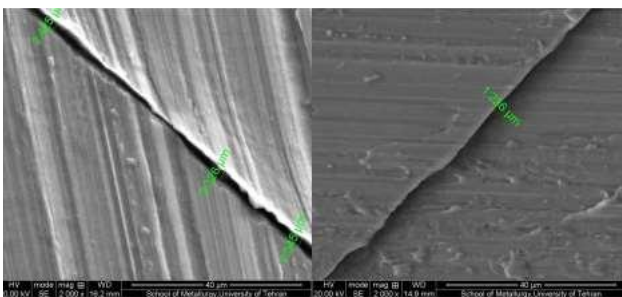
**Table 1. Mean microgap (µm) for each implant-abutment assembly**

Groups	Mean±SD	Maximum	Minimum	CV	P-value
Test (GapSeal®)	0.87±0.35	1.236	0	18	0.0001*
Control (no sealant)	3.43±1.61	3.99	2.46	63	

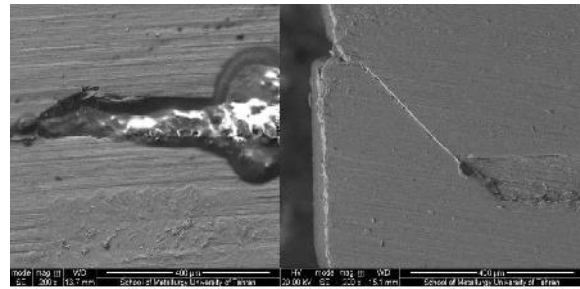
\*denotes a statistically significant difference; CV=Coefficient of variation, SD=Standard deviation

The dimension of microgap in the experimental group (GapSeal®) was significantly smaller than that in the control group (no sealant material; P<0.0001). The size of microgap in the experimental group measured ranging from 0 to 1.236 µm with a mean±SD of 0.87±0.35 µm, while in the control group, the range was from 2.46 to 3.99 µm with a mean±SD value of 3.43±1.61 µm.

Fisher's exact test showed that the incidence of microleakage was significantly lower in the test group (P<0.0001). Accordingly, in the control group, 100% of the samples showed microleakage of the methylene blue dye, while in the test group, GapSeal® prevented the leakage of fluid at the IAI. Examples of each specimen are given in Figures 4 and 5.



**Figure 4. The dimension of microgap as observed under scanning electron microscopy (SEM; 20 kV, at ×2000 magnification) for the test group (Right) and for the control group (Left).**



**Figure 5. Penetration of methylene blue dye (microleakage) into the implant-abutment interface in the control group (Left) and in the test group (Right) under scanning electron microscopy (SEM; 20 kV, at ×200 magnification).**

**Discussion:**

This study was conducted to investigate the effect of GapSeal® on microgap and microleakage at the IAI with the external hexagonal connection. The results showed that the use of GapSeal® reduces microgap and microleakage at the IAI.

Implant-assisted restorations and the bone act as a functional unit, and the mismatch between the implant assembly components causes adverse effects on both the bone and the implant.<sup>(11)</sup> Complications associated with microgap at the IAI can be divided into two categories; first, biological complications such as peri-implant mucositis, peri-implantitis, crestal bone resorption, and halitosis, and second, mechanical problems including abutment screw loosening and abutment/implant fracture.<sup>(6)</sup> Moreover, bacteria can penetrate and colonize the empty spaces of the IAI and release their toxins and metabolites into the surrounding tissues.<sup>(6)</sup> Besides, microleakage can lead to the passage of fluids, microorganisms, molecules, and ions into the duct that can cause biological and mechanical problems such as loosening of the screw.<sup>(4)</sup>

Several articles point to the fact that cyclic loading increases the size of microgap at the IAI, specifically in external-hex implant systems.<sup>(12,13,16,20)</sup>

The mastication forces exerted on the restorations create micromovement at the IAI. Also, microgap increases during opening and closing of the mouth and produces a pumping effect at the IAI. As a result, bacteria can readily colonize the empty spaces of the implant assembly.<sup>(8)</sup> Con-



sequently, inflammatory reactions and mechanical and biological problems occur. In the present study, all groups were subjected to cyclic loading to mimic the conditions of the oral environment before the assessment of microgap and microleakage.<sup>(6)</sup>

Without the use of sealing materials, due to the lack of full adaptation of the implant-abutment walls, the leakage will happen. Also, over time, the misfit between the walls will affect the torque of the screw, and ultimately, deforms and increases the microleakage.<sup>(17)</sup> The methods used to strengthen the implant-abutment connection can also affect the leakage. There is a negative correlation between the tightening torque and the severity of the leakage.<sup>(5)</sup>

Martin-Gili et al examined the leakage of fluids and microgap in both internal and external connections of screw-type abutments before and after occlusal loading.<sup>(8)</sup> The average microgap was 2.34  $\mu\text{m}$  in the internal connection after the occlusal loading and 4.14  $\mu\text{m}$  in the external connection. In their study, for the first time, mechanical conditions in the mouth were artificially simulated according to the human chewing criteria. A methylene blue dye was also used to determine the microleakage, which has a high absorption spectrum. They concluded that by increasing the number of mechanical cycles, the gap would increase due to the deformation of the titanium. Also, the amounts of methylene blue and microgap were greater in the external connections compared to the internal ones.<sup>(8)</sup> In the present study, the mean microgap in the control group was 3.43  $\mu\text{m}$ , which is very close to the findings of the mentioned study. However, in the present study, methylene blue dye leakage was reported qualitatively.

Rismanchian et al evaluated microgaps and microbial leakage at the level of 36 abutments of Straumann® system in four groups.<sup>(11)</sup> The abutments included Cast On, Castable, Solid, and Synocta. Their results showed that the use of different types of abutments affects the mean microgap and the mean cultured colonies in all IAIs during the first 5 hours, but the effect on microleakage at 24 hours, 48 hours, and 14 days was not significant.<sup>(11)</sup> In the cited study, the specimens were not loaded, but in the present study, all specimens were subjected to cycling loading,

and the dimension of microgap was measured in six randomly selected sections under the microscope. Therefore, it seems that in the present study, the measurements were made more accurately and more objectively.

In a study by Dias et al, the size of microgap and the amount of bacterial leakage between the implants and the abutments were investigated in five different systems with external hexagonal connections.<sup>(18)</sup> According to their results, the microgap width was reported to be less than 3  $\mu\text{m}$  in all studied systems.<sup>(18)</sup> In the present study, the mean microgap in the control group was 3.43  $\mu\text{m}$  after cyclic loading. One of the weaknesses of the cited study was the examination of the samples under static and non-loading conditions.

The size of the microgap at the IAI has been reported to be about 50  $\mu\text{m}$ .<sup>(8)</sup> Such value was reported to be 7-74  $\mu\text{m}$  in the study by Rismanchian et al based on the type of abutment.<sup>(11)</sup> In a study by Piattelli et al, the size of the microgap was 2-7  $\mu\text{m}$  in a screw-type abutment and 7  $\mu\text{m}$  in a cemented-type abutment.<sup>(15)</sup> In a study by Jensen et al, the microgap size was less than 10  $\mu\text{m}$  in all implants.<sup>(21)</sup> In the current study, the mean microgap size was 3.43  $\mu\text{m}$  in the control group and 0.87  $\mu\text{m}$  in the test group. Different sizes of microgap in various studies suggest that further studies and novel techniques are required to improve the implant-abutment connection.

Numerous methods have been recommended to prevent or reduce bacterial contamination at the IAIs, such as the use of sealant materials, decontamination of the internal cavity of the implant, and the use of shape memory alloys.<sup>(9)</sup> The present study demonstrated that the application of GapSeal® does not guarantee a complete seal but significantly reduces the number of gaps and microleakage. These data are consistent with the findings of a study by Nayak et al who investigated the effect of GapSeal® and O-ring on the microleakage at the IAI.<sup>(10)</sup> Their results showed that GapSeal® is more effective in reducing the leakage than O-ring.<sup>(10)</sup> Accordingly, the results of this study show the positive effect of GapSeal® on microleakage reduction. Also, Nayak et al examined their specimens without applying mechanical forces.<sup>(10)</sup> However, in this study, a cyclic loading device was implemented to mimic the mastication process in the mouth. Nayak et

al concluded that because of the low viscosity of GapSeal®, it quickly flows into the interface region of the abutment and creates a better sealing than O-ring.<sup>(10)</sup> However, in this study, microleakage was evaluated using the colorimetric method, and methylene blue dye penetration was evaluated qualitatively.

The other materials proposed for sealing of the IAI are silicon membranes. Piattelli et al<sup>(15)</sup> and Pimentel et al<sup>(22)</sup>, using a silicon membrane, tried to seal the microgap at the IAI. According to their results, the silicon membrane reduced bacterial penetration but did not entirely prevent microleakage. The disadvantages of silicon membranes include film thickness and early degradation in the oral cavity.<sup>(15,22)</sup> In this study, GapSeal®, a silicon gel, was used, and it was found that the amount of gap was significantly reduced but there were still hollow spaces for bacterial and endotoxin penetration.

GapSeal® is a silicone gel that degrades over time. Further studies are needed to assess the longevity of GapSeal® and the use of antimicrobials with this material. In this study, in the control group, due to the mismatch of the implant and the abutment surfaces, significant leakage was observed.

The present study was conducted in vitro; therefore, the actual oral conditions could not be simulated. As mentioned, after the degradation of GapSeal®, its ions are released into the peri-implant tissues. As recommended by the manufacturer, GapSeal® needs to be replaced every five years,<sup>(17)</sup> so it is necessary to conduct clinical trials with regard to its biological effects.

This study had a double-blind design, and a sufficient number of samples was used in each group. In the era of modern implantology, numerous efforts have been made to prevent peri-implantitis. Reinfection of empty spaces within the IAI is a key pathogenic factor for peri-implantitis.<sup>(23)</sup> Microleakage-related factors include the applied torque, adaptation of the components, and occlusal loading.<sup>(23)</sup> Despite the precision in the process of producing implant components, implant materials cannot effectively seal the IAI.<sup>(23)</sup>

In conclusion, GapSeal® can increase the lifespan of implants by reducing the microgap size and the amount of microleakage at the IAI. Due to the lack of studies on GapSeal®, further stud-

ies on its effects are needed.

### Conclusion:

Within the limitations of the present in-vitro study, it was found that application of GapSeal® reduces microleakage at the IAI and might potentially increase the success rate of implant-assisted restorations through decreasing the biological and biomechanical complications.

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### Conflict of interests

The authors state no conflict of interest in connection with this study

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