

Sealing properties on the implant-abutment interface of a flowable silicone: an *in vitro* study

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Introduction: The literature has shown that colonization of the implant-abutment interface (IAI) by microorganisms may result in peri-implantitis and bone loss. **Objective:** The aim of this *in vitro* study was to analyze the sealing properties of flowable silicone at this interface in external hexagon implants undergoing loading tests. **Methods:** Two groups of external

hexagon implants ($n = 10$) were filled with blue dye. In the control group, no material was applied to the implant-abutment interface. The experimental group of specimens had silicone applied to this interface. **Results:** In all implants of the control group (with no silicone), IAI sealing failures occurred before reaching 100,000 cycles (cycle range from 20,000

to 79,720); whereas all experimental group implants (with silicone) reached 1,000,000 cycles without sealing failures. **Conclusion:** The experiments showed that the experimental group presented significantly increased capability of sealing the IAI in comparison with the control group ($p < 0.001$). **Keywords:** Dental implants. *In vitro*. Silicones.

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Introduction

The use of oral implants to rehabilitate partially and completely edentulous patients has been widely recommended, but failures may occur and techniques minimizing their occurrence must constantly be researched. The factors related to failures include the following: compromised osseointegration due to intraoral bacteria and concurrent inflammatory reactions, occlusal overload and diminished implant life caused by infection. Infection develops due to bacterial infiltration into the peri-implant space, and spaces between the implant and the prosthetic components attached to it.¹

The majority of dental implant systems are comprised of two components: the intrabone part (implant), which is placed during the first surgical phase; and the transmucosal part (abutment), which is delivered after successful osseointegration, as support to the prosthetic restoration. Once the abutment is subgingivally placed, it makes contact with the soft peri-implant tissue, and the spread of bacteria into the implant body is almost inevitable.¹

Several implant and abutment designs have been developed by manufacturers. In general, implant-abutment connections can be divided into external or internal types. The connection configuration plays an important role in transferring occlusal forces to the bone, and mechanical stability of the implant-abutment connection is critical to avoid prosthetic complications and biological implications arising from these factors. Under occlusal forces, micro movements may occur between the abutment and the implant,

thereby resulting in loosening of the abutment screw or the crown. These micro movements help create microgaps, leading to bacterial leakage into the implant-abutment interface (IAI), which causes local inflammation, thus resulting in bone loss on the marginal ridge.^{2,3}

In studies employing static tests, no bacterial infiltration was observed when abutments were cemented to the implant.⁴ In other cases, the period of contamination between implant and abutment was reduced with the use of silicone to connect prosthesis and implant.⁵

The objective of this study was to analyze the effect of sealing the implant-abutment interface of external hexagon implants with silicone, after a mechanical cycle test. This study raised the hypothesis that the experimental group would show better sealing than the control group (with no silicone).

“Failure of the implant-abutment fixture to adapt may cause uneven masticatory loads on the surfaces, thus resulting in bone loss around the implant.”

Material and methods

In this study, two groups of implants were compared, each group being comprised of ten external hexagon implants (Conexão Sistema de Prótese, Arujá, São Paulo, Brazil) filled with 0.02 ml of toluidine blue. In the first group (control), no material was applied to the implant-abutment connection. The second group (experimental) had silicone applied to the interface.

The silicone selected was Pesilox™ (Adespec, São Paulo, Brazil), which was applied evenly around the external hexagon implant platform with the aid of a syringe. Both connection and torque were applied immediately after using Pesilox™. For both groups, the connection to the abutment was made by applying a torque of 10 N, measured with an electronic torque wrench.

Twenty samples were put into their respective receptacles and fixed with acrylic resin, in accordance with ISO 14801 standard and in compliance with the angle and spacing criteria for loading geometry (Fig 1).

After applying torque, the space between the acrylic resin and the receptacle edge was filled with water, so that the color change, indicating dye extravasation, could be visualized. The samples were set on the cycler in accordance with ISO 14801 standard, according to which they should be subjected to a frequency of 2 Hz in an aqueous medium and cycled until dye extravasation, or up to a maximum of 1 million cycles in case of no extravasation.

Results

All samples from the control group showed dye extravasation before 100,000 cycles (Table 1); whereas no sample from the experimental group showed dye extravasation within a period of up to 1 million cycles. Figure 2 shows a sample from each group after cycling. The left sample is an example from the control group and clearly shows dye extravasation. The right sample is from the experimental group which remained sealed and presented no dye extravasation.

The median for the control group was of 56,189 cycles. Mann-Whitney test revealed statistically significant difference between groups according to the number of cycles until dye extravasation. The number of cycles for extravasation to occur was considerably lower in the control group in comparison with the experimental group ($p < 0.001$). An average of 54,430 cycles was needed to observe dye extravasation in the control group (the sample data for the control group showed normal distribution), and all samples in the experimental group reached

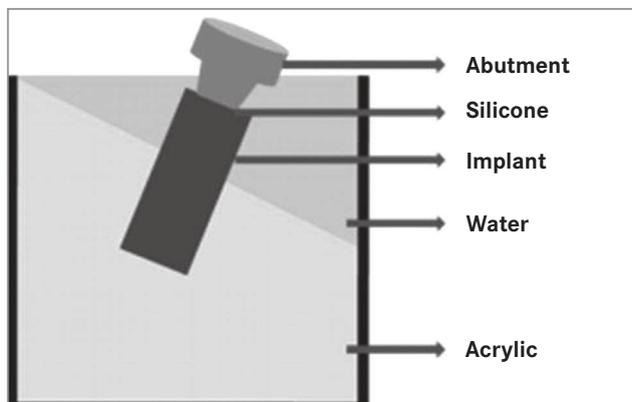


Figure 1: Specimen illustration.

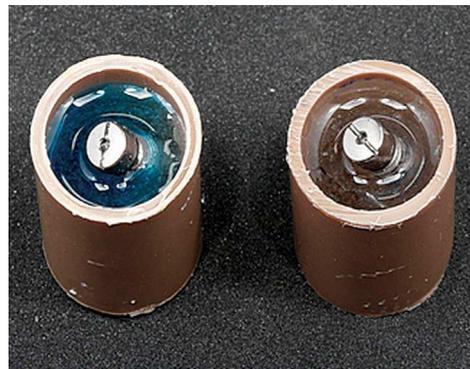


Figure 2: Comparison of specimens showing that dye extravasation was observed only in the control group (on the left).

Table 1: Descriptive results.

Group	Sample	Dye extravasation	Number of cycles until extravasation
Control (no silicone on implant abutment interface)	1	Yes	20,000
	2	Yes	30,195
	3	Yes	30,195
	4	Yes	50,161
	5	Yes	50,161
	6	Yes	62,217
	7	Yes	62,217
	8	Yes	79,720
	9	Yes	79,720
	10	Yes	79,720
Experimental (with silicone on implant abutment interface)	1	No	*
	2	No	
	3	No	
	4	No	
	5	No	
	6	No	
	7	No	
	8	No	
	9	No	
	10	No	

* cycling interrupted after 1 million cycles without extravasation.

Table 2: Statistical results.

	Control group	Experimental group
Sample size	10	10
Minimum (# of cycles)	20,000	1,000,000
Maximum (# of cycles)	79,720	-
Mediana	56,189*	1,000,000
Median	54,430	1,000,000
Standard deviation	22,202	
Standard error	7,021	

* statistically significant difference $p < 0.001$.

1,000,000 cycles with no dye extravasation (showing no normal distribution, thus justifying a nonparametric test) (Table 2).

Discussion

Failure of the implant-abutment fixture to adapt may cause uneven masticatory loads on the surfaces, thus resulting in bone loss around the implant.⁶ Considering that the masticatory load applied by the implant on the bone support is higher than that applied by a natural tooth due to the absence of periodontal ligament, if the force used exceeded the physiological threshold, then the implant could be lost due to overload.⁷ With better adaptation of prosthetic components parts, the stress transferred to the bone would be lower.⁸ In this study, the sealing capability of the implant-abutment interface of external hexagon implants undergoing mechanical loads *in vitro* was evaluated, simulating a functional implant.

Successful implantation is dependent on several factors and follows some basic principles, for example, loading support and distribution on adjacent tissues. In this sense, it is important to evaluate loading: as implants are used to collectively support a fixed dental prosthesis, the forces exerted on each implant and stress distribution over tissues have critical biological effects on the stresses and deformations expected during mechanical action.⁹

In this study, mechanical cycling tests were performed (up to 1 million cycles) to simulate 40 months of masticatory function.^{10,11} On the other hand, some studies have evaluated infiltration based on static tests only.¹²

However, even with mechanical cycling, it was observed that silicone effectively sealed the implant-abutment interface.

In the implant-abutment system, the connection usually presents microgaps that are responsible for bacterial infiltration, causing tissue inflammation and compromising restoration longevity.¹ Implant contamination is favored by several types of periodontal pathogens growing within the microgap, thus leading to peri-implantitis.¹³

Several authors have tested different implants and material used in the implant-abutment connection in an endeavor to prevent microleakage. Duarte et al¹² evaluated the microleakage in external and internal hexagon implants using static tests. For the samples of the experimental group, silicone or dental sealants were used as sealing material in the cervical area of the implant. The specimens were analyzed for up to 63 days in order to check for infiltration which was observed after 14 and 35 days in the control and experimental group, respectively. Based on these results, the authors stated that the types of material used in the study were not able to seal the interface.

Tests in edentulous patients, using a 0.2% chlorhexidine solution inside the implant (in the experimental group) and saline (in the implant control group), resulted in no significant difference with regard to infiltration; however, the bacterial volume detected in the test group was smaller compared with the control.¹⁴ Duarte et al¹² and Groenendijk et al¹⁴ observed that the presence of the above-mentioned types of material had no significant effect on postponing or preventing infiltration.

On the other hand, another study¹⁵ stated that, with the use of silicone in patients with a high oral hygiene index, contamination analysis performed two months after prosthetic reconstruction was positive for seven out of nine samples for the control group *versus* two out of eight implants for the group in which silicone was used. In other words, contamination can be reduced by means of using silicone, as it was also observed in the present study.

The IAI sealing was evaluated with dye, a method similar to that used by another author,¹⁶ instead of using microorganisms.^{5,12,14,15,17,18} In studies based on bacteria, the implant and abutment are screw-retained to one another and submerged in a culture solution. After a certain incubation period, the abutment is unscrewed and a sample is taken from the inside chamber of the implant. With the use of these methods, it is impossible to identify the exact time when infiltration occurs, and contamination could occur at the time of sampling, showing false-positive results. For this reason, the use of dye inside the implant was preferred because it more accurately indicates the time when the sealing ruptures and extravasates.

Koutouzis et al¹⁹ carried out an *in vitro* study with cyclic simulation and identified the differences in implant designs that could affect a potential invasion by oral microorganisms into implants, which is a similar result to that observed by Tesmer et al.²⁰ Authors have also reported that bacterial colonization at the interface occurs in different types of connections: external hexagon, internal hexagon and tapered.^{21,22} Teixeira et al²³ observed that, at present, there are no prosthetic connection systems able to completely prevent bacterial colonization within implants.

Several techniques and types of material have been used at the implant-abutment interface to seal the connection. Studies have shown that infiltration can be postponed, but not to a significant extent, thus resulting in the sealing failure observed for these types of material.^{12,14} On the other hand, in the present dynamic study, Pesilox™ silicone applied to the external hexagon implant-abutment interface significantly reduced infiltration. The successful sealing of the silicone used in this study could be related to its flowable properties, in association with careful and uniform delivery around the platform with the use of a syringe, and attachment to the abutment immediately after applying the silicone.

External hexagon implants were tested in this study because they are considered the worst case scenario in terms of prosthetic connection, but the limitations of this study should be considered, as this was the only connection tested. The biocompatibility of Pesilox™ silicone still requires further evaluations before clinical use. Another limitation refers to the laboratory nature of the study, in which the samples could not fully reproduce the mandibular movements in different directions and forces, even with the use of a cyclor. Additionally, the role of the mechanical control of the biofilm should be considered, with fundamental importance in the pathogenesis of peri-implant mucositis and peri-implantitis. With the methodology of this *in vitro* study, it was not possible to assess this factor.

Future studies are needed to evaluate different prosthetic connections and confirm both the efficiency and biocompatibility of silicones delivered to the IAI.

By means of this dynamic study, we could conclude that the use of a silicone-based material effectively sealed the implant-abutment interface, possibly preventing microbial infiltration into it, which is considered one of the factors responsible for dental implant failure.

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