For some decades, external hexagon implants have been used for oral rehabilitation in single, partial, and edentulous patients.1,2 Despite the success of oral rehabilitation using osseointegrated dental implants, the intervention remains prone to limitations3–5 and biologic,6–8 mechanical,9–18 and esthetic failures.19 These failures occur predominantly in single implant-supported prostheses.2 The most common biomechanical failure in single implant-supported prostheses is screw loosening11 and a consequent vertical misfit of the implant-abutment interface.20–22

According to Gehrke et al,2 external connections compared with internal connections present lower fracture strength and a higher mean microgap.2 Many studies examine the clinical consequences of misfit at the implant-abutment interface. Consequences include bacterial invasion into and between implant components,23,24 and loosening and rotating of the retention screws leading to complete treatment failure.8,25–30 Thus, long-term success of oral rehabilitation using osseointegrated implants is reliant on precise fit and preload of the implant-abutment components.28

In order to minimize these mechanical limitations, Seloto et al31 investigated the effects of sealing agents on preload maintenance of screw-retained implant-supported prostheses post-mechanical cycling. Int J Oral Maxillofac Implants 2020;35:479–484. doi: 10.11607/jomi.7978

Keywords: abutment, implant-supported prosthesis, preload, screw

Purpose: This in vitro study evaluated the effectiveness of a sealing agent on vertical misfit of the implant-abutment interface in an external hexagon implant system before and after mechanical cyclic loading. Effects on preload maintenance of retaining screws after mechanical cycling were also assessed. Materials and Methods: External hexagon implant systems were divided into two groups (n = 12) according to the presence of an anaerobic sealing gel (control group—no sealing gel; experimental group—sealing gel applied). A prefabricated UCLA abutment was attached to the external hexagon implant with a digital torque wrench in accordance with the recommendations of the manufacturer. Specimens were tested through mechanical cyclic loading (1 × 10^6 cycles, 2 Hz, and 130 N). Vertical misfit of the implant-abutment interface was analyzed using a stereomicroscope, and reverse torque values were obtained using a digital wrench. Misfit and reverse torque data were measured and analyzed via analysis of variance (ANOVA) and the Tukey least significant difference test (α = .05). Results: The sealing gel promoted lower vertical misfit values in the test group after mechanical cycling compared with before cycling (P = .009). The control group showed lower reverse torque values for retaining screws compared with the initial torque after mechanical cyclic loading (P < .0001). However, sealing gel application promoted higher reverse torque values in the test group postcycling (P = .0003). Conclusion: Anaerobic sealing agent application improved vertical misfit of the implant-abutment interface and preload maintenance of screw-retained implant-supported prostheses post-mechanical cycling. Int J Oral Maxillofac Implants 2020;35:479–484. doi: 10.11607/jomi.7978

Keywords: abutment, implant-supported prosthesis, preload, screw

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simulate the stomatognathic system. Vertical misfit of the implant-abutment interface is one of the most common failures of and has an essential role in the clinical performance of oral rehabilitation using implant-supported prostheses. It is therefore timely to evaluate the effectiveness of a sealing agent on vertical misfit of the implant-abutment interface under mechanical cycling.

Hence, the purpose of this study was to investigate the effectiveness of a sealing agent on vertical misfit of the implant-abutment interface and preload maintenance of retention screws of external hexagon implants under mechanical cyclic loading. The null hypotheses tested were that (1) application of the sealing agent would not significantly influence vertical misfit after mechanical cycling, (2) mechanical cyclic loading would not affect vertical misfit of the implant-abutment system, and (3) sealing agent would not promote significant differences in retention screw preload maintenance after mechanical cyclic loading.

**MATERIALS AND METHODS**

A total of 24 external hexagon implants (DSP Biomedical, 4.0 × 10.0 mm) were divided into two groups (n = 12 each): EHUt control group; and EHUE experimental group). Prior to immersing specimens in polyurethane resin, the implants and prosthetic components were cleaned with deionized water using an ultrasonic unit (Cristofoli). After washing for 5 minutes, samples were dried with an air jet. The external hexagon implants were placed in polyurethane resin (Max Rubber Ind.) using a two-piece metal matrix. To stimulate oblique loading, specimens were inserted at 30 degrees of inclination in relation to their long axis. The matrix was covered with solid vaseline (Rioquímica) before implant immersion in order to facilitate removal. The metallic indenter was lubricated (Graxa Azul Universal, FBS Lubrificantes Especiais) to reduce friction. The specimens were secured with hot glue to prevent movement during mechanical testing. Implant-abutment specimens were immersed in constantly circulating distilled water at 37°C ± 2°C during mechanical cycling. After mechanical cycling, vertical misfit was analyzed as described earlier. Vertical misfit measurements were performed using a stereomicroscope (SteREO Discovery V20, Carl Zeiss) and a computer. Images were obtained using a camera (AxioCam HRC, Carl Zeiss) connected to the microscope (Figs 1 to 4). Images were processed using specific software (AxioVision, Carl Zeiss). In order to standardize horizontal positioning of the implant-abutment specimens under the stereomicroscope lens, a silicone matrix was created (Fig 5). Nine measurements were carried out in three different regions; three measurements were done at the first position of the set in the silicon matrix (opposed to the 30-degree inclination of the implant); and three measurements were made by rotating the specimen 120 degrees. The last three measurements were performed by rotating the specimen 240 degrees in relation to the initial position. Subsequently, arithmetic means of the vertical misfit values were calculated.

Vertical misfit measurements were performed prior to and after mechanical cyclic loading. Loading was carried out with an electromechanical machine in order to simulate masticatory fatigue (MSFM, ELQUIP). The values obtained before mechanical cycling were used as control values. The specimens were randomly submitted to an oblique (30 degrees) and dynamic loading force of 130 ± 10 N, at 2 Hz for 1 × 10^6 cycles (Fig 6). A semicircular metallic loading indenter (4-mm diameter) was positioned on the occlusal side of a metallic device coupled to the UCLA abutments. This was to simulate a crown, and is in accordance with the ISO 14801 standard. The metallic indenter was lubricated (Graxa Azul Universal, FBS Lubrificantes Especiais) to reduce friction. The specimens were secured with hot glue to prevent movement during mechanical testing. Implant-abutment specimens were immersed in constantly circulating distilled water at 37°C ± 2°C during mechanical cycling. After mechanical cycling, vertical misfit was analyzed as described earlier. Vertical misfit and preload maintenance data were assessed for normality with the Shapiro-Wilk test, and analyzed by two-way repeated measures analysis of variance (ANOVA) and the Tukey least significant difference test (α = .05).
RESULTS

Table 1 shows the vertical misfit measurements of the UCLA abutment/external hexagon implant system. There were no significant differences in misfit values before and after mechanical cyclic loading in the control group ($P = .101$). In the test group, lower vertical misfit values were recorded after mechanical cycling compared with before mechanical cycling ($P = .009$). Regardless of the mechanical cycling period, there was no significant difference in vertical misfit with or without anaerobic sealing gel ($P > .05$).
Table 1 Mean ± SD of Vertical Misfit Values (μm) of Abutment/External Hexagon Implant Interface According to the Presence of Anaerobic Sealing Agent and Under Mechanical Cycling

<table>
<thead>
<tr>
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<th>EHUC</th>
<th>EHUE</th>
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<tbody>
<tr>
<td>Before mechanical cycling</td>
<td>5.55 ± 1.49 Aa</td>
<td>5.44 ± 1.90 Aa</td>
</tr>
<tr>
<td>After mechanical cycling</td>
<td>4.59 ± 1.73 Aa</td>
<td>4.01 ± 1.75 Ba</td>
</tr>
</tbody>
</table>

EHUE = external hexagon implant + UCLA abutment with anaerobic sealing gel (experimental test group); EHUC = external hexagon implant + UCLA abutment without anaerobic sealing gel (control group). Different letters (uppercase in columns, lowercase in rows) indicate statistically significant differences (P < .05).

Table 2 Mean ± SD of Torque and Reverse Torque Values (N) of Retention Screw on External Hexagon Implants According to the Presence of Anaerobic Sealing Agent

<table>
<thead>
<tr>
<th></th>
<th>EHUC</th>
<th>EHUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torque</td>
<td>30.13 ± 0.09 Aa</td>
<td>30.12 ± 0.09 Ba</td>
</tr>
<tr>
<td>Reverse torque</td>
<td>24.26 ± 2.75 Bb</td>
<td>38.29 ± 5.51 Aa</td>
</tr>
</tbody>
</table>

EHUE = external hexagon implant + UCLA abutment without anaerobic sealing gel (control group); EHUC = external hexagon implant + UCLA abutment with anaerobic sealing gel (experimental test group). Different letters (uppercase in columns, lowercase in rows) indicate statistically significant differences (P < .05).

Despite the vertical misfit values for the control and test groups being insignificantly different postloading, the lower misfit values of the test group should be noted (Table 1). The results of this study explain previous findings where misfit at the implant-abutment interface has been associated with loosening of the retention screw following mechanical cycling.\(^2\),\(^17\),\(^21\),\(^22\),\(^27\),\(^28\),\(^40\)

The control group showed a torque decrease of 19.49% applied to the implant-abutment system. However, applying sealing agent to the retention screws promoted a 27.12% torque increase (Table 2). This result is in line with the vertical misfit values recorded in the present study for control and test groups following mechanical cyclic loading (Table 1).\(^2\),\(^20\)

The sedimentation effect describes the phenomenon that all machined surfaces present a certain degree of microroughness.\(^20\) Thus, when torque is applied, contact between the retention screw threads and the inner implant surface initially occurs as a result of their microroughness. After a few seconds or minutes, deformation and flow of surfaces occurs, in a process known as inclusion relaxation.\(^31\) According to Breeding et al,\(^41\) deformation and flow of surfaces reduces torque by 2% to 10%. This explains the clinical significance of retightening retention screws some minutes after the first torque was applied.\(^29\),\(^41\),\(^42\)

In this study, mechanical cyclic loading fatigue was performed in order to investigate the effectiveness of a sealing agent on vertical misfit of the implant-abutment interface. The equipment was calibrated to operate for \(1 \times 10^6\) cycles, which simulates approximately 5 years in the oral cavity.\(^20\) The test group had significantly different vertical misfit values after mechanical cyclic loading (P = .009, Table 1). Although there was no significant difference in control group vertical misfit before and after mechanical cyclic loading, a slight decrease should be noted (Table 1). Assembly adjustments caused by deformations after loading could explain the decreased vertical misfit values after mechanical cyclic loading.\(^2\)

DISCUSSION

The use of a sealing agent promoted no difference in vertical misfit regardless of the mechanical cycling period; thus, the first null hypothesis was accepted (Table 1). The second null hypothesis was rejected since mechanical cyclic loading had influenced vertical misfit of the implant-abutment system (Table 1). Finally, analysis of the effectiveness of the sealing agent on preload maintenance led to a rejection of the third null hypothesis (Table 2).

In this study, mechanical cyclic loading fatigue was performed in order to investigate the effectiveness of a sealing agent on vertical misfit of the implant-abutment interface. The equipment was calibrated to operate for \(1 \times 10^6\) cycles, which simulates approximately 5 years in the oral cavity.\(^20\) The test group had significantly different vertical misfit values after mechanical cyclic loading (P = .009, Table 1). Although there was no significant difference in control group vertical misfit before and after mechanical cyclic loading, a slight decrease should be noted (Table 1). Assembly adjustments caused by deformations after loading could explain the decreased vertical misfit values after mechanical cyclic loading.\(^2\)
As previously mentioned, the surfaces of the implant components are not completely smooth. This creates microspaces between the retention screw and implant inner surface, as shown in Fig 7. These interfere negatively with preload maintenance of screw-retained implant-supported prostheses.31 The sealing agent fills empty spaces between the screw and inner walls of the implant due to its flow capacity. This creates a single structure that absorbs shock and vibration under external loading influence.31

According to Seloto et al,31 higher preload can be obtained with higher insertion torque, as well as a lower friction coefficient between the component surfaces.31 These factors could be influenced by the finish and etching of the screw surface, thread hardness, material, torque velocity, screw tolerance, lubrication, and contact of the implant-abutment screw interface system. The sealing agent acted as lubrication due to its viscosity, reducing friction between the component surfaces31 and increasing the screw preload16 and reverse torque.31 Hence, anaerobic sealing gel could be used to minimize the most common biomechanical limitations and failures of external connections, retention screw loosening, and vertical misfit of the implant-abutment interface.

According to the manufacturer, the sealing agent is intended only as an anaerobic adhesive. It is designed for the locking and sealing of screws, which require normal disassembly using specific hand tools.44 For other intentions, use of the sealing agent is advised against.44 The substance itself is not dangerous and contains no nocive substances outside EU - Regulation (EC) No 1272/2008.44 Postcuring, the sealing agent is fully secure and immovable.44 It is relevant here to emphasize that this was an in vitro study. As such, evaluation of the biocompatibility and cytotoxicity of the sealing agent in situ and/or in vivo conditions was not one of the aims of the present study. Without future studies proving the effectiveness of the sealing agent in clinical conditions, the use of this agent by clinicians cannot be condoned.

Some limiting factors should be considered in reference to this study. First, only one sealing agent was used, and the implant components were all from one manufacturer. Consequently, results may not be transferable to designs or items produced by other manufacturers. In addition, it is important to re-emphasize that this study was an in vitro study. It is therefore not recommended that this sealing agent be used clinically before further analyses evaluate its biocompatibility, cytotoxicity, and solubility in oral fluid.

**CONCLUSIONS**

Based on the findings and within the limitations of this in vitro study, the following conclusions were drawn. Mechanical cyclic loading resulted in satisfactory adaptation of the implant-abutment interface under sealing agent action. Sealing agent application yielded more satisfactory preload maintenance of the UCLA abutment/external hexagon implant system. It did not interfere with vertical misfit of the implant-abutment interface.

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**REFERENCES**


**Fig 7** Microcomputed tomography scan of the UCLA abutment and external hexagon implant system.


