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# EVALUATION OF THE EFFECTIVENESS OF GAPSEAL IN ELIMINATING MICRO-LEAKAGE AT THE IMPLANT-ABUTMENT INTERFACE

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**Abstract:**

The study examined the effectiveness of the GapSeal in prevention of bacterial invasion through a micro gap in the implant-abutment joint by evaluating clinical parameters, as well as qualitative and quantitative assessment of the level of contamination of the internal components of dental implants. The results of clinical and microbiological studies confirmed the effectiveness of GapSeal, which resulted in minimal bacterial contamination and no signs of inflammation in the dental implant area.

**Keywords:** dental implants, bacterial invasion, microflow, peri-implantitis, mucositis, implant-abutment interface

**INTRODUCTION.** Two-component dental implant systems (DIS), consisting of an intraosseous implant and an abutment, are considered the best treatment option for prosthetics of dental defects. However, the presence of a micro gap at the implant-abutment interface (IAI) can lead to bacterial penetration, which can contribute to the development of peri-implantitis [1, 3]. Thus, ensuring the tightness of the IAI from bacterial colonization can be a long-term success factor. There are many types of dental implants with a distinctive joint design that have certain advantages and disadvantages. Traditionally, there are such types of connections as internal and external hexagonal, monolithic, conical screwless, screw cone, planar internal and external connections, etc. [7, 9, 10]

The modifications of the abutment that have occurred are numerous and complex. For example, the outer hexagon has undergone several modifications in height and width. In addition to the size change, other modifications were also carried out to improve the original design of the outer hexagon, which also affected the tightness of the IAI [6, 8].

Experimental studies on the degree of tightness of implantation systems depending on the type of connection of the elements by evaluating microbial contamination of the internal interface, as well as the effectiveness of sealing preparations (GapSeal) were conducted by us in a static position of the samples, which does not allow us to assess the effect of cyclic loading on the size of the micro gap and bacterial contamination through IAI. It should be borne in mind that transverse occlusal loads (cyclic load) on the prosthesis during operation cause bending and micro-movement of the entire DI system, increase the gap at the joint and create a pumping effect between the inner surfaces of the implant and surrounding tissues [2, 4, 5].

Based on the above, the study of the level of micro-leakage in the IAI area is This is an urgent task, which is due to the wide range of joint design typical for each manufacturer of dental implant systems.

**THE AIM OF THE STUDY** was to study the effectiveness of GapSeal in preventing micro-leakage in the IAI by evaluating bacterial contamination after 6 months of functional load.

**MATERIALS AND METHODS.** An open prospective randomized clinical trial using the "split-mouth" design was conducted at the Department of Maxillofacial Surgery of the Tashkent State Dental Institute. The study included 40 patients with partial secondary adentia, who were selected in accordance with the following criteria for inclusion in the study: the presence of a bilateral terminal or bilateral included defect in the distal parts of the dentition; the width of the KG around the DI > 2 mm; sufficient bone tissue in the area of the planned DI; signed informed consent of the patient.

Patients under the age of 18 and over 70 years old were excluded from the study; with complete adentia or unilateral dental defects; with scars, ulcers, erosions on the mucous membrane; poor oral hygiene, active smokers; with mucositis, peri-implantitis; a history of unsuccessful dental implantation or GBR / gingivoplasty; patient's refusal to participate; allergic to drugs used in the study; systemic use of drugs that affect healing; bruxism; with autoimmune and inflammatory diseases of the oral cavity; with

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periodontitis of moderate and severe severity. General exclusion criteria: pregnancy, lactation, chronic diseases at the stage of decompensation, tumor processes, systemic diseases of connective tissue, violation of the hemostasis system or taking drugs that affect clotting; taking immunosuppressants, GCS; taking drugs that affect bone metabolism; hepatitis, AIDS and tuberculosis.

23 men and 17 women were selected, the average age was 49.5 ± 2.7 years. The total number of defects was 80, 35 in the upper jaw, and 45 in the lower jaw. The number of included and terminal bilateral defects was 52 and 28, respectively. Prior to the interventions, all patients underwent a standard general clinical and laboratory examination.

The subjects underwent two-stage delayed-load dental implantation according to the standard procedure. A total of 114 TSIII SA dental implants (Osstem Implant, Seoul, South Korea) were installed. Based on the design of the study, GapSeal was applied to the inner surface of the dental implant attachment on one half of the dentition before installing the abutment, and the abutment was fixed on the other half without applying a sealing material.

Clinical research methods included examination of the oral cavity at each stage of implant treatment (hyperemia, pain, rashes, purulent discharge, bleeding, etc.), probing depth, values of the modified gingival index (MGI), plaque index (PI) and Bleeding on Probing (BoP) 6 months after fixation of the orthopedic structure. Probing depth was measured at 6 points around the implants (mesial-buccal, mid-buccal, distal-buccal, mesial-lingual, mid-lingual, and distal-lingual) 6 months after loading).

For microbiological evaluation, DI was isolated with sterile cotton pads. All samples were taken immediately after detaching the abutment/crown. A sterile gas-tight syringe (Hamilton, Grisons, Switzerland) with a volume of 25 ml was injected with 10 ml of sterile saline solution into the implant shaft. A sterile removable 22-gauge needle (51 mm long) was used, which was replaced after each sample collection. The saline solution was immediately drawn back into the syringe and transferred to a sterile Eppendorf tube containing 250 ml of BHI. The implant was abundantly washed with chlorhexidine solution and dried. All dental plaque present on the implant neck or artificial crown was removed. The abutment/crown was fixed according to the manufacturer's instructions. The hole to the DI shaft was filled with PTFE tape and a light-curable composite restoration material.

The samples were cultured on blood agar. 50 ml of a pure sample and 50 ml of a sample diluted in a 1:10 ratio in sterile BHI were seeded in two copies and incubated at 37°C under aerobic conditions or at 37°C under anaerobic conditions for up to 5 days. After the incubation period, the Petri dishes were removed, and the growth of bacterial colonies was evaluated. The bacterial density was calculated and expressed in colony-forming units ($*10^2$ CFU/ml) using the OpenCFU program. The microflora was identified by morphological characteristics, enzymatic activity, and pathogenicity factors. The enzymatic activity was studied in accordance with the differential characteristics of the genus: the saccharolytic activity was determined in liquid and semi-liquid carbohydrate-containing media with indicator systems.

The statistical analysis was performed using the OriginPro 8.6 program (OriginLab Corporation, USA) using the One-way ANOVA method. $p<0.05$ was considered statistically significant.

**RESULTS.** The analysis revealed statistically significant ($p<0.05$) differences in clinical parameters – bleeding during probing, probing depth, MGI – high values were observed in the control group of dental implants without sealant. Bleeding during probing was found around two dental implants with sealant, and in the control group – in 15. The plaque index had no statistically significant differences between the groups (Table 1).

**Table 1. Clinical indicators of the studied groups**

| Indicator | GapSeal (n = 57) | Control (n = 57) |
|---|---|---|
| Bleeding on Probing<br>positive result, n (%)<br>mean | <br>2 (3,5%)<br>1,05 ± 0,22* | <br>15 (26,3%)<br>2,12 ± 0,36* |
| Probing depth | 0,88 ± 0,28* | 2,24 ± 0,84* |
| MGI | 0,52 ± 0,32* | 2,54 ± 0,68* |
| PI | 1,81 ± 0,42 | 2,21 ± 0,22 |

** p <0,05*

In 4 patients, signs of mucositis were visualized around dental implants without sealant – hyperemia, swelling and pain, which became an indication for the appointment of local anti-inflammatory therapy.

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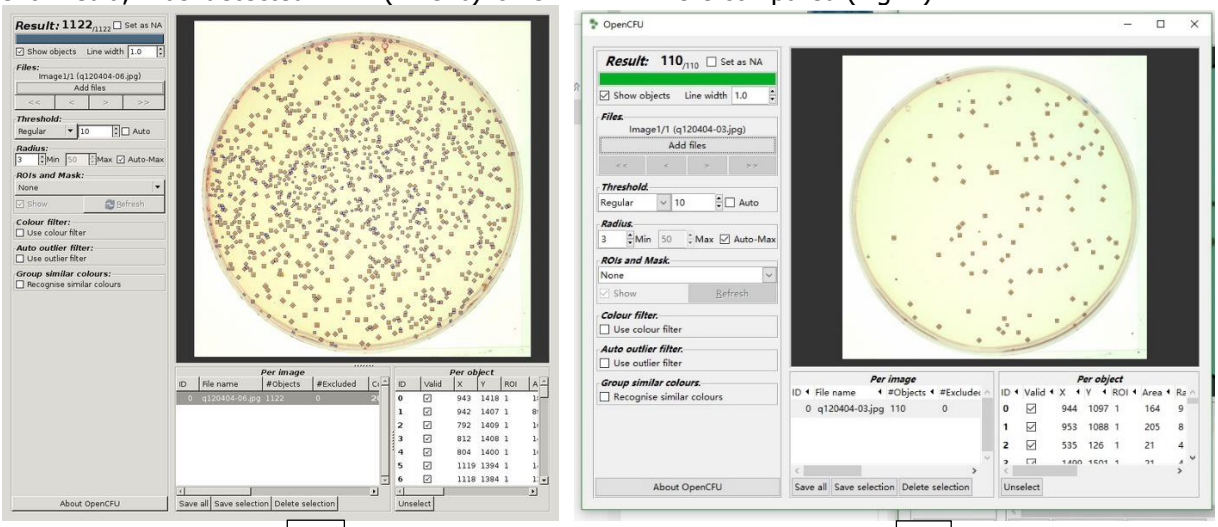
Microbiological examination also revealed statistically significant differences. Internal bacterial colonization, which is indicated by the isolation of bacteria from the internal interface of the implant after culture of samples in nutrient media, was detected in 7 (12.3%) of 57 samples of dental implants with GapSeal and in all 57 samples of dental implants of the control group. The total number of CFU isolated from each sample was calculated and the levels of bacterial contamination were compared (Fig. 1).




а б

**Fig. 1. CFU counting process using the OpenCFU program: a – control, b – sample with GapSeal**

In 7 samples of dental implants with sealant, in which microbial invasion was detected, the contamination index was in the range of 6.22 ± 2.05 *$10^2$ CFU/ml. High values were obtained in the samples of the control group – the average value was 255.64 ± 8.94 *$10^2$ CFU/ml (Table 2).

**Table 2. Bacterial contamination (*$10^2$ CFU/ml)**

| CFU | Samples | | | |
|---|---|---|---|---|
| | GapSeal | | control | |
| | Aerobic culture | Anaerobic culture | Aerobic culture | Anaerobic culture |
| **no growth** | 52 (91,2%) | 50 (87,7%) | 2 (3,5%) | 1 (1,8%) |
| **1 – 250** | 5 (8,8%) | 7 (12,3%) | 24 (42,1%) | 22 (38,6%) |
| **251 – 1000** | 0 | 0 | 28 (49,1%) | 28 (49,1%) |
| **>1000** | 0 | 0 | 3 (5,3%) | 6 (10,5%) |

The species composition was dominated by Enterococcus faecalis, which were found in 5 (71.4%) contaminated dental implant samples with GapSeal and in 45 (78.9%) samples of the control group. The reason is that Enterococcus faecalis is a facultative anaerobe from 1.0 to 1.5 microns in size, which is small enough to penetrate through micro–gaps from 2.3 to 100 microns in size at the junction of the implant and the abutment. Lactobacilli, C gingivalis, Bacteroides fragilis, and S mitis were found in four samples of dental implants with GapSeal. The above microbes were identified in all samples of the control group. In addition, A actinomycetemcomitans and S oralis were found (Fig. 2).

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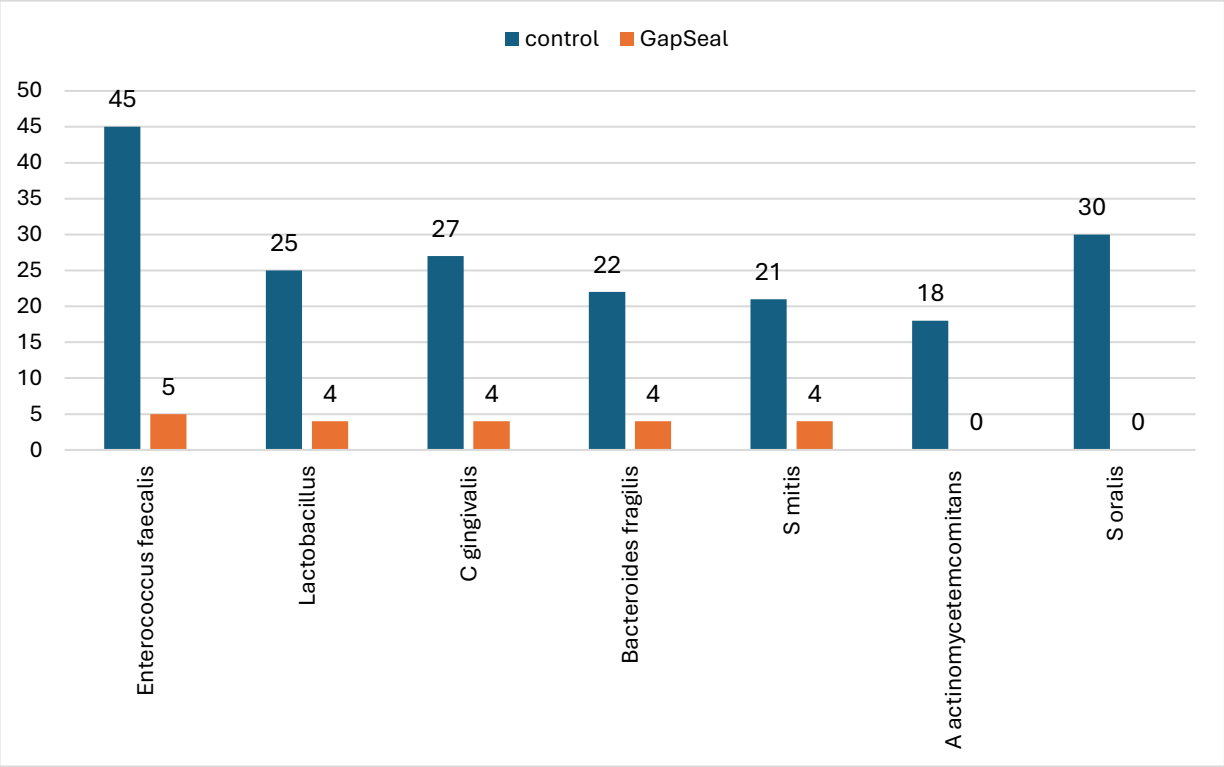


**Fig. 2. Frequency of microorganisms' indication**

**CONCLUSION.** The results of the study demonstrated the high effectiveness of the GapSeal sealing preparation, which significantly reduced in vivo the level of bacterial invasion into the internal structures of the dental implant through the implant-abutment interface in clinical conditions after cyclic loading (using of fixed orthopedic structures on dental implants for 6 months). The effect was due to both a decrease in the micro gap at the implant-abutment junction and the presence of an antibacterial substance (thymol) in the sealant. The study confirmed the prospects of using GapSeal for the prevention of inflammatory complications caused by bacterial invasion into the internal structures of dental implants.

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