

# Long-term Assay of Iodoform Pomade in the Bacterial Control of the Inner Ambient of Dental Implants: A Randomized Clinical Trial

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**Purpose:** Bacteria can colonize the gaps in the implant-abutment interface, which can compromise the success of the implants. An antiseptic pomade was developed to try to control this contamination. The goal of this work was to assess the long-term effectiveness of the pomade. **Material and Methods:** A group of 50 patients of both sexes, aged between 25 and 80 years, was followed for one to five years in a randomized, double-blind clinical trial, with split mouth design, at the Clinest-Clinical Center of Research in Stomatology, in Juiz de Fora, MG, Brazil. Patients were randomly assessed for eligibility when they arrived at the clinic for dental implant procedures. Patients were followed up between 12 and 64 months and were included in groups of 12, 18, 24, 30, 36 and 60 months. Each patient had at least two implants placed and in all cases one implant without the ointment, was allocated to the control group and one or more implants were allocated to the test group, with the ointment applied to the cover screw. A total of 176 implants were studied, with  $n = 79$  in the control group and  $n = 97$  in the test group. Clinical signs and symptoms were searched such as pain, discomfort, inflammation, fistula, malodor and loosening of the cover screw. After removing the cover screw, the ointment was collected, and its organoleptic properties were evaluated. Its antimicrobial action was tested by assessing its ability to inhibit bacterial growth. **Results:** The signs and symptoms were absent in all implants in the test group. The control group showed signs/symptoms of bacterial colonization, such as: malodor in 47 implants; 20 implants with mild erythema around the platform; 07 implants with loose screws, including four with exposure of the cover screw and one without the cover screw, and 14 with fistula, pain and discomfort. After the flap was raised, 11 implants showed inflammatory tissue around the cover screw, with no external signs of inflammation. Among these implants 7 had malodor and 4 did not. The implant without the cover screw, did not presented malodor. The total number of implants with signs/symptoms due to bacterial colonization of the internal spaces was 52 in the control group. The ointment's organoleptic properties were reduced in the patients examined after three years but remained present. The antimicrobial action of the ointment was present after 5 years. **Conclusions:** The ointment was effective in controlling bacterial contamination of the internal spaces of the implants during the use of the cover screw, remaining effective for a period of five years. The ointment's organoleptic properties decreased after three years, but antiseptic

activity was maintained throughout the five-year study period. *Clin Int J Oral Science* 2002; 15 (1): 1- 13

**Key Words:** Antiseptic, Bacterial Contamination, Dental implants, Iodoform, Peri-implantitis

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## Introduction

**B**acterial colonization often occurs in the internal spaces of dental implants and / or in the spaces between the prosthetic abutments.<sup>1-5</sup>

The implant-abutment interface can accommodate a wide variety of bacteria, which colonize these spaces and can cause aggressions in the adjacent soft and hard tissues, such as mucositis and peri-implantitis.<sup>6</sup>

The gaps that allow the entry of microorganisms measured by SEM, between the abutment and the implant platform, can vary in different types of connections. They are larger in the external and internal hexagon systems (from 45µm to 60µm) and smaller in the conical systems (from 3µm to 5µm) but bacterial penetration can occur in all of them.<sup>4</sup>

These spaces are inevitable, and many manufacturers, clinicians and researchers have neglected their clinical significance.<sup>7,8</sup>

When this contamination occurs during the period of osseointegration, it can result in unfavorable tissue responses and lead to signs and symptoms such as pain, discomfort, malodor, abscess with formation of fistulas, which lead to bone loss and can compromise the success of the implant.

Even if the implants were not contaminated during installation, it will certainly occur during re-entry surgery at the time of abutment installation. The presence of bacterial colonization after the installation of the prostheses can be easily perceived clinically both by the peri-implant inflammation and by the characteristic bad odor, a common finding in any implant dentistry clinic.

In the case of contamination after exposure of the implant, different resources were used to eliminate or reduce this problem, such as the supragingival location of the implant platform<sup>5,9-13</sup>, the Morse-taper connection,<sup>14</sup> a silicone ring between the abutment and the implant,<sup>4</sup> and the application of antibiotics and antiseptics.

During the period of osseointegration, and throughout the use of implants, antibiotics and antiseptics were tested with little success due to their short pharmacological activity.

An ointment (Proheal, BiomacMed, Juiz de Fora, MG, Brazil) was developed<sup>7,8</sup> to control

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this contamination before and after exposure to the implant. The formulation composed of Iodoform 15,16 and Calendula Oil 17-24 was initially studied in 213 volunteer patients (811 implants), 149 patients in the development of the ointment and in 64 patients, after the final formulation, comprising a total of 252 implants in this last group. This study showed that the ointment achieved a 98% success rate in controlling bacterial contamination within the implants during the osseointegration period.<sup>7</sup> A pilot of this study was carried out and presented as a technical report.<sup>25</sup>

The aim of this work was to evaluate the long-term effectiveness of the ointment in controlling bacterial contamination of the dental implant's internal spaces.

## Material and Methods

From February 1997 to August 2002, a group of 50 patients of both sexes, aged between 30 and 80 years, was followed for one to five years in a randomized, double-blind clinical trial, using the split mouth design at Clinest - Clinical Center of Research in Stomatology (Juiz de Fora, MG, Brazil), to test the long-term effectiveness of an ointment in controlling bacterial contamination of the internal spaces of the implants and to assess whether the ointment remained pharmaceutically active for a long period of time. The split mouth design was used in this study, meaning that each patient had at least two implants installed, one without the ointment acting as a control group and the other, acting as a test group, with the ointment applied to the cover screw (Figure 1).

All patients received the necessary information and signed the Informed Consent Form.

Patients were randomly assessed for eligibility when they arrived at the clinic for implant procedures.

Patients who returned six months after implant installation were included in another study.<sup>7,8</sup>



**Fig 1** Pomade around the cover-screw at the time of installation.

In this study, the ointment was evaluated in patients who missed regular follow-up and were late for reentry surgery.

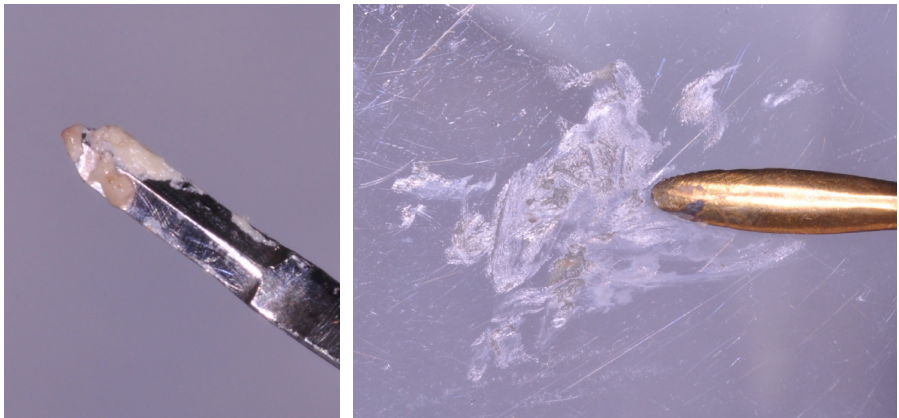
The initial follow-up times of patients were organized in groups of 6 months from one to five years, with patients being grouped as close to the initial procedure as possible (i.e., all the patients that will return between 12 and 18 months were included in the group of 12 months).

To assess the effectiveness of the ointment, clinical signs and symptoms, such as pain, discomfort, inflammation, fistula, malodor and loosening of the cover screw, were investigated, without knowing to which group the implant belongs. After removing the cover screw, the ointment was collected, and its organoleptic properties were evaluated. Its antimicrobial action was tested by assessing its ability to inhibit bacterial growth, using a bacterial culture. To assess the antiseptic activity of the pomade, a portion was

Months	Patients	Implants	Control group	Test group
12	12	39	17	22
18	11	34	15	19
24	13	49	24	25
30	03	14	06	08
36	05	19	08	11
60	06	21	09	12

collected (Fig 2), and put in a bacterial culture of the patient's saliva seeded on a culture medium. The culture was incubated for 48

hours at 37oC and the inhibition of bacterial growth was observed.



**Fig 2** Ointment collected during re-entry surgery and then tested in bacterial culture. (a) ointment on the instrument; (b) and sprayed on a Petri dish.

## Results

Fifty patients returned later, that is, at least 12 months after the initial implant installation, and were grouped according to the follow-up time.

Twenty-three patients returned before 24 months.

The follow-up times were organized in groups of 6 months, from one to five years. The groups studied were 12, 18, 24, 30, 36,

and 60. The groups of 42, 48 and 54 months did not exist because no patients returned between 40 and 60 months. The last six patients returned after 64 months and were included in the 5 years group (60 months). The total number of implants studied was 176, 79 in the control group and 97 in the test group. The distribution is shown in Table 1.

After removing the cover screw, it was found that there the ointment on the screw (Fig 3) and inside the implant (Fig 4). The

organoleptic properties of the ointment, such as smell, color and density to the touch, were present in the ointment.

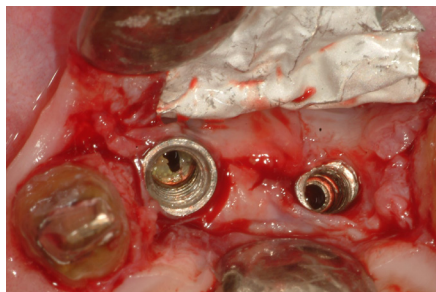
Regardless of the follow-up time, in all implants in the test group, the organoleptic properties of the ointment were practically intact. In patients who returned after three years or more, the smell and color of the ointment seemed to be reduced by

approximately 40% compared to the time of its placement, at the implant installation (Fig. 5 and 6). However, this is a subjective assessment and cannot be fully quantitatively reliable.

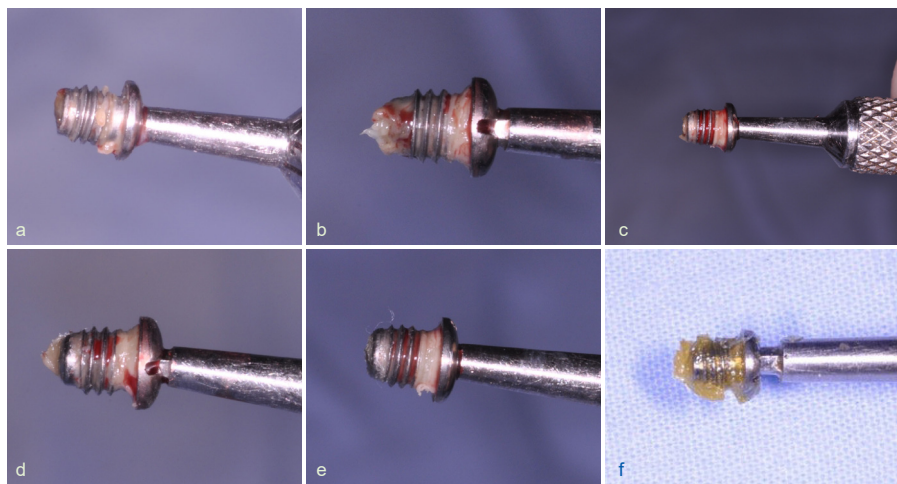
There were no signs of inflammation or fistula in any implant in the test group (Fig. 7 and 8).



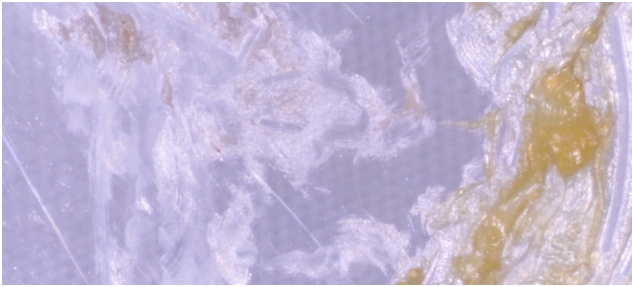
**Fig 3** Pomade around the cover-screw at the time of removal.



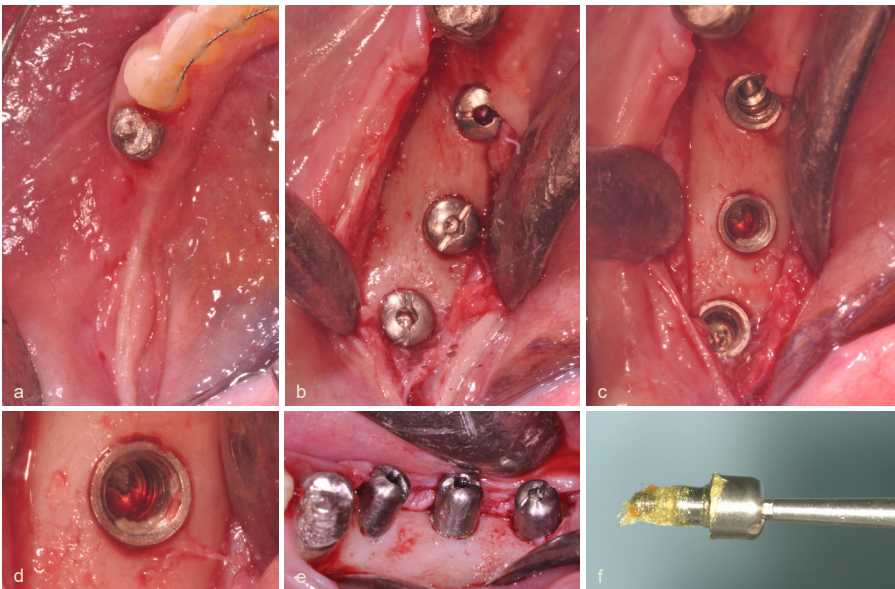
**Fig 4** Pomade inside the implants after seventeen months, during the re-entry surgery.



**Fig 5** Cover screw removed after (a) 12; (b) 18; (c) 24; (d) 36 and (e) 60 months, respectively; (f) an unused pomade on a cover-screw for color comparison.



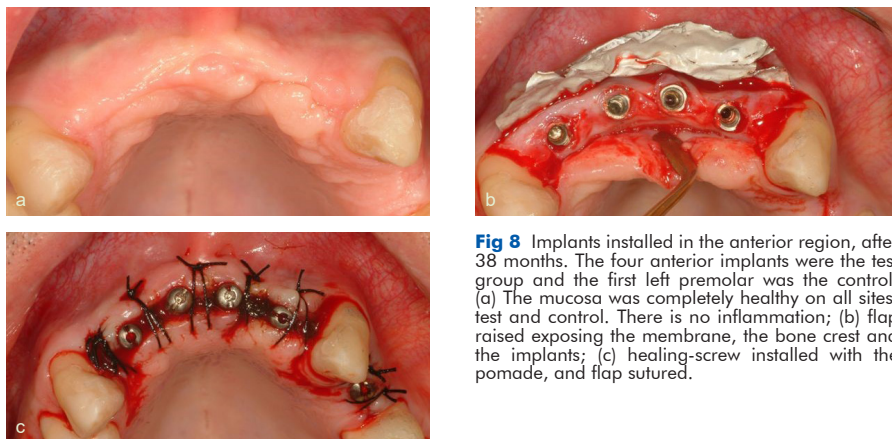
**Fig 6** Color differences between unused pomade (left) and pomade that was used in an implant after 3 years (right).



**Fig 7** Clinical case of test-group implants installed with the pomade after 24 months. (a) Healthy mucosa over the implants; (b) uncovered cover-screw showing healthy bone around the implants; (c) remaining pomade inside the implants; (d) detail of the pomade inside the implant; (e) healing screw installed with the pomade; (f) pomade around the healing screw. Note the color of the not used pomade.

The control group showed signs/symptoms of bacterial colonization, such as: malodor in 47 implants; 20 implants with mild erythema around the platform; 07 implants with loose screws, including four with exposure of the cover screw and one without the cover screw, and 14 with fistula, pain and discomfort. After the flap was raised, 11 implants showed

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**Fig 8** Implants installed in the anterior region, after 38 months. The four anterior implants were the test group and the first left premolars was the control. (a) The mucosa was completely healthy on all sites, test and control. There is no inflammation; (b) flap raised exposing the membrane, the bone crest and the implants; (c) healing-screw installed with the pomade, and flap sutured.

The antiseptic activity assessed by the bacterial culture also showed similar results. All samples collected showed almost the same inhibition of bacterial growth. A small reduction in the inhibition of bacterial growth was noted in the cases in which the pomade was present in implants for three years or more, but according to the protocol, sufficient inhibition was present, and the antimicrobial action of the ointment was present after 5 years.

## Discussion

Attempts have been made to control bacterial contamination of the internal environment of dental implants and their components, but so far no reliable evidence has been presented in the literature showing that any product has been consistently successful in this process.<sup>4,5,9-14</sup> Most of these products used, such as hydrogen peroxide, antibiotics or antiseptics, do not have long-term pharmacological activity to control microorganisms during the period of

osseointegration, let alone over the time of use in prostheses.

The present ointment was previously tested in a clinical study, 8 and showed satisfactory results. This study attempted to extend the follow-up time of the previous study to assess the long-term action of the ointment. The results show that the pharmacological action of the ointment remained beyond five years, which confers a great clinical safety zone. The results also show that the ointment can not only control the odor and, but also the other signs and symptoms and was effective during the five-year study period, a time that is well beyond the average term required for surgical and clinical activity prosthetic.

The control group demonstrated the problems frequently encountered in implantology, which until then did not have an adequate solution to the problem of bacterial control. The limitation of this study was the total randomness of the controls, only occurring when the patients attended, regardless of a scale and the small sample size. Other clinical tests must be performed, and the

results compared, in order to establish stronger evidence.

## Conclusions

The study demonstrated, within its scope, that the ointment was effective in controlling bacterial contamination of the internal environment of the implants with the cover screw and remaining effective for a period of five years. The organoleptic properties decreased, but are still present after three years, and the antiseptic activity was maintained during the study period.

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