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.

Materials and Methods: A group of 50 patients of both genders, between the ages of 25 and 80 was followed from one to five years in a pragmatic, blind, randomized, clinical trial using split-mouth design at the Clinest-Clinical Center of Research in Stomatology, in Juiz de Fora, MG, Brazil. Patients were randomly assessed for eligibility as they came to the clinic for surgical procedures. Patients had random follow-up dates between 12 to 64 months and were included in groups from 12, 18, 24, 30, 36 and 60 months. Each patient had at least two implants placed: one without the pomade, which acted as the control group and the other, which acted as the test group, with the pomade applied on the cover-screw. Overall, 176 implants were studied, n=79 from the control group and n=97 from the test group. Investigators looked for clinical symptoms such as inflammation, fistula, malodor and loss of the cover-screw. It was also observed the organoleptic properties of the pomade and tested its antiseptic activity using a bacterial culture.

Results: The symptoms were absent in all test group implants. The control group showed signs/symptoms of bacterial colonization, such as: malodor in 47 implants; 20 implants with clear erythema around the platform; 07 implants having loose screws, and among these four with a cover-screw exposition and one without the cover-screw, and 14 having a fistula. Besides these, 11 implants had inflammatory tissue around the cover-screw, without external signal of inflammation showed after the flap was raised. Among this implants 4 did not show malodor as also not the implant without the cover-screw. The total number of implants with signs/symptoms of bacterial colonization in the control group was 52. The organoleptic properties of the pomade were reduced after three years, but remained present, as did its antiseptic activity.

Conclusions: The pomade was effective in controlling bacterial contamination of the inner ambient of the implants during the osseointegration period and it remained effective for a period of five years. The organoleptic properties decreased after three years, but the antiseptic activity was maintained during the entire study period of five years.

Key Words: antiseptic, bacterial contamination, dental implants, iodoform, peri-implantitis

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Bacterial colonization frequently occurs in the inner ambient of the dental implants and/or in the spaces between the surgical or prosthetic abutments.\textsuperscript{1-5} The implant-abutment interface can accommodate a wide variety of bacteria, which in turn colonize these spaces. This bacterial colonization generally causes inflammatory reactions in adjacent soft and hard tissue, such as mucositis and peri-implantitis.\textsuperscript{6} The gap, measured by SEM, can be less than 10\,\mu m and can exist in many different types of abutment/implant geometries, but bacterial penetration can occur in all of them.\textsuperscript{4} These spaces are inevitable and most manufacturers, clinicians and researchers have so far neglected their clinical significance.\textsuperscript{7,8}

When such contamination occurs during the osseointegration period, it can result in abscess and fistula formation, which then can produce bone loss that compromises the success of the implant. Even if the implants were not contaminated during their installation, certainly it will occur during the re-entry surgery at the time of abutment installation. The presence of bacterial colonization can easily be perceived clinically by both peri-implant inflammation and malodor, the latter being a common finding in any implant dentistry clinic.

In the case of contamination after implant exposure, different resources have been used in order to eliminate or to reduce this problem, such as the supragingival location of the implant platform,\textsuperscript{5,9-13} the Morse-taper connection,\textsuperscript{14} a silicone ring between the abutment and the implant,\textsuperscript{4} and the application of antibiotics and antiseptics. In the osseointegration period, antibiotics and antiseptics have been tested without success due to the short pharmacological activity of the drugs and vehicles used.

A pomade (Proheal, Maxtron, Juiz de Fora, MG, Brazil) was developed\textsuperscript{7,8} to try to control contamination both before and after the implant exposure. The formulation was composed of Iodoform,\textsuperscript{15,16} Calendula oil, Beeswax, Lanolin and Nipazol.\textsuperscript{17-24} The pomade was studied initially in 213 volunteer patients, 149 patients while being developed and later was tested in 64 patients who had a total of 252 implants installed. This study showed that the pomade reached a 98\% success index in controlling bacterial contamination within the implants during the osseointegration period.\textsuperscript{7} A pilot of this study was carried out and presented as technical report.\textsuperscript{25} The goal of this work was to assess the long-term efficacy of the pomade in controlling bacterial contamination of the inner ambient
of the dental implant, during the osseointegration period.

In this study the pomade was assessed in patients that lost their regular follow up, and came late to the re-entry surgery. Fifty patients returned later, i.e., at least 12 months after the initial implant installation, and were grouped according to follow-up time. 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 from the control group and 97 from the test group. The distribution is shown in Table 1.

MATERIAL AND METHODS

From February 1997 to August 2002 a group of 50 patients of both genders, between the ages of 30 and 90 was followed from one to five years in a pragmatic, blind, randomized, clinical trial using split-mouth design at the Clinest-clinical center of research in Stomatology, in Juiz de Fora, MG, Brazil to test the long-term effectiveness of the pomade in controlling the bacterial contamination inside the implants and to assess if the pomade remained pharmologically active for a long time. The split-mouth design was used in this study, meaning every patient had at least two implants installed, one without the pomade acting as the control group and the other, acting as the test group, with the pomade applied on the cover-screw (Fig 1). Patients were randomly assessed for eligibility as they came to the clinic for surgical procedures. The patients that returned six month after the implant installation were included in another study.\textsuperscript{7,8}

![Fig 1 Pomade around the cover-screw at the time of installation.](image-url)
In order to assess the effectiveness of the pomade, investigators looked for clinical symptoms such as inflammation, fistula, malodor and loss of the cover-screw, without know what group the implant belongs. They also observed the organoleptic properties of the pomade and tested the antiseptic activity of the pomade using a bacterial culture. After the cover screw was removed, pomade was found to be present on the screw (Fig 2) and inside the implant (Fig 3). The pomade’s organoleptic properties such as smell, color and texture were also present in the pomade that was on the cover screw and in the implants. To assess the antiseptic activity of the pomade, a portion was collected (Fig 4), and put in a bacterial culture of the patient’s saliva seeded on a culture medium. The culture was incubated for 48 hours at 37°C and the inhibition of bacterial growth was observed.

### Table 1 Patient follow-up and implant distribution

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**Fig 2** Pomade around the cover-screw at the time of removal.

**Fig 3** Pomade inside the implants after seventeen months, during the re-entry surgery.
RESULTS

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 returned between 12 and 18 months were included in the group of 12 months). Six patients returned for initial follow-up after 64 months and were included in the 5 years group. Twenty-three patients returned before 24 months and six patients returned after five years, as showed. No patient returned between 40 and 60 months. Regardless of initial follow-up time, in all the implants of the test group the organoleptic properties of the pomade were virtually intact. The smell and the color seemed to be reduced by approximately 40% of their initial presentation in the patients that returned after three years or more (Fig 5 and 6). However, this is a subjective evaluation and cannot be totally reliable. There were no signs of inflammation nor any fistula in any test-group implants (Fig 7 and 8).

Fig 4 Pomade collected at the re-entry surgery and then used in the bacterial culture. (a) pomade on the instrument; (b) and sprayed on a glass dish.
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).
The control group of implants presented with various signs/symptoms of bacterial colonization, such as: malodor in almost sixty percent of the implants, ie, 47 implants; 20 implants presenting with clear erythema around the platform; 07 implants having loose screws, and among these four with a cover-screw exposition and one without the cover-screw; and 14 having a fistula. Besides these, eleven implants (11) had inflammatory tissue around the cover-screw, without external signal of inflammation showed after the flap was raised. From this group 4 implants did not show malodor as also not the implant without the cover-screw. Thus, total number of implants with signs/symptoms of bacterial colonization in the control group was 52.

The organoleptic properties of the pomade were reduced after three years, but remained present, as did its antiseptic activity.
The organoleptic properties of the pomade were reduced after three years, but remained present. 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.

**DISCUSSION**

Attempts have being made to control bacterial contamination of the inner ambient of dental implants, but heretofore no reliable evidence has been presented in the literature showing that any product has been consistently successful in doing so.\(^4,5,9-14\) Most of these products used such as hydrogen peroxide, antibiotics or antiseptics do not have the necessary durability or long-term pharmacological activity to control microorganisms during the

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Fig 8  Clinical case of implants installed in the anterior region, after 38 months. The four anterior implants were the test group and the first left premolar 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.
osseointegration period. Only the non-submerged, platform implants and the Morse-taper connection possessed the aforementioned qualities. However, no study proved or presented compelling evidence of their efficacy.

The pomade was tested before in a short RCT study\(^8\) -- and showed satisfactory results. This study tried to extend the follow-up time of this previous study to evaluate the pomade’s long-term action. The results show that the pharmacological action of the pomade remained beyond five years what gives a large clinical safety zone. The results also show that not only could the pomade control malodor and help to maintain cover-screw stability but also that the antiseptic activity of the pomade was effective throughout the study period of five years. The control group was demonstrative of the problems that are frequently encountered in the field of implant dentistry, which heretofore has had no adequate solution for the problem of bacterial control. The limitation of this study was the small sample size and large and long-term RCT must be done to establish more strong evidences.

**CONCLUSIONS**

Considering the limitation of the study such as the small number of the participants, it demonstrated that the pomade was effective in controlling bacterial contamination of the inner ambient of the implants during the osseointegration period and that it remained effective for a period of five years, which is well beyond the average, clinical, post-operative timeframe. The organoleptic properties were diminished but still presents after three years, and the antiseptic activity was maintained during the length of the study as showed by bacterial culture.

**REFERENCES**


