Effectiveness of Iodoform Antiseptic Pomade in the Control of Bacterial Dental Implant-Abutment Interface Contamination: A Randomized Clinical Trial

Mauro Cruz, DDS, OrthE, MFSE, MS[1] / José Maria Almeida Castro, PharmD[2]

Purpose: *Bacterial contamination of the internal spaces (gaps) of dental implants is a frequent occurrence that can cause serious problems. The aim of this study was to test and clinically improve the composition of an ointment in the microbial control of these spaces and then evaluate its effectiveness.* ***Material and Methods:*** *An ointment composed of Iodoform and Calendula Oil was improved and tested in a randomized, doble-blind, clinical trial, performed with a group of 213 volunteer patients (811 implants) of both genders between the ages of 30 and 90 at the Clinest-Clinical Center of Research in Stomatology, Juiz de Fora, MG, Brazil, from February 1997 to July 1999. Patients were randomly assessed for eligibility as they came to the clinic for implant procedures. The first group of 149 patients was used to improve the compound by controlling the results. From this group, 104 participants were studied and 45 were excluded. It was not used a control group in this phase. The ointment was applied to the threads of the cover screw at the time of implant installation. Patients were monitored monthly for six months to assess signs and symptoms of pain, discomfort, peri-implant inflammation, fistula and malodor. When any of these signs and symptoms were detected with the concomitant use of the ointment, the formulation was changed, changing the percentage of components and the new formulation was used in the next patient. When the patients had no more signs and symptoms, a group of 64 patients was studied in a split-mouth design to confirm the results without changing the composition. The mouth side were randomly assigned following a simple randomization protocol to the experimental or control group. Of this latter group of patients, 252 implants were studied. One implant in each patient was chosen to be the control, making a total of 64 implants in the control group and 188 implants in the test group.* ***Results:*** *The final formulation showed a reduction of 98% of the signs and symptoms, assayed, such as pain, discomfort, peri-implant micro-abscesses and inflammation. The control group showed 19 implants with mild inflammation, 13 with moderate inflammation, 3 implants with abscess and fistula, and malodor in 35 implants, when the cover screw was removed. Pain and discomfort were presents in all cases of moderate inflammation and abscess. In the test group, a total of 184 implants were healthy, four implants had a mild inflammatory process. It was also observed that the number of loose screws was reduced considerably. In reentry surgery, malodor was absent in all cases.* ***Conclusions:*** *This preliminary study allowed*

the improvement of the formulation according to the clinical signs and symptoms and concluded that the final formulation was effective in controlling bacterial contamination of the internal spaces of the implants. Clin Int J Oral Science 2001; 14 (1): 1-12

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

Introduction

Bacterial colonization frequently occurs in the internal spaces of the dental implants and/or in the spaces between the surgical or prosthetic abutments[1,2] and has been studied by many techniques such as microscopy, culture techniques and others.[1,3,4]

Gaps in the implant-abutment interface can serve as reservoir for bacteria, which can cause inflammatory reactions in adjacent soft and hard tissues. These micro spaces are larger in the external and internal hexagon connections ranging from 45 µm to 60 µm and smaller in the conical systems, around 3 µm to 5 µm, but the invasion of bacteria can occur in all of them4 immediately after the implantation and along the permanence of the implant. These spaces contamination is inevitable, and most manufacturers, clinicians and researchers[5] have so far neglected their clinical significance, although previous researchers have suggested that this bacterial colonization plays an important role in the etiology of peri-implantitis.[6]

A wide variety of bacterial species can colonize these spaces. The species consisted mainly of facultative and anaerobic streptococci, Gram-positive anaerobic rods such as Propionibacterium, Eubacterium and Actinomyces species and Gram-negative anaerobic rods including Fusobacterium, Prevotella and Porphyromonas species.[7]

During the re-entry surgery, in many cases, in which the mucosa appears healthy, a connective tissue with inflammatory infiltrate, can be found often around the implant and the cover-screw as a result of this internal bacterial contamination of the implants.[1]

Contamination during the osseointegration phase, can result in abscess and fistula formation, lead to bone loss, and compromises the success of the implant. Even if the implants were not contaminated during their installation, it will certainly occur during re-entry surgery or later, due to gaps in the abutment-implant interface, in which bacteria can freely enter and exit.[4] The presence of bacterial colonization can be easily perceived clinically by both peri-implant inflammation and malodor, the latter being a common finding in any implant dentistry clinic.

In case of contamination after implant

[1]Director, Clinest - Clinical Center of Research in Stomatology, Juiz de Fora, MG, Brazil.

Correspondence to: Clinest - Clinical Center of Research in Stomatology, Av. Rio Branco, 2288/1205 Juiz de Fora, MG, 36016-310, Brazil.
E-mail: mc@maurocruz.com.br

exposure, different resources have been used in order to eliminate or to reduce this problem, such as the supra-gingival location of the implant platform,[8-11] the Morse-taper connection,[12] a silicone ring between the abutment and the implant,[4] and the use of antibiotics and antiseptics in the connections. All of these devices and features have some kind of limitation. Antibiotics and antiseptics have been recommended by experts, in conferences, personal communication and in publications, such as Buckley's solution, hydrogen peroxide, neomycin, metronidazole, sodium hypochlorite and chlorhexidine. However, they showed unsatisfactory results regarding the lack of stability in loco and the time of action. It was necessary to search for a more effective option, with a longer time of action. With components that remain stable and durable within the body in contact with organic fluids.[13,14]

As a result, an ointment (Proheal®, Maxtron, Juiz de Fora, MG, Brazil) was developed trying to achieve these goals.[15] The formulation was comprised of Iodoform, Calendula oil, and special excipients.

Iodoform was chosen because of its effectiveness against anaerobes, long-acting properties and long-term use in humans in many areas of medicine.[16]

All the components were chosen based on their proven results in humans with no relevant clinical collateral effects.[17-25]

The aim of this work was to test and improve the composition of an ointment, during the osseointegration phase of the implants, through clinical signs and symptoms and, after, to evaluate the effectiveness of the final formulation in the microbial control of the internal spaces of the implants.

Material and Methods

A pomade composed of Iodoform and Calendula oil, was improved and tested in a randomized, doble-blind, controlled clinical trial performed with a group of 213 volunteer patients (811 implants) of both genders between the ages of 30 and 90 at the Clinest - Clinical Center of Research in Stomatology, Juiz de Fora, MG, Brazil, from February 1997 to July 1999. Patients were randomly assessed for eligibility as they came to the clinic for dental implant procedures. The formulation was tested, quantitatively, directly on the patients, with its free and clarified approval (Informed Consent Form), since all components are of regular use in human beings, in several areas of medicine, for a long time, and there was no risk for the patients, except, at most, the effect of a placebo.[16-25]

The first group of 149 patients was used to improve the compound by controlling the results, of the clinical data. During this phase 45 patients were removed from the study due to different reasons such as: refused to participate, lost to follow-up, became out of the criteria, moved, and other reasons. Only 104 participants were used in the study. In this phase it was not used a control group. The pomade was applied on the cover-screw in the moment of the implant installation (Fig 1).

Thus, during the tests, the formulation was changed, with the percentage of components varying according to clinical responses, until the final composition.

Implants were monitored monthly for six months to assess signs and symptoms of pain, discomfort, peri-implant inflammation,

fistula and malodor.

When any of these signs and symptoms were detected, with the use of the ointment, the formulation was changed, and the new formulation used on the next patient.

When the patients had no more symptoms, a group of 64 patients was studied in a split-mouth design to confirm the results without changing the composition of the ointment. From this group of patients, a total of 252 implants were studied. One implant in each patient was chosen to be the control group (n = 64), without the antiseptic and the others to the test group (n = 188), which received the antiseptic.

The examiners were blind to the test or control implant group. The control implant was chosen preferably in the opposite site or far from test implants.

In this phase, all patients adhered the protocol and could be followed-up during the time of the study.

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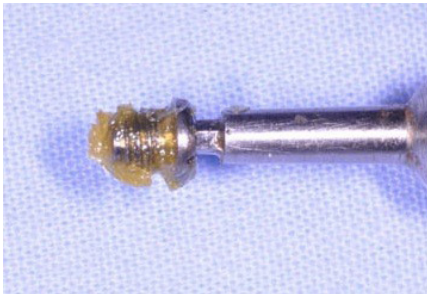

Fig 1 Proheal applied on the cover-screw, before being installed.

Results

In the first 104 patients the pomade was improved until to reach the ideal compound. The test period was from February 1997 to April 1998. The second phase that included the group of 64 patients tested in the splitmouth design was from April 1998 to July 1999. In this last phase the control group showed 19 implants with a mild inflammation, 13 with moderate inflammation, 3 implants with abscesses and fistula. All of these implants had malodor when the cover-screw was removed, 35 implants (Fig. 2, 3, 4 and 5). Overall 29 implants were healthy.

The test group showed a reduction of 98% of the signl and symptoms assayed, that is 184 of 188 implants were healthy. Four implants had a mild inflammatory process, and among these, two implants appeared to have a fistula, although this has not been clinically confirmed. It was also observed that the number of loose screws was considerably reduced in the test group (3 loose screw). In the control group 17 loosening screw were found.

It appears that the compound had an anti-rotational effect on the cover screw, preventing it from loosening.

Malodor, in re-entry surgery, was in fact absent in all cases. In all implants and cover screws, the ointment was present. The color and smell of the ointment was reduced, but they were still present (fig. 6).

Fig 2 - Bacterial contamination of the spaces between implant and cover-screw during osseointegration phase.

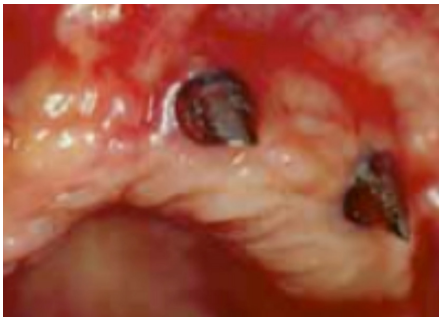

Fig 2.1 Fistula over the implants installed in the region of the upper left canine and lateral incisor during the osseointegration period.

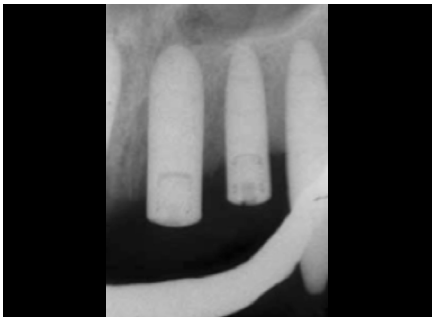

Fig 2.2 Peri-implant bone loss due to contamination of the interconnection spaces.

Fig 2.3 Reentry surgery. Soft tissue inflammation and bone loss around the implants.

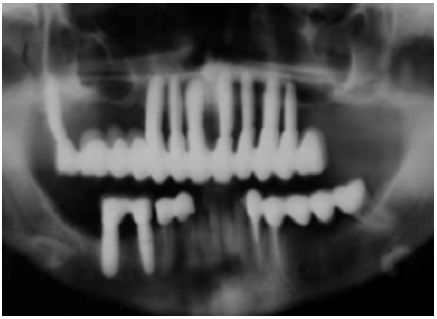

Fig 2.4 Final prostheses installed.Bone health without progression of peri-implantitis.

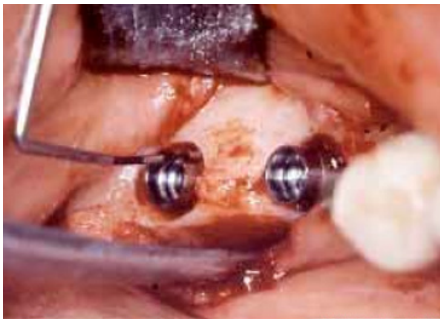

Fig 3 Aggressive peri-implant bone loss, during osseointegration phase due to bacterial contamination of the implant/cover screw interface.

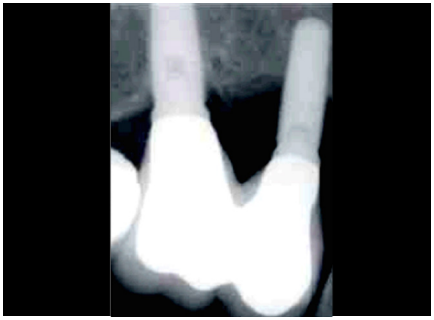

Fig 4 Final prosthesis. Bone loss due to contamination of the internal spaces of the implants. Image one year after treatment.

Fig 5 - Peri-implant abscess during the period of osseointegration caused by bacterial contamination of the internal spaces of the implants.

Fig 5.1 Implants installed in the mandibular molar region. The distances and the level of the implants are in accordance with the protocol. The bone crest is regular, with favorable healing conditions.

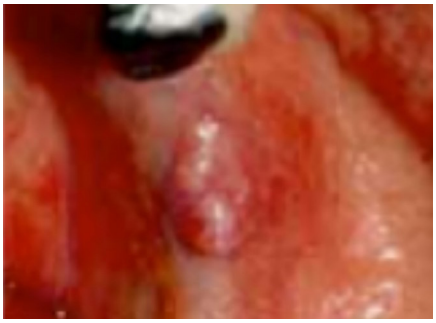

Fig 5.2 After six months, in the reentry surgery, a fistula was present in the tissues on the implants.

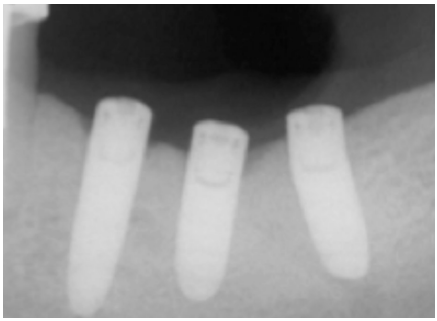

Fig 5.3 Periapical radiography shows bone loss around the implants.

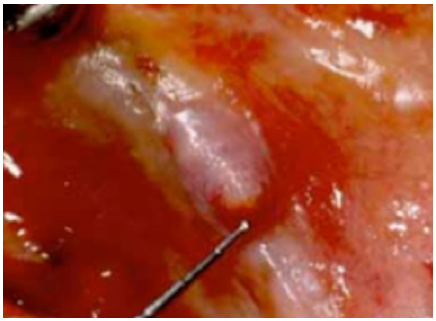

Fig 5.4 Abscess puncture with a periodontal probe.

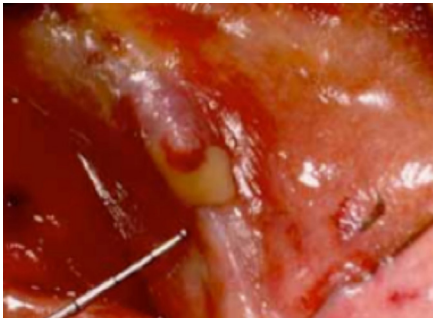

Fig 5.5 Abscess drainage. Abundant purulent secretion.

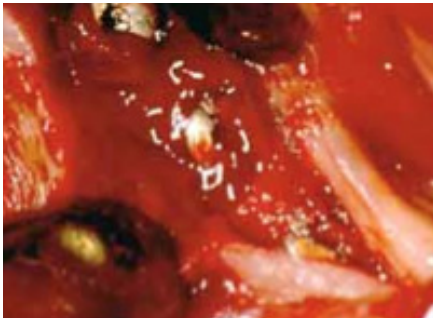

Fig 5.6 Inflammatory tissue around the implants.

Fig 5.7 Exposition of the implants after removing the inflammatory tissue.

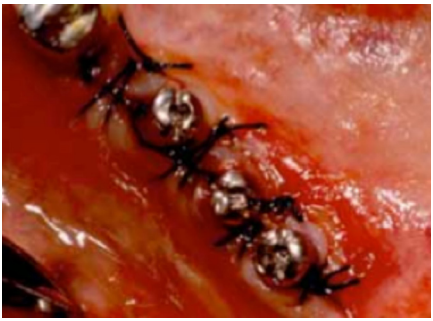

Fig 5.8 Disinfection of implants, installation of healing abutments with Proheal and suture.

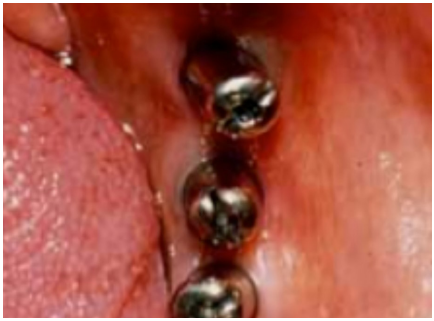

Fig 5.9 Clinical aspect after 60 days. Occlusal view.

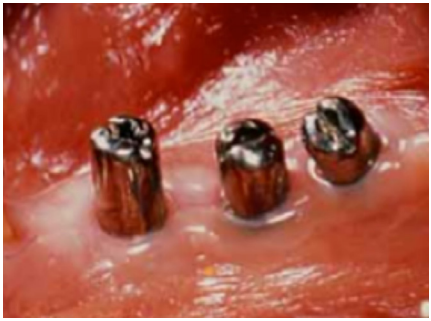

Fig 5.10 Side view.

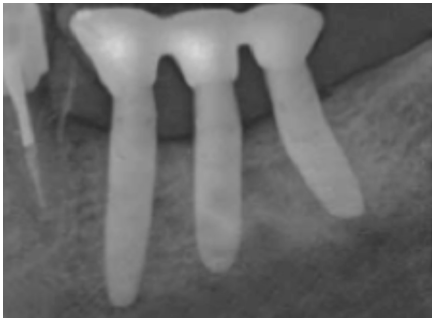

Fig 5.11 Adjacent bone around implants after 4,2 years of prostheses installation.

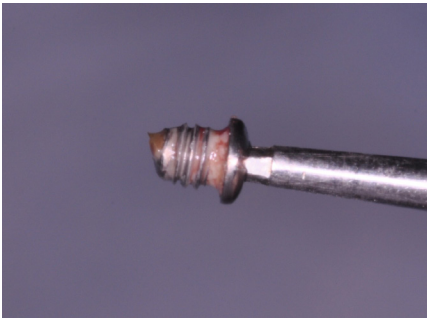

Fig 6 Proheal around the cover screw six months after installing the implant. The color and smell of the ointment is slightly altered.

Discussion

Bacterial contamination of the internal spaces of the implants, between the surgical and prosthetic components and between the prosthetic components themselves, can drastically alter the conditions of the peri-implant tissues,[1,2] but it seems to be ignored by many authors. Many studies of the behavior of implant / abutment connections[5,12] have reported that the lack of passive adjustment is a problem, but they have only focused on the problem from the biomechanical point of view. Others, however, have sought alternatives to control the problem of bacterial contamination.[2,4,7]

As the presence of gaps between components cannot be avoided, chemical or pharmacological resources seem to be the way out. The biggest challenge was to keep an effective antiseptic inside the gaps for a long period of time, capable of meeting the clinic's needs. However, the drugs used so far have not been effective in overcoming the problem.[3,8-11] Therefore, the search for a new product with these resources of long-term effectiveness seemed to be an interesting and useful idea.

This work empirically sought, based on clinical responses, a formulation capable of giving this response. The components could be tested quantitatively in this way, since they are already widely used in humans in several areas of medicine. In this way, there was no risk for patients except at most, the effect of a placebo.[16-25]

During the first phase it was very important the patient cooperation and the symptoms observed to improve the compound until its final formulation. In the second phase the comparison between the groups allowed to assay the effectiveness of the compound. The two groups showed that the pomade was able to control the bacterial contamination, and to reduce the symptoms.

The final formulation of the ointment performed well considering its permanence and efficiency in keeping the implant free of microorganisms. Side effects also did not occur. The reduction in cover screw loosening was not expected, but it was also very welcome. Malodor, one of the most common complaints from patients, was completely controlled by the antiseptic. The results were encouraging and showed that the ointment can provide real clinical benefits. Controlling the contamination of implants and abutments is an important step in implant dentistry.

Clinical trials should be carried out to strengthen this evidence and, if confirmed, bring benefits to the dental implant technique.

Conclusions

This preliminary study led to the conclusion that the final formulation of the antiseptic ointment was effective in controlling bacterial contamination of the internal spaces of the implants, while waiting for osseointegration. The signs and symptoms evaluated, such as pain, discomfort, peri-implant abscesses, inflammatory episodes and malodor, were drastically reduced.

The results were encouraging, and no side effects were seen.

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