Sutures coated with antiseptic pomade to prevent bacterial colonization: a randomized clinical trial

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Objective. The aim of this study was to assess if an antiseptic pomade could reduce the bacterial colonization on multifilament sutures.

Study Design. A randomized clinical trial was conducted with 40 volunteer patients of both sexes aged 18-70, randomly separated into experimental (n = 20) and control (n = 20) groups. The experimental group received pomade-coated sutures (iodoform + calendula) and the control group uncoated sutures. Two millimeters of the suture was harvested from each patient from the 1st to the 15th postoperative day. The bacteria that had adhered to them were cultured. The number of colony-forming units per milliliter (CFU/mL) was determined and the groups were compared using the Mann-Whitney statistical test ($P < .05$).

Results. The experimental group showed a significant reduction in bacterial growth compared with the control group ($P = .002$).

Conclusions. In this experimental model, the antiseptic pomade was effective in reducing bacterial colonization on silk braided sutures. (Oral Surg Oral Med Oral Pathol Oral Radiol 2013;116:e103-e109)

Sutures can be a source of surgical wound contamination[1-3] owing to bacterial adherence to them[4] and the suture acting as a means of transmitting bacteria to oral tissues.[1] The adherence of bacteria is highly variable and is dependent not only on the specific microbial species and suture structure, but also on the chemical composition of the suture material.[3-5] Among the different suture materials, this phenomenon is more pronounced with multifilament threads.[5-7]

Once suture material becomes contaminated, biologic agents, chemical agents, or other mechanisms of wound decontamination become ineffective owing to biofilm formation and the subsequent protection it affords to biofilm populations.[5] Handling of sutures within the oral cavity, as well as their removal, may also induce bacteria to spread, with greater risk of more serious complications for patients with chronic illnesses, such as diabetes and heart disease.[8,9] Therefore, contaminated sutures are a real risk with any surgical procedure.[4,5,7,8,10,11]

Development of an antibacterial suture has been under consideration for many years.[4,12-16] Sutures impregnated or coated with antibacterial agents have been developed in an attempt to reduce bacterial adherence and colonization. A suture made from Polyglactin 910, coated with the antiseptic agent triclosan, is an example of one such product that has been used in different situations.[13,15,17-21] Other suture materials and antibacterial agents also have been tested.[14,22-26]

Although black silk sutures for intraoral surgical procedures have stood the test of time for well over a century, in the past 2 decades oral surgeons have sought another option owing to biofilm adherence on these sutures. They recognize the superior characteristics of silk[27-29] but are always concerned about bacterial colonization on its surface.

An antiseptic composed of iodoform (15.5%) and calendula oil (5.0%) as active components,[30-35] developed to control bacterial contamination of the inner

Statement of Clinical Relevance

Although multifilament sutures have stood the test of more than a century, oral surgeons have looked for another option owing to biofilm adherence on these sutures. An antiseptic coating that controls the bacterial adherence can facilitate its clinical use.

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ambient of dental implants,[36-42] has been tested as a coating for this type of suture. The long-lasting effectiveness of this antiseptic in microbiologic control at implant interfaces,[43] in addition to absence of side effects on oral tissue, has been shown in different study models.[44,45] The aim of the present study was to assess whether this antiseptic pomade could reduce the bacterial colonization of silk braided sutures after oral surgery.

MATERIALS AND METHODS

A randomized, blind, controlled clinical trial was conducted with 40 volunteer patients of both sexes aged 18-70 at the Clinical Center of Research in Stomatology, Juiz de Fora, MG, Brazil, from December 2009 to February 2010 according to the CONSORT statement. The purpose was to test the effectiveness of an antiseptic composed of iodoform (15.5%) and calendula oil (5.0%) as active components (excipient q.s.p. lanolin, nipazol, and beeswax), in the control of the bacterial colonization of silk braided sutures after oral surgery.

Inclusion criteria consisted of patients who needed an oral surgical procedure, had no pathologic or infectious process (such as a third molar extraction or dental implant placement), good oral and systemic health, and good oral hygiene. The exclusion criteria were diabetes, smoking history, use of any type of local or systemic medicine, and presence of any metabolic or degenerative diseases or any allergy to the formulation components.

Patients were randomly assessed for eligibility as they came to the clinic for surgical procedures. A total of 78 patients were assessed, but of this number only 40 were admitted to the trial; the remaining 38 did not meet the inclusion criteria. Patients who met the inclusion criteria were invited to join the trial, until each group reached n = 20 (Figure 1). Those who were included in the trial signed informed consents after being thoroughly informed about the research. Once consent was obtained, the subject was randomly assigned to the experimental or control group in accordance with a simple randomization protocol. The research was approved by the Ethics Committee of the Federal University of Juiz de Fora, no. 123/2009, according to the Helsinki statement.

Three different surgeons with similar experience were involved in the study. To ensure standardization among the examiners, they were calibrated according to the consensus technique and adjusted by the concordance percentage (Cohen kappa = 0.85).

Twenty minutes before each surgical procedure, the patients were instructed to use chlorhexidine (0.2%) as a mouth rinse for 1 minute. The suture types were not standardized and differed according to the surgery performed. In the experimental group (n = 20), the thread of the black 4-0 silk braided sutures (Demetech Sutures, Miami, FL, USA) was covered with the antiseptic pomade (Proheal; BiomacMed, Juiz de Fora, MG, Brazil), and in the control group (n = 20) the thread (black 4-0 silk braided sutures) was used without the pomade. The pomade was applied to the suture thread by the surgeon immediately before performing the suture. The surgeon placed the pomade on the tip of the thumb and index finger, then slid the thread between them until it was saturated with pomade.

At the end of each surgical procedure, the circulating nurse on duty at the time, took an envelope, and wrote the patient's name on it along with type of sutures the patient received and the group to which the patient belonged. Subsequently, the envelope was stored in a box containing the other envelopes, which were opened only after the final laboratory results were obtained.

All patients complied with a pharmaceutical protocol, including 2 g amoxicillin and 4.0 mg dexamethasone administrated 1 hour before surgery. In the postoperative period, only analgesics were prescribed for all patients. Patients were instructed not to use any medicine after the procedure that had not been prescribed by the oral surgeon. This demand was made in an attempt to avoid any deviation from the expected standard of the postoperative course. During the postoperative course, local hygiene was maintained only by the patient using water-soaked gauze beyond their regular hygiene procedures.

On the 1st, 3rd, 5th, 7th, and 15th postoperative days, a surgeon or a nurse, who did not know to which group the patient belonged, harvested 2 mm from the external part of the suture thread from each patient (Figure 2). Thus, patients, nurses and surgeons who participated in sample harvesting, and laboratory examiners were blinded.

The samples were prepared to culture the bacteria that had adhered to and grown on them. Harvested pieces were immediately placed in sterile tubes to maintain a viable bacterial culture. Each tube contained 1.0 mL buffer solution containing 4.2 mg sodium chloride (NaCl), 3.1 mg anhydrous dipotassium phosphate, 0.3 mL bidistilled glycerin, and 0.7 mL distilled water. All samples were labeled and stored on ice in a thermal container until processed by the laboratory. The storage time did not exceed 3 hours after collection.

Each tube containing a sample was kept in constant mechanical flux at 12 rpm for 10 minutes, inducing deposits to be formed. The deposits were discarded and the suspension was then subjected to serial 10-fold dilutions.

The first dilution of 10^{-1} was prepared by pipetting 1 mL of the suspension and diluting it in 9 mL saline solution (0.85% NaCl). From the first 10^{-1} dilution (1:10) subsequent dilutions were prepared (10^{-2} (1:

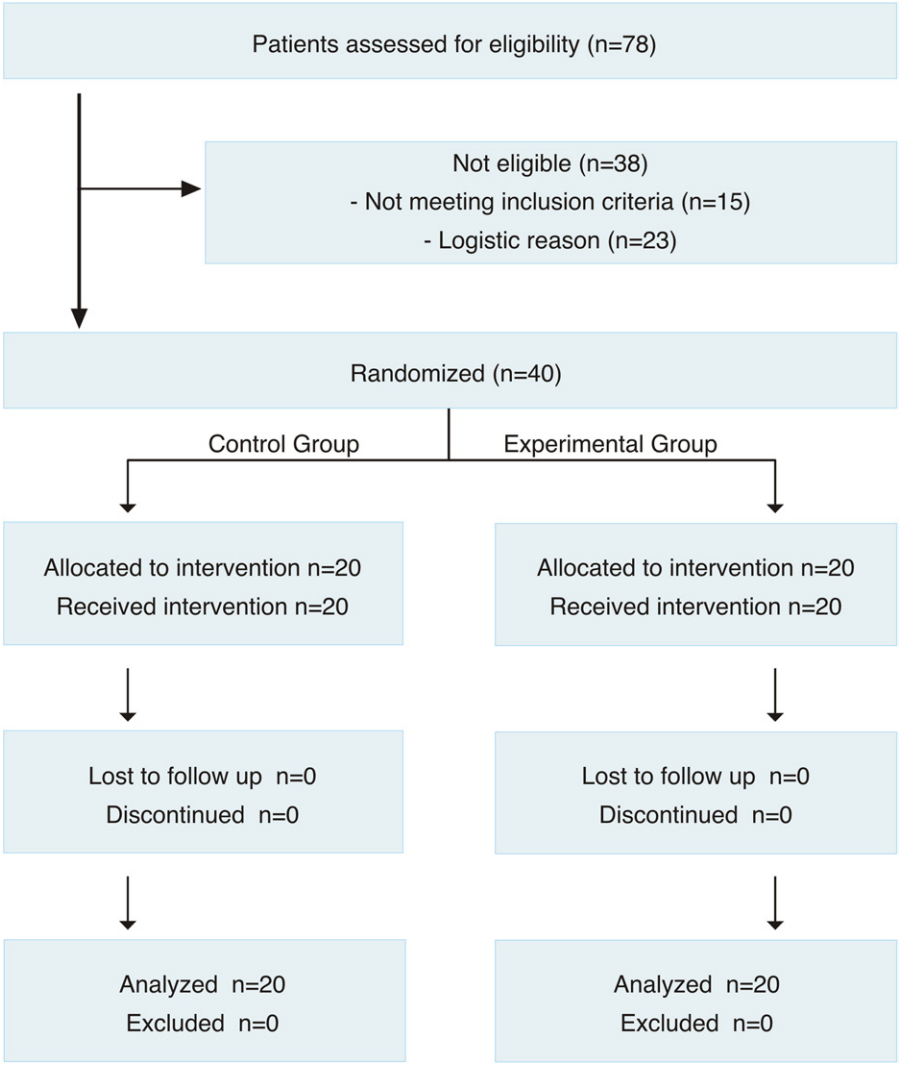

Fig. 1. Participant flow diagram.

100), 10^{-3} (1:1,000), and so on, up to 10^{-10}) by transfering 1 mL of each dilution to obtain the next. The tubes were kept under constant homogenization.

One milliliter of each dilution was plated on a medium of blood agar plus defibrinated sheep blood (5 mL blood agar per 100 mL base medium), reaching a pH of 6.8 ± 0.2.

The plates were incubated at 37°C under microaerophilic conditions (5% CO_2) for 48 hours.

After incubation (Figure 3), the number of colony-forming units per milliliter (CFU/mL) was recorded with the aid of a colony counter. The 2 dilutions that grew 30-300 colonies were chosen, and an arithmetic mean between the 2 values was obtained. The final number of CFU/mL was determined by multiplying the mean number of colonies counted by the corresponding dilution factor.

Data were tabulated and submitted to a comprehensive statistical analysis. The Mann-Whitney *U* test at a significance level of 5% ($P < .05$) was used to compare the bacterial contamination of the silk braided threads between the groups.

RESULTS

All of the patients followed the protocol properly, and no one was removed from the study (Figure 1). No postsurgical inflammation, infection, or allergic reaction occurred in the 2 groups. The clinical data were collected and laboratory procedures performed without incident, ensuring that the results were reliable and in accordance with the goal of the study.

Although there were statistically significant differences between the 2 groups, the similar trend in bacterial growth in the 2 groups can be seen as a sign of the regularity of the protocol followed and of having the 2 groups in generally the same clinical environment.

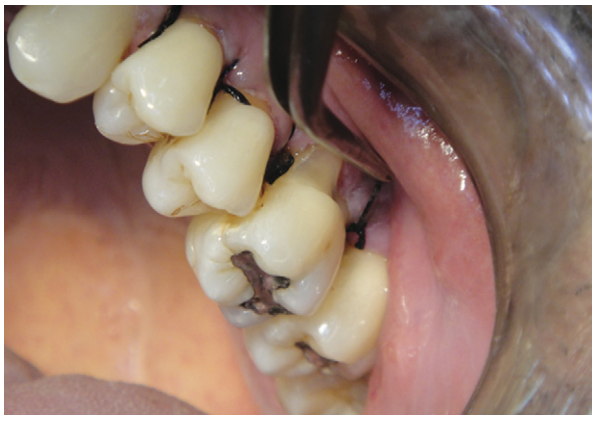

Fig. 2. Suture sample being collected from the external tip of the suture thread.

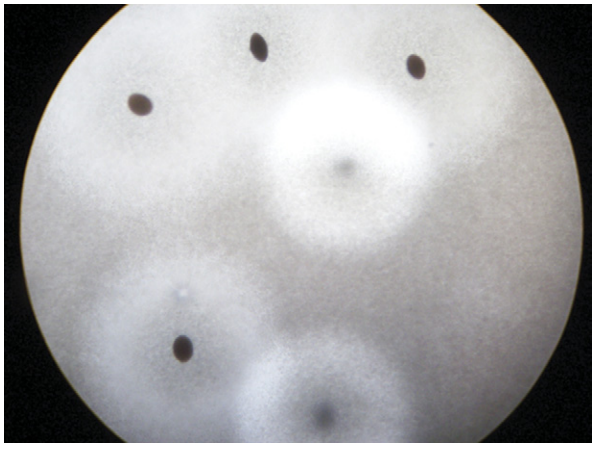

Fig. 3. Colony-forming units (CFU/mL).

The number of CFU/mL along the postoperative timeline in the 2 groups are shown in Table I and Figure 4. The biggest difference occurred at 10^{-8} dilution.

When comparing the experimental and control groups, it was found that the overall difference in bacterial growth between them was significant ($P = .002$; Table I). Moreover, there was an overall statistically significant difference in bacterial growth along the postoperative timeline, with less bacterial growth in the experimental group throughout the entire period.

The mean bacterial growth between the groups showed that the number of CFU/mL in the control group on the third postoperative day was higher than that of the experimental group on the 15th day.

DISCUSSION

The findings of the present study provide insight into the mechanism by which the use of a suture coated with a bactericidal agent would protect wounds, in agreement with earlier reports.[3,4,15,19] In addition, this study demonstrated that the antimicrobial activity of the compound was sustained over a long period of time, including the early period in the postoperative timeline, when a surgical wound is usually most subject to microbial exposure resulting from technical complications, such as mastication and brushing. This study also documented that the antiseptic activity of iodoform did not decrease when the follow-up time exceeded the optimal time for the presence of sutures.

Overall, the results of this study showed that antibacterial-coated sutures exhibited an inhibitory bactericidal activity against bacteria that commonly colonize oral surgical wounds. The results also showed that the silk braided sutures coated with the antiseptic had a satisfactory clinical behavior for routine use without the risk of bacterial contamination of the surgical wound.

Oral sutures are partially embedded in tissue and partially bathed in saliva, with a mean concentration of microorganisms of $\sim 7.5 \times 10^8$/mL. Sutures placed in gingival and oral mucosa may therefore produce prolonged tissue responses as a consequence of the continual influx of microbial contamination along the suture channel.[1,5,7] Earlier studies found that multifilament braided sutures not only produced a more prolonged tissue response, but also harbored a larger quantity of bacteria than monofilament sutures.[1,2,5-7]

Many clinicians prefer multifilament sutures, especially the silk variety, because monofilament is more difficult to manipulate, exhibits poor knot security and has sharp ends that irritate oral tissue. However, the use of multifilament sutures has been challenged by some studies, which suggest that this type of suture can act as a wick, leading bacteria into the wound, causing severe inflammation.[1]

The rationale for using silk braided sutures in this research is that among natural suture materials, many surgeons consider this silk suture to be the gold standard, as demonstrated by its handling characteristics and its extensive use among oral surgeons.[2] Experimental studies have been carried out to develop an effective antibacterial suture,[3,4,12,14-16,19-24] but development of an approved surgical suture has been slow, partly because of technical issues involving product safety, stability, and standardization.

Early studies examined the effectiveness of chlorhexidine in different suture materials and surgical sites.[24,26] Tissue-based studies in an animal model have suggested that triclosan-coated braided sutures exhibited no adverse effect on wound healing but did exhibit antibacterial activity sufficient to prevent in vivo bacterial colonization.[17]

Deliaert et al.,[20] in a double-blind, randomized, prospective, pilot study to test the effect of triclosan-coated sutures on wound healing in women undergoing breast reduction surgery, stated that there was no evidence of any

Table I. Quantity of CFU/mL that was recorded in the groups along the postoperative timeline

	Day					
	1	*3*	*5*	*7*	*15*	*Total*
CG average	7.7×10^5	4.3×10^7	1×10^8	3×10^8	3.1×10^8	1.3×10^8
CG SD	2.4×10^6	1.3×10^8	2.2×10^8	6.8×10^8	3.7×10^8	3.8×10^8
EG average	2×10^3	3×10^5	2.4×10^6	2×10^7	2.1×10^7	7.7×10^5
EG SD	6.1×10^3	7.2×10^5	6.9×10^6	4.4×10^7	5×10^7	2.1×10^7
P value	.002	.006	.004	.002	.002	.002

CG, Control group; *EG,* experimental group.

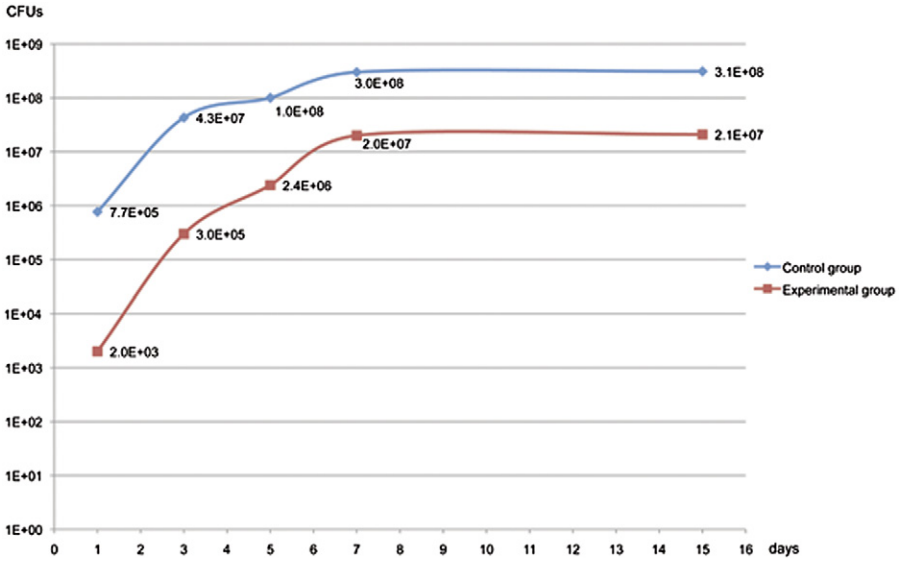

Fig. 4. Group comparison of microbial growth, assessed by the number of colony-forming units per milliliter (CFU/mL), from the 1st postoperative day to the 15th.

effectiveness of triclosan coating, and that triclosan seemed to have adverse effects on wound healing. These findings are contrary to others reported in different studies conducted in general and oral surgery.[3,4,15,19]

The combination of iodoform and calendula oil in the compound used in the present study for coating sutures has not been formulated previously. However, these components used separately or in different combinations have been in use for almost a century in different fields of health care, mainly endodontics and pediatric dentistry.[30-32] Iodoform itself has long and well documented use in dentistry and in general medicine.[30,31,33,35]

Cruz and Castro[37,38] assessed the antimicrobial efficacy of the pomade during the osseointegration period and reported a high success rate of 98%. The time of action of the pomade was tested for 6 months, but in another prospective study, Cruz reported that the pharmacologic action of the pomade was intact after 5 years.[39,40] No other study, using any type of antiseptic alone or in combination, has reported such a long time of pharmacologic action. Carneiro,[43] in an in vivo study, tested the antimicrobial effect of this aforementioned compound to control the bacterial growth inside dental implants during the osseointegration period. The results showed that the pomade was effective in reducing microbes ($P = .0003$).

Earlier studies[44,45] have used a similar methodology and evaluated the effect of this pomade on tissue adjacent to submerged dental implants during the osseointegration period. The authors evaluated the cells under optical microscopy looking for cellular alterations and found no adverse effects within the tissue.

Cruz[41] reviewed the literature regarding medicines used to control the bacterial content of the inner environment of dental implants and noted that this formulation was the most effective and reliable among all encountered.

The small sample size was a limitation of the present study, because this increased the possibility of bias if some patients were more efficient than others in maintaining hygiene after surgery. Patients were randomized to minimize this possibility of bias, but a larger number of participants could also have minimized possibilities for this variable. Nevertheless, the statistically significant difference between the groups was so great ($P =$

.002) that a larger sample size probably would not have altered the results significantly.

Therefore, the efficacy of this antiseptic pomade as a coating for sutures should be investigated further by a larger study evaluating its clinical outcomes, microbiology, and economic benefits. Further studies should be conducted to compare antiseptic-coated silk braided suture with a monofilament suture.

CONCLUSION

In this experimental model, the iodoform antiseptic pomade was effective in reducing bacterial colonization on silk braided sutures after oral surgery.

A statistically significant reduction of microbial growth occurred in the experimental group compared with the control group. The difference occurred right from the first day of the postoperative timeline and remained even beyond this time frame.

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