

Comparison of a Bioadhesive Gel (HOBAGEL)[®] and Chlorhexidine in Healing After Avulsion of Lower Third Molars



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Objective: to evaluate a bioadhesive gel based on cetylperidinium chloride, triclosan and essential oils (HOBAGEL) as a disinfectant device, after the avulsion of a lower eighth, comparing it with chlorhexidine gel 0.5%.[®] **Materials and methods:** 64 patients with an indication for avulsion of included lower third molars (Class 1B/2B Pell and Gregory) for pericoronitis were enrolled in the randomized, double-blind case-control study. Following the surgical procedure, the use of a gel based on cetylperidinium chloride, triclosan and essential oils was prescribed in the Test Group, while a gel based on 0.5% chlorhexidine was prescribed in the Control Group. Patients were clinically evaluated for complications at 3 and 7 days after surgery. During the visits, the pain reported by the patient and the extent of consumption of pain killers (ketoprofen 80mg) were recorded using the VAS scale. **Results:** with regard to postoperative pain (VAS scale) in the Test group at 3 days a value of 4.53 ± 1.57 was obtained while in the Control group it was 4.52

± 2.03 while on the 7th day in the Test Group 5.09 ± 1.94 and Control Group 5.13 ± 2.01 . Consumption of pain killers was 512 ± 264 mg Test Group and 490 ± 265 mg Control Group. The differences were not statistically significant ($p > 0.05$) using a paired t-test. **Conclusions:** The present study shows an overlap in the action of chlorhexidine gel 0.5% and bioadhesive gel with triclosan, essential oils and cetylperidinium chloride (HOBAGEL)[®] with regard to the percentage of alveolitis, infectious complications and postoperative discomfort of the two Study Groups.

Keywords: Avulsion including eighth notes, Chlorhexidine gel, Cetylperidinium chloride, Alveolitis.



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Introduction

Avulsion of the lower third molars is one of the most frequent surgeries in oral surgery and maxillofacial surgery units. The lower third molar is the dental element that most frequently occurs included, with a prevalence between 19 and 30%; mesio-inclination is the most frequent condition (about 41%), followed by normoinclination (26%), dystoangulation (12%) and Horizontal (11%)¹⁻³

The main cause of symptomatic third molar extraction is pericoronitis, a pathological condition that tends to recur, with increasing frequency and intensity, until the avulsion of the affected element occurs. The presence of damage to the supporting tissues of the contiguous dental elements, caries of the included element, the presence of odontogenic cysts on them represent the other main causes of extraction of the lower third molars.⁴

As with any surgical procedure, complications can sometimes arise during surgery or in the postoperative period. The severity and frequency of these complications have decreased in the last decade, thanks to the improved ability to identify cases at risk and the refinement of the technique. The three most common complications related to the extraction of the third molar are alveolar osteitis, infections and nerve injuries.⁵ Osteitis, which has an incidence varying between 1 and 2.5%, manifests itself with pain of severe intensity, is characterized by the disintegration of the primary blood clot inside the alveolus, which is empty or full of malodorous white material, devoid of granulation tissue and surrounded by slightly reddened gums.^{6,7}

Postoperative infections are a rather rare event, however, they occur in about one case in 100 and, in rare episodes, they can also be extremely serious to the point of threatening the patient's very survival. Cases of infection requiring hospitalization are mainly associated with avulsion of wisdom teeth that had already given rise to previous infections or in patients compromised from a systemic point of view.^{5,6}

Proper postoperative treatment is still the subject of controversy regarding the need to administer antibiotic therapy or not. It is reported in the literature that a single dose of amoxicillin 2g one hour before surgery significantly decreases the risk of infection.^{8,9} Some studies show that

The administration of antibiotic prophylaxis reduces postoperative ^{pain,8,9} while a course of antibiotics reduces the risk of infection in eighth avulsions and the possibility of osteitis sicca, but there is no evidence of a decrease in edema, swelling or lockjaw, plus the patient undergoing antibiotic therapy has a greater risk of suffering side effects such as nausea, vomit.^{10,9} The use of disinfectants to reduce the bacterial load within the oral cavity, both before and after surgery, on the other hand, is very important to reduce the frequency of infections and alveolitis. The most frequently used device is chlorhexidine, in a 0.5% gel formulation or in 0.12 or 0.2% collution.¹¹

The use of chlorhexidine, however, is often associated with the onset of undesirable side effects: some of which have been known for some time (chromatic alteration of the dental elements, burning in the oral cavity, dysgeusia), while others are more recently identified (cytotoxicity on dentists, unilateral and bilateral parotid irritations, accentuated mineral precipitation with the formation of tartar deposits, negative immunological reactions).^{12,13} The variety of side effects and the ascertained, limited or absent, healing action of chlorhexidine promote the search for therapeutic alternatives to this active ingredient.

Cetylperidinium chloride is a quaternary ammonium compound that has a strong antiseptic action against gram+ bacteria and to a lesser extent against gram-bacteria. The combination of triclosan and essential oils has shown efficacy in reducing bacterial plaque, periodontal inflammation, bleeding on probing and pain in the absence of obvious side effects.^{2,13 p.m.}

The present prospective randomized study aims to evaluate the disinfectant efficacy of a bioadhesive gel based on cetylperidiniochloride, triclosan and essential oils (HOBAGELs[®]) in cases of avulsion of lower eighths alternating with traditional treatment with chlorhexidine 0.5% gel. The frequency of alveolitis and infection were evaluated by performing a 3- and 7-day check-up, the postoperative discomfort reported by patients through the vas scale of perceived pain in the first week and the consumption of pain killers (ketoprofen 80 mg).

Materials and methods

Between July 2016 and January 2017, at the Department of Oral Surgery (dir. Prof. M. Chiapasco) of the San Paolo Hospital in Milan, 120

patients were treated.

avulsion of lower third molars, for a total of 134 elements extracted. Of these, 85 had pericorinitis (63%), 11 caries of the contiguous dental element (8%), 28 destructive caries of the third molar (20%), 10 osteolytic lesions associated with the included element (7%). In order to standardize the initial condition, only cases in which the indication for avulsion was represented by pericoronitis alone were taken into consideration. Only third molars class 1B or 2B of Pell and Gregory were considered so that the difficulty and invasiveness of the intervention were homogeneous in all cases and in both Study Groups for a total of 64 lower molars. The study is double-blind: the blinded subjects are the surgical operators and the statistician designated for data analysis. For each patient, an orthopantomography of the dental arches and a ConeBeam CT scan were requested if the third molar had apparent relationships with the inferior alveolar nerve.

Inclusion Criteria

Anamnesis

- Ages 18-60.
- Absence of systemic pathologies or presence of compensated systemic pathologies (diabetes, heart failure, hypertension, renal failure, hepatic failure, respiratory failure and other dysendocrine/dysmetabolic pathologies).
- Adequate patient compliance (mild mental illness, mild congenital or acquired malformations).

Clinic

- Oral hygiene compatible with the maintenance of an adequate level of oral health (FMPS and FMBS < 25%).
- Need for avulsion of a lower third molar due to pericoronitis.
- Third molar belonging to classes 1B or 2B (Pell and Gregory classification).

Exclusion Criteria:

Anamnesis

- Inadequate patient compliance (psychiatric pathologies).
- Use of drugs.
- Alcohol habit (> 10 units of alcohol per day).
- Smoking habits (>10 cigarettes a day).
- HCV+, HIV+.

- Compensated systemic pathologies (diabetes, hypertension, renal failure, liver failure, respiratory failure, other dysendocrine and dysmetabolic diseases).
- Coagulation disorders or alterations in coagulation (congenital, acquired or drug-related).
- Autoimmune diseases, immunosuppressed patients or patients on immunosuppressants.

Clinic

- Inadequate oral hygiene and incompatible with an adequate level of oral health (FMPS/FMBS > 25%).
 - Need for third molar avulsion for conditions other than pericoronitis.
 - Pell and Gregory classification different from 1B or 2B.
- All extractions were performed by the same surgical team and with the same approach under local anesthesia. The randomization took place randomly through envelopes.

The sample of 64 patients was divided into two Study Groups (Control Group: 32; Test group: 32) by means of randomization performed by means of envelopes.

The Control Group was prescribed chlorhexidine gel 0.5% as a local antiseptic post-extraction, while the Test Group was prescribed HOBAGEL.[®] In both groups, the dosage was 3 applications per day for 7 days. All patients received prophylaxis (2 g of amoxicillin + clavulanic acid 1 hour before surgery) and antibiotic therapy (1 g of amoxicillin + clavulanic acid every 12 h for 6 days after surgery). Pain control was achieved by prescribing ketoprofen 80 mg, to be taken as needed on a full stomach.

Surgical Technique

All the operations were performed by the same team and with the same surgical technique. Surgical operators become aware of the patient's group only at the end of the surgical procedure. After performing a truncal and plexic anesthesia with mepivacaine 2% plus adrenaline 1:100000, an intrasulcular incision was made on the seventh with a distal discharge to create the access flap to the element to be extracted, the flap was then raised to full thickness. If necessary, ostectomy and odontotomy were performed by means of a straight handpiece with external irrigation with sterile saline. After avulsion of the dental element, it was

A revision of the post-extraction socket was performed and abundant washes with sterile saline solution. Finally, the flap was closed with the application of 4/0 silk sutures. In the Control group, at the end of the extraction, a 0.5% chlorhexidine gel was applied around the post-extraction socket, while in the Test group,

HOBAGEL® (Clinical Case Control Group figures 1-10; Clinical Case Test Group figures 11-21). Patients were clinically evaluated by a blinded operator to highlight any complications 3 and 7 days after surgery. During the visits, the patient's reported pain and the extent of consumption of pain killers (ketoprofen 80 mg) were recorded using the VAS scale.

Results

Sixty-four patients (40 females and 24 males) with a mean age of 27.1 years (age range 18-46 years) were enrolled in the study for a total of 64 lower third molars. All extractions were completed and all patients performed the scheduled check-ups. No post-extraction bone and/or alveolar exposures occurred at all the sites analyzed. To highlight the possible presence of statistically significant differences in terms of parameters analyzed between the two study groups ($p < 0.05$) a paired t-test was used in case of distribution



Fig. 1 Preoperative OPT: element 48 class 2B, with no apparent relationship with the inferior alveolar nerve.



Fig. 2 Physical examination: element 48 semi-included.



Fig. 3 Preparation of the flap with intrasulcular incision at 47 and with distal discharge.



Fig. 4 Flap detachment and element identification 48.



Fig. 5 Dislocation of the element 48.



Fig. 6 Avulsion of the element 48.



Fig. 7 Post-extraction socket of 48, after curettage and washing with sterile saline.



Fig. 8 Suture with affixing of silk stitches 4/0.



Fig. 9 Wound disinfection with chlorhexidine gel 0.5%.



Fig. 10 Wound healing 7 days after surgery.

with equal variance of the samples while "Mann-WhitneyRank Sum Test" in case this condition is not verified. As for post-operative pain, analyzed using the VAS scale, in the Test group at day 3 a value of 4.53 ± 1.57 was obtained while in the Control Group it was 4.52 ± 2.03 while at the 7th day in the Test Group 5.09 ± 1.94 and Control Group

5.13 ± 2.01 . The differences were not statistically significant. Consumption of pain killers in the 7 days after surgery was 512 ± 264 mg Test Group and 490 ± 265 mg Control Group, non-significant difference ($p > 0.05$). In both Study Groups, no infectious complications were found. In the control group, one patient (#28) reported paresthesia in the right lower lip that resolved spontaneously 10 days after extraction. In the test group, two patients (#3; #30) reported lingual paresthesia that resolved respectively after 20 days and 2 months after surgery following administration of Assonal[®] (2 tablets per day until sensitivity was recovered).

Discussion and Conclusions

Several studies in the literature show an overlapping action in reducing plaque accumulation and the percentage of gingivitis between mouthwashes with essential oils and those containing chlorhexidine. The effectiveness of the



Fig. 11 Preoperative OPT: element 38 class 2B, with no apparent relationship with the inferior alveolar nerve.



Fig. 12 Physical examination: element 38 semi-included.



Fig. 13 Preparation of the flap with intrasulcular incision at 37 and with distal discharge.



Fig. 14 Flap detachment and element identification 38.



Fig. 15 Odontotomy of element 38 with crown separation.



application of a

The antiseptic action of essential oils is reiterated by Fine et al. 2010¹⁵ which, in a double-blind RCT, demonstrates how they are able to significantly reduce bacteremia in subjects with gingivitis. Gola and Roncati¹⁶ compared in an RCT the use of a 0.25% chlorhexidine-based toothpaste with the

Fig. 16 Avulsion of the crown of the element 38.

A double-sided adhesive gel based on triclosan, essential oils and cetylperidinium chloride following tooth extractions. The study verified an overlapping action of chlorhexidine and gel with regard to the reduction of the bacterial load and plaque index. However, the gel has shown greater efficacy in improving



Fig. 15 Avulsion of the root block of the element 38.



Fig. 16 Post-extraction socket of 38, after curettage and washing with sterile saline.



Fig. 19 Suture with affixing of silk stitches 4/0.



Fig. 20 Wound disinfection with HOBAGEL.®



Fig. 20 Wound healing 7 days after surgery.

patient comfort, type of healing, and postoperative pain reduction. In fact, an interference attributable to chlorhexidine on the healing process, independent of its undoubted antibacterial activity, has been described by some authors,^{17,18} who hypothesize an inhibitory activity on the proliferation of fibroblasts and keratinocytes. The same negative side effect does not

it is present with essential oils.¹⁹ The clinical results obtained must be interpreted on the basis of the formulation of the new gel, which includes a mix of various substances. The intense bioadhesiveness of the product is determined not only by the lipophilic substrate of many components, but above all by the original mix of rubbers and resins (mixed Na/Ca salt of the methyl-vinyl-ether copolymer and Ma carboxy-methyl-cellulose).

The effect of re-epithelialization of the tissues is obtained instead by the peculiarities of other substances including, in the foreground, hyaluronic acid at different molecular weights.

The present study shows an overlap in the action of chlorhexidine gel 0.5% and gel with triclosan, essential oils and cetylperidinium (HOBAGEL)® with regard to the percentage of alveolitis and inflammatory complications of the two Study Groups. Even the pain recorded by VAS scale 3 and 7 days after surgery and assessed indirectly through the consumption of pain killers does not show significant

differences between the two antiseptic protocols.

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Comparative evaluation of the efficacy of a novel bioadhesive gel (HOBAGEL®) and chlorhexidine in patients undergoing lower third molar extraction

Aim: The objective of this study was to evaluate the effectiveness of an antiseptic gel containing cetylpyridinium chloride, triclosan and essential oil compared to chlorhexidine 0,5% gel after extraction of third molar wisdom tooth. **Materials and methods:** 64 patients undergoing lower third molar extraction (1B/2/B Pell and Gregory classification) for pericoronitis were enrolled in a randomized, case-control, double-blind study. After surgery the Test Group used an antiseptic gel containing cetylpyridinium chloride, triclosan and essential oil whereas the Control Group used chlorhexidine 0,5% gel. Clinical observation and pain evaluation (VAS Scale) was made 3 and 7 days after surgery. Consumption of pain killers (ketoprofen 80mg) was considered. **Results:** 3 days after surgery, in Test Group the VAS Scale was $4,53 \pm 1,57$ and $4,52 \pm 2,03$ in the Control Group, whereas after 7 days there was $5,09 \pm 1,94$ for the Test Group and $5,13 \pm 2,01$ for the Control Test. The average consumption of pain killers was 512 ± 264 mg for Case Group and 490 ± 265 mg for Control Group. No significant statistical difference was detected between the Groups ($p > 0.05$) using unpaired t-test. **Conclusions:** No significant statistical difference was found between the Groups in improving the postoperative discomfort, reducing the use of pain killers and rate of alveolitis.

Key words: Chlorhexidine gel, Cetylpyridinium chloride, Wisdom tooth extraction.