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## Research Article

# Prospective clinical trial on the effectiveness of Topical Anesthetic in second stage surgeries of Dental Implants

## Abstract

**Objectives:** The aim of this study is to evaluate the effectiveness of gel topical anaesthesia in second surgeries of dental implants according to the different treated areas of the oral cavity, as well as the type of oral mucosa in which is effective.

**Material and methods:** Thirteen partially and completely edentulous patients with 30 implants in total were included in the study. The oral mucosa was dried and the anesthetic gel (Benzocaine 20%) was applied with a cotton roll for 2 minutes. The effectiveness was evaluated with an exploratory probe. Those implants whose cover screw was not submerged in a depth higher than 2-4 mm were selected. In the event of the gel topical anaesthesia not being effective, reinforcement with conventional infiltrative anaesthesia was made. Pain was measured with Visual Analogue Scales (VAS), and the gum thickness with periodontal probe. A one-way Anova and a Pearson correlation were used to perform the statistical analysis ( $p \leq 0.05$ ).

**Results:** The 66.67% of the sample needed reinforcement through conventional anesthetic infiltration. No statistically significant differences were found in the comparison of pain with different gum thickness ( $p=0.59$ ), although a higher feeling of pain was actually observed in those patients who were firstly subjected to a second-stage surgery ( $p=0.0335$ ).

**Conclusion:** The use of gel topical anaesthesia cannot be considered as the sole treatment to eliminate the feeling of pain, but as a coadjuvant to infiltrative anesthesia. No significant differences have been found between the different treated areas of the oral cavity, nor in the thickness or type of oral mucosa.

## Introduction

Pain is one of the most ancient worries of human being and was considered as a natural event of human body. The development of basic sciences allowed the control of pain to carry out certain surgical acts [1].

In view of the need of painless dental treatments, turning to anesthesiology becomes necessary. The percentage of patients having fear of the anesthetic injection is especially high [1-4].

Topical anesthetic has been used for decades with certain indications regarding intra-oral use, with the particular aim of eliminating the painful feeling produced by the infiltration of other local anesthetics or the reduction of nausea in diagnostic procedures, which affect the pharyngeal area, such as exploring the pharyngeal or laryngeal area or endoscopies of high digestive via [1,2,5-7].

So far the use of topical anaesthesia in dentistry has been more popular between those specialized in pediatric dentistry, but the great demand of adult patients for an initial topical anaesthesia to avoid pain produced by needle has led to the development by the chemical industry of gels and nebulizers with ideal effectiveness and non-toxic for human beings [1,6,8,9]. Topical anaesthesia acts on the terminal nervous branches of the superficial mucosa [10,11]. Therefore, it can be assumed that in an intervention affecting only this area, with restricted depth, an unnecessary anesthetic puncture might be avoided.

Currently, dental implants used in prosthetic oral rehabilitation can be made in a surgical stage (with the healing cap initially exposed to the oral medium) or in two surgical stages (implant submerged under the gum and not exposed to the oral cavity) [12-14].

Second-stage surgeries of dental implants are made in implants that have been submerged placed and must be uncovered through a second surgical act in order to conform the surrounding mucosa and perform the prosthetic restoration to be supported [13,14]. They are frequently made in a very thin keratinized gum or free gingivae in which the implant cover screw is visible, and rising up the periosteum is not necessary to have it removed [15,16]. The patient comes from a dental implant surgery in which has experienced several punctures. The trauma that might suffer the patient before a new puncture to infiltrate anaesthesia could be worse than applying topical anaesthesia with a minimum surgical incision.

Several studies are focused on the possibility of avoiding this second surgical act to simplify the treatment and for the sake of convenience. Those studies compare both protocols (1 stage vs. 2 stages), as well as its indications and contraindications, although due to different clinical situations, such as the lack of primary stability or absence of keratinized mucosa, second-stage surgeries remain as an essential procedure [13,14,17,18].

The aim of this study is to prove that the use of topical anaesthesia is effective in oral surgical operations as second-stages to uncover the cover screw of a dental implant when it is already submerged. The null hypothesis is that topical anaesthesia is insufficient to eliminate pain in second surgeries of dental implants, and there are no differences in the effectiveness between maxilla and mandible. The Scientific Investigation Ethics Committee of the Universitat Internacional de Catalunya has approved this study.

## Material and Methods

### Patient selection

A data collection sheet was filled with the name, age, sex, intervention date, implants details, gingival biotype and the location are of the implant for every 13 patient, who also signed an specific inform consent of the study.

### Inclusion and exclusion criteria

Patients who were made a second surgical stage of dental implants were included in the study. Therefore, the inclusion criteria will be the same than the criteria of the first stage. The inclusion criteria for implant placement were the following: patients with physical and psychical normality conditions, partial or complete edentulous selected to be treated with implants, non-smokers or controlled smokers (10 cigarettes /day maximum), healthy patients or whose local or systemic disease is controlled and does not contraindicate any type of implantological oral surgery.

Those patients who had not signed the informed consent of surgery and implants, those allergic to any component of the conventional local anaesthesia (infiltrative or topical), having active neoplasia, uncontrolled systemic disease or contraindicating the placement of dental implants were not candidates for its placing and therefore a second surgery would not be possibly done without a first one.

The specific inclusion criteria of the second-stage surgery of dental implants were that of the patients who had been subjected to a surgical treatment with implants and whose healing screw was superficially submerged (up to 4 mm measured with a periodontal probe once the topical anesthetic has taken effect).

All those patients who presented allergies to any type of component of the anesthetics, pregnancy, those who had not signed the surgery informed consent, who have had any type of analgesic in the last 24 hours or who have had peri-implant pathology during the healing period were excluded.

### Implant Location

Every measurement was made by the same researcher in order to avoid discrepancies or possible bias. The evaluation of the implant depth was visually made, whereas the probing was carried out with a conventional exploratory probe in order to localize the cover screw; the measurement was done with a periodontal probe over the area, once the topical anaesthetic had been applied and its effect checked.

### Application of the anaesthetic solution

A 0.12% Chlorhexidine solution must be locally applied on the area to be treated (where the dental implant is localized) and dried with sterile gauze conventionally used in dentistry in order to favour the diffusion of the anesthetic preparation. The preparation (Hurricane, 20%, Benzocaine, Laboratorios Clarben S.A. Madrid, Spain) impregnated in a cotton pellet was applied onto the area during a period of at least 2-3 minutes.

In the event of pain during the measurement, an injected anesthetic reinforcement (Ultracain, 4% Articaine, Epinephrine 1:100.000, Laboratorios Normon S.A. Madrid, Spain) was applied, thereby avoiding that feeling to the patient during the treatment.

The pain perceived was recorded with the Visual Analogue Scale (VAS), which comprises a 10 cm line representing the continuous spectrum of the painful experience. The use of infiltrative anaesthesia required was also registered. The VAS line can be vertical or horizontal terminating in right-angles ends. Descriptions are to be found on the ends, being «no pain» at one end and «the worst conceivable pain» at the other, with no other description along the line [19,20]. The patient himself indicates his personal experience of each implant by writing a cross on the line.

### Surgical technique

Every patient underwent a previous radiographic control (periapical radiograph or orthopantomography) to estimate the localization, the conditions of the adjacent anatomic structures and the osseointegration of those implants. At the time of the surgery the implant was found visually, radiographically and with a conventional exploratory probe. At this point of the intervention, the possible discomforts of the patient were evaluated. Once the cover screw is localized, we will proceed to measure the depth at which that screw is

placed with a periodontal probe (having marks which allow the exact millimeter depth measurement). If a depth higher than 2–4 mm is observed and the patient has not presented any discomfort, we will start the incision on a surface covering the dental implant with n° 3 flat handle scalpel having a scalpel blade of n° 15, 15c or 11. Once the implant was localized, its head was released by adapting the mucosa to the abutment shape. A circular scalpel or Punch having the diameter of the implant head was occasionally used. After preparing the mucosa, the cover screw is removed with a specific screwdriver and is placed in the corresponding healing abutment. The intervention area was sutured, if needed.

Whenever possible, the papillary regeneration technique proposed by Palacci was made in the second-stage surgery. With this technique, a scalloped with gingival appearance and a papillary formation is obtained since the beginning of the surgery. It consists in pushing the keratinized gingivae from the palate/lingual towards the buccal direction so as to increase the tissue volume, thereby allowing the dissection and rotation of the pedicle flat, by falciform type incisions in the periimplant areas, to subsequently create the interimplantar papillae [21].

The patient was not subjected to any additional pharmacological treatment, so the only recommendations were painkillers in case of discomfort and also following the postoperative instructions.

### Data collection and statistical analysis

Every analyzed data were moved to the Statgraphics Plus 5.1 program to carry out the statistical study. The statistical study consisted in relating quantitative and qualitative variables in a one-way Anova study (comparison of pain with type of implant, gingival biotype, position in the arch, first surgery, sex and subject) and only quantitative variables, so a correlation multivariable analysis was used (pain vs. gingival thickness).

The percentage of patients who needed reinforcement with conventional infiltrative anesthetic was calculated using tabulation and observing the bar diagram and the pie diagram. The possible statistically significant differences were individually analyzed, between means and standard deviations. The P-value was calculated checking if it was  $\leq 0.05$  and the charts were observed distinguishing between level code, means and 95.0 percentages, LSD intervals and the box-and-whisker plot.

## Results

Thirteen patients were included in the present study (3 men and 10 women, mean age  $62.92 \pm 18.92$ ), with a total amount of 30 implants. Each patient presented from 2 to 12 implants to be rehabilitated.

Every patient was treated with gel topical anesthetic (Hurricane, 20%, Benzocaine Laboratorios Clarben S.A. Madrid, Spain) and, in the event of not being effective, a conventional anaesthetic technique was applied by infiltration (Ultracain, 4% Articaine 1:100.000 Epinefrine, Laboratorios

Normon S.A. Madrid, Spain). The 66.67% of the total amount of implants required reinforcement with infiltrative anaesthetic. Therefore, the data obtained in this study support the null hypothesis, this is, that topical anesthetic is insufficient to eliminate pain in second surgeries of dental implants, and there are no differences in the effectiveness between maxilla and mandible (Figure 1).

### Comparison of pain and different studied variables

Pain was numerically considered (statistically speaking), since it is a quantitative variable and a 0 - 9.9 range (mean 4.491) was showed according to the VAS pain measurement scale (comprised between 0 and 10 when transformed to numeral values).

The remaining studied variables were considered as feature type due to its qualitative nature and therefore a graphic study with a one-way Anova was carried out, comparing means, median and standard deviations, except the gingival thickness, because, being a quantitative value, a Pearson correlation or multivariable analysis was carried out.

### Pain vs. First second surgery of the patient

There were statistically significant differences, since the p-value was  $< 0.05$ . Patients subjected for the first time to a second surgery felt more pain than those who had already experienced a similar surgical act (Figure 2).

### Pain vs. gingival thickness

The analysis made was multivariable or correlative, because the nature of both variables is quantitative and tries to group data with similar features and also observe if any of the variables presents a  $p\text{-value} \leq 0.05$ . Neither statistically significant difference nor any type of relationship was found (Figure 3).

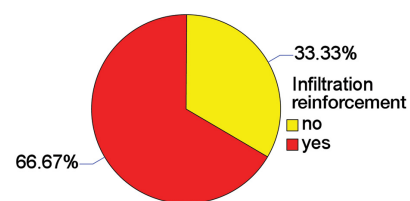


Figure 1: Pie Chart: Percentage of the sample that needed conventional infiltrative anaesthetic reinforcement.

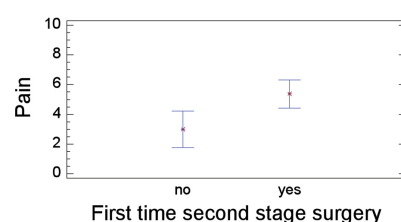


Figure 2: Differences in the degree of pain, considering if the patient had been previously exposed to a second stage surgery.

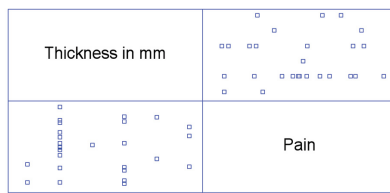


Figure 3: Multivariable analysis of pain and gingival thickness.

## Discussion

Pain is a defense mechanism of the human body produced as a response in the face of an attack towards it. It is an unpleasant subjective feeling present in our patients when exposed to a surgical act [1]. Not only this, it is difficult for the patient to exactly quantify the degree of pain suffered and also a chronic pain, frequently related to a depressive condition of the patient, is not valued in the same way than an acute pain [3,19].

Different measurement methods for rating pain have been described with the aim of transforming the subjective experience in an approximate objective. The subjective measurement can be one-dimensional (intensity) or multi-dimensional (intensity, quality, emotions). A great amount of methods are available, such as the numerical scale described by Downie in 1978, the simple descriptive scale by Keele in 1948 or the Visual Analogue Scale described by Huskinson in 1976 [19]. In our study, we decided to use the Visual Analogue Scale (VAS), which is a continuous numeric one-dimension scale; it is simple, solid, sensitive and reproducible, and therefore useful for the reassessment of pain of the same patient but in different moments [20].

Local anesthetics are those drugs, which act on a limited area of the organism, depending on its application, and are divided in topical and parenteral [1,9]. Developments of anesthetic techniques, as well as the different application methods, have allowed us having of a broad range of techniques available to eliminate pain in different clinical situations. Starting from the use of cocaine as an analgesic of choice drug, the procaine synthesis by Alfred Einhorn in 1904 and later in 1948 the lidocaine synthesis by Nils Löfgren, anesthetic solutions have been evolving towards a more specific, scientific and safe anesthesiology, thus allowing a regular use of anesthetic techniques in medicine. Topical anesthetics are preparations of high concentrations of local anaesthetics, which diffuse until their arrival to the terminal nervous branches [1,9].

Scientific literature confirms the effectiveness of topical anaesthesia in superficial periodontal treatments [2,5,22,23], placing the clamp in absolute isolations with rubber dam [24], temporary orthodontic anchorages [25,26], biopsies [3,11], decreasing painful feeling when needle insertion [1,2,5,6,10], pediatric use [8], extraction of deciduous teeth or abscess drainage [8], implant-abutment connection in oral implantology [27], as well as a psychological tool to

reduce patient's anxiety [2,8] but no study demonstrate its effectiveness in second-stage surgeries to uncover dental implants.

It is proved that a great variety of anesthetic agents have pharmacological effects, but there is no evidence of an ideal topical agent [1]. 5% lidocaine is an effective topical agent and, combined in 2.5% with 2.55% prilocaine is even more effective [4]. The eutectic mixture of these amides, 2.5% lidocaine and 2.5% prilocaine (EMLA) is a commonly used agent [1,3,4,6]. 15% benzocaine (ester) with 1.7% amethocaine and 20% benzocaine are also effective [6-8].

The application time of the agent on the area to be treated has also been proved. A minimum of 2-3 minutes and a maximum of 10-20 minutes on the area to be treated is essential to obtain a proper effect [6,10,25]. An application time equal or higher than 30 minutes can produce ulcerations on the oral mucosa [28].

The palatal mucosa shows a higher resistance to the effectiveness of local agents [6]. Topical anaesthetic does not guarantee a pain-free treatment when it implies soft tissues with a thickness higher than 5 mm [1,6], although other studies note that the effectiveness does not exceed a depth of 2-3 mm [25].

Different studies mention the lack of alteration in the perception of pain by some topical use anesthetics, because it is a sensitive technical process, for the variability of pain threshold in different patients, a poor effectiveness or an application time lower than necessary [1,4,8].

An application of the local topical anaesthesia with the proper dosing has not showed toxicity levels [1,9]. However, they should not be applied in elderly patients, patients having hypersensitivity to ester and amide-type anesthetics, patients having allergy to paraminobenzoic acid, severe hypertension, ventricular tachycardia, hyperthyroidism, bradycardia, partial heart blocks, myocardial disease or severe arteriosclerosis [29]. The most common secondary effects are tissue irritation or temporary taste disorders, although cases of cyanosis and even anaphylactic shocks have been described [9].

Dental implants inserted in the oral cavity with the aim of being rehabilitated can be left exposed to the oral cavity in the same surgical time or covered under the gum [14,30-32]. Several reasons justify that an implant should be left covered and a second minor surgical act should be carried out, as for instance, the lack of primary stability at the time of the insertion, the presence of intra-oral factors that may lead to premature uncontrolled or undesired loads on these implants during the osseointegration stage, or the use of biomaterials in the guided tissue/bone regeneration [13,14,31,32]. Another important issue to justify a two-stage implant procedure is the manipulation of the soft tissues around them for aesthetic reasons or for the lack of keratinized gum around to provide protection, facilitate hygiene and improve the long-term prognostic [13,21].

The elimination of this second surgical act is the object of study of many authors in order to avoid discomforts to the patient and simplify the surgical technique. The comparison of both protocols (1 stage vs. 2 stages), its indications and contraindications, are also objects of different studies, without statistically significant differences so far [12-14,17,18]. If covering the implant is unavoidable, there are different techniques which have been studied with the aim of minimising the disadvantages of this second surgical stage of the implants, such as for instance the use of diode lasers, CO2 laser or the use of punch type circular scalpel [15, 16], but there is no published study regarding the use of a topical anesthetic agent.

## Conclusions

The conclusions that might be extracted from this study are:

The use of gel topical anaesthesia (20% benzocaine) cannot be considered as the sole treatment to eliminate the feeling of pain, but as a coadjuvant to the infiltrative anaesthesia. 66.67% of the sample needed a conventional anaesthetic reinforcement through puncture.

No significant differences have been found in the perception of pain between the different treated areas of the oral cavity, between maxilla and mandible or between anterior and posterior.

No statically significant differences have been found in the thickness and type of oral mucosa.

Statistically significant differences ( $p$ -value<0.05) have been found in those patients who had not been subjected before to this process of second-stage surgeries of implants. Patients who had already experienced this treatment presented a lower feeling of pain. The reason might be that those patients already knew second-stage surgeries of implants, they were conscious of its nature, therefore they faced the treatment more relaxed and confident. Stress and anxiety could make the organism react in a more emphasized way in the face of a treatment unknown to the patient.

There is a need of more clinical studies evaluating the topical anesthetic in second-stage surgeries, however application times should be changed, the anaesthetic agent concentration and its absorption methods.

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