©Operative Dentistry, 2014, **39-3,** 000-000

# Efficacy of an Anesthetic Gel in the Reduction of Pain During Impression Making

E Bressan • G Paniz • L Gobbato
A Franco • D Lops

**Clinical Relevance**

This study suggests that the described anesthetic gel can be effective in significantly reducing patient discomfort during the displacement of the gingival tissue.


## SUMMARY

**Introduction: Gingival tissue displacement can be an uncomfortable procedure, often performed without injectable local anesthesia. The present study evaluated the efficacy of an anesthetic gel in reducing pain during this procedure.**

**Material and Methods: Thirty patients undergoing definitive dental impression, for fabricating full-coverage restorations, were evaluated for pain perception on displacement of the surrounding gingival tissues. All the participants were randomly divided into two groups. Five minutes before the insertion of the displacement cord, the anesthetic gel, a mixture of 5% lidocaine and 5% prilocaine, was applied in the sulcus of test group patients. Each patient was asked to complete the Visual Analogue Scale (VAS) and the Verbal Rating Scale (VRS).**

**Results: In the two scales considered, test group patients showed a statistically significant pain reduction (VAS $p$=0.0002, VRS $p$=0.01054) compared to control group patients.**

**Conclusions: Within the limitations of this study, a clinically significant efficacy of the anesthetic gel was noticed during gingival displacement procedures.**


Eriberto Bressan, professor and chairman, University of Padova, Dental School, Department of Periodontology, Padova, Italy

*Gianluca Paniz, University of Padova, Prosthodontics, Padova, Italy

Luca Gobbato, University of Padova, Dental School, Department of Periodontology, Padova, Italy

Anna Franco, Department of Periodontology, Padova, Italy

Diego Lops, resident, Department of Prosthodontics, Dental Clinic, School of Dentistry, University of Milan, Milan, Italy; Department of Prosthodontics, Azienda Ospedaliera San Paolo–Polo Universitario, Milano, Italy

*Corresponding author: via Cesarotti 31, Padova, 35100, Italy; e-mail: panizg@hotmail.com

DOI: 10.2341/12-490-C

## INTRODUCTION

Many patients are afraid of dentistry, and they often associate dental procedures with pain. Even if patients have different abilities to tolerate painful and stressful dental procedures, the World Health Organization estimates the percentage of those who are dentist-phobic between 15% and 20%.[1,2]

The aim of modern dentistry is to provide the patient with maximum comfort during any session and, to achieve this goal, it is important to reduce the pain and to eliminate, as much as possible, the anxiety induced by stimuli such as anesthesia, needles, scalpels, and drills. Although different types of anesthetic agents are available, fear of injections is one of the main reasons patients avoid dental care. A nontraumatic anesthesia would provide patients with greater comfort, avoiding all pre- and post-infiltration problems, such as injection pain and swelling, lip numbness, and tongue paresis.[3] Different alternatives, such as biofeedback, reassurance, hypnosis, distraction, transcutaneous electronic nerve stimulation (TENS), and nitrous oxide, have been utilized to reduce pain associated with dental procedures, but none of them can completely replace anesthesia by local injection.[4]

An anesthetic gel, containing 5% prilocaine and 5% lidocaine (Oraqix, Dentsply Pharmaceutical, York, PA, USA), has been recommended to reduce pain during routine treatments, such as obtaining probing depths, scaling, and root planing. Jeffcoat and others[5] showed that Oraqix gel provides valid pain reduction during scaling and root planing, especially in advanced cases of periodontal disease. Donaldson and others[6] emphasized that Oraqix gel is statistically significantly more effective than placebo in reducing pain caused by periodontal debridement. Furthermore, the favorable anesthetic efficacy of anesthetic gel in pain-sensitive patients was confirmed by Magnusson and others[7]. Van Steenberghe and others[8] indicated that for scaling and root planing, the subgingival application of the Oraqix anesthetic gel offers substantial advantages over injection anesthesia; its efficacy on the gingival sulcus was related to the ability to remain in situ, thanks to a particular mixture that permits a status change from liquid to gel in contact with the body temperature (37°C) and the capacity to become active in 30 seconds and to last 20 minutes.[6,9]

While taking a dental impression, the transfer of an accurate replication of the patient's hard and soft tissue to the dental laboratory is a crucial factor, especially with subgingival margins.[10] Since definitive impressions replicate both the tooth structure and the surrounding gingiva, success is based on creating an accurate preparation, on selecting the appropriate impression material and impression techniques, and on managing properly the periodontal tissues.[11,12] In addition to creating an area free of fluid and debris, gingival tissue should be displaced to expose the tooth finish line when making a definitive impression.[13] In order to achieve this purpose, a displacement cord has been extensively recommended.[14] Unfortunately, such a technique can be an invasive method that often causes patients discomfort.[15] Novel techniques were studied to reduce or to eliminate patient discomfort; a clinical trial by Yang and others[16] demonstrated that the injection-type displacement material, with or without aluminum chloride, ensures adequate tissue retraction and is preferable to retraction cord since the application of this material is painless.[16]

Even if pain is a subjective experience, several methods to describe it have been described with different pain scales. The Visual Analogue Scale (VAS) is represented by a 100-mm horizontal blank ruler where the patient is asked to mark the position that best describes the pain, taking into account the left and the right end point marked, respectively, "no pain" and "worst pain imaginable."[17] The Verbal Rating Scale (VRS) is a six-point scale with the following choices: "no pain," "very mild pain," "mild pain," "moderate pain," "severe pain," and "very severe pain."[18]

The purpose of the present clinical study was to verify the efficacy of Oraqix anesthetic gel during the displacement of gingival tissues to reduce patient pain perception. The null hypothesis was that there is no difference in pain perception during displacement cord insertion with or without the use of Oraqix anesthetic gel.

## MATERIALS AND METHODS

Thirty patients (16 females and 14 males) undergoing definitive dental impression were randomly selected for this study and randomly divided into two groups: the test group (TG) was treated with Oraqix, and the control group (CG) was treated with chlorexidine digluconate gel (Corsodyl Dental Gel*30G, GlaxoSmithKline, Verona, Italy).

Treatments were performed in a private dental clinic (Padova, Italy), and the local Internal Ethics Committee (Protocol N.0103#) approved the study protocol. Informed consent was obtained from all the subjects included in the study. In obtaining the informed consent and in conducting the study, the principles outlined in the Declaration of Helsinki on Experimentation Involving Human Subjects were adhered to as revised in 2000. In addition, the sample size was determined considering a power of 90% using a two-tailed test at the 5% level of significance and a minimum detectable difference

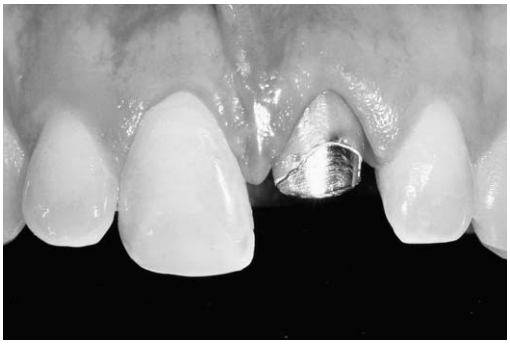

Figure 1: *Tooth prepared for receiving full coverage restoration with vertical finishing line.*

between the groups (test and control) of 1 (VAS unit) with a standard deviation of 0.91.

All patients enrolled were healthy with no systemic diseases or immunodeficiency or neurological/psychiatric handicap. They also were able to comprehend the pain scales and signed an informed consent prior to inclusion in the study. Patients with history of allergy, sensitivity, or any form of reaction to local anesthetics of the amide type, in pregnancy or lactation, with significant cardiovascular, renal, or liver disease, were excluded. All patients presented good oral hygiene, with healthy periodontal tissues (periodontal pocket depth $< 4$ mm; negative bleeding on probing) and a plaque index lower than 20%.

Every patient had one nonvital tooth with a provisional restoration in place for at least 6 weeks. All the teeth were prepared with vertical tooth preparation the day of the provisional restoration insertion. The day of the definitive impression, gingival displacement procedures were performed in both groups. A double cord technique was used. At

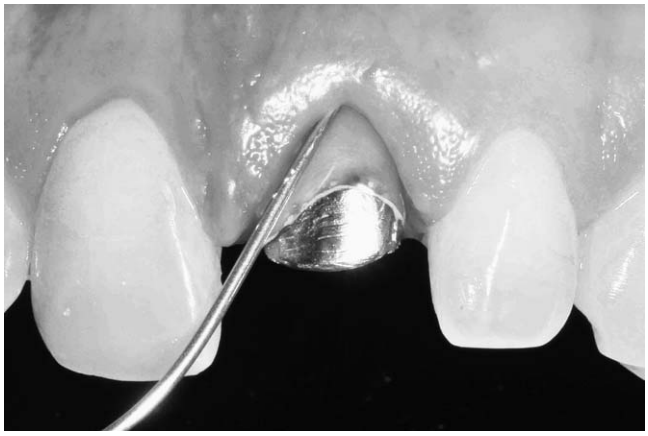

Figure 2: *Application of non injectable anesthetic gel in the sulcus.*

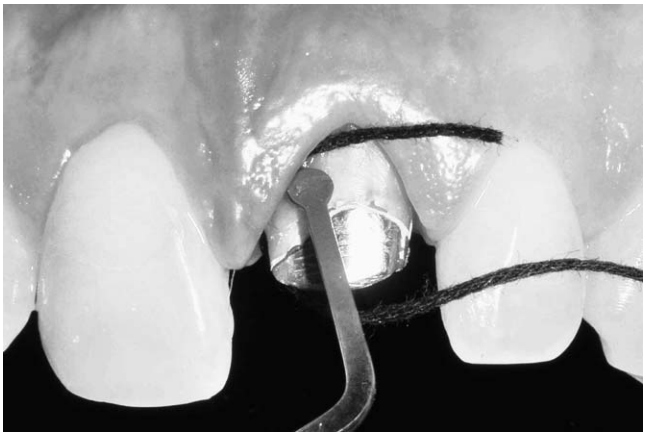

Figure 3: *Insertion of 000 cord in the sulcus.*

first, a "000" cord was positioned at the bottom of the gingival sulcus (Ultrapack Cord, Ultradent Products Inc, South Jordan, UT, USA). Subsequently, a "1" cord was placed over the first one (Ultrapack Cord). Before cord insertion, anesthetic Oraqix gel was applied in the sulcus of TG patients, left in situ for 30 seconds according to the manufacturer's instructions, and then cleaned out with abundant water irrigation. The same procedure was performed for the CG in which a chlorexidine digluconate gel was applied instead of the Oraqix gel. After 10 minutes of gingival displacement, the second cord was removed, and the definitive impression was taken with a polyether material (Impregum Penta Soft, 3M ESPE, St Paul, MN, USA) For each patient, sex, age, use of Oraqix, number of teeth examined, sulcus depth, bleeding during cord insertion, and pain experienced during the procedure were recorded.

Patients were assigned to one of the two treatment groups using a computer-generated randomization table. All patients participated in the study with a

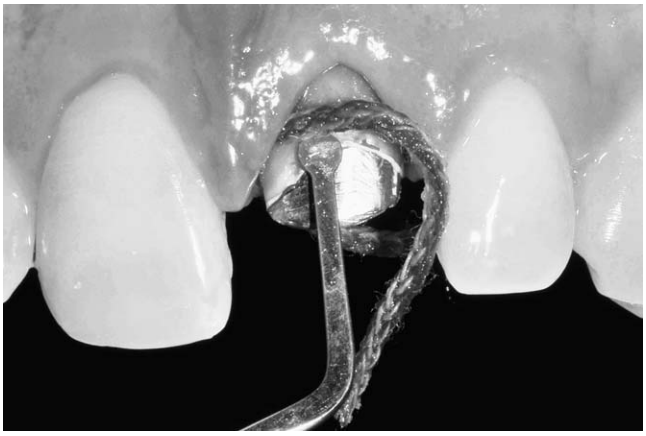

Figure 4: *Insertion of 1 cord in the sulcus.*

Table 1: *Study Sample Data. Mean Values and Standard Deviations Are Reported for Each Variable Examined.*

| Variables | Test Group (n=15) | | Control Group (n=15) | | *p*-Level |
|---|---|---|---|---|---|
| | Mean Values | SD | Mean Values | SD | |
| Age (y) | 46.13 | 8.3 | 46.66 | 15.78 | NS |
| Sulcus v (mm) | 1.53 | 0.66 | 1.26 | 0.41 | NS |
| Sulcus m (mm) | 1.83 | 0.64 | 1.63 | 0.51 | NS |
| Sulcus l/p (mm) | 1.63 | 0.58 | 1.43 | 0.37 | NS |
| Sulcus d (mm) | 1.7 | 0.7 | 1.53 | 0.48 | NS |
| Mean sulcus (mm) | 1.67 | 0.28 | 1.46 | 0.19 | NS |

*Abbreviations: SD, standard deviation; NS, not significant.*

single tooth. Fifteen teeth were assigned to the CG and 15 teeth to the TG. In the case of patients presenting with multiple teeth to be treated, the selection was performed by tossing a coin. Allocation concealment was achieved using a sealed coded opaque envelope containing the treatment of the specific subject. The sealed envelope containing treatment assignment was opened during the surgery immediately before the gel positioning.

Immediately after the cord insertion was completed, every patient, blinded to the study groups, was asked to assess their discomfort on two different pain scales: the VAS and the VRS. All statistical data were elaborated with the SAS System, an integrated system of software products (2012 SAS Institute Inc., SAS Campus Drive, Cary, North Carolina 27513, USA), and different variables, including the VAS and VRS scales, were examined. Different VAS values were reported in millimeters (between 0 and 100 mm), as determined by the patients' designation on the scale. The VRS values were divided into six different classes:

- Class 0: no pain
- Class 1: very mild pain
- Class 2: mild pain
- Class 3: moderate pain
- Class 4: severe pain
- Class 5: very severe pain

Analysis of variance for unpaired populations was used to compare the two groups according to the VAS scale. Nonparametric data on VRS scales were analyzed with the Pearson chi-square test.

## RESULTS

Data of all 30 patients are reported in Table 1. The mean age for both groups was approximately 46 years, while sulcus depth appeared deeper in TG (1.67 mm) than in CG (1.46 mm). The pain experienced by patients during the displacement of the gingival tissues was evaluated with the VAS scale of pain (Table 2).

The results on the VRS scale are shown in Table 3. The percentage of patients graded in each class of value was utilized as a criterion of reference. The worst pain perceived was classified as moderate, corresponding to class 3. Most of the TG patients were distributed in the first three classes, and their pain was considered mild, while most of the CG patients were in class 3 (73%).

Table 2: *Pain Experienced by Patients and Evaluated with VAS Scale of Pain.*

| Variables | 0: Oraqix (n=15) | | 1: Control (n=15) | | *p*-Level |
|---|---|---|---|---|---|
| | Mean Values | SD | Mean Values | SD | |
| Age (y) | 46.13 | 8.3 | 46.66 | 15.78 | NS |
| Sulcus v (mm) | 1.53 | 0.66 | 1.26 | 0.41 | NS |
| Sulcus m (mm) | 1.83 | 0.64 | 1.63 | 0.51 | NS |
| Sulcus l/p (mm) | 1.63 | 0.58 | 1.43 | 0.37 | NS |
| Sulcus d (mm) | 1.7 | 0.7 | 1.53 | 0.48 | NS |
| Mean sulcus (mm) | 1.67 | 0.28 | 1.46 | 0.19 | NS |
| VAS values (mm)[a] | 19.26 | 12.48 | 43.6 | 17.67 | 0.0002 |

*Abbreviations: SD, standard deviation; NS, not significant.*
[a] *VAS mean values have been compared using an analysis of variance F-test.*

Table 3: *VRS Values. Pearson Chi-Square: 11.23077 (p=0.01054).*

| VRS Values | Test Group | | Control Group | |
|---|---|---|---|---|
| | n | % | n | % |
| Class 0: no pain | 2 | 13.33 | 1 | 6.67 |
| Class 1: very mild pain | 5 | 33.33 | 1 | 6.67 |
| Class 2: mild pain | 6 | 40.00 | 2 | 13.33 |
| Class 3: moderate pain | 2 | 13.33 | 11 | 73.33 |
| Class 4: severe pain | 0 | 0.00 | 0 | 0.00 |
| Class 5: very severe pain | 0 | 0.00 | 0 | 0.00 |
| Total | 15 | | 15 | |
| Median | Class 1: very mild pain | | Class 3: moderate pain | |
| Mode | Class 2: mild pain | | Class 3: moderate pain | |

## DISCUSSION

This clinical study was designed to reveal whether the anesthetic gel Oraqix is effective in pain reduction during gingival tissue displacement for restorative needs. The data support rejecting the null hypothesis that no pain differences would be present with or without the utilization of the anesthetic gel. These results agree with those demonstrating its effectiveness as a valid alternative to the traditional injection technique during periodontal procedures such as scaling and root planing.[5,6,7]

Also, as in the findings of Gracely and Dubner[17] and Paice and others,[18] the three scales utilized in the present study for pain assessment reported clinical differences between TG and CG groups. As the utilization of displacement cord is common for definitive impression, it is also an uncomfortable procedure; hence, this gel represents a valid alternative to traditional anesthesia for reducing patient discomfort on gingival retraction, as reported by Azzi[15] and Yang and others.[16]

By analyzing the examined group of 30 patients, the efficacy of Oraqix gel was not influenced by sex, age, tooth position, and bleeding during cord insertion. Instead, the main variable of pain experienced, examined through the three different scales, demonstrated that the discomfort perceived in patients treated with Oraqix gel was significantly lower than the control group. As shown in Table 2, VAS values for TG patients were lower than CG patients. It is interesting to note that none of the patients treated with Oraqix gel reported a result >60 mm. For the VRS scale (Table 3), similar results are confirmed. Most of the CG patients belonged to class 1 and 2 (very mild pain = 33.44% and mild pain = 40.00%), while most of the CG patients belonged to class 3 (moderate pain = 73.33%). A deeper analysis of the table shows that about 86.67% of TG patients perceived mild pain (classes 0, 1, and 2), while most of the CG patients (73.33%) perceived moderate pain (class 3). Significant results are present in the analysis of sulcus depth, which was higher in TG (1.67 mm) compared to CG (1.46 mm). Even if sulcus depths are similar, it is interesting to note that Oraqix gel was effective with an average sulcus depth of 1.67 mm.

Due to the reduced sample size, further studies are necessary for the analysis of sulcus depth and anesthetic gel efficacy, but the clinical feeling reported improved results related to the presence of deeper sulcus. A shallow sulcus represents a difficult site to properly contain the applied gel. In fact, this anesthetic gel was originally created for application in periodontal pockets able to contain the gel in situ during its modification from liquid to gel. For this reason, the utilization of the provisional restoration to apply the liquid could be an interesting method to insert the material inside the sulcus, reducing its migration. Even if the results of this clinical study are encouraging, the limited sample size did not allow us to relate the efficacy of this anesthesia to different types of tooth preparation or to gingival biotypes, and the several limitations should be considered. With regard to the dimensions of the peri-implant soft tissues, an interesting analysis could be carried out on the utilization of Oraqix gel in the clinical procedures related to implant-supported restorations.

## CONCLUSIONS

Within the limitations of this study, the anesthetic gel Oraqix, a mixture of 5% lidocaine and 5% prilocaine, was clinically effective in reducing pain experienced during gingival tissue displacement with cord insertion. However, further studies with increased sample sizes are required in order to better

evaluate the efficacy in relation to different periodontal biotypes and preparation design.

### Conflict of Interest

The authors of this article certify that they have no proprietary, financial, or other personal interest of any nature or kind in any product, service, and/or company that is presented in this article.

*(Accepted 5 August 2013)*

### REFERENCES


1. Gatchel RJ, Ingersoll BD, Bowman L, Robertson MC, Walker C (1983) The prevalence of dental fear and avoidance: A recent survey study *Journal of the American Dental Association* **107(4)** 609-610.
2. Klages U, Ulusoy O, Kianifard S, Wehrbein H (2004) Dental trait anxiety and pain sensitivity as predictors of expected and experienced pain in stressful dental procedures *European Journal of Oral Sciences* **112(6)** 477-483.
3. Milgrom P, Coldwell, SE, Getz, T, Weinstein P, Ramsay DS (1997) Four dimensions of fear of dental injections *Journal of the American Dental Association* **128(6)** 756-766.
4. Stoltenberg JL, Osborn JB, Carlson JF, Hodges JS, Michalowicz BS (2007) A preliminary study of intrapocket topical versus injected anaesthetic for scaling and root planing *Journal of Clinical Periodontology* **34(10)** 892-896.
5. Jeffcoat MK, Geurs NC, Magnusson I, MacNeill SR, Mickels N, Roberts F, Robinson P, Salamati A, Yukna R (2001) Intrapocket anesthesia for scaling and root planing: Results of a double-blind multicenter trial using lidocaine prilocaine dental gel *Journal of Periodontology* **72(7)** 895-900.
6. Donaldson D, Gelskey SC, Landry RG, Matthews DC, Sandhu HS (2003) A placebo-controlled multi-centred evaluation of an anaesthetic gel (Oraqix®) for periodontal therapy *Journal of Clinical Periodontology* **30(3)** 171-175.
7. Magnusson I, Geurs NC, & Harris PA, Hefti AF, Mariotti AJ, Mauriello SM, Soler L, Offenbacher S (2003) Intrapocket anesthesia for scaling and root planing in pain-sensitive patients *Journal of Periodontology* **74(5)** 597-602.
8. Van Steenberghe D, Bercy P, De Boever J, Adriaens P, Geers L, Hendrickx E, Adriaenssen C, Rompen E, Malmenäs M, Ramsberg J. (2004) Patient evaluation of a novel non-injectable anesthetic gel: A multicenter crossover study comparing the gel to infiltration anesthesia during scaling and root planing *Journal of Periodontology* **75(11)** 1471-1478.
9. Friskopp J, Nilsson M, & Isacsson G (2001) The anesthetic onset and duration of a new lidocaine/prilocaine gel intra-pocket anesthetic (Oraqix®) for periodontal scaling/root planing *Journal of Clinical Periodontology* **28(5)** 453-458.
10. Chiche GJ, Harrison JD, & Caudill R (1994) Impression considerations in the maxillary anterior region *Compendium* **15(3)** 318-322.
11. Millar B (2001). How to make a good impression (crown and bridge) *British Dental Journal* **191(7)** 402-405.
12. Anusavice KJ, & Phillips RW (2003) *Phillip's Science of Dental Materials* 11th ed. Elsevier, St Louis, MO 205-255.
13. Benson BW, Bomberg TJ, Hatch RA, Hoffman W Jr. (1986) Tissue displacement methods in fixed prosthodontics *Journal of Prosthetic Dentistry* **55(2)** 175-181.
14. Donovan TE, Gandara BK, & Nemetz H (1985) Review and survey of medicaments used with gingival retraction cords *Journal of Prosthetic Dentistry* **53(4)** 525-531.
15. Azzi R (1983) Comparative study of gingival retraction methods *Journal of Prosthetic Dentistry* **50(4)** 561-565.
16. Yang JC, Tsai CM, & Chen MS (2005) Clinical study of a newly developed injection-type gingival retraction material *Chinese Dental Journal* **24** 147-151.
17. Gracely RG, & Dubner R (1987) Reliability and validity of verbal descriptor scales of painfulness *Pain* **29(2)** 175-185.
18. Paice JA, & Cohen FL (1997) Validity of a verbally administered numeric rating scale to measure cancer pain intensity *Cancer Nursing* **20(2)** 88-93.