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The anesthetic onset and duration of a new lidocaine/prilocaine gel intra-pocket anesthetic (Oraqix®) for periodontal scaling/root planing

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Abstract

Background: A new non-injection anesthetic, lidocaine/prilocaine gel (Oraqix®, AstraZeneca) in a reversible thermosetting system, has been developed to provide local anesthesia for scaling/root planing (SRP). The aim of this study was to determine the anesthetic onset and duration of the gel for SRP in patients with periodontitis.

Methods: 30 patients were randomized to either 30 s, 2 min, or 5 min of treatment with the gel prior to SRP of a tooth. The gel was applied to periodontal pockets with a blunt applicator. On completion of the SRP of each tooth (2–3 teeth treated/patient), the patients rated their pain on a 100-mm visual analogue scale (VAS).

Results: The median VAS pain score was 7.5 mm in the 30-s group, 28.5 mm in the 2-min group, and 15.5 mm in the 5-min group, with a significant difference between the 30-s and 2-min groups ($p=0.03$). In 2 patients in the 5-min group, but none in the other groups, the SRP was interrupted due to pain. The mean duration of anesthesia measured as pain on probing were 18.1, 17.3, and 19.9 min in the 30-s, 2-min, and 5-min groups, respectively. There were no reports of numbness of the tongue, lip, or cheek, neither were there any adverse local reactions in the oral mucosa. The gel was easy to apply and did not interfere with the SRP procedure.

Conclusion: Oraqix® provides anesthesia after an application time of 30 s, with a mean duration of action of about 17 to 20 min.

Key words: anesthesia; lidocaine; prilocaine; periodontal; treatment; topical

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Periodontal scaling/root planing (SRP) is an unpleasant and painful procedure for which local anesthesia is frequently used. The main anesthetic techniques used in conjunction with periodontal SRP are nerve block/infiltration anesthesia either alone or in combination with topical anesthesia. The main drawbacks of existing topical products are lack of efficacy due to inadequate depth of penetration, too short duration of action, and difficulties of administration. Since many patients fear injection needles and there is a general desire to avoid numbness of the lip and tongue, there is a need for a fast-acting and effective topical anesthetic.

A new lidocaine/prilocaine intra-pocket anesthetic gel (Oraqix®) has been developed. Oraqix® contains the active ingredients lidocaine and prilocaine base (25 mg/g of each substance), together with thermosetting agents.

At room temperature, Oraqix® is a low-viscosity fluid, whereas at body temperature it becomes an elastic gel. When applied to a periodontal pocket, it remains at the application site, thereby limiting the risk of its spreading to other areas. The objectives of the pres-

ent study were to evaluate the onset and duration of anesthesia as well as the safety aspects following a single dose of Oraqix® prior to SRP.

Material and Methods

Study design

This was a randomized, parallel-group, open-labeled study using active treatment only. Thirty eligible dental patients were recruited from a periodontal specialist clinic in Sweden.

Patients were screened for eligibility and randomized to receive Oraqix® for 30 s, 2 min, or 5 min prior to SRP. 2 to 3 teeth were selected for treatment and treated sequentially. Oraqix® was applied to the periodontal pockets around the first selected tooth by means of a blunt applicator. Timing commenced immediately after the periodontal pockets around the tooth had been filled. SRP commenced immediately after the allotted time period had expired.

At the end of the SRP procedure for each selected tooth, the intensity of pain during the procedure was rated by the patient on a visual analogue scale (VAS), here called VAS_{tooth}, and on a verbal rating scale (VRS) here called VRS_{tooth}. Once the first tooth had been completed, the procedure was repeated on the next tooth.

When the SRP on a tooth was completed, the presence of anesthesia was checked by periodontal probing using "normal probing force" every 5 min until sensation returned or until 30 min had passed since the end of SRP. This intermittent probing was carried out while the next tooth was being treated.

Interruption of the SRP procedure due to pain was recorded for each tooth. Once an interruption occurred, the procedure was discontinued on the tooth in question.

At the end of treatment, after leaving the dental chair, the patients rated their overall pain on a VAS, here called $VAS_{overall}$, and on a VRS, here called $VRS_{overall}$, together with the degree of discomfort on a VRS. They were asked about the taste of Oraqix®. The dental hygienist rated overall ease of application and overall ease of SRP following the application of Oraqix®.

Possible general and local side effects were monitored throughout the treatment period. A follow-up phone call was made 24–48 h after the treatment day to inquire about side effects.

Patients

10 patients were allocated to each treatment group. However, one of the patients who was randomized to the 30-s group had an application time of 5 min. Thus, 11 patients were included in the 5-min group, 10 patients in the 2-min group, and 9 patients in the 30-s group. All patients who entered the study also completed it.

Inclusion criteria: patients with a minimum of two teeth, each with at least one periodontal pocket ⩾6 mm in depth requiring SRP, age 18–60 years, pain on probing or a history of moderate or severe pain or discomfort with periodontal SRP, able to comprehend the VAS scale, and written informed consent. The patients selected for inclusion in this study reflected the typical patient with moderate to severe periodontal disease.

Exclusion criteria: a history of allergy, sensitivity, or any form of reaction to amide-type local anesthetics, administration of an analgesic/anesthetic/sedative in the 12 h prior to the procedure, teeth selected for the trial were not to be root filled or have root hypersensitivity, pregnancy and/or lactation, significant cardiovascular, renal, or liver disease, malignancy, previous enrollment in the present study, acute infections in or around the teeth selected for the trial, ulcerative necrotic lesions on the marginal gingiva, and teeth to be included in the trial were not to adjoin one another.

Oraqix® properties and handling

Oraqix® contains the active ingredients lidocaine 25 mg/g and prilocaine 25 mg/g and a thermosetting system. It was applied by inserting a 23-G blunt applicator to the bottom of the periodontal pockets before release of the substance. The pockets were filled until the gel became visible at the gingival margin. The dose of Oraqix® used was assessed from 0.1 ml graduations on the side of the syringe and was converted into grams.

Pain and discomfort assessments

The patient indicated on the VAS (a 100 mm, horizontal, blank ruler) the position which best described their pain in response to the question "How much pain did you feel during the scaling/root planing procedure?" The ruler had the left end-point marked "no pain" and the right end-point marked "worst pain imaginable" (Scott & Huskisson (1976). Directly after the patients' ratings on the VAS, they also rated their pain on a five-point VRS with the choices: "no pain", "mild pain", "moderate pain," "severe pain", and "very severe pain".

The overall discomfort from the procedure (application of the gel and the SRP) was assessed by the patient on a 5-point VRS with the following ratings: "no discomfort at all", "mild discomfort", "moderate discomfort", "severe discomfort", and "very severe discomfort".

Taste

The acceptability of the Oraqix® taste was assessed by asking the patient the following questions: "How much were you bothered by an unfavorable taste from the Oraqix®?" with possible responses "no discomfort at all", "mild discomfort", "moderate discomfort", "severe discomfort", and "very severe discomfort", and "Will the unpleasant taste experienced from Oraqix® affect your willingness to have Oraqix® at your next visit for SRP?" with possible reply options "not at all", "slightly", "quite a lot", and "I would not like to have Oraqix® again due to the unpleasant taste".

Overall ease of application, overall ease of scaling

The dental hygienist rated the overall ease of application of the gel to the periodontal pocket using a VRS with the options "very easy", "easy", "moderately difficult", and "difficult". The hygienist also assessed whether the presence of Oraqix® in the periodontal pockets interfered in any way with the SRP procedure. A VRS was used with the options "no, not at all", "slightly", "a lot", and "very much".

Statistical methods

From the VAS_{tooth} scores a mean was calculated for each patient. Application time groups were compared using mean VAS_{tooth} score per patient as the primary variable. The comparisons were performed as two-sided 95% confidence intervals estimating the group difference using a nonparametric method based on ranks corresponding to the

Table 1. Demographics and pocket depth before treatment

Group	*n*	Age (years) median (range)	Sex M/F (*n*)	Pocket depth (mm) median (range)
30 s	9	46 (29–55)	2/7	5 (2–8)
2 min	10	47 (38–56)	5/5	4.5 (1–10)
5 min	11	52 (34–59)	3/8	5 (1–8)

Wilcoxon rank-sum test. No multiplicity adjustments were used.

To investigate the duration of action, a time-to-event procedure with Kaplan-Meier survival estimates was used. Since the actual duration of action was not recorded, it was approximated for each patient as the mean of the time until first pain on probing and the last time with no pain on probing. If no pain on probing was reported, the patient was "censored" at the last probing time. The mean duration of action time was estimated for each application group and a test of homogeneity of survival curves over application groups was performed.

The Spearman coefficient of rank correlation was used for the analysis of the correlation between the mean VAS_{tooth} and $VAS_{overall}$ pain scores in several combinations. A general linear model was used for the analysis of the correlation between VAS_{tooth} and mean periodontal pocket depth per tooth.

The number of patients was chosen empirically rather than based on statistical considerations.

Results

The patients included in the study were Caucasian males and females. Demographics and baseline characteristics are summarized in Table 1.

20 teeth were treated in the 30-min group, 20 teeth in the 2-min group, and 22 teeth in the 5-min group. In total, 39 incisors/canines, 17 premolars, and 6 molars were treated. The median pocket depth was similar in the three groups (Table 1). No difference between groups in the baseline characteristics was apparent. Out of the total number of 62 teeth, only 2 in the 30-s group, 3 in the 2-min group, and 8 in the 5-min group were in the lower jaw. Hence no separate analysis was made of the difference between jaws.

The SRP times per tooth ranged from 3.2 min to 9.5 min. The three application time groups were similar, with median SRP times of 5.7, 6 min, and 5.9 min for the 30-s, 2-min, and 5-min groups respectively.

The dose of Oraqix® given ranged from 0.1 g to 0.7 g per patient, with a median dose of 0.2 g per patient for each application time group.

Pain and discomfort assessments

The median of the mean VAS_{tooth} was lower in the 30-s group than in the 2- and 5-min groups, with scores of 7.5, 28.5, and 15.5 mm respectively (Fig. 1 and Table 2). There was a significant difference between the 30-s group and the 2-min group ($p=0.03$). Between the 30-s group and the 5-min group there was a similar trend, although it did not reach statistical significance ($p=0.09$) (Table 2).

A significant correlation ($p<0.05$) was found for the mean VAS_{tooth} versus $VAS_{overall}$ pain scores ($r=0.959$), the $VAS_{overall}$ versus $VRS_{overall}$ pain scores ($r=0.742$), and the VAS_{tooth} versus VRS_{tooth} pain scores ($r=0.754$).

No significant correlation was found between the VAS_{tooth} score and the mean periodontal pocket depth per tooth ($p=0.64$).

The overall discomfort from the procedure, including both the application of Oraqix® and SRP, was rated as similar (not statistically significant) for all application time groups. There were no scores for severe or very severe discomfort for any of the application time groups (Fig. 2).

Duration of action

The Kaplan-Meier estimates of the mean duration of action were 18.1, 17.3, and 19.9 min for the 30-s, 2-min, and 5-min groups respectively (Table 3).

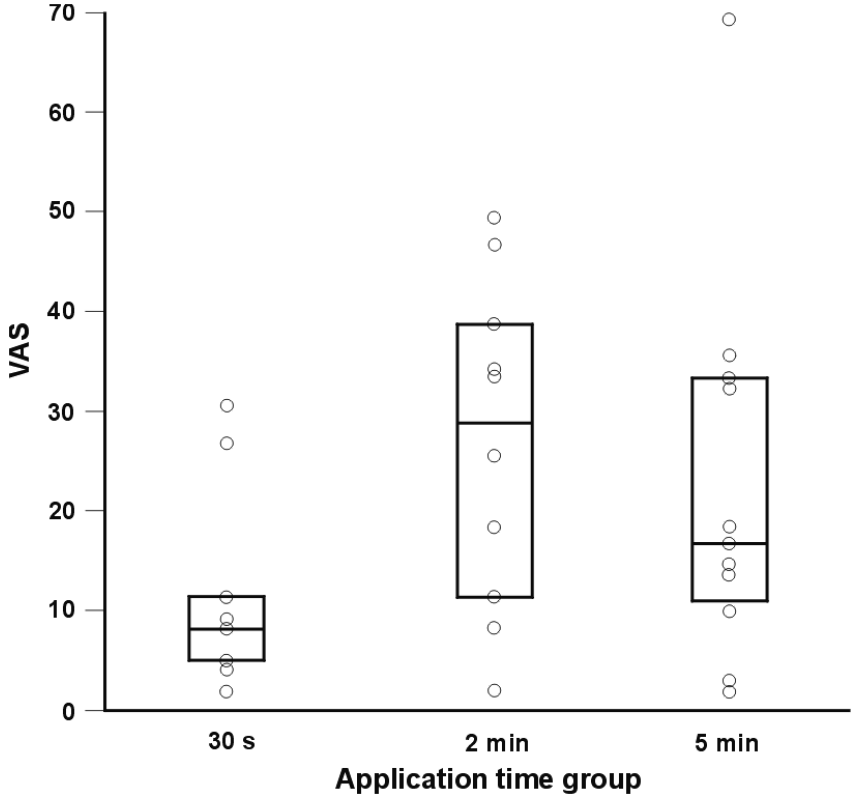

Fig. 1. Box plot of mean VAS_{tooth} scores. The bottom and the top edges of the boxes are the 25th and 75th percentiles, while the center horizontal line is the 50th percentile (median). The circles represent the individual mean values.

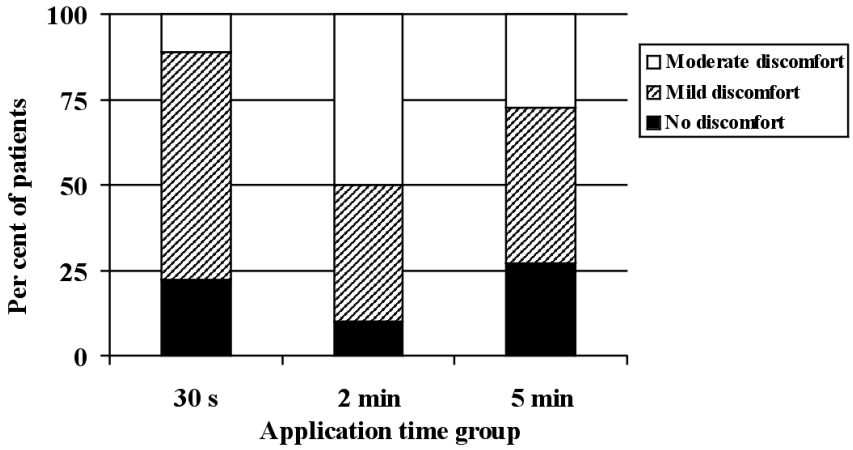

Fig. 2. The overall discomfort from application of gel and SRP. No patient reported severe discomfort or very severe discomfort.

No significant differences between the groups were seen.

There were no interruptions due to pain in the 30-s and 2-min groups. In the 5-min group there were 3 interruptions due to pain. 2 of them occurred in the same patient, but on two different teeth treated sequentially.

Taste

10 patients reported that Oraqix® had an unfavorable taste. Their ratings were as follows: 1 patient experienced "moderate discomfort", 7 patients "mild discomfort", and 2 patients "no discomfort at all" from the taste of the gel. None of these patients reported that the taste would affect their willingness to have Oraqix® at their next visit for SRP.

Overall ease of application, overall ease of scaling

The hygienists rated the overall ease of application of Oraqix® to the periodontal pockets as "very easy" in 6 patients and "easy" in the remaining 24 patients. Oraqix® did not interfere at all with the SRP procedure in any patient.

Side-effects

No local reactions were seen on visual inspection of the gingiva after the application of Oraqix®. 1 patient (5-min group) reported minor pain during Oraqix® application to each of her two teeth treated. No significant general signs/symptoms were recorded.

Table 2. The estimated absolute difference in mean VAS_{tooth} scores

Group comparison	Lower CI limit	Hodges-Lehman estimate (mm)	Upper CI limit	*p*-value
30 s–2 min	−30.0	−14.5	−0.5	0.03
30 s–5 min	−22.5	−7.0	1.8	0.09
2 min– 5 min	−10.0	5.8	21.0	0.36

CI=95% confidence interval.

Table 3. Kaplan-Meier estimate of mean Oraqix® duration of action in minutes

Group	Point estimate of mean	Lower confidence interval	Upper confidence interval
30 s	18.1	15.2	21.1
2 min	17.3	12.9	21.8
5 min	19.9	16.5	23.2

Discussion

More than 25% of adults surveyed in one study expressed at least one clinically significant fear of injections (Milgrom et al. 1997). Almost 1 in 20 respondents indicated avoiding, canceling, or not turning up for dental appointments through of fear of dental injections. The general fear of dental injections included pain from injection and fear of bodily injury from the injection. Another publication (Skaret et al. 1998) confirms Milgrom's results in a population of 18-year-olds in Norway. Those who reported >1 previous experience of pain were about 10× more likely to report a high level of dental anxiety. The skill of the clinician, the patient's personality, and the interaction between clinician and patient are important factors for the perception of pain and anxiety.

Pretreatment interviews indicate that about 2/3 of patients associate gingival scaling with some degree of pain and unpleasantness (Svensson et al. 1994).

Injection is the most commonly used method of administration to achieve sufficient anesthesia. The anesthetic is given either as a nerve block or by infiltration or as a combination of the two methods. The main drawbacks of injections are distress associated with needle insertion and inconvenient post-procedure paresthesia of lip and tongue. A number of topical anesthetics are used in dentistry, most often to prevent needle insertion pain. Oral mucosal needle insertion pain is significantly less after a 30-s application of 5% lidocaine ointment, compared to placebo (Yaacob et al. 1981). Topical anesthetics are also used in conjunction with SRP, especially on recall patients. However, the ones that are available today have a low degree of efficacy.

EMLA® cream (lidocaine/prilocaine 5%) has also been used for the prevention of procedure-related pain in the mouth (Svensson et al. 1994, 1993, Donaldson & Meechan 1995, Holst & Evers 1985). However, since it was not was designed for the use in the mouth, it easily spreads out (Svensson & Petersen 1992), although this is unpractical in clinical dental practice. The advantages of developing the EMLA® eutectic mixture concept of lidocaine/prilocaine into a temperature-controlled gelling property of Oraqix® is obvious. Following intra-pocket administration, Oraqix® is occluded and re-

mains in place at the site where the nociceptors are expected to be activated during the periodontal procedure. There is no information available to date about whether only periodontal nociceptors are inactivated by Oraqix® or whether pulp antinociception can also be achieved. In our study the seven out of nine patients in the 30-s group graded the overall SRP pain as none or mild.

The patients' rating of the $VAS_{overall}$ ratings were closely correlated with the mean VAS_{tooth} ratings. For future SRP studies of more than one tooth, the $VAS_{overall}$ pain score could be a convenient and valid measure of the procedure-related pain.

Another advantage of the Oraqix® intra-pocket administration is the relatively small degree of discomfort from a bad taste. This is in contrast to currently available topical anesthetics, which often have an unpleasant, bitter taste that has to be masked by flavoring.

Patients who received Oraqix® in this study for 30 s before the SRP procedure commenced had lower mean pain ratings than patients in both the 2-min and 5-min application groups. This suggests that the active components of the Oraqix® are rapidly absorbed into the oral tissue. Since the pain rating scores are higher in the 2-min and 5-min groups, it is most likely that there is a limited duration of anesthesia, even though the gel was contained in the periodontal pocket until SRP began. Our interpretation of this observation is that the SRP procedure was completed while the anesthesia was still effective when the procedure commenced in the 30-s group. The Oraqix® results are similar to results from EMLA® studies on genital mucous membranes (Ljunghall & Lillieborg 1989, Rylander et al. 1990).

The likely explanation for the lower pain intensity score with a short application time for Oraqix® is the rapid elimination of the anesthetics from the body tissues by the local blood flow, which is probably accelerated by lidocaine/prilocaine-induced vasodilation. Lidocaine and prilocaine exhibit a biphasic, dose-dependent, vascular response. At low concentrations they cause vasoconstriction, and at higher concentrations they cause vasodilation (Covino & Wildsmith 1998).

The method of assessing duration of action, using a dental probe to ascertain whether a sensation could be felt, may not have fully reflected the SRP procedure. The logical alternative would be an estimate of the duration in conjunction with an SRP procedure.

However, a scaling stroke on the root surface changes the conditions at the place of the stroke. Moving the instrument to another part of the root or to another tooth does not give identical conditions. For this reason, periodontal probing was used as the indicator of perceived pain for the duration of action measure. In light of the fact that predominantly incisors, canines, and premolars were included in the present study and that the periodontal pockets around these teeth are more pain-sensitive than pockets at molars (Heins et al. 1998), the probing appears to be justified. The estimated mean duration of action was 17 to 20 min, with no significant difference between the application time groups.

The present study also indicates that the use of a 23-G blunt-ended applicator is highly acceptable and that Oraqix® can easily be administered into the periodontal pocket. The results also show that Oraqix® does not interfere with the SRP procedure in any way.

In conclusion, Oraqix® intra-pocket anesthetic used for periodontal anesthesia in conjunction with SRP provides anesthesia after an application time of 30 s and has duration of action sufficient for the intended purpose. Oraqix® is easy to apply and does not interfere with the SRP, shows no clinical signs of mucous membrane irritation, and its taste does not affect the patients' willingness to have the gel at their next visit.

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Zusammenfassung

Der Anästhesiebeginn und die -dauer eines neuen Lidocain/Prilocain Gels in Taschen (Oraqix®) für parodontales Scaling und Wurzelglättung

Hintergrund: Eine neues nicht zu injizierendes Anästhetikum, Lidocain/Prilocain Gel (Oraqix®, Astra Zeneca) in einem reversiblen thermischen System, wurde entwickelt, um die lokale Anästhesie für die Wurzelreinigung und -glättung (SRP) zu verbessern. Das Ziel dieser Studie war die Bestimmung des Anästhesieeintrittes und der -dauer durch dieses Gel bei SRP bei Parodontitis-Patienten.

Methoden: 30 Patienten wurden zufällig zur 30 Sekunden, 2 Minuten oder 5 Minuten Behandlung mit dem Gel vor der SRP eines Zahnes eingeteilt. Das Gel wurde mit einem stumpfen Applikator in die parodontalen Taschen appliziert. Nach der Vollendung der SRP eines jeden Zahnes (2–3 behandelte Zähne/Patient) beurteilten die Patienten ihre Schmerzen auf einer 100 mm visuellen Analogskala (VAS).

Ergebnisse: Der mittlere VAS Score war 7.5 mm in der 30 Sekundengruppen, 28.5 mm in der 2 Minutengruppe und 15.5 mm in der 5 Minutengruppe mit einer signifikanten Differenz zwischen der 30 Sekunden und der 2 Minutengruppe ($p=0.03$). Bei 2 Patienten in der 5 Minutengruppe, aber keinem in einer anderen Gruppe, wurde das SRP wegen Schmerzen unterbrochen. Die mittlere Dauer der Anästhesie, gemessen als Schmerz auf Sondierung, war 18.1, 17.3 und 19.9 Minuten in der 30 Sekunden, 2 Minuten und 5 Minutengruppe. Es gab keine Berichte über eine Taubheit der Zunge, der Lippen oder der Wangen. Irgendwelche negativen lokalen Reaktionen an der Mukosa wurden nicht beobachtet. Das Gel war leicht zu applizieren und beeinflußte die SRP Prozedur nicht.

Zusammenfassung: Oraqix® fördert die Anästhesie nach Applikation von 30 Sekunden mit einer mittleren Dauer von ungefähr 17 bis 20 Minuten.

Résumé

Prise et durée d'un nouveau gel intra-poche anesthésique (Oraquix®) lidocaine/prilocaine pour le détartrage et le surfaçage

Un nouvel anesthésique non-injectable, un gel de lidocaine/prilocaine (Oraquix®, Astra-Zeneca) dans un système thermique réversible a été mis au point afin de créer une anesthésie locale lors du détartrage et du surfaçage radiculaire (SRP). Le but de cette étude a été de déterminer la prise et la durée anesthésique de ce gel pour le SRP chez des patients avec parodontite. 30 patients ont été traités avec ce gel pendant 30 s, 2 min ou 5 min avant le SRP d'une dent. Le gel a été placé dans les poches parodontales avec un applicateur arrondi. A la fin du SRP de chaque dent (2 à 3 dents traitées par patient) les patients ont quantifié leur douleur sur une échelle analogue visuelle de 100 mm (VAS). Le score de douleur VAS moyen était de 7.5 mm dans le groupe de 30 s, 28.5 mm dans le groupe 2 min et de 15.5 min dans celui de 5 min avec une différence significative entre les groupes 30 s et 2 min ($p=0.03$). Chez 2 patients du groupe 5 min mais chez aucun des 2 autres groupes le SRP a été interrompu à cause de la douleur. La durée moyenne d'anesthésie mesurée en tant que douleur au sondage était respectivement de 18.1, 17.3 et 19.9 min pour les groupes 30 s, 2 min et 5 min. Il n'y a eu aucune plainte d'anesthésie de la langue, des lèvres ou des joues ni aucu-

ne réaction locale négative de la muqueuse buccale. Le gel a été facilement appliqué et n'a absolument pas gêné le SRP. L'Oraquix® apporte une anesthésie après un temps d'application de 30 s avec une durée d'action de 17 à 20 min.

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