

# A preliminary study of intra-pocket topical *versus* injected anaesthetic for scaling and root planing

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#### Abstract

**Aim:** Compare the efficacy of topical benzocaine gel to injected lidocaine during scaling and root planing.

**Materials and Methods:** In each of 21 participants undergoing root planing, two dental quadrants were randomly assigned to receive topical 20% benzocaine gel delivered subgingivally (TOP) or injection anaesthesia using 2% lidocaine (INJ). Baseline, intra- and immediate post-operative pain was assessed using the Heft–Parker pain scale. Intra-subject differences (INJ–TOP) were analysed using paired *t*-tests and mixed models. **Results:** Baseline and post-operative pain did not differ between treatments (p > 0.50). The injected anaesthetic, however, was associated with less intra-operative pain than the topical (INJ–TOP = -24.9 mm, p = 0.005) Six participants required rescue (injected) anaesthesia during treatment with the topical. Eleven participants (52%) preferred topical over injected anaesthetic. Among these 11, intra-operative pain scores did not differ significantly (TOP = 38.6 mm, INJ = 28.4 mm, p = 0.23). Among those who preferred the injected anaesthetic, intra-operative pain scores differed significantly (TOP = 84.7 mm, INJ = 43.8 mm, p = 0.03).

**Conclusions:** Intra-pocket benzocaine gel is less effective than injected lidocaine in controlling pain during scaling and planing. Anaesthetic preference was related to the level of pain experienced during treatment with the topical. Larger studies are needed to confirm these findings.

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Patients vary in their ability to tolerate painful or stressful dental procedures (Klages et al. 2004). Although effective

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The authors declare that they have no conflict of interests.

Supported by NIDRC DE09737 and the Erwin Schaffer Chair in Periodontal Research. None of the authors have or have had any financial relationship with Ultradent Products Inc., maker of the benzocaine gel application system, or any company that manufactures or markets dental anaesthetics. anaesthetic agents are available, fear of injections is a common reason patients avoid dental care (Milgrom et al. 1997). While no single technique has been identified to completely replace local injection anaesthesia, several alternatives, such as reassurance, biofeedback, distraction, transcutaneous electronic nerve stimulation (TENS), hypnosis, and nitrous oxide have been used to alleviate pain associated with dental procedures.

Topical anaesthetics have been used in dentistry to reduce or eliminate discomfort associated with needle penetration (Hutchins et al. 1997, Abu Al-Melh et al. 2005, Algareer et al. 2006) and control pain during periodontal procedures. When compared with placebos, lidocaine-containing bioadhesive patches can significantly reduce pain during scaling and root planing (Carr & Horton 2001b). The patch, however, must remain in contact with the tissue up to 15 min. beforehand (Carr & Horton 2001a). Lidocaine plus prilocaine in a thermosetting agent also has been shown to be effective in controlling intra-operative pain during scaling and root planing (Jeffcoat et al. 2001, Donaldson et al. 2003, Magnusson et al. 2003). Topical anaesthetics may also

Although topical 20% benzocaine gel can reduce pain associated with intra-oral injections (Meechan 2000), no studies have evaluated its efficacy as a stand alone agent for non-surgical periodontal procedures. The purpose of this randomized, split-mouth study was to compare the analgesic efficacy between an intra-pocket topical 20% benzocaine gel and conventional local injection anaesthesia (2% lidocaine with 1:100,000 epinephrine) during scaling and root planing.

#### **Materials and Methods**

The University of Minnesota Institutional Review Board approved the study protocol. All participants provided written informed consent.

Patients scheduled to undergo scaling and root planing were screened for eligibility in outpatient dental clinics. Patients were included if they were at least 18 years old, able to comprehend the visual analogue scale and had at least two dental quadrants each with three or more non-adjacent pockets 5 mm or deeper. Patients who were pregnant or lactating, required antibiotic prophylaxis before root planing, were allergic to lidocaine or benzocaine, or were currently taking an analgesic, steroid or non-steroidal anti-inflammatory drug(s) were ineligible. Patients with denture-related soreness, periodontal abscesses, gross caries or sensitive teeth were also excluded. Inclusion in the study was not based on a patient's level of anxiety concerning dental injections.

Before scaling and root planing, each subject completed a medical and dental history questionnaire and underwent a soft tissue and periodontal examination. Participants were individually instructed in the use of the Heft–Parker visual analogue pain scale (Fig. 1) by one of two experienced investigators (J. L. S., J. B. O.) who were not involved in providing treatment (Heft & Parker 1984). Pain was assessed before treatment (baseline), approximately midway through treatment (intra-operatively), and immediately after treatment (postoperatively). No painful or other stimuli were administered before obtaining baseline scores. The timing of the intra-operative assessment was based on the operator's estimate of the time required for instrumentation.

At the first of two study sessions, one qualifying dental quadrant was randomly assigned to receive either 20% benzocaine gel (test) or injected 2% lidocaine with 1:100,000 epinephrine (control). Randomization schedules were generated using a list of random numbers strictly maintained by the investigators. Therapists - third and fourth year pre-doctoral dental students - did not have access to these schedules. At a subsequent visit, a second qualifying quadrant was treated using the other method. One quadrant was treated per study visit and visits were separated by at least 7 days. Both curettes and ultrasonic instruments were used until the student and a supervising faculty member judged that the root surfaces were smooth, hard and free of accretions. No attempt was made to standardize the lateral forces applied to either the hand or ultrasonic instruments, although the same therapist treated both study quadrants in a participant. Therapists and participants knew which anaesthetic they administered or received.

A 1.2 cc pre-filled syringe with a blunt-tip applicator (Ultracare, ® Ultradent Products Inc., South Jordan, UT, USA) was used to apply the benzocaine gel subgingivally at sites in the chosen quadrant with probing depths 5 mm or more. Scaling and root planing was performed after waiting 1-2 min. The topical anaesthetic could be reapplied at any point during the appointment at the discretion of the therapist or participant. Injection (rescue) anaesthesia was administered if a participant felt the pain was intolerable after two applications of the benzocaine gel. If rescue anaesthesia was required, a final pain score was

Place a mark on the line below to show the amount of pain that you feel.



Fig. 1. The Heft-Parker visual analogue pain scale.

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obtained before administration of rescue anaesthesia.

At the completion of the second study visit, participants were asked which anaesthetic they preferred, if any. Reasons for any preference, however, were not recorded.

#### Statistical methods

Paired *t*-tests and mixed linear models were used to analyse pain scores. Because this was a split-mouth study, we analysed subject-based differences between scores, injected anaesthetic minus topical anaesthetic, or INJ-TOP. It was not necessary to transform these raw differences to improve their distribution. We used mixed models to estimate the treatment difference (INJ-TOP) adjusting for quadrant, baseline pain score, treatment length and interactions when needed. Differences between groups were considered statistically significant if  $p \leq 0.05$ . Pain scores were also analysed using the Wilcoxon signed-rank test. Results were similar to paired *t*-tests and therefore were not reported.

#### Results Demographic and study quadrant characteristics

Twenty-one subjects (15 males, six females) were randomized; all completed the study. The average age (SD) was 53 (12) years with a range of 32–78 years. Twenty had no history of periodontal treatment. Table 1 gives the distribution of dental quadrants by treatment assignment along with selected periodontal findings.

The mean treatment time for both groups (test and control quadrants) was 79 min. Treatment time ranged from 55 to 130 min. for quadrants treated with topical anaesthetic and from 55 to 105 min. for injected anaesthetic. Between 0.4 and 1.5 ml of the benzocaine gel was applied in test quadrants. The amount of gel applied to each tooth site was not recorded. Overall though, quadrants with multiple pockets  $\geq$  5 mm had more gel applied than quadrants with fewer sites.

#### Pain scores and participant preference

Test and control quadrants did not differ significantly in baseline pain scores (Table 2). The injected anaesthetic, however, was associated with significantly less intra-operative pain than topical (p < 0.005). This difference remained statistically significant (p < 0.05) in mixed models that adjusted for baseline pain scores, quadrant, treatment length and two-way interactions (results not shown). The order of anaesthetic use (topical *versus* injected) was not associated with differences in pain scores. Pain levels immediately after scaling and root planing did not differ significantly between topical and local anaesthetic (p = 0.50).

Males and females reported similar intra-operative pain scores with the injected anaesthetic (33.3 versus 36.7 mm, respectively, p > 0.2). Compared with males, however, females had higher intra-operative pain scores with topical and the difference in scores (INJ-TOP) differed significantly between the sexes [mean difference (95% confidence interval) = -53.0 mm(-86.3, -19.7) for females, -13.6 mm (-34.7, 7.5) for males, p = 0.05]. Age (in years) was not associated with differences in intra-operative pain scores (p = 0.60). Neither age nor sex was significantly associated with differences in post-operative pain scores (p > 0.2).

Intra- and post-operative pain scores were significantly correlated in quadrants treated with the injected anaesthetic (Pearson's correlation = 0.63, p = 0.002) but not in quadrants treated with the topical anaesthetic. No other pairwise correlation, comparing baseline, intra- and post-operative pain scores, was statistically significant (p > 0.1).

No participant reported an adverse event, although six of the participants (28.6%) required rescue anaesthesia when treated with the topical anaesthetic. Because these six participants could not tolerate scaling and root planing with topical anaesthesia alone, the mean difference in pain scores (injected minus topical) was much smaller when they were excluded from the analyses, which biased the results in favour of topical anaesthesia (Table 3). Therefore, the primary analyses (Table 2) were based on results from all study participants.

Eleven of 21 participants (52%) preferred topical over injected anaesthetic. Comparing groups in terms of anaesthetic preference, there were no significant differences in age, sex, baseline pain scores, treatment time, or the number Table 1. Characteristics of quadrants by treatment assignment

Outcome	Topical benzocaine	Injected lidocaine	<i>p</i> -value
Quadrant treated (UR/UL/LL/LR)	3/6/6/6	5/2/5/9	0.36*
Number of teeth per quadrant, mean (SD)	6.0 (1.2)	5.8 (1.2)	$0.20^{\dagger}$
Sites per quadrant with $PD \ge 5 \text{ mm}$ , mean (SD)	8.5 (5.4)	8.2 (3.9)	$0.77^{\dagger}$
(minimum, median, maximum)	(3, 8, 29)	(4, 7, 17)	
Sites per quadrant with $PD \ge 7 \text{ mm}$ , mean (SD)	1.2 (2.1)	1.1 (1.9)	$0.82^{+}$
(minimum, median, maximum)	(0, 0, 9)	(0, 0, 6)	

\*From  $\gamma^2$  test.

<sup>†</sup>From paired *t*-test.

UR, maxillary right; UL, maxillary left; LL, mandibular left; LR, mandibular right; SD, standard deviation.

Table 2. Heft-Parker pain scores by treatment assignment; all measurements in millimeters

Time	Topical benzocaine mean (SD)	Injected lidocaine mean (SD)	95% CI of the difference, injected – topical	<i>p</i> -value*
Baseline	5.1 (7.2)	7.0 (10.2)	- 1.8 to 5.4	0.29
	$(0, 3, 28)^{\dagger}$	(0, 3, 40)	(-18, 2, 26)	
Intra-	60.6 (42.6)	35.7 (27.6)	-44.0 to $-5.7$	0.005
operative	(0, 54, 166)	(0, 36, 112)	(-157, -23, 35)	
Post-	35.3 (27.4)	30.0 (19.6)	-17.2 to 6.5	0.50
operative	(0, 28, 84)	(0, 36, 63)	(-79, 0, 33)	

\*From paired t-test.

<sup>†</sup>The trio of numbers in parentheses is, respectively, the minimum, median, and maximum. SD, standard deviation; CI, confidence interval.

*Table 3.* Differences in pain scores according to need for rescue anaesthesia; all measurements in millimeters

	Intra-operative scores, injected – topical	Post-operative scores, injected – topical
All participants Excluding six participants who required rescue anaesthesia	-24.9 (p = 0.005) -17.5 (p = 0.046)	-5.3 (p = 0.36) 1.3 (p = 0.78)

of tooth sites with PD  $\ge 4$  mm for the quadrant treated with topical anaesthetic (p > 0.2 for all comparisons). Intra-operative pain scores did not differ significantly for participants who preferred the topical (TOP = 38.6 mm, INJ = 28.4 mm, p = 0.23) Among those who preferred the injected anaesthetic, however, intra-operative pain scores were significantly higher during treatment with the topical (TOP = 84.7 mm, INJ = 43.8 mm, p = 0.03).

#### Discussion

We found that on average, topical 20% benzocaine gel, delivered subgingivally via a blunt tip applicator, was associated with significantly more intra-operative pain during scaling and root planing than infiltration or regional block anaesthesia with 2% lidocaine and 1:100,000 epinephrine. Excluding the six participants who required rescue anaesthesia

reduced the apparent advantage of local anaesthesia over topical to 17.5 mm (p = 0.046). These six participants had high pain under topical anaesthesia so excluding them produced a smaller apparent disadvantage for topical. Despite significantly lower analgesia efficacy, the benzocaine gel was preferred by just over half the participants.

Topical anaesthetics may be preferred over injected anaesthetics for a number of reasons. Fear of pain is a common reason patients avoid professional dental care (Milgrom et al. 1997, Kaakko et al. 1998, Matthews et al. 2001), and for some the sight of an anaesthetic needle may be the most fearful experience in dentistry (Kleinknecht et al. 1973). Topical agents are safe when applied to oral mucosa (Hersh et al. 1996). Moreover, when compared with injected anaesthetics, relatively high concentrations of the active ingredient(s) can be used in topical preparations without producing toxic concentrations in plasma (Meechan 2000). Case reports suggest that topical anaesthetics alone may be adequate for some patients to control pain during restorative care (Vickers & Punnia-Moorthy 1993, Vickers et al. 1997) and oral surgical procedures such as tooth extractions (Gangarosa 1974, Taware et al. 1997) and soft tissue biopsies (Roller & Ship 1975).

Previous studies have found that intra-pocket topical gels are more effective than placebos at controlling pain during scaling and root planing (Friskopp et al. 2001, Jeffcoat et al. 2001). While we found local injection anaesthesia controlled pain more effectively on average than the benzocaine gel, it is clinically relevant that 71% of participants did not request rescue anaesthesia when treated with the topical gel. This latter finding is consistent with that of van Steenberghe et al. (2004), who reported that 70% of participants in an open-label study of a topical lidocaine and prilocaine preparation preferred the topical to injection anaesthesia. Most made this choice because local anaesthesia resulted in prolonged post-operative numbness. Thus, patients may be willing to tolerate mild to moderate pain to avoid dental injections (van Steenberghe et al. 2004, Crawford et al. 2005). Notably, patients who refuse local anaesthesia for routine dental procedures because of fear or anxiety would not have volunteered for our study. Therefore, our results may apply only to patients who are otherwise willing to receive intra-oral injections. In a clinical setting, it is possible that a larger proportion of patients may tolerate pain with the topical anaesthetic (and refuse rescue anaesthesia) because of fear, anxiety or post-operative numbness.

In our study, treatment was provided by undergraduate dental students. The result may have differed if we used more experienced therapists. The effect of operator experience on pain during scaling and root planing is unknown, although our use of inexperienced therapists may account for the greater need for rescue anaesthesia compared with previous studies (Jeffcoat et al. 2001). Notably, however, post-operative pain scores in the quadrants receiving local anaesthetic ("faint" to "weak" pain on the Heft-Parker scale) were similar to those reported in an earlier trial in which treatment also was performed by predoctoral dental students (Pihlstrom et al. 1999).

Our treatment protocol for scaling and root planing involved both hand and ultrasonic instrumentation. As recommended by the manufacturer, we allowed the topical benzocaine gel to remain in contact with the tissue for 1-2 min. before commencing with hand and powered instrumentation. It is possible, however, that some of the anaesthetic was washed away during ultrasonic instrumentation. Because ultrasonic scalers are commonplace in clinical practice, however, it was important to include this method of treatment in the study protocol.

We found that the difference in intraoperative pain scores (INJ-TOP) was significantly greater in females than males, indicating that females reported more intra-operative pain with the topical than did males. The number of females in this study, however, was small (N = 6) and we view this finding with appropriate caution. This finding, however, is consistent with reports that suggest females have a lower pain threshold to experimentally induced noxious stimulation (Rilev et al. 1998) and report more chronic pain conditions than males (Martin et al. 2007). Additional studies will be needed to confirm or refute our initial finding that the relative efficacy of topical versus injected anaesthetics during root planing differs between the sexes.

This preliminary study involved relatively few participants and the results will need to be confirmed in larger studies. Nonetheless, we found local injection anaesthesia to be on average significantly more effective than intrapocket topical anaesthesia (20% benzocaine) in reducing intra-operative pain during scaling and root planing. For some patients, however, intra-pocket administration of 20% benzocaine gel remains a viable anaesthetic option for non-surgical periodontal procedures. Additional studies will also be needed to determine if topical anaesthetics are more efficacious than injected anaesthetics in patient subgroups with selected baseline pain scores or levels of dental fear or anxiety.

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#### **Clinical Relevance**

Scientific rationale for the study: Fear of dental injections is a common reason patients avoid dental care. Case reports suggest topical anaesthetics alone may be adequate for a number of invasive dental procedures to control pain. Previous studies suggest that topical anaesthetics are more effective than placebos in redu-

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cing pain associated with scaling and root planing. No studies, however, have compared topical to injected anaesthetics for this procedure.

*Principal findings*: In this splitmouth scaling and root planing study, on average patients experienced more intra-operative pain in quadrants treated with topical 20% benzocaine gel than in quadrants and root planing. *Journal of Periodontology* **75**, 1471–1478.

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treated with injected 2% lidocaine (p = 0.005).

*Practical implications*: These preliminary findings suggest injected 2% lidocaine with 1–100,000 parts epinephrine is more effective than topical benzocaine in reducing intra-operative pain during scaling and root planing. This document is a scanned copy of a printed document. No warranty is given about the accuracy of the copy. Users should refer to the original published version of the material.