Original Article

The effectiveness of Oraqix versus $TAC_{(a)}$ for placement of orthodontic temporary anchorage devices

Thomas S. Kwong[a]; Budi Kusnoto[b]; Grace Viana[c]; Carla A. Evans[d]; Keiko Watanabe[e]

ABSTRACT

Objective: To test the hypothesis that there is no difference in the actions and effectiveness of topical anesthetics TAC Alternate ($TAC_{(a)}$) and Oraqix in placing temporary anchorage devices (TADs).

Materials and Methods: Each topical anesthetic was placed on opposing sides in the maxilla or mandible using blinded applicators for 3–9 minutes followed by the TAD placement. A total of 21 patients ranging from 10–25 years old were studied. During the procedure the primary investigator (PI) used the sound, eye, and motor scale to measure the movements elicited by the patient. The PI also noted the time taken for the topical anesthetic to be effective and the amount that was applied. Following the placement of the TADs, the patients were given the Wong-Baker FACES Scale and the Visual Analog Scale to rate the degree of discomfort. The nonparametric Wilcoxon signed-rank test was used to test the effectiveness of the treatments based on the three ordinal scales, the dosage, and the onset time.

Results: The time it took for the $TAC_{(a)}$ to provide adequate anesthesia averaged 4.43 minutes and for Oraqix the time was 6.33 minutes ($P = .00$). The minimum dosage of $TAC_{(a)}$ to provide adequate anesthesia averaged 0.25 mL, and for Oraqix the minimum dosage averaged 0.31 mL ($P = .00$).

Conclusions: The hypothesis was rejected. $TAC_{(a)}$ was more effective than Oraqix in placing TADs with a recommended dose of 0.20–0.30 mL and a minimum application time of 3 minutes. (*Angle Orthod.* 2011;81:754–759.)

KEY WORDS: Topical anesthetics; Temporary anchorage devices; Oraqix; TAC Alternate

INTRODUCTION

Compound topical anesthetics (CTAs) have their place in orthodontics and dentistry in general. Because they can anesthetize selective soft tissue surface layers (i.e., the mucosal lining and the periosteum) and do not penetrate into bone, their use can be especially advantageous for temporary anchorage device (TAD) placement.[1] Compounding is defined as the process by which the pharmacist or doctor combines, mixes, or alters pharmaceuticals or ingredients to create a custom-made medication in accordance with a prescription.[2] It should be noted that some important anatomic structures near the placement site remain sensitive, providing the practitioner with biofeedback from the patient during placement.[1] Notwithstanding the recent US Food and Drug Administration (FDA) warnings, there still arguably is a place for doctor-prescribed, doctor-applied CTAs for use on an individualized basis.[3]

CTAs have been used by many clinicians to place TADs, but there has been little documented evidence as to its effectiveness. This study was set out to compare the effectiveness of two topical anesthetics on placing TADs, namely Oraqix (Dentsply Pharma-

[a] Resident, Department of Orthodontics, College of Dentistry, University of Illinois at Chicago, Chicago, Ill.

[b] Associate Professor and Clinic Director, Department of Orthodontics, College of Dentistry, University of Illinois at Chicago, Chicago, Ill.

[c] Associate Professor and Biostatiscian, Department of Orthodontics, College of Dentistry, University of Illinois at Chicago, Chicago, Ill.

[d] Professor and Department Head, Department of Orthodontics, College of Dentistry, University of Illinois at Chicago, Chicago, Ill.

[e] Associate Professor, Department of Periodontics, College of Dentistry, University of Illinois at Chicago, Chicago, Ill.

Corresponding author: Dr Thomas S. Kwong, Resident, Department of Orthodontics, College of Dentistry, University of Illinois at Chicago, 801 S. Paulina St, Chicago, IL 60612 (e-mail: thomaskwong8@yahoo.com)

Accepted: February 2011. Submitted: February 2011.
Published Online: May 12, 2011

ceutical, York, Pa) and TAC Alternate ($TAC_{(a)}$; Professional Arts Pharmacy, Lafayette, La).

Oraqix is an FDA-approved topical anesthetic gel for scaling and root planing (SRP) and gingival curettage which contains 2.5% lidocaine and 2.5% prilocaine. The topical anesthetic comes preloaded in a carpule and has an applicator from the manufacturer. Each carpule of Oraqix contains 1.7 g of the gel and has a maximum recommended dose of 8.5 g. There are no studies to show that Oraqix is effective during TAD placement, but there are studies that show its effectiveness during SRP and during injections, which both include the mucosal architecture.[4–7]

$TAC_{(a)}$, on the other hand, is a compound mixture of 20% lidocaine, 4% tetracaine, and 2% phenylephrine and has become more popular in the orthodontic world but needs some additional evidence as to its effectiveness. $TAC_{(a)}$ comes from the pharmacy in a container and is typically applied to the mucosa with a cotton applicator without knowing the exact volume of anesthetic. The manufacturer's recommended dosage of $TAC_{(a)}$ is typically 2 mL or 2 cc applied for 2 to 3 minutes,[8] but it is difficult to measure the volume with a cotton swab.

According to Pryor et al.,[9] TAC with cocaine was the first topical anesthetic mixture found to be effective for use in simple suturing to the face and scalp and intact skin. During this time, TAC was composed of 0.5% tetracaine, 0.05% epinephrine, and 11.8% cocaine. Later, there were studies that showed that because of its toxicity, expense, and classification as a restricted narcotic, use of TAC with cocaine was decreasing.[10] $TAC_{(a)}$ was considered, therefore, a safer modification of the original formulation, with lidocaine in place of the controlled narcotic.

The purpose of this study is to determine the effectiveness of Oraqix vs $TAC_{(a)}$ for placement of orthodontic TADs. Effectiveness was measured by comparing the response of the patient to discomfort during the placement of the TAD, the onset time, and the amount of each topical anesthetic placed on the mucosa.

MATERIALS AND METHODS

This study was conducted exclusively at the University of Illinois at Chicago College of Dentistry, Department of Orthodontics and was approved by the Institutional Review Board (Protocol 2007-0513). The inclusion criteria for patients in this study were age 10 to 25 years, male or female, medically and dentally healthy, no known drug allergies, no medications, and treatment planned for a minimum of two TADs bilaterally in the maxilla or mandible. Patients excluded from the study were those who had palatal implants, had previously failed TAD placement, or had any craniofacial anomaly. Since the majority of the palatal implants placed at the research site were single implants, they were excluded from the study.

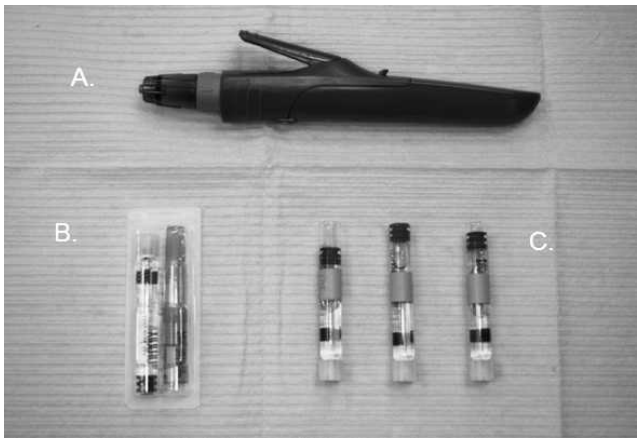

Figure 1. (A) Topical dispenser. (B) Oraqix carpule with applicator tip. (C) $TAC_{(a)}$ carpule with orange labels.

Twenty-one patients between the ages of 10 and 25 years were available to be treated with the placement of bilateral orthodontic TADs. Fourteen patients were between 10 and 15 years old, two were between 16 and 17 years old, and five were between 18 and 25 years old. All of the patients were aware that participation in this study was voluntary. An informed consent form was given and explained to the patients and parents prior to the start of the procedure.

The site of TAD placement was then located with a blunt ended explorer, and the mesial-distal dimension of bone was evaluated for adequacy with a periapical radiograph or panoramic radiograph. The sites included either the upper right and upper left quadrants or the lower right and lower left quadrants. The $TAC_{(a)}$ was placed into a sterilized Oraqix carpule and was marked with an orange label (Figure 1). The sites of the TAD placement were then dried off with a piece of gauze so that there was no saliva contamination.

The reason for placing both topical anesthetics into carpules was to blind the patient so he or she could not identify which anesthetic was being placed on their mucosa. The Oraqix dispenser has a plastic latch that when pushed produces a click, and each click produced approximately 0.07 mL of topical anesthetic. An initial dose of 0.20 mL (three clicks of the dispenser) of the topical anesthetic (either $TAC_{(a)}$ or Oraqix) was applied to the attached gingiva while the primary investigator (PI) started a stopwatch and waited for 3 minutes to elapse. After 3 minutes, the orthodontist tested for numbness by pushing firmly on the area with a blunt end dental explorer. If the patient was numb and elicited no signs of discomfort, the orthodontic TAD was placed without removing the

Score	Designation	Sounds	Eyes	Motor
0	Comfort	No sounds indicating pain	No eye signs of discomfort	Hands relaxed, no tenseness
1	Mild discomfort	Nonspecific possible pain indication	Eyes wide show of concern, no tears	Hands show some tension
2	Moderately painful	Specific verbal complaint. e.g. ow!	Watery eyes	Random movement of arms/body grimace, twitch
3	Painful	Verbal complaint of intense pain	Crying tears running down face	Movement of hands to make aggressive physical contact, pulling head away

Figure 2. SEM scale.

topical anesthetic. If at 3 minutes the patient was not numb and felt some sensitivity, the previously applied topical anesthetic was wiped off with a piece of gauze and another 2 minutes was added to the time with the addition of 0.07 mL, which was equivalent to one click of topical anesthetic. The same procedure was then repeated for a maximum of 9 minutes. Once the TAD was successfully placed, the topical anesthetic was removed with a piece of gauze.

During the procedure, the PI assessed the level of anesthesia by grading the patient's visual response using the SEM scale (Figure 2), which is a subjective measure of the sound, eye, and motor movement of the patient during the procedure. If the patient was not numb by 9 minutes, the study was terminated and local anesthesia was administered by injection to complete the placement. Immediately after each TAD was placed, the patient was given a survey with the Wong-Baker FACES Scale (WBS) (Figure 3) ranging from 1–5 (5 being the worst) and the Visual Analog Scale (VAS) (Figure 4) ranging from 0–10 (10 being the worst) to fill out about their experience with each procedure.

Age, race, gender, WBS, VAS, SEM, site, dosage, and time were all recorded during the procedure. The nonparametric Wilcoxon signed-rank test was used to test the effectiveness of the treatments based on the three ordinal scales, the dosage, and the onset time.

RESULTS

Forty-two TADs were placed in 21 patients. There was one patient out of the 21 who could not tolerate either topical anesthetic. After the maximum time of 9 minutes and maximum dose used in this study of 0.41 mL (six clicks of the dispenser), the PI injected 0.45 mL (one-fourth carpule) of 2% lidocaine with 1:100,000 epinephrine, and the TAD was placed with no complications. There also was another patient who was not able to have the TAD placed on one side after the maximum time and dose was used with the Oraqix topical anesthetic, and 2% lidocaine was used instead. The patient, however, was able to tolerate the placement of the TAD with $TAC_{(a)}$ on the contralateral side.

After the procedure, the WBS and VAS scores for both topical anesthetics were compared, and the results suggest that Oraqix scored higher values and $TAC_{(a)}$ scored lower values. The time it took for the $TAC_{(a)}$ to provide adequate anesthesia averaged 4.43 $\pm$ 1.57 minutes, and the time it took for Oraqix was 6.33 $\pm$ 2.31 minutes ($P = .00$). The average minimum dosage of $TAC_{(a)}$ to provide adequate anesthesia averaged 0.25 $\pm$ 0.05 mL, and the average minimum dosage it took for Oraqix was 0.31 $\pm$ 0.08 mL ($P = .00$) (Table 1).

The results showed statistically significant differences in all the paired variables between Oraqix and $TAC_{(a)}$, with $TAC_{(a)}$ showing to be more effective (Table 2).

DISCUSSION

The results from this study indicate that based on the dosage, onset time, the patients' responses to WBS and VAS, as well as the PI's observation of their

Figure 3. Wong-Baker FACES scale.

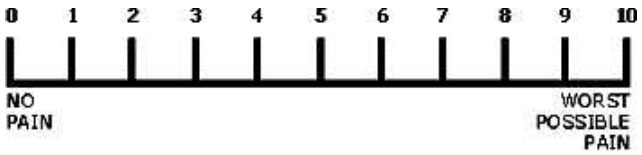

Figure 4. Visual Analog Scale.

Table 1. Summary of Oraqix and TAC Alternate ($TAC_{(a)}$)

	Oraqix	$TAC_{(a)}$
Active ingredients	2.5% Lidocaine, 2.5% prilocaine	20% Lidocaine, 4% tetracaine, 2% phenylephrine
Effective dose, mL	0.31 ± 0.08	0.25 ± 0.05
Onset time, min	6.33 ± 2.31	4.43 ± 1.57
Shelf life, mo	36	6
Price, $US/g	3.29	1.80
Contraindications	• Hypersensitive to amide type local anesthetics • Idiopathic methemoglobinemia	• Allergies to amide and ester-type anesthetics • Glucose-6-phosphate dehydrogenase deficiency and congenital or idiopathic methemoglobinemia • Cardiovascular disease (contraindication for a vasoconstrictor)

SEM movement that $TAC_{(a)}$ is a more effective topical anesthetic during the placement of TADs than Oraqix.

The orthodontic patient population at the research site consists mainly of teenagers to young adults; therefore, the study was limited to 10- to 25-year-old patients. The decision to place TADs in certain cases was determined by the attending faculty to achieve ideal orthodontic treatment results. Twenty-one patients were collected in the current study as compared with 17 by Reznik et al.,[11] who did a similar study, but compared $TAC_{(a)}$ to 20% benzocaine. The age range in the current study was from 10–25 years compared with a larger age range of 12–76 years in the study by Reznik et al.,[11] which could introduce more variability in the results.

Twenty-six TADs were placed in the maxilla and 16 TADs were placed in the mandible. The TADs were placed at the mucogingival junction or more coronal in order to avoid the unattached gingival tissue. In the study by Resnik et al.[11] there was no mention as to where the TADs were placed. In their study, intervention for each patient extended over a 5-day period; the first TAD and topical anesthetic were placed on day 1, and the second TAD and topical anesthetic were placed on day 5. They did not mention in their article as to why there was a 5-day wait period. In the current study, both TADs and topical anesthetic were placed at the same visit and rated at the same time. The idea was that the patient would be able to compare and rate the topical anesthetic he or she preferred on the same day. The topical anesthetic was placed by the PI, but the TAD placement was completed by the resident who was managing the case for educational purposes.

The difference in effectiveness and pain ratings between $TAC_{(a)}$ and Oraqix could be due to the presence of an ester (tetracaine) and an amide (lidocaine) anesthetic as well as a vasoconstrictor (phenylephrine) in $TAC_{(a)}$. The higher percentage of lidocaine in $TAC_{(a)}$ could also have an effect on the effectiveness of the topical anesthetic. Several studies have been performed to compare mixtures of topical anesthetics, most commonly EMLA (2.5% lidocaine and 2.5% prilocaine) vs single anesthetic agents. Both McMillan et al.[12] and Donaldson and Meechan[13] found the combination topical anesthetics to be more effective than the single topical anesthetic agents for minor manipulations of the gingiva. In this case, the $TAC_{(a)}$ had an extra anesthetic agent as compared to Oraqix, which may contribute to the increased effectiveness in terms of placing TADs.

In previous studies, Oraqix was used mainly for SRP procedures by placing the topical anesthetic into the periodontal pocket. There were no other studies that used Oraqix as a topical anesthetic to place TADs. The current results showed that Oraqix was not as effective for the placement of TADs as $TAC_{(a)}$, suggesting that Oraqix should be limited to its use in SRP procedures as confirmed with previous studies.[4–6]

There were no side effects when placing both the topical anesthetics and TADs for all of the patients in this study, and there were no postoperative complaints of pain, numbness, or swelling. The mucosal tissue after removing the topical anesthetic was clinically acceptable with no sloughing of the tissue or erythematous areas. The most common answer to the question ''How did the procedure feel?'' was that the patient felt some type of pressure. The patients were all very understanding of the procedure and had no complaints afterwards. Clinicians need to reiterate to the patient before the procedure that complete numbness will not occur and that while the TAD is being placed, pressure will be felt, but if any sharp pain is noted, the clinician should be informed immediately.

It is difficult to predict and measure the level of anesthesia of the periosteum and cortical bone with any type of anesthetic. The question still remains whether topical anesthetics such as $TAC_{(a)}$ are more effective than the traditional local infiltration anesthetics. More studies will need to be completed relating topical anesthetics to the injection method. In the current study, the onset time of the topical anesthetic was determined and can now be used as a guide for clinicians to follow.

Every click of the Oraqix dispenser produced approximately 0.07 mL of topical anesthetic onto the mucosa. Determining the minimum effective dose of the topical anesthetic in this study can now help clinicians know the approximate amount of $TAC_{(a)}$

Table 2. Wilcoxon Signed Rank Test

Paired Variables	N	Mean Rank	*P* Value
Oraqix FACES - $TAC_{(a)}$ FACES			
Negative rank	2[a]	5.00	.002
Positive rank	14[b]	9.00	
Ties	5[c]		
Total	21		
Oraqix VAS - $TAC_{(a)}$ VAS			
Negative rank	3[a]	3.00	.004
Positive rank	12[b]	9.25	
Ties	6[c]		
Total	21		
Oraqix SEM sound - $TAC_{(a)}$ SEM sound			
Negative rank	1[a]	4.50	.008
Positive rank	10[b]	6.15	
Ties	10[c]		
Total	21		
Oraqix SEM eye - $TAC_{(a)}$ SEM eye			
Negative rank	1[a]	5.00	.013
Positive rank	9[b]	5.56	
Ties	11[c]		
Total	21		
Oraqix SEM motor - $TAC_{(a)}$ SEM motor			
Negative rank	2[a]	5.00	.017
Positive rank	10[b]	6.80	
Ties	9[c]		
Total	21		
Oraqix time - $TAC_{(a)}$ time, min			
Negative rank	1[a]	3.00	.004
Positive rank	11[b]	6.82	
Ties	9[c]		
Total	21		
Oraqix dose - $TAC_{(a)}$ dose, mL			
Negative rank	1[a]	3.00	.004
Positive rank	11[b]	6.82	
Ties	9[c]		
Total	21		

[a] Oraqix $<$ $TAC_{(a)}$.
[b] Oraqix $>$ $TAC_{(a)}$.
[c] Oraqix $=$ $TAC_{(a)}$.

needed in the placement of TADs. The patients were blinded from which anesthetic was being placed on their mucosa by having both topical anesthetics in carpules. However, the PI was not blinded from which topical was being placed since the PI was the one who put the carpules into the dispenser. Future studies could have the PI blinded by having an auxiliary load the carpule into the dispenser instead of the PI.

A thorough medical history needs to be taken prior to the application of any topical anesthetic to screen for patients who may be allergic to amides or esters, or who may have glucose-6-phosphate dehydrogenase deficiency and congenital or idiopathic methemoglobinemia or cardiovascular disease.[14] If a patient presents with hypertension, $TAC_{(a)}$ should not be used since it contains phenylephrine, and the traditional local infiltration with an anesthetic without epinephrine should be used. All of the patients in this study met the inclusion criteria of being healthy with no known drug allergies or medications, but in orthodontic practice there may be some patients who may not fit these inclusion criteria and will have to be treated accordingly.

Even though the data sets showed high variability, the parametric and nonparametric tests showed statistically significant differences between all variables. In studies dealing with pain, variability always exists since everyone does not perceive pain the same way. Differences in age and gender could also be a factor in the variability. Though there were many studies that have used $TAC_{(a)}$ for medical purposes, this current study and the study conducted by Reznik et al.[11] showed that $TAC_{(a)}$ can be used successfully for TAD placement. Even though both studies did not test against the same topical anesthetic, the superior anesthetic in both studies was $TAC_{(a)}$.

CONCLUSIONS

- $TAC_{(a)}$ was demonstrated to be more effective than Oraqix in placing orthodontic TADs.
- It is recommended that 0.20–0.30 mL of $TAC_{(a)}$ be applied for a minimum of 3 minutes to be effective in placing TADs.
- $TAC_{(a)}$ proved to be the topical anesthetic that provided more comfort to the patient during the placement of TADs.

ACKNOWLEDGMENT

We appreciate Dentsply Pharmaceutical for providing the Oraqix topical anesthetic in this study.

REFERENCES

1. Baumgaertel S, Razavi M, Hans M. Mini-implant anchorage for the orthodontic practitioner. *Am J Orthod Dentofacial Orthop*. 2008;133:621–627.
2. United States Pharmacopeial Convention. Good compounding practices. In: The United States Pharmacopeia: USP 28: the National Formulary: NF 23: by authority of the United States Pharmacopeial Convention Inc, meeting in Washington, April 12–16, 2000. Rockville, Md: United States Pharmacopeial Convention; 2004:2457, 2620.
3. Kravitz ND. The use of compound topical anesthetic: a review. *J Am Dent Assoc*. 2007;138:1333–1339.
4. Friskopp J, Nilsson M, Isacsson G. The anesthetic onset and duration of a new lidocaine/prilocaine gel intra-pocket anesthetic (Oraqix) for periodontal scaling/root planing. *J Clin Periodontol*. 2001;28:453–458.
5. Magnusson I, Geurs NC, Harris PA, Hefti AF, Mariotti AJ, Mauriello SM, Soler L, Offenbacher S. Intrapocket anesthesia for scaling and root planing in pain-sensitive patients. *J Clin Periodontol*. 2003;74:597–602.
6. Al-Melh MA, Andersson L. Comparison of topical anesthetics (EMLA/Oraqix vs. benzocaine) on pain experienced

during palatal needle injection. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*. 2007;103:16–20.
7. Shavit I, Hadash A, Knaani-Levinz H, Shachor-Meyouhas Y, Kassis I. Lidocaine-based topical anesthetic with disinfectant (LidoDin) versus EMLA for venipuncture. *Clin J Pain*. 2009;25:711–714.
8. Kravitz ND, Kusnoto B. Placement of mini-implants with topical anesthetic. *J Clin Orthod*. 2006;40:602–604.
9. Pryor GJ, Kilpatrick WR, Opp DR. Local anesthesia in minor lacerations: topical TAC vs lidocaine infiltration. *Ann Emerg Med*. 1980;9:568–571.
10. Kundu S, Achar S. Principles of office anesthesia, part II: topical anesthesia. *Am Fam Physician*. 2002;66:99–102.
11. Reznik D, Jeske A, Jung WC, English J. Comparative efficacy of 2 topical anesthetics for the placement of orthodontic temporary anchorage devices. *Anesth Prog*. 2009;56:81–85.
12. McMillan AS, Walshaw D, Meecha JG. The efficacy of EMLA and 5% lignocaine gel for anaesthesia of human gingival mucosa. *Br J Oral Maxillofac Surg*. 2000;38:58–61.
13. Donaldson D, Meechan JG. A comparison of the effects of EMLA cream and topical 5% lidocaine on discomfort during gingival probing. *Anesth Prog*. 1995;42:7–10.
14. Baumgaertel S. Compound topical anesthetics in orthodontics: putting the facts into perspective. *Am J Orthod Dentofacial Orthop*. 2009;135:556–557.