

# Comparison between Topical and Injection Anesthetics on Pain Related to Orthodontic Miniscrew Placement: A Split-mouth Study

Manal A Al-Melh<sup>1</sup>, Hanan Badr<sup>2</sup>, Lars Andersson<sup>3</sup>

## ABSTRACT

**Aims and objectives:** The aims of this study were to compare the anesthetic effect of a lidocaine/prilocaine (L/P) topical anesthetic with placebo on pain from needle sticks and to compare the anesthetic effect of the L/P topical anesthetic with an infiltrative anesthetic on pain from orthodontic miniscrew placement.

**Materials and methods:** Pain elimination was analyzed from two interventions: (a) needle stick and (b) miniscrew insertion. When assessing pain from needle stick, one side of the mandible received 2.5% lidocaine/2.5% prilocaine topical anesthetic, and the other side received placebo. When evaluating pain from miniscrew placement, one side of the mandible received L/P topical anesthetic and the other side received infiltrative anesthetic. The findings were recorded on a Visual Analogue Scale after needle stick and after miniscrew placement. Subjective assessment was analyzed by a questionnaire.

**Results:** The L/P topical anesthetic significantly eliminated the pain from needle stick (Mann–Whitney test of medians, 29.0 vs 0.0, respectively,  $p < 0.001$ ). However, the injection anesthetic eliminated the pain from the miniscrew placement better than the L/P topical anesthetic (Mann–Whitney test of medians, 0.0 vs 5.5, respectively,  $p < 0.001$ ). Eighty percent of the subjects felt more comfortable with L/P topical anesthetic than injection anesthetic. Pain from needle stick pain was reported to be the most uncomfortable part of the study.

**Conclusion:** The L/P topical anesthetic efficiently eliminated pain from needle stick. The L/P topical anesthetic did not completely eliminate pain from miniscrew placement as the injection anesthesia, but it did reduce pain to tolerable levels.

**Clinical significance:** L/P topical anesthetics can significantly eliminate pain from needle stick injections, and L/P topical anesthetics can reduce pain from orthodontic miniscrew placement to tolerable levels.

**Keywords:** Injection anesthesia, Miniscrews, Needle stick, Pain, Topical anesthesia.

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## INTRODUCTION

Temporary skeletal anchorage devices, also known as mini-implants or miniscrews, are commonly used in orthodontic procedures to enhance anchorage.<sup>1</sup> Mini-implants allow dental movement to be achieved at the transverse, vertical, and anterior–posterior planes without adverse effects.<sup>2,3</sup>

Placement of miniscrews requires the use of injection anesthesia, which is commonly associated with discomfort and pain.<sup>4</sup> Some orthodontic patients reject the treatment option that involves the placement of miniscrews because an injection anesthesia is necessary. The orthodontic patients' subsequent rejection of the miniscrew placement may compromise the treatment, and the final result of the orthodontic treatment may not be ideal.<sup>4</sup>

The pain experienced from injection anesthesia is usually linked to two painful procedures, which are the needle stick itself and the later injection of the anesthetic solution.<sup>5</sup> Therefore, some orthodontists in clinical practices today use topical anesthesia to anesthetize the mucosal tissues before inserting the injection needle and the orthodontic miniscrew.

Compound topical anesthetics (CTAs) have shown promising results in various orthodontic procedures, and they are considered to be an effective alternative for orthodontic patients who fear injection anesthesia and miniscrew placement.<sup>6</sup> Although injection anesthesia is more effective than topical anesthetics in blocking the innervated structures within the bone, topical anesthetics can

<sup>1</sup>Department of Developmental and Preventive Sciences, Kuwait University, Faculty of Dentistry, Kuwait

<sup>2</sup>Department of Community Medicine, Kuwait University, Faculty of Medicine, Kuwait

<sup>3</sup>Department of Oral and Maxillofacial Surgery and Oral Medicine, Faculty of Odontology, Malmö University, Sweden

**Corresponding Author:** Manal A Al-Melh, Department of Developmental and Preventive Sciences, Kuwait University, Faculty of Dentistry, Kuwait, Phone:+96567722222, e-mail: mabualmelh@hsc.edu.kw

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provide benefits to the treating orthodontist. Topical anesthetics can permit patients to report and describe the pain if the miniscrew was placed nearby sensitive anatomic structures, which helps in preventing serious injury.<sup>6</sup> Moreover, injection of the infiltration anesthetic can cause tissue ballooning which can obscure the area for miniscrew placement. This can be prevented by using an effective combination of topical anesthetics.<sup>6–8</sup>

One study compared the effectiveness of topical benzocaine 20% vs a combination of lidocaine, tetracaine, and phenylephrine in delivering adequate analgesia for the placement of orthodontic temporary anchorage devices (TADs), and it was found that a combination product was significantly more effective.<sup>9</sup> CTAs can eliminate the need for injection and improve the orthodontic patient's acceptance of the miniscrew placement procedure.<sup>10,11</sup>

Lidocaine/prilocaine (L/P) topical anesthetics, in a creamy eutectic mixture or a thermosetting gel confirmed to be very effective in reducing or eliminating pain associated with needle stick injections, suturing of facial lacerations, and different orthodontic procedures.<sup>12-18</sup>

The effect of L/P topical anesthetics on pain from needle stick injection was previously studied in the maxillary vestibule and palatal mucosae. These studies showed that the L/P topical anesthetics were more effective in eliminating pain from needle stick than 20% benzocaine in the maxilla.<sup>14-16</sup> More recently, a study showed that the L/P topical anesthetic can significantly reduce pain from immediate placement of orthodontic elastomeric separators.<sup>19</sup> To the authors' knowledge, no study was conducted to assess the effect of the L/P topical anesthetic on pain from needle sticks in the mandible.

A systematic review was conducted to evaluate the effectiveness of some common anesthetic techniques for decreasing pain during mini-implant placement. It was demonstrated that CTAs that contain 20% lidocaine had greater effects than topical anesthetics that include lower amounts of lidocaine and the common topical anesthetic consisting of 20% benzocaine.<sup>20</sup>

According to clinical experience, some orthodontic patients rejected miniscrew placement procedure because of the idea of receiving a needle stick prior to miniscrew placement. This was true even if they were told that they will receive a topical anesthetic prior to needle insertion. Also, for some patients who went through a bad experience with a needle stick, the thought of a needle can trigger fear which may lead to procedure rejection. Hence, for miniscrew placement, it would be advantageous to offer those patients anesthetic options that do not involve any needles.

The aims of this study were to compare the anesthetic effect of a 2.5% lidocaine 2.5% prilocaine(L/P) topical anesthetic with a placebo on pain from needle sticks and to compare the anesthetic effect of the L/P topical anesthetic with an infiltrative anesthetic on pain from miniscrew placement in the mandible.

## MATERIALS AND METHODS

An advertisement about volunteering undergraduate dental students, staff members, and dental assistants from the Faculty of Dentistry at Kuwait University, who were interested in the topic of miniscrew application and familiar with the procedure, was announced. The study sample size was calculated in order to have a significant difference of at least 1.00 cm in visual analog scale (VAS) and a standard deviation of 1.1 between the two methods of anesthesia. A sample size of around 19 (18.6) subjects was needed at power test of 80% and considering alpha error ( $\alpha$ ) = 0.05 and beta error ( $\beta$ ) = 0.2.

The study included 20 healthy adult subjects with the age ranging from 24 to 40 years old (mean age of  $32.2 \pm 5.3$  years and median of 32 years). After thorough explanation of the aims of the study and the procedures to be conducted, a written consent was obtained from all participating subjects. Additionally, all the subjects were informed that their participation was completely

voluntary and that they could withdraw from the study at any time.

The present study was planned as a split-mouth design. The study's experimental design and protocol were approved by the Ethical Committee of the Health Sciences Center at Kuwait University(VDR/EC/2165).

The inclusion criteria included healthy subjects with healthy gingival and bone tissues. Moreover, the subjects should have an existing recent panoramic radiograph, which shows adequate interradicular space between the lower second premolars and first molars. The exclusion criteria comprised of subjects with the absence of lower second premolars or lower first molars and existing prosthetic implants replacing missing lower second premolars or lower first molars. The study also excluded subjects with any pathology associated with the lower second premolars and first molars and the interradicular bony area at the site of application were excluded from the study. In addition, pregnant women and subjects with systemic diseases and/or are taking systemic analgesics, and subjects with allergies toward any of the components of the anesthetic agents were excluded from the study.

Before the start of the procedure, the subjects were asked to rinse their mouths with a chlorhexidine mouth wash for 30 seconds. Only the subjects were blinded during the study by wearing sunglasses with gauze taped to inner side of the lenses to block direct vision. Also, the sunglasses had padded lens frames and thick side frames which helped obscure side vision.

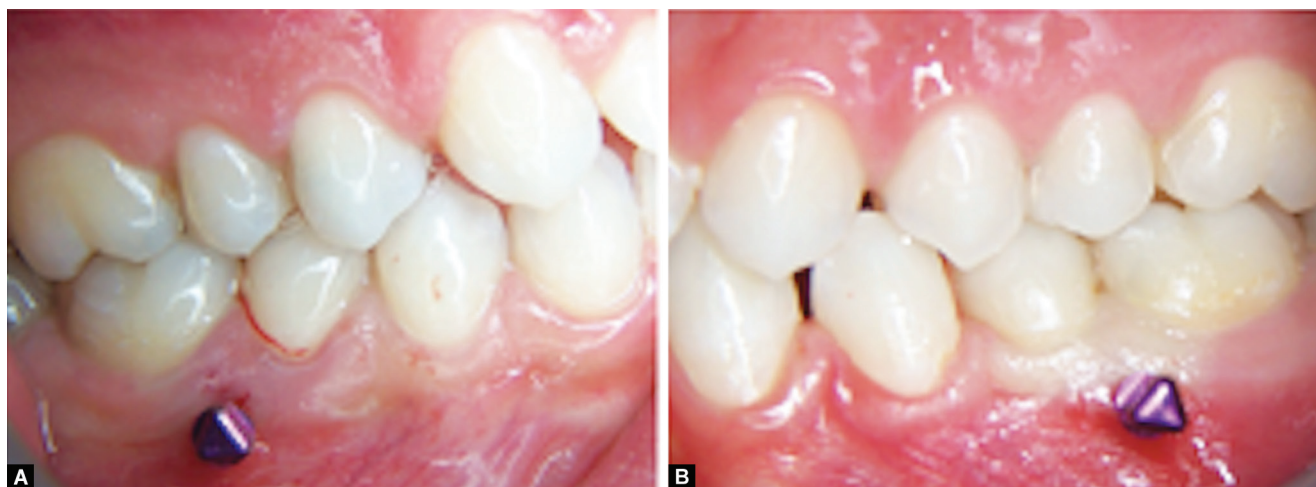
The gingival tissues of the first molars and second premolars from both sides of the mandibular arch were dried by using gauze and an air-water syringe. A suction device and cotton rolls were used to achieve a dry field prior to the application of agents and throughout the procedure. The subjects had their mouths open during the entire experimental procedure.

This was a split-mouth design study with one side of the mandible receiving the L/P topical anesthetic (Oraqix®, DENTSPLY International, Pennsylvania, USA) and the other side of the same jaw receiving the injection anesthetic. The sides onto which the L/P topical anesthetic and the injection anesthetic were applied were alternated for every patient. The procedure always started with the L/P topical anesthetic side due to limited anesthetic duration as well as the sensitivity of moisture control.

Before placement of the miniscrew, the subject's panoramic radiograph was used to examine the area for the miniscrew placement. The miniscrew system used in this study was the Vector TAS (Vector Temporary Anchorage System, Ormco, California, USA), which included the smallest miniscrew with dimensions of 6 mm length and 1.4 mm width and a Vector TAS Modular Driver. The placement of the topical anesthetic, injection anesthetic, and miniscrews was performed by the main investigator who is a highly trained orthodontist with good operator skills.

For the registration of pain level, the subjects were requested to remove their sunglasses and instantly record their findings on a VAS at two different time points: after the needle stick and after the miniscrew placement. The overall pain was measured by the subjects by means of a 100-mm horizontal nongraded VAS, with the left end point marked as "no discomfort/pain," and the right end point marked as "worst possible discomfort/pain." The subjects were informed that the procedure will be halted should they feel intolerable discomfort or pain during the miniscrew placement.

At the end of the experimental part of the study, the miniscrews were carefully removed using the same Vector TAS miniscrew driver



**Figs 1A and B:** Placement of the miniscrew on (A) the right side of the mandible, which received injection anesthesia, and (B) the left side of the mandible, which received the topical anesthesia (Oraqix®)

that was used to place them. The subjects were allowed to rinse their mouths with water. After that, the subjects were asked to fill out a questionnaire.

The questionnaire contained questions about the type of pain/discomfort experienced during the miniscrew placement, and the numbing effect right after the study, 10 minutes after the study, and 1 hour after the study. Moreover, the questionnaire included questions about the presence of lip numbness and effectiveness of the anesthesia for miniscrew placement.

Procedural comfort was assessed based on the subject's experience from the application of the topical anesthetic, administration of the needle stick, injection of the anesthetic solution in the injection anesthetic side, and the placement of the miniscrew. After 1 day, the subjects were interviewed regarding the occurrence of any side effects related to the procedures conducted.

### L/P Topical Anesthesia Side

On one side of the mandible, a quarter of a carpule of the 2.5% lidocaine/2.5% prilocaine (L/P) topical anesthetic gel, Oraqix® (DENTSPLY International, Pennsylvania, USA), was placed on the attached gingiva and alveolar mucosa between the first molar and second premolar areas. The L/P topical anesthetic was placed using an Oraqix® dispenser and a blunt dispensing needle. The procedure of dispensing the topical anesthetic gel was noninvasive and entirely painless as the gel was applied directly on the mucosal tissue in the area of miniscrew placement.

To improve the viscosity of the L/P topical anesthetic, prior to loading the vial in the dispenser, it was placed in bowl containing warm water with a temperature of 37°C, which approximately simulated the intraoral temperature for most individuals. The reason for performing this procedure was because the L/P topical anesthetic is a thermosetting gel, indicating that it is in a low-viscosity fluid state in room temperature, and it hardens to an elastic gel within intraoral temperature.<sup>12,13</sup>

After a waiting period of 8 minutes, the anesthetic effect of L/P topical anesthetic was tested by inserting a short injection needle (gauge # 30, Novocol Dental Hypodermic Needles) through the mucosa up to bone contact. The needle was inserted in the area where a buccal injection anesthesia would ideally be given. Then,

the subjects were asked to promptly grade the discomfort/pain experienced from the needle stick using the VAS.

Using a piece of gauze, the topical anesthetic was wiped off. Then, a periodontal probe was used to demarcate the area for miniscrew placement. Afterward, using the miniscrew driver, the miniscrew was manually placed in the area between the lower second premolar and first molar, through the mucosa, and engaging the cortical bone. Using gentle and controlled pressure, the miniscrew was inserted through the bone until the miniscrew collar was about 1 mm away from the mucosal tissue (Fig. 1). Next, the subjects were asked to register the pain/discomfort experienced during the miniscrew placement using the VAS. The subjects were then allowed to rinse their mouths with water.

### Injection Anesthesia Side

To closely simulate the application procedure in the topical anesthesia side, a placebo Vaseline® (Unilever, USA) was placed on the attached gingiva and alveolar mucosa between the mandibular second premolar and the first molar on the other side of the mandible of the same subject. The method for applying Vaseline® on the gingiva and alveolar mucosa was by using an irrigation syringe. To simulate the topical anesthesia side, there was a waiting period of 8 minutes after applying Vaseline®.

A nonaspirating syringe (Hu-Friedy) was prepared with a short injection needle (gauge # 30, Novocol Dental Hypodermic Needles) and an anesthetic carpule. After 8 minutes, the short injection needle was inserted through the buccal vestibular mucosa and up to bone contact.

Before administering the infiltrative anesthetic solution, the subjects were asked to instantly record the pain or discomfort experienced from the needle stick using the VAS. Then, a quarter carpule of an injection anesthetic containing 2% lidocaine hydrochloride and 1:100,000 epinephrine (Octocaine 100, Novocol Pharmaceutical of Canada) was given in the buccal vestibule in the area between the lower second premolar and the first molar.

After a waiting period of 2 minutes, the area for miniscrew placement was demarcated by using a periodontal probe. Next, the miniscrew was placed manually using the same protocol as the L/P topical anesthetic side. Then, the subjects were requested to grade

the pain or discomfort experienced during the placement of the miniscrew by using the VAS.

**Statistical Methods**

The data management, analysis, and graphical presentation were carried out using the computer software, "Statistical Package for Social Sciences, SPSS version 25.0" (IBM Corp, Armonk, New York, USA). The descriptive statistics for all the subjects reporting the least pain sensation when comparing both sides have been presented as numbers and percentages. The continuous variable (age) was presented as mean ± standard deviation (ci) and as median. The normality of the data was tested and was found not-normally distributed; therefore, nonparametric tests were used. Mann-Whitney test was used to compare the median of pain between the injection anesthesia side and the topical anesthesia side during needle stick and miniscrew placement procedures. The two-tailed probability *p* value of <0.05 and confidence interval [CI] at 95% were considered statistically significant.

**RESULTS**

**Visual Analog Scale**

The median pain scores reported by the subjects after the needle stick was significantly higher on the injection anesthesia side (29.0 mm) compared to the topical anesthesia side (0.0 mm), as illustrated in Figure 2 and Table 1. Hence, the L/P topical anesthetic significantly eliminated the pain from needle stick. However, the opposite pattern of response from the subjects was observed during the miniscrew procedure.

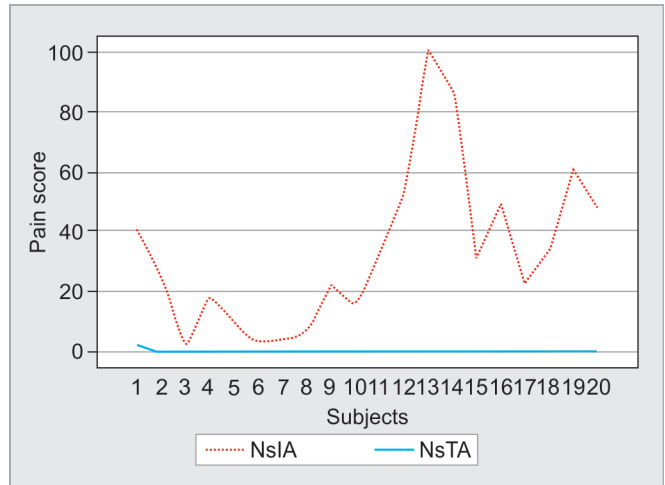
As shown in Table 1 and Figure 3, the median pain scores reported by the subjects for the injection anesthesia side were significantly much less than that of the topical anesthesia side (0.0 vs 5.5 mm, respectively) after placement of the miniscrew.

Although Figure 2 [needle stick infiltration anesthesia (NsIA) vs needle stick topical anesthesia (NsTA)] and Figure 3 [miniscrew infiltration anesthesia (MiIA) vs miniscrew topical anesthesia (MiTA)] show differences between the sides that are statistically significant, it is apparent that the difference between the sides in Figure 3 is much less than that in Figure 1.

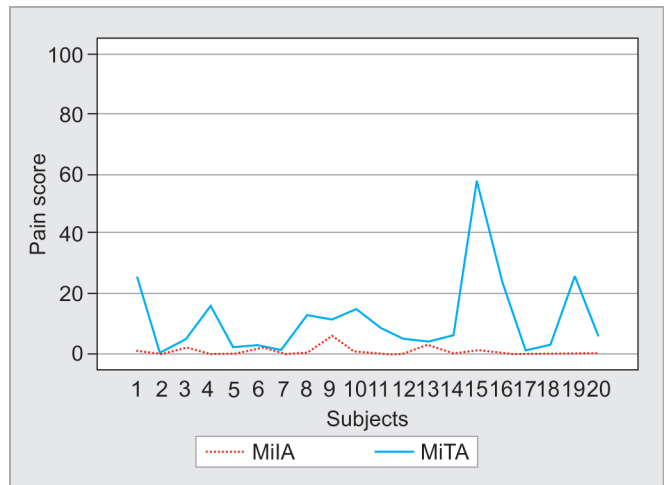
**Table 1:** Mean and median VAS pain scores after the needle stick and miniscrew placement procedures (n = 20)

Procedure	Mean ± SD (mm)	Mini-max (mm)	Median* (Q1-Q4)(mm)	<i>p</i> value
<b>Needle stick</b>				<0.001
Infiltration anesthesia side	33.4 ± 27.1	2.0–100.0	29.0 (10.5–49.5)	
Topical anesthesia side	0.1 ± 0.4	0.0–2.0	0.0 (0.0–0.0)	
<b>Miniscrew</b>				<0.001
Infiltration anesthesia side	0.7 ± 1.5	0.0–6.0	0.0 (0.0–1.0)	
Topical anesthesia side	11.7 ± 13.6	0.0–57.0	5.5 (3.0–15.75)	

\*Mann-Whitney test



**Fig. 2:** VAS pain scores after the needle stick according to the type of anesthesia placed (n = 20)



**Fig. 3:** VAS pain scores after miniscrew placement according to the type of anesthesia placed (n = 20)

**The Questionnaire**

The subjects' perception about the needle stick and miniscrew placement procedures is illustrated in Figure 4. Regarding the numbing effect of the topical anesthetic and injection anesthetic, the immediate numbness was assessed. Seventy percent of the subjects could not discern the difference in numbness between the sides. Fifteen percent of the subjects reported more numbness on the topical anesthesia side, and 15% of the subjects reported that the injection side was number. However, 10 minutes and 1 hour after the study, all the subjects reported that the injection anesthesia side felt number. In addition, all the subjects reported intense lip numbness in the injection anesthesia side.

Comparing the effectiveness of the infiltration anesthetic to the topical anesthetic during placement of the miniscrew, 60% of the subjects felt that both the injection anesthetic and topical anesthetic were equally effective procedures for miniscrew placement, 35% of the subjects reported the injection anesthesia was more effective and 5% of the subjects stated that the topical anesthetic was more effective (Fig. 4).



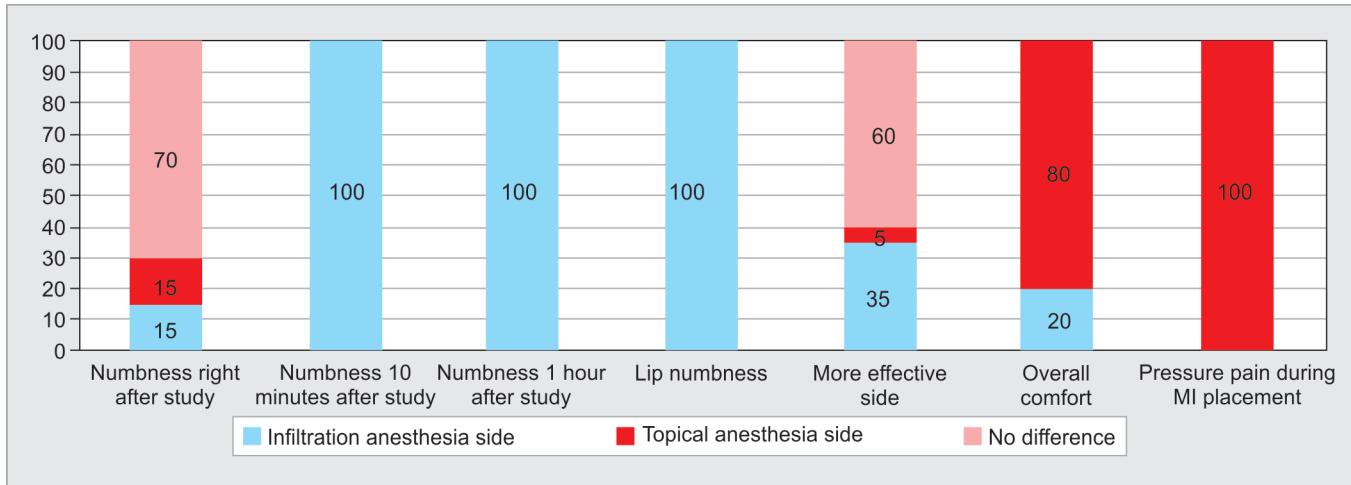


Fig. 4: subjects' perception about the injection anesthesia vs the topical anesthesia during the miniscrew placement procedure (n = 20)

The type of pain following placement of the miniscrew in the topical anesthesia side was also assessed. Although all the subjects described the pain from miniscrew placement as pressure in nature in the topical anesthesia side, the majority of them (80%) reported more comfort with the procedure (Fig. 4). Twenty percent of the subjects felt more comfort with the injection anesthesia procedure.

When the subjects were asked to report which was the most uncomfortable procedure, 75% of them mentioned that needle stick was the most uncomfortable procedure, and 25% of them reported that the miniscrew placement was the most uncomfortable part of the study.

When subjects were interviewed 1 day after the study, all the subjects reported no side effects related to any of the procedures performed.

## DISCUSSION

The difference between the sides (N<sub>STA</sub> vs N<sub>slA</sub> and M<sub>iTA</sub> vs M<sub>ilA</sub>) with regards to the intervention conducted (needle stick vs miniscrew placement) was statistically significant. However, the difference between the sides with respect to miniscrew placement was much less than needle stick. This was due to the presence of an anesthetic form (topical vs infiltrative) on both sides prior to placement of the miniscrew. As for the needle stick, the side that received the L/P topical anesthetic was compared to the side that had a placebo. Vaseline® was selected as the placebo to simulate a common clinical situation when only an infiltrative anesthetic was given before miniscrew placement.

A study by Kwong et al. compared the effectiveness of the CTA TAC Alternate (TAC<sub>(a)</sub>) to Oraqix® in placing TADs in the maxilla and mandible. The study demonstrated that TAC<sub>(a)</sub>, which consisted of 20% lidocaine, 4% tetracaine, and 2% phenylephrine, was more effective than Oraqix® in placing TADs.<sup>21</sup> In that study, 0.20 mL (three clicks of the dispenser) of topical anesthetic agents was placed on the attached gingiva only for a period of 3–9 minutes. The topical anesthetic was wiped off prior to another application of the anesthetic, and it was not removed prior to placement of the TAD.

Compared to the study by Kwong et al.,<sup>21</sup> the amount of L/P topical anesthetic gel used in our study was a quarter carpule, which was equivalent to 23 clicks of the dispenser. It is possible that the specific amount and composition of the L/P topical anesthetic

applied, good moisture control, broad area of application, and the application time of 8 minutes, may have enhanced the effectiveness of the L/P topical anesthetic.

Contrary to the study by Kwong et al.,<sup>21</sup> prior to placement of the miniscrew, the L/P topical anesthetic gel was removed with a piece of gauze. Although the gel was transparent, the thickness of the gel can obscure the area of miniscrew insertion. Thus, removal of L/P topical anesthetic was done to have a clear visual field for accurate miniscrew placement. The procedure of removing the topical anesthetic prior to placement of the miniscrew was in agreement with a study by Lambertson et al.<sup>22</sup>

The L/P topical anesthetic was placed for 8 minutes in the mandibular vestibular mucosa and at the site of orthodontic miniscrew placement. The reason for the waiting time of 8 minutes was based on previous studies which showed that although the L/P topical anesthetic was effective from the second minute after application. Moreover, it significantly eliminated pain from needle injections in the maxillary vestibular mucosa from the fifth minute to the seventh minute, and it eliminated pain in the palate from the eighth minute.<sup>14–16</sup> Another study showed that the L/P topical anesthetic gel significantly reduced pain from orthodontic separator placement in the maxilla from the sixth minute.<sup>19</sup> In our study, since the placement of miniscrew is more invasive than a needle stick, an adequate time of 8 minutes was allowed for effectiveness.

Our study showed that improving the viscosity of the topical anesthetic maintained the material longer on the tissues and increased its effectiveness for miniscrew placement. To enhance the viscosity of the gel, prewarming the gel to intraoral temperature helped in the application process and in restraining the material in the area of application.

Lambertson et al.<sup>22</sup> compared the effect of a CTA, containing a mixture of 10% prilocaine, 10% lidocaine, and 4% tetracaine, with needle-injected anesthetic on discomfort from miniscrew placement in the buccal locations. However, the CTA did not provide adequate anesthesia for managing discomfort from miniscrew placement. In the same study, the placement of the miniscrew was performed by different residents, which can affect the pain registration outcome. In contrast, the placement of the miniscrews in our study was only performed only by the primary investigator.

A study compared the acceptability and effectiveness of 20% lidocaine and injection anesthesia for placement of mini-implants. The study concluded that patients had less pain with the use of injection anesthesia, and they also preferred this type of anesthetic.<sup>23</sup> In our study, the injection anesthetic eliminated the pain during the miniscrew placement, but using a combination of 2.5% lidocaine and 2.5% prilocaine as a thermosetting gel provided better procedural comfort to most of the subjects receiving the miniscrew.

In this study, the type of pain experienced by all the subjects receiving the miniscrew in the L/P topical anesthetic side was pressure, which was reported by the subjects as mild and tolerable. In addition, most of the subjects (75%) reported that the needle stick was the most uncomfortable procedure. These findings differ from a study by Valieri et al., which showed that 72.5% of the patients reported that pressure during mini-implant placement was the most uncomfortable experience.<sup>23</sup>

The area of miniscrew placement was aimed to be between the mandibular first molar and the second premolar. This area of miniscrew application was selected based on a study which showed that this area serves as an ideal placement site in for miniscrews in the mandible due to the quality of the cortical bone.<sup>24</sup>

There are some limitations related to this study. The relatively small sample size was considered as one of the limitations. Another limitation of the present study was the lack of enough orthodontic patients needing miniscrew treatment. For this reason, this study was conducted on non-orthodontic subjects who were undergraduate dental students, staff members, and dental assistants. Those subjects were knowledgeable about the topic of TADs since it was taught during the orthodontic courses. However, all participating subjects had no previous experience with miniscrew placement. Hence, the subjects showed interest in being voluntary to explore the application of miniscrews on themselves.

## CONCLUSION

It can be concluded that the L/P topical anesthetics significantly eliminated pain from needle stick in mandibular vestibular mucosa. Moreover, the L/P topical anesthetic did not totally eliminate the pain from miniscrew placement as the injection anesthesia, but it did reduce the pain to acceptable levels. Therefore, the L/P topical anesthetic can serve as an applicable alternative for patients who fear needles.

## CLINICAL SIGNIFICANCES

- L/P topical anesthetics can significantly eliminate pain from needle stick injections in the mandibular vestibular mucosa. Hence, L/P topical anesthetics can be used effectively prior to needle stick injections for orthodontic miniscrew placement.
- L/P topical anesthetics can reduce pain from orthodontic miniscrew placement to tolerable levels. Hence, for patients who refuse needle stick injections for orthodontic miniscrew placement, the L/P topical anesthetics can serve as a suitable alternative to injection anesthesia.

## ACKNOWLEDGMENTS

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