Evaluating the Efficacy of EMLA Topical Anesthetic in Sealant Placement With Rubber Dam

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Abstract

Purpose: The purpose of this study was to investigate the efficacy of EMLA (eutectic mixture of local anesthetics, 2.5% lidocaine and 2.5% prilocaine) cream in reducing discomfort from pressure applied by rubber dam clamp.

Methods: A consecutive sample of 31 patients, ages 6 to 12 years who presented for sealants from September 2002 through March 2003, participated in this within-subjects controlled clinical study. The facial pain scale (FPS) measured discomfort of dental dam placement on first permanent molars on opposite sides of the mouth after EMLA and placebo application for 5 minutes on the gingiva surrounding each tooth.

Results: 18 subjects (58%) were female, and 13 (42%) were male. Twenty (65%) of the teeth studied were permanent maxillary first molars, and 11 (35%) were permanent mandibular first molars. Fourteen (44%) patients were 9 years old or younger, and 17 (56%) patients were over 9 years old. The mean FPS score for EMLA teeth of 0.47±0.27 was significantly lower than that for non-EMLA teeth of 0.64±0.24 ($P<.001$). EMLA vs non-EMLA FPS scores by age, gender, and arch were not significantly different.

Conclusions: The EMLA cream was effective in reducing discomfort caused by the dental dam clamp. (*Pediatr Dent.* 2004;26:497-500)

KEYWORDS: **EMLA,** TOPICAL ANESTHETIC, DENTAL ANESTHESIA, ANESTHETIC AGENTS, RUBBER DAM, DENTAL SEALANTS, CROSSOVER STUDIES

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Advances in dental materials and tooth cutting devices, such as air abrasion and laser, have reduced the need for large cavity preparations and hence for local anesthetic.[1] Sealant and composite resin restoration procedures, however, are still technique sensitive and may require a rubber dam for proper placement. Placement of a rubber dam clamp may cause significant discomfort in patients. A potent, low-dosage, topical anesthetic quickly absorbed into the dental papilla (keratinized tissue such as that of the palate) could be useful in treating children who need sealants and preventive restorative resins that do not require local anesthetic but need dental dam application for good isolation.

Some practitioners may give papillary injections before placing the clamp or give no anesthesia at all. In a study by Roghani et al[1] in a population of adults, the 5% EMLA cream was superior in performance to all other topical anesthetics, including 1% dyclonine, 10% benzocaine, 10% cocaine, 10% lidocaine, and placebo. In a study by Vickers et al[2] 5% EMLA cream, 5% xylocaine, and NUM (5% lignocaine, 1.7% amethocaine) were compared to placebo. All 3 topical agents were found to be effective in pain reduction during needle insertion, with EMLA being the most effective agent. According to a study by Holst and Evers,[3] also conducted in adults, EMLA is more effective than "conventional" intraoral topical agents in the palate. Thus, the present authors selected EMLA cream to investigate its efficacy in reducing discomfort from pressure applied by a rubber dam clamp.

EMLA cream is a 5% eutectic mixture of local anesthetics, manufactured by Astra Pharmaceuticals[4] (Figure 1). It is a 1:1 oil/water emulsion of a eutectic mixture of 2.5% lidocaine and 2.5% prilocaine bases. Vickers et al[2] states that this eutectic mixture has a lower melting point above 16°C, as compared to lidocaine (66°C) and prilocaine (36°C) alone. This physical property allows it to become liquid in the oral environment and aids in rapid transmucosal absorption of the bases.

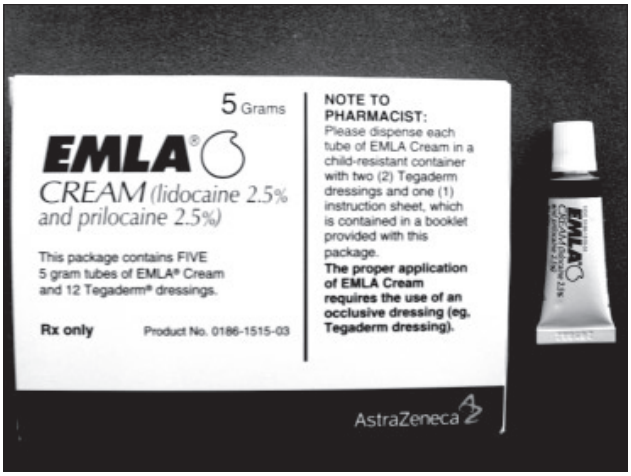

Figure 1. EMLA cream.

On the skin, the normal dosage of EMLA is 2.5 g per 20- to 25-cm^2 area, and the maximum dosage is 2 g on a 10-cm^2 area in 1 hour. No dosage has yet been established for mucous membrane. According to Astra Pharmaceuticals,[4] the absorption of 10 g of EMLA cream applied to genital mucous membranes for 10 to 60 minutes was as follows: 148 to 641 ng/ml for lidocaine and 40 to 346 ng/ml for prilocaine. Ensberg et al[5] measured the uptake of EMLA in children following application to the skin and noted that the use of 2 g over a 16-cm^2 area for 4 hours never produced plasma levels of either active agent in excess of 155 ng/ml, which is well below the toxic concentration. The systemic toxicity is approximately 5,000 ng/ml for lidocaine and prilocaine. When 60 g of EMLA was applied over 400 cm^2 for 24 hours, peak blood levels of lidocaine were approximately 1/20 of the system level, and prilocaine 1/36 of toxic level. The maximum pediatric dosage recommended by AstraZeneca pharmaceuticals[4] for children 1 to 6 years and weighing more than 10 kg is 20 g over 100 cm^2 for 4 hours and for children 7 to 12 years and weighing more than 20 kg is 20 g over 200 cm^2 for 4 hours.

The objective of this study was to investigate the effect of EMLA cream in reducing discomfort from pressure from a rubber dam clamp applied to dental papillae.

Methods

Treatments were done by one operator in a regular dental chair at a community dental clinic primarily serving a Hispanic population. A consecutive sample of subjects was obtained from regular scheduled clinic patients. The study utilized a within-subjects design. The inclusion criteria for subjects were as follows:

1. patients' treatment plans specified application of a sealant on at least 1 first permanent molar;
2. noncontributory medical history (with no history of congenital/idiopathic methemoglobinemia, glucose-6-phosphate dehydrogenase deficiency, or allergy to amide local anesthetics);
3. age 6 to 12 years;
4. mentally able to complete the facial pain scale[6] (Figure 2).

The FPS is a series of images, one of which is selected by a child as being indicative of the pain he or she is experiencing at that time. Patients who were mentally delayed or who had behavioral difficulties in the dental chair on prior visits were excluded because these characteristics might lead to inaccurate FPS scores.

The study and consent form were approved by the Institutional Review Board of Lutheran Medical Center in Brooklyn, NY. The study was explained to each parent, and informed consent was obtained before the procedure. The operator described the procedure to each patient in an identical fashion before beginning.

Only permanent first molars were studied, whether completely or partially erupted. The left and right sides of the same arch were clamped with a no. 14 clamp to allow one side to receive EMLA and the other Vaseline as a placebo. To eliminate bias, patients did not see the EMLA cream and placebo while they were being applied with a cotton tip. Whether the clamp was placed on the EMLA side or placebo side first was decided randomly by flipping a coin. No verbal or nonverbal cues were given to the subject as to which substance was being applied.

The area of EMLA application, limited to attached gingiva, was dried and isolated with dry angles on the buccal aspect and with cotton rolls on the lingual aspect. For the maxillary arch, only dry angles were used. In the mandibular arch, a cotton roll was held by the operator on the lingual aspect of the tooth next to the EMLA cream. A slow-speed suction remained in the patient's mouth to prevent the patient from swallowing and to obtain a dry field.

The topical substance was placed in a dappen dish with a radius of 7 mm and a depth of 4 mm, which translates to 0.5 g of EMLA or placebo. The same amount of either EMLA or Vaseline was applied each time. The amount was small enough to be safe in case of swallowing but large enough to cover the gum area around a first permanent molar.

One operator (SL) implemented tell-show-do with each patient in the same manner and told each patient that he or she would be asked their level of pain on each side of the mouth by pointing to a picture. The facial pain scale was shown to the patient approximately 5 seconds after the dental dam clamp was placed and before any other procedures were done to either molar. The operator maintained a consistent, neutral tone of voice, facial expression, and behavior during pain assessment to avoid influencing patient responses.

The ratings were analyzed using the *t* test because each face on the scale has a numeric value that is a continuous variable (Figure 2). A *P* value of less than .05 was considered statistically significant. The paired samples *t* test was used to determine if the difference in ratings for EMLA and placebo was statistically significant. An independent samples *t* test was used to determine if the differences in mean values between groups of different ages, arches, and genders were statistically significant.

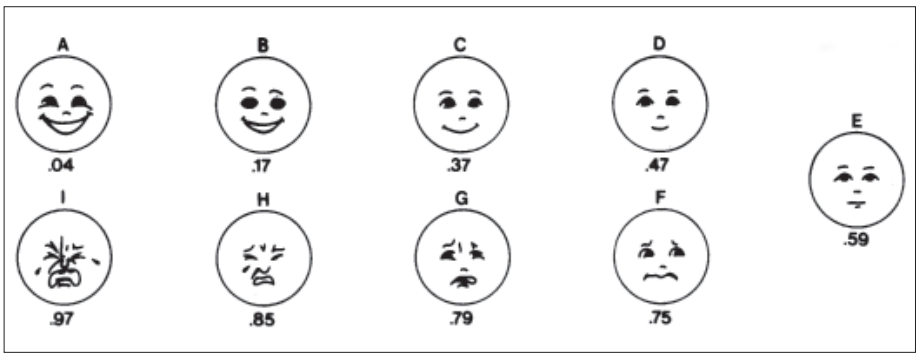

Figure 2. Facial pain scale.

Results

A consecutive sample of 31 patients, ages 6 to 12 years who presented for sealants from September 2002 through March 2003, participated in this study: 18 (58%) were female, and 13 (42%) were male. Twenty (65%) of the teeth studied were permanent maxillary first molars, and 11 (35%) were permanent mandibular first molars. Fourteen (44%) patients were 9 years old or younger, and 17 (56%) patients were over 9 years old.

Mean and median FPS ratings are found in Table 1. The overall difference in mean FPS ratings for EMLA and placebo was statistically significant ($P<.001$); the difference between medians for EMLA and placebo was larger than the difference in means. Regarding the FPS ratings for EMLA and placebo teeth, the difference between boys and girls was not statistically significant, nor were the differences between upper and lower arches, or groups aged 9 years or younger and over 9.

Discussion

This study's subjects reported less discomfort with EMLA cream than placebo. Thus, EMLA cream was effective in reducing discomfort caused by dental clamps. The mean FPS scores of EMLA and non-EMLA teeth were more than 1 face apart, and the median scores were 2 faces apart—indicating a difference in the child's experience. Differences in FPS ratings by age, gender, and arch were not significant.

Sealants are an effective means of preventing cavities in permanent molars with prominent pits and grooves. Sealants are placed most often in patients aged 6 to 12 years. Sealants can be placed as soon as isolation is achievable, but permanent first molars are not in full occlusion until 3 years after emergence. For this reason, isolation of children's permanent first molars can be difficult during sealant application.

Use of topical anesthetics is especially beneficial to pediatric patients because isolation is essential in sealant and resin restoration, and dental dam clamps can be uncomfortable. Although EMLA has some disadvantages, such as unsatisfactory taste and time of application, its use may be more strongly indicated in keratinized tissue than other topicals. Holst and Evers[3] reported that, in some sites such as the palate, EMLA is more effective than conventional intraoral topical agents. This led to the selection of EMLA for application around the gingiva before dental dam placement in this study.

Holst and Evers[3] found that 2 minutes was enough for EMLA to produce a higher degree of mucosal analgesia in the lower buccal fold in children. In the palatal area, the pain was not totally blocked by any of the investigated preparations until after 5 minutes of application of EMLA. Meechan and Donaldson[7] chose 5 minutes as the time of application for their study because they considered it to be the limit of practical usefulness in the oral cavity and because the topical application of EMLA for 4 minutes was shown to be effective in oral mucosa in adults. Therefore, in the present study, 5 minutes was selected as the topical application period.

The facial pain scale (Figure 2) has been used frequently to evaluate the pain associated with therapeutic regimens and, in this study, was used to measure discomfort of dental dam clamp placement after EMLA application for 5 minutes. Each image is linked to a point on a

Table 1. Mean and Median FPS Ratings

		Mean FPS ratings (±SD)		Median FPS ratings	
Characteristic	**N**	**EMLA**	**Placebo**	**EMLA**	**Placebo**
Whole group	31	0.47±0.27*	0.64±0.24*	0.47	0.75
Gender†					
Girls	18	0.49±0.29	0.64±0.29	0.47	0.75
Boys	13	0.45±0.26	0.64±0.16	0.47	0.75
Arch†					
Upper	20	0.49±0.28	0.65±0.23	0.47	0.75
Lower	11	0.42±0.25	0.61±0.27	0.47	0.75
Age†					
≤9 yr	17	0.49	0.65	0.59	0.75
> 9 yr	14	0.42	0.61	0.32	0.75

*$P<.001$, 2-tailed paired-samples t test.
†$P>.5$, 2-tailed independent-samples t test.

numeric scale. The FPS provides quantitative ratings to represent a child's pain, such that the numerical values represent the magnitude of pain from a child's perspective.

Visual analogue scales (VAS) such as the FPS are regarded as the most sensitive measurements of pain experience in adults, according to Huskisson et al.[8] Manner et al[9] reported good agreement between VAS and a verbal scale in assessing pain experience in children as young as 4 years of age. In the McGrath[6] study, 200 children aged 3 to 17 years were asked to directly scale the feelings depicted by the faces. Children over 5 years of age rated the faces consistently, regardless of their age, sex, or health status. Their own perceptions of affective magnitude rather than numbers arbitrarily assigned by the investigator determined the numeric values of each face.

The scores range from 0 to 1 and are at least 0.04 apart. That the differences in the mean FPS ratings for EMLA and non-EMLA teeth overall were more than once face apart (from face D to somewhere between faces E and F, Figure 2) indicates a meaningful difference in the subjective level of pain for some children: the mean FPS rating for the non-EMLA teeth indicated that some discomfort was present. Whether this gain in comfort is worth the increased working time was not assessed in this study and must be investigated further.

The present study had several limitations. Part of the cream was absorbed into the cotton rolls in the mandibular arch. Although the cream did not seem to dissolve in saliva as easily as benzocaine gel, some of it did float away in saliva. Thus, this study was, to some extent, technique sensitive because the extent of isolation was important. Although the clamps were placed one after the other and the order was unplanned, the sequential nature of clamp placement may have affected pain perception slightly. If the first one was uncomfortable, the patient might have an expectation for the second one to be more painful or just as painful. If the patient had a small mouth, having 2 clamps present at the same time could bring discomfort in and of itself. Most patients in the study, however, were cooperative, and none of the subjects complained about having both sides clamped.

Placing the clamps sequentially close to the same time may have introduced bias through an anticipatory effect and additional discomfort. Such placement, however, did guarantee a similarity of the child's mood and oral condition during placement of both clamps. While administering the FPS shortly after clamp placement did not allow for equalization of pressure to occur, the ratings would at least reflect the child's initial experience of the pain associated with the clamp. Lastly, the sample size was relatively small, but was offset by the within-subjects design because the control subjects were identical to the experimental subjects.

While other studies reported that 5 minutes was more effective for pain reduction than 3 minutes, no specific optimal time for maximum effect has been established through research. Although 5 minutes made a difference in patient response, longer application time may be more effective but was not studied in this experiment. The authors recommend that further study be conducted.

Conclusions

1. Application of EMLA cream for 5 minutes before dental clamp placement reduced discomfort more than placebo (no comparison with local infiltration was made).
2. Age, gender, and arch did not make a significant difference in the results.

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