



Topical anesthesia for stainless steel crown tooth preparation in primary molars: a pilot study

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Background: Placement of full-coverage restorations such as stainless steel crowns (SSCs) for pulpectomy treated primary molars is essential for successful outcomes. The tooth preparation process for SSCs can cause discomfort to gingival tissues since the crown should be seated 1 mm subgingivally. The purpose of this prospective trial was to compare the effectiveness of subgingival and transmucosal application of topical anesthetics on dental pain during SSC tooth preparation among 6- to 8-year-old children.

Methods: A consecutive sample of 27 children, aged 6-8 years, who required an SSC after pulp therapy in primary molars were randomly divided into three groups. Group A received infiltration anesthesia before tooth preparation for SSC placement, whereas in Group B and C, only topical anesthesia was applied subgingivally and transmucosally. Wong-Bakers Faces pain rating scale (WBFPS) scores were recorded after tooth preparation. Faces, Legs, Activity, Cry and Consolability (FLACC) scores were evaluated by two blinded and calibrated investigators through video recordings of the patient during tooth preparation. Data were tabulated, and inter-group comparisons were performed using the Kruskal-Wallis and analysis of variance tests.

Results: Out of the 27 participants, 48% were boys and 52% were girls, with an overall mean age of 6.83 years. Group A showed the least pain scores according to both the scales, followed by Group B and Group C. The pain intensity was statistically significant on both the pain scales with $P = 0.003$ for FLACC and $P < 0.001$ for WBFPS.

Conclusion: Subgingival application of topical anesthesia reduced pain to a certain extent but not as effectively as infiltration anesthesia during SSC tooth preparation in primary molars. Transmucosal application of topical anesthesia did not reduce discomfort when compared to the other two interventions.

Keywords: Crowns; Stainless Steel; Subgingival Topical Anesthetics; Tooth Preparation.



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INTRODUCTION

Full-coverage restorations in pulpectomy treated primary molars are essential for maintaining the structural integrity of the tooth [1]. Preformed metal crowns are more durable than tooth fillings as they completely encase the primary tooth [2-4]. Stainless steel crowns (SSCs) require lesser tooth removal than esthetic zirconia crowns

[5]. SSCs require minimal tooth preparation involving occlusal reduction and proximal slicing to create just enough space for crown fitting. The crown should be seated subgingivally without biological width violation. Hence, SSCs are placed 0.5-1 mm subgingivally to avoid microleakage, and attain good retention and marginal adaptability [6-8].

Subgingival tooth preparation causes soft tissue discomfort; hence, SSC tooth preparation is always

Received: May 12, 2020 • Revised: June 27, 2020 • Accepted: July 9, 2020

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performed under infiltration anesthesia [6]. Although adequate anesthesia is imperative for pain control in clinical dentistry, it is the most common trigger for dental pain and anxiety in children [9,10]. Using topical anesthesia instead of infiltration anesthesia for SSC tooth preparation can avoid needle-related pain and anxiety [11]. Topical anesthetics have been used in clinical dentistry for minor dental procedures such as orthodontic separator placement, mini-implant placement, rubber dam clamp placement, and scaling and root planing, which can evoke pain in the absence of anesthesia. Studies have been conducted to compare the effects of topical anesthesia and infiltration anesthesia on dental pain during such procedures [12-19]. However, evidence suggesting the use of topical anesthetics for SSC tooth preparation is lacking.

SSC tooth preparation in primary molars requires minimal time, thus endorsing the idea of using topical anesthetics for this procedure. Topical anesthetics typically act for 10-15 min [20]. When topical anesthetics are applied on the dried mucous membrane, they reversibly inhibit peripheral sensory nerve fibers, altering pain thresholds. Thus, the surface anesthetic action largely depends on the drug permeability [21]. One method to improve the surface permeability is to alter the mode of drug delivery [22].

Topical anesthetics are available as gels, ointments, sprays, patches, etc. [23]. A commonly used topical anesthetic is 20% benzocaine gel, which has a major drawback of getting washed away easily by saliva due to lack of adhesion and does not adequately flow into the subgingival spaces [24]. This can be avoided by transmucosal or subgingival drug delivery. The use of transmucosal and subgingival topical anesthetics has been reported separately for different clinical procedures. Nakamura et al. [25] employed transmucosal topical anesthetic delivery through an anesthetic soaked hemolytic adhesive patch and found it to ameliorate needle-related pain during infiltration anesthesia. Transmucosal topical anesthetic delivery through a 20% lidocaine patch (DentiPatch[®], Noven Pharmaceuticals,

Inc., Miami, Florida, USA) has also been evaluated in several clinical trials [26-29]. DentiPatch[®] is a 2 cm patch placed on the gingival margin to achieve topical anesthesia for as long as 30 min and is used as a pre-injection anesthetic in dentistry [28]. Nonetheless, its safe intraoral use, particularly in children, is controversial [30]. Subgingival delivery of topical anesthesia has also been studied for its effectiveness during scaling and root planning, and rubber dam clamp placement. [13-16,31].

However, comparison studies on the effect of transmucosal and subgingival topical anesthetic delivery for SSC tooth preparation is scarce. Our study aims to compare the effectiveness of subgingival and transmucosal application of a topical anesthetic on dental pain during SSC tooth preparation in 6 to 8-year-old children.

METHODS

This pilot study was designed as a randomized controlled trial with three parallel arms to compare the subgingival and transmucosal application of a topical anesthetic using infiltration anesthesia in 6 to 8-year-old children requiring SSC tooth preparation. The study was conducted from December 2019 to January 2020. The sample source was outpatients reporting to the institution's department of pediatric and preventive dentistry. After procuring approval and ethical clearance from the institutional review board (SRMU/M&HS/SRMDC/2020/PG/020), 27 healthy children, aged 6-8 years, were recruited by consecutive sampling. Only children who underwent lower primary molar pulpectomy during the previous dental visit and had Frankel's behavior rating of 3 or 4 (FR3 - positive, FR4 - definitely positive) were included. Children with special health care needs, underlying systemic condition, or history of local anesthetic allergy were excluded from this study. Written informed consent was obtained from the parents after elaborating on the details of the research.

The children were randomly divided into three groups

using the lottery method, and each group was assigned an intervention again through the lottery system. Each participant was assigned a registration number, and simple randomization into three groups was performed using the fishbowl method. Group A received infiltration anesthesia before tooth preparation, whereas Groups B and C received subgingival and transmucosal application of a topical anesthetic, respectively. A single well-trained pedodontist performed all treatments using uniform routine behavior management techniques. Participant blinding was done by asking the child to close their eyes as a part of behavior management while receiving the assigned anesthetic.

1. Infiltration anesthesia

The pedodontist administered infiltration anesthesia to the children in Group A using insulin syringes after topical anesthetic application (20% benzocaine, Precaine[®]-B, strawberry flavor, Pascal Company, Inc., Bellevue, WA, USA) for 30 s on the dried injection site. The anesthetic agent used was 1 ml of 2% lignocaine with 1:80,000 adrenaline (Lignox[®] 2% A, INDOCO REMEDIES LTD., Mumbai, Maharashtra, India). Infiltration was administered by placing the needle parallel to the long axis of the primary molar at the buccal vestibular depth between the molar roots, with an average delivery time of 2 min. An additional 1 min waiting time was allowed before starting the tooth preparation.

2. Topical anesthesia

For children in Groups B and C, a bite block was placed in their mouth with low-speed suction to maintain a dry field. The tooth was air-dried and isolated with cotton rolls during topical anesthetic application (20% benzocaine, Precaine[®]-B, strawberry flavor, Pascal Company, Inc., Bellevue, WA, USA).

3. Subgingival placement of topical anesthesia

The topical anesthetic (20% benzocaine gel) was loaded in a 2 ml syringe (Dispo Van[®], Hindustan Syringes & Medical Devices Ltd., Faridabad, Haryana,

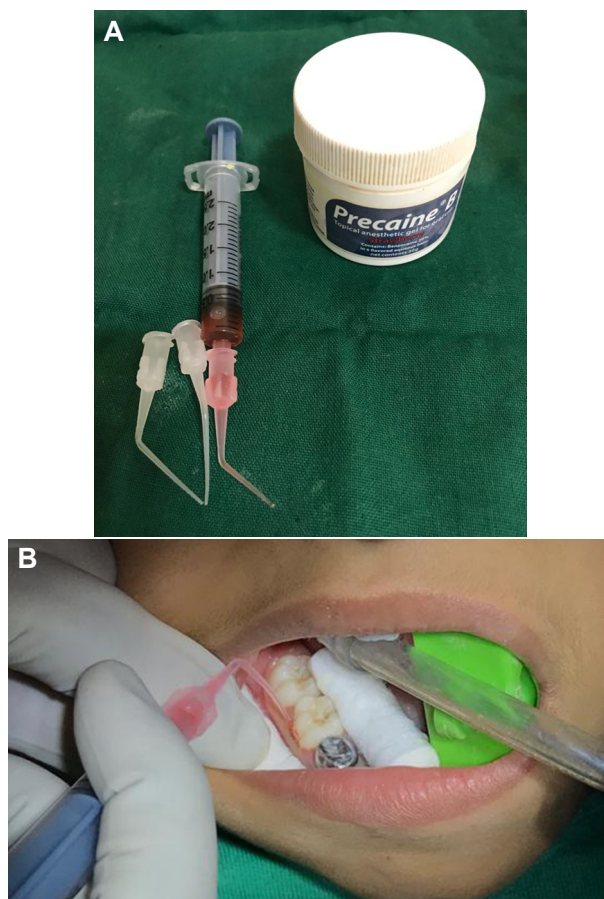


Fig. 1. (A) Topical anesthetic loaded in a Dispo Van[®] syringe with a disposable tip, (B) Subgingival application of topical anesthesia

India) with a disposable tip (DM-MD-MTIPS, Meta Biomed Inc., Colmar, France) (Fig. 1A). The applicator tip was placed subgingivally, and 0.2 ml of the anesthetic was uniformly dispensed by walking the tip along the gingival sulcus for 2 min (Fig. 1B). The anesthetic was left in place for 1 min before commencing tooth preparation.

4. Transmucosal application of topical anesthesia

An adhesive patch consisting of a gauze with a thin long cotton roll (3 mm length) in the center was prepared. Approximately 0.2 ml of 20% benzocaine gel solution was dispensed on the cotton and gauze (Fig. 2A). The patch was placed both buccal and lingual to the tooth, covering the marginal and attached gingiva (Fig. 2B). The patch was held in position for 2 min and then discarded. After 1 min, tooth preparation was initiated.



Fig. 2 (A) Topical anesthetic loaded on the prepared transmucosal patch, (B) Transmucosal application of the topical anesthetic

5. Tooth preparation

After achieving adequate anesthesia, crown preparation was performed by the pedodontist. The tooth was occlusally reduced by 1 mm using a pear-shaped diamond bur (FO-32C Dia-burs, MANI Inc., Tochigi, Japan) following the occlusal anatomy of the involved lower primary molar. Proximal slicing was done using a tapered fissure bur (TC-11F Dia-burs, MANI Inc., Tochigi, Japan) to break the contact points and create space for seating the crown. All tooth surfaces were reduced by at least 0.5 mm with a feather edge margin ending 0.5-1 mm subgingivally. Sharp line angles were rounded, and an SSC (KIDS crown, YOGI enterprises, Navi Mumbai, Maharashtra, India) of appropriate size was tried in to obtain a snug fit when seated subgingivally. The tooth preparation took an average of 10 min for all participants. The selected SSC was cemented to the tooth using Type I glass ionomer cement (GC Gold Label 1, GC India

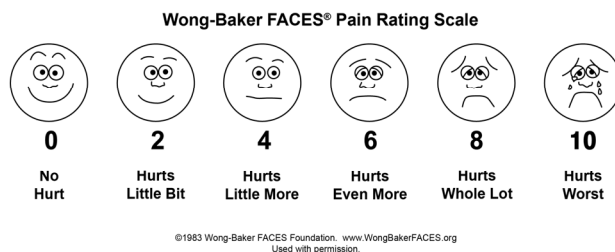


Fig. 3. Wong-Bakers Faces pain rating scale sheet given to the participants for circling the appropriate response after treatment

Dental Pvt. Ltd., Medak, Telangana, India) before the local anesthetic effect wore off.

The time taken and the rate of intervention and tooth preparation were monitored using a digital stopwatch on a smartphone (Apple iPhone 7 plus, Apple Pioneer Place, Portland, Oregon, USA) by a separate investigator.

6. Recording the outcomes

A WBFPS sheet (Fig. 3) was given to the children immediately after tooth preparation. The child was asked to point out to the face that best described the pain they experienced, after explaining what each face depicted. The tooth preparation was video recorded using a smartphone (Apple iPhone 7 plus, Apple Pioneer Place, Portland, Oregon, USA) with good quality audio and video facility. This video was evaluated by a single-blinded reviewer (KS) for providing FLACC scores.

7. Statistical analysis

Data were tabulated using a Microsoft Excel (Microsoft Corporation, Redmond, Washington, USA) spreadsheet. Statistical analysis was performed using Statistical Package for Social Sciences (SPSS 20, IBM SPSS Statistics for Windows; version 20.0; IBM Corp., Armonk, NY, USA). One-sample Kolmogorov-Smirnov normality test revealed skewed distribution of the variables. Hence, Kruskal-Wallis and analysis of variance tests were used for intra-group comparisons of the WBFPS and FLACC scores.

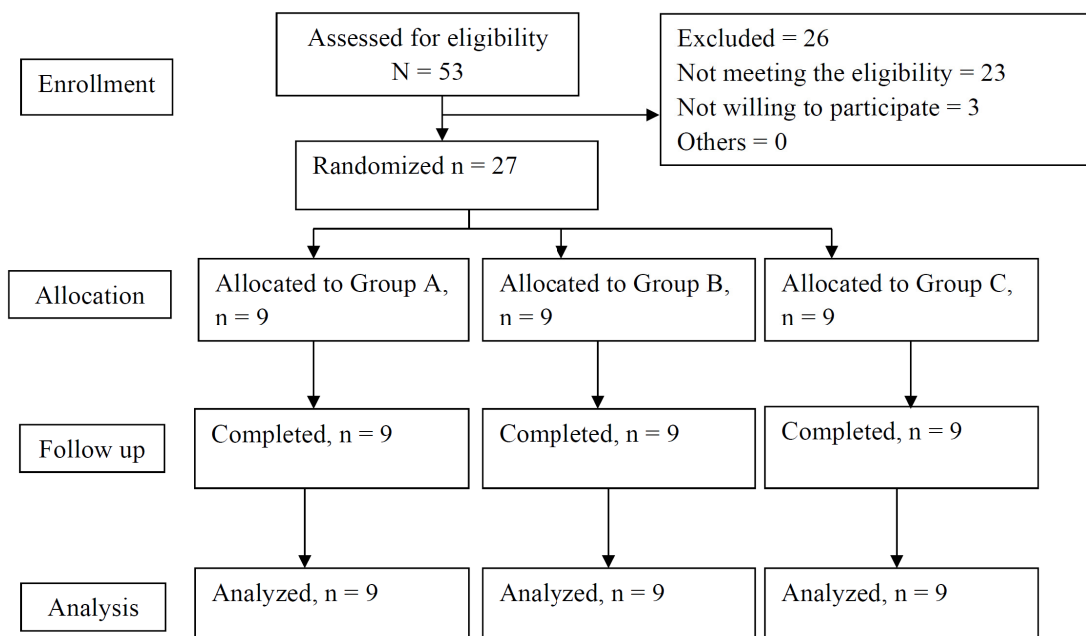


Fig. 4. CONSORT flow diagram

Table 1. Age and sex-based distribution in groups A, B, and C

Group	Sex distribution			Age distribution	Height	Weight
	Male	Female	N	Mean \pm SD (in years)	Mean (in cm)	Mean (in kg)
A	2	7	9	6.88 \pm 0.92	120.8	20.8
B	4	5	9	6.72 \pm 0.83	118.3	19.5
C	7	2	9	6.88 \pm 0.92	121.5	22.3
Total	13	14	27	6.83	120.2	20.86

SD, standard deviation

Table 2. Inter-group comparisons between groups A, B, and C based on the WBFP and FLACC scale scores

Group	A	B	C	P value
WBFP scale	0.56 \pm 0.52	1.33 \pm 0.86	2.67 \pm 0.7	< 0.001*
FLACC score	1.22 \pm 0.66	1.33 \pm 1.3	2.89 \pm 0.78	0.003*

*Significant at 1% interval, Kruskal-Wallis test

FLACC, faces, legs, activity, cry and consolability; WBFP, Wong-Bakers Faces pain rating

RESULTS

The trial was completed with good compliance. No allergic reactions or untoward effects were observed. A total of 27 children, aged 6-8 years, participated in this pilot study. Fig. 4 shows the CONSORT flow chart with details on the number of participants recruited and randomized. Table 1 shows the sex distribution, mean age, height, and weight of the participants in all groups.

The sex distribution showed a total of 13 males (48%) and 14 (52%) females. The mean age of the children was 6.83 years. The mean height and weight of the children were 120.2 cm and 20.86 kg, respectively.

Table 2 shows the inter-group comparisons based on the WBFP and FLACC scales. The mean pain score according to the WBFP scale was higher in Group C followed by Group B and A with a statistically significant P value ($P < 0.001$) in the Kruskal-Wallis and ANOVA tests. With respect to the pain behavior rating using

Table 3. Post-hoc analysis between groups A and B, A and C, and B and C based on the WBFP and FLACC scale scores

Pain score	Group	P value
WBFP scale	A and B	0.044
	A and C	< 0.001*
	B and C	0.004*
FLACC score	A and B	0.96
	A and C	0.001*
	B and C	0.01*

FLACC scores, Group A scored the least closely followed by Group B, and the highest scores were observed in Group C. The differences were statistically significant, with $P = 0.003$.

On comparing the pain variation with respect to the age, no statistical differences were seen in the WBFP ($P = 0.17$) and FLACC scores ($P = 0.409$). Table 3 shows post-hoc comparisons between the groups. Differences between Groups B and C and Groups A and C were statistically significant.

DISCUSSION

SSCs are definitive restorations for primary molars [1]. Preformed metal crowns require minimal tooth preparation to seat the crown subgingivally, thus warranting only soft tissue anesthesia to avoid discomfort or pain [6]. Hence, in this study transmucosal and subgingival application of topical anesthesia were compared with infiltration anesthesia in 6- to 8-year-old children requiring SSCs.

Oulis et al. [32] in their randomized controlled trial concluded that mandibular infiltration anesthesia provides adequate anesthetic effect for SSC placement in primary molars both in the primary and mixed dentition. Hence, in this study consisting of children aged 6-8 years, the same method was followed for the control arm. A 20% benzocaine gel was used as it is the most commonly used conventional topical anesthetic. Benzocaine is an ester derivative that blocks sodium influx into the axon by binding to the intracellular surface of sodium channels [33]. Lignocaine, which is used for infiltration anesthesia

is an amide anesthetic. Kishimoto et al. [34] compared the effects of lignocaine and benzocaine delivered through transmucosal patches based on trigeminal somatosensory evoked potentials. They observed that an amide anesthetic like lignocaine had similar efficacy to benzocaine when used as a topical anesthetic and concluded that 2% lidocaine with epinephrine used as a topical anesthetic in an adhesive patch was as potent as 20% benzocaine. However, in our study, topical anesthesia was delivered using 20% benzocaine and 2% lignocaine as infiltration anesthesia.

For subgingival delivery of the topical anesthetic, several studies have employed a lidocaine and prilocaine periodontal gel 2.5%/ 2.5% (Oraqix[®], Dentsply Pharmaceutical, York, USA) [13-16,31]. Oraqix[®] delivers the anesthetic into the gingival sulcus with a blunt applicator tip present in the device. Oraqix[®] is in the fluid state initially and transforms into the gel elastic phase at body temperature inside the gingival sulcus [13]. Our study followed a simpler method. Berteretche et al. [12] loaded a 2 ml disposable syringe with a topical anesthetic solution and used a bent metal tip with a 2.2 mm diameter to dispense the drug. The anesthetic agent was placed along the implant shoulder, left idle for 1 min, and then all the other components were placed. In our study, disposable Metapex[®] (Meta Biomed Co. Ltd., South Korea) tips were used to dispense the anesthetic by walking it around the gingival sulcus. Similarly, transmucosal patches were prepared by loading 20% benzocaine on an adhesive patch with a cotton gauze, as suggested by Nakamura et al. [25] instead of commercially available systems like DentiPatch[®].

There is limited research comparing various topical anesthetics for pre-injection anesthesia in dentistry [35-38]. A few studies have investigated topical anesthetic use for purposes other than reducing needle-related pain. Most of these studies compared two different topical anesthetics delivered through different modes [13-16,31]. Documented evidence comparing topical anesthesia with infiltration anesthesia is scarce. Lamberton et al. [39] and Valieri et al. [40] compared infiltration anesthesia with

Oraqix[®] and/or benzocaine topical anesthesia for mini-implant insertion. Our study aimed to identify if subgingival delivery or transmucosal delivery of 20% benzocaine provided a similar effect to infiltration anesthesia with 2% lignocaine for pain during SSC tooth preparation. Although the procedures for which the studies were conducted vary, the results of our concurred with the findings of Lambert et al. [39] and Valieri et al. [40]. Both studies concluded that procedural pain was greater when only topical anesthesia was applied, and patients preferred mini-screw/mini-implant placement under infiltration anesthesia.

Yoon et al. [13], in their split-mouth study, compared Oraqix[®] with 20% benzocaine for rubber dam clamp placement. They found no significant differences in the pain scores between the drugs and concluded that Oraqix[®] is more effective than benzocaine in children of 9 years or older. On the contrary, in our study, subgingival and transmucosal delivery of the same drug was compared in children 6-8 years of age with significant differences in pain scores. Studies by Hersh et al. [41], Taware et al. [42], Shebab et al. [28], and Carr and Horton [43] proved that transmucosal delivery of a topical anesthetic through DentiPatch[®] reduced needle-related pain better than lignocaine gel. Carr and Horton [43] concluded that bio-adhesive patches containing topical anesthesia are an alternative to infiltration anesthesia for selected dental procedures like scaling and root planning. Taware et al. [42] also suggested a bio-adhesive drug delivery system as a potential replacement for infiltration anesthesia in dentistry, whereas Kreider et al. [26] and Wu and Julliard [27] identified that DentiPatch[®] and benzocaine topical anesthesia showed no statistical differences in pain reduction during needle insertion and local anesthetic delivery. However, they concluded that patients preferred DentiPatch over gel anesthetics, as more objective pain reduction was seen with transmucosal anesthetic placement.

Statistical tests in this study revealed that subgingival anesthetic delivery offered more pain reduction than transmucosal delivery according to both WBFPs ($P < 0.001$) and FLACC scores ($P = 0.003$). This could be

because of better topical anesthetic sustenance in the gingival sulcus when compared with mucosal application. Tooth preparation involves bur movement subgingivally, which momentarily disturbs the soft tissue when compared with clamps that constantly offend the gingival tissue, which should also be considered. When considering studies comparing transmucosal delivery of topical anesthesia, it should be understood that needle insertion is done at one point in the mucobuccal fold as opposed to varied bur movements in the gingival sulcus during tooth preparation.

Further, in our study, FLACC scores show almost similar mean pain intensity values for subgingivally placed topical anesthesia (1.22 ± 0.66 , $P = 0.003$) and infiltration anesthesia (1.33 ± 1.3 , $P = 0.003$). This indicates that subgingival anesthetic delivery has the potential to provide profound anesthesia if better armamentarium can be employed. Similarly, transmucosal patches with better adhesion systems can improve drug permeability and sustenance.

Our study has certain limitations. Firstly, the armamentarium used were not sophisticated like the commercially available DentiPatch[®] or Oraqix[®]. The subgingival and transmucosal delivery systems employed in this study can be made from tools available in any regular operating dental clinic. The topical anesthetic used in this study does not have thermosetting properties like the Oraqix[®], and the adhesive patch used contained an anesthetic soaked cotton gauze. Using an anesthetic impregnated moisture-resistant adhesive patch will provide better results. Secondly, the sample size was too small and inadequate to generalize the results obtained. This study was conducted as a pilot study, and further studies with a larger sample size are needed. Thirdly, the compared drug was different for the control arm and the intervention arms. We aimed to compare the effects of intervention with infiltration anesthesia, which undoubtedly would provide profound anesthesia. This was done to understand if the interventions of interest are as effective as the gold standard. Finally, only participants requiring SSCs in lower primary molars were included. Since the tissue

characteristics of the palatal region vary significantly, a separate study has to be conducted to understand the effect of topical anesthesia on reducing pain during SSC tooth preparations in maxillary primary teeth.

Within the limitations of this study, we can conclude that subgingival topical anesthesia reduces dental pain more effectively than transmucosal application of the same anesthetic during SSC tooth preparation. However, both these methods of delivering topical anesthesia are not as effective in reducing dental pain when compared with infiltration anesthesia. Conducting this study on a larger sample with more sophisticated armamentarium will pave the way for future research leading to better clinical practice.

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Shankar P: Conceptualization, Methodology, Project administration, Supervision, Writing - review & editing

Senthil D: Investigation, Resources, Supervision, Validation, Visualization

Trophimus Gnanabagyan J: Project administration, Supervision, Writing - review & editing

DECLARATION OF INTERESTS: The authors declare no conflicts of interest.

FUNDING: No funding was acquired for this study.

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