Children's Preference of Benzocaine Gel Versus the Lidocaine Patch

Sonia J. Wu, DMD **Kell Julliard, MA, MFA**

Dr. Wu is a former resident, Pediatric Dental Department, and Mr. Julliard is research program director, Lutheran Medical Center, Brooklyn, NY. Correspond with Mr. Julliard at kjulliard@lmcmc.com

Abstract

Purpose: This study compared pain, acceptance, and preference associated with 2 topical anesthetics: benzocaine gel and lidocaine patch (DentiPatch).

Methods: Thirty patients aged 3 to 10 years participated in this within-subjects study. All children required identical or similar dental work bilaterally (restorations, extractions, endodontic procedures, or sealants). Subjects chose either DentiPatch or benzocaine gel at the first visit. The anesthetic the child did not choose was used at the second visit. The Whali-Wong scale was used to measure comfort before and after application of topical anesthetic and after injection, and the Sounds, Eyes, Motor (SEM) scale measured pain upon injection.

Results: At the first visit, 80% of subjects selected DentiPatch; 60% of subjects made their choice based on appearance. Younger children more than older children were influenced by appearance in their selection. After trying both topical anesthetics, 77% preferred DentiPatch; final preference and either age or gender were not significantly related. The gel had greater scores than the patch for the Sounds pain value and for the SEM scale composite score.

Conclusions: The lidocaine patch was associated with some objective evidence of reduced pain compared to the gel and was preferred by most children.(*Pediatr Dent*. 2003;25:401-405)

KEYWORDS: TOPICAL ANESTHETIC, BENZOCAINE GEL, LIDOCAINE PATCH, DENTIPATCH

Received July 1, 2002 *Revision Accepted February 6, 2003*

Behavior management in pediatric dentistry encompasses various elements ranging from creating a "pain-free" environment to acceptance of treatment by a child. A "pain-free" environment for the child typically is created by using psychological tactics and topical anesthetic agents such as benzocaine gel prior to injection. The use of the topical gel, however, is not always accepted by the child and, therefore, can increase anxiety and pain during dental treatment. The use of a transoral delivery system with whimsical design marketed towards young children could help remedy this problem, as well as make the dental visit more interesting and less intimidating for the young child.

A transoral system called the DentiPatch is manufactured by Noven Pharmaceutical, Inc, and contains 46.1 mg of lidocaine USP (20% concentration). This system claims to reduce needle pain and obtain site-specific anesthesia and has unit-dose convenience. Noven Pharmaceuticals, Inc, recommends that this product be used for mild topical anesthesia before superficial dental procedures like scaling and root planing and for topical anesthesia prior to administration of local anesthesia. The adhesive patch is 1 cm wide, 3 cm long, and approximately 2 mm thick. The area of application is dried either with gauze or air followed by application of the DentiPatch with firm finger pressure until it adheres. This delivery system prevents topical anesthetic from being washed away from the target sight, decreasing its effectiveness.[1] The time of application is from 2.5 to 5 minutes with a maximum of 15 minutes for maximal anesthetic effects in adult patients.[1] According to Houpt et al,[2] the onset of anesthesia is within 5 minutes of application, and peak anesthetic effects occur at 15 minutes.

Other studies show that dental soft tissue anesthesia is within 2.5 to 5 minutes with peak anesthetics after 15 minutes of placement with the anesthetic effect present for at least 40 minutes after the 15-minute wear period.[3] This transoral delivery system has been shown to be highly effective[2-4] and safe[2,4] in adults as a topical anesthesia, whereas in children it was shown to decrease verbal indicators of injection pain compared to the use of topical gel.[5]

The objective of this study was to compare pain, acceptance of, and preference for this patch with that associated with the use of benzocaine gel.

Methods

This study enrolled patients from the pediatric dental clinic at the Sunset Park Family Health Center of Lutheran Medical Center in Brooklyn, NY, which primarily serves a Hispanic population. The inclusion criteria for subjects were the following:

1. relatively noncontributory health history (patients with diseases such as asthma and heart murmurs were included);
2. compliance with dental visits;
3. mentally able to complete Whali-Wong questionnaires;[6]
4. bilateral need for topical anesthetic.

Patients who were mentally delayed, had learning problems or delayed speech development, and behavioral diagnoses such as attention deficit disorder were excluded because the authors did not have the resources to evaluate them ahead of time to determine if they were sufficiently cooperative. The study was approved by the Institutional Review Board, and informed consent was obtained appropriately.

This study used a "within-subjects" design in 2 phases. In both phases, subjects were seen for restorations, endodontic procedures, extractions, or sealant placement. Patients were required to have identical or similar work on contralateral sides of the mouth in both phases of treatment. For example, patients were excluded if they needed an extraction in the clinic on the first visit and operative procedures on the second visit. If one or more of the following were used on one side of the mouth in phase 1, then the same one or more were used on the other side in phase 2: sealants with rubber dam, preventive resin restorations with rubber dam (including enamel or enamel-dentin), pulpotomies with rubber dam, stainless steel crowns with rubber dam, or extractions. (The only exception was a patient who had a composite restoration on one side and a stainless steel crown placed on the other side.) Regarding local anesthetic, patients were only entered into the study if they had identical administration (ie, palatal injections, infiltrations, or blocks) in both phases.

On the first visit, subjects were given the choice of 2 alternative methods of topical anesthesia. Whichever method the child did not pick was used on the second visit, and the child was informed of this. The 2 methods of topical anesthesia were the DentiPatch (20% concentration lidocaine patch by Noven Pharmaceuticals, Miami, Fla) with whimsical design (Figure 1) and cherry-flavored 20% benzocaine topical anesthetic gel (Patterson Brand, St. Paul, Minn). In this study, one operator applied the topical gel, administered local anesthetic when needed, and conducted any needed operative treatment or extractions.

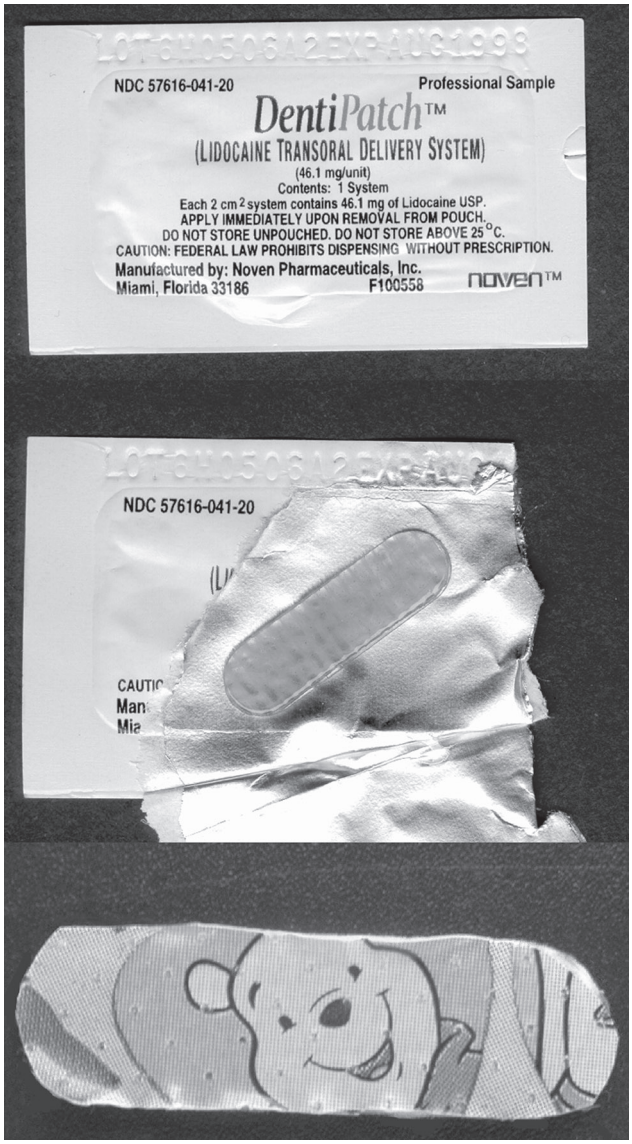

Figure 1. Top=packet containing patch. Center=patch on top of opened packet. Bottom=patch with design added by operator prior to being cut in half.

The area of application of topical anesthetic was air dried with a triplex syringe, and the topical anesthetic was placed for 4 minutes. This time period was selected to reduce the dosage of the active ingredient and to achieve soft tissue anesthesia. Regarding the DentiPatch itself, one half of it was utilized for the same reason, and the operator added a whimsical design to the outer surface of the patch in the form of an adhesive bandage or sticker (Figure 1). A dry field was obtained by use of gauze or by having the child lightly bite on a low-speed suction to keep the lips,

tongue, and saliva from area. (If the patch was placed in the mandible for topical anesthesia of a block, the patch was ligated to prevent aspiration.) For the topical gel, gauze was placed over the area during application. After application of the topical anesthetic for 4 minutes, local anesthetic was administered if the preparation was to go past the depth of the enamel. If no local anesthetic was utilized, an Ivory 12A or 13A clamp (Miles Inc, St. Louis, Mo) was still used.

Table 1. Reasons Given for Initial Selection and Final Preference and Changes in Reasons N (%)

Reason for initial selection	Reason for final preference					
	Appearance	Taste	Feel	Novelty	Don't know	Total
Appearance	6	8	3		1	18 (60%)
Taste		3		1		4 (13%)
Novelty	1	2	4		1	8 (27%)
Total	7 (23%)	13 (43%)	7 (23%)	1 (3%)	2 (7%)	30 (100%)

In this study, the patch was cut in half vertically and applied to the area for only 4 minutes to gain enough soft tissue anesthesia to reduce pain without significantly increasing dosage of local anesthetic. According to Noven Pharmaceuticals, the total amount of drug absorbed during 15 minutes of application in adults is confined to the area and the maximum is less than 0.1 mg/mL, which is 1/100 the amount of the toxic dosage in adults, 0.5 mg/mL.[1] The amount of lidocaine absorbed from the patch in children in the study was further reduced by decreasing the dosage through length of time of absorption and amount (surface area).

Two scales were employed to measure comfort or pain: the Whali-Wong scale and the SEM scale.[7] The Whali-Wong scale is a subjective scale similar to the Faces Pain scale validated to assess pain following surgery.[6] Its responses range from 1 to 9, with 1 being the most comfortable and 9 the least comfortable. The SEM[7] is an objective scale based on observations and ranges from 1 to 4, with 1 being the most comfortable and 4 being the most painful. In this study, the Whali-Wong scale was not utilized to measure pain but to measure comfort of the patient during application of the topical anesthetic and after injection.

Before applying the child's choice of topical anesthesia, the Whali-Wong scale was used to determine baseline comfort. The subject was asked to fill out the scale again after removal of topical anesthesia (placed for 4 minutes) and once again after injection if that was needed. The SEM scale was utilized to measure pain or comfort during injection. Administration of local anesthetic was completed by the use of a 30-gauge needle and 2% lidocaine with 1:100,000 epinephrine. An assistant recorded the observations.

The patient completed a questionnaire with the assistance of the operator. At the first visit, when the patient was given the choice of topical anesthetic, the patient was asked why he or she had chosen the topical anesthesia. At the second visit, after the restorative procedures were completed, the patient was asked which mode of topical anesthesia the patient liked and why.

Correctness of SEM scale values was enhanced by 3 calibration sessions with assistants involved in the study that were completed before initiation of the study. During these calibration sessions, the operator oversaw that scales were recorded correctly and determined that the assistant's observed values were the same as those of the operator. If the values between the assistant and operator were not calibrated, then the assistant was not utilized for the study. Thus, only 4 out of 8 assistants participated in completing the SEM scales. Throughout the 2 phases of treatment (visits), the operator and assistant confirmed together that observations were correctly recorded.

Student's *t* test was used to analyze mean differences of continuous variables. The chi-square test was used to determine differences between categorical values. A *P* value of less than .05 was considered significant.

Results

Thirty subjects, 16 boys (53%) and 14 girls (47%), between the ages of 3 and 12 years (mean=7.9±2.4 years) participated in this study. Two subjects (7%) were Asian, and the remaining 28 (93%) were Hispanic. During treatment, topical anesthetic was applied to the maxillary anterior in 2 (7%), maxillary posterior in 15 (50%), mandibular block in 3 (10%), and mandibular posterior buccal in 10 (33%) regions. Five subjects (17%) did not require local anesthetic, and 25 (83%) required local anesthetic.

Of the 30 patients in this study, 24 (80%) selected the DentiPatch over gel on the first visit. Patients were asked at the end of the second visit which mode of topical anesthetic they liked best: 22 subjects (73%) preferred the patch and 8 subjects (27%) preferred the gel. All 6 patients who selected the gel at their first visit chose the gel as their favorite mode at the second visit. The reasons patients gave for selecting or preferring the patch or gel were categorized into 5 different groups: appearance, taste, feel, novelty, and don't know. Patients' reasons for initial selection of patch or gel at the first visit and for final preference at the second visit as well as any changes in reasons are found in Table 1. On the first visit, the mean age of subjects differed according to reason for selection. The mean age of those selecting by appearance was 6.9 years, by taste 8.8 years, and by novelty 9.5 years (*P*=.02). At the second visit, final preference and mean age were not significantly related (appearance=6.7 years, taste=7.5 years, feel=9.1 years, and don't know=9.5 years).

Table 2. Mean Sounds, Eyes, Motor Values for Gel and Patch During Injection (Mean±Standard Deviation, N=25)

Pain scale	Gel	Patch	All
Whali-Wong			
Before topical*	2.7±1.5	2.7±1.9	2.7±1.7
After topical*	3.2±1.8	3.2±1.7	3.2±1.7
After local	3.6±1.6	4.0±2.1	3.8±1.9
Sounds	1.9±0.6†	1.4±0.6†	1.6±0.7
Eyes	1.9±0.8	1.6±0.8	1.8±0.8
Motor	1.7±0.5	1.4±0.7	1.6±0.6
SEM scale total	5.6±1.5‡	4.4±1.8‡	5.0±1.7

*Means reflect entire group, N=30. This data was captured before injection.
†*P*=.003.
‡*P*=.02.

The reason that patch or gel was chosen at the first visit was often not the same reason given for final preference at the end of the second visit (Table 1). At the first visit, girls seemed to select their mode of treatment more because of appearance (61%) and boys more because of novelty (88%; *P*=.07). In this sample, however, the mean age of the boys (8.7 years) was greater than that of the girls (6.9; *P*=.04). Linear regression showed that age (*P*=.05) was the significant factor governing selection, rather than gender (*P*=.1). Of the 22 patients who preferred the patch, 12 (55%) were girls; of the 8 who preferred the gel, 6 (75%) were boys (*P*>.15).

Whali-Wong scale values were similar for patch and gel (Table 2). During injections (N=25), the gel was associated with higher scores than the patch for the Sounds value (*P*=.001), and the composite SEM scale score (*P*=.02; Table 2).

The most painful region during injection in this study was the mandibular block region, showing higher values for Eyes (*P*=.005), Motor (*P*=.02) and SEM scale composite scores (*P*=.03).

Discussion

In this group of subjects, children ultimately preferred the patch over benzocaine gel (77% patch, 23% gel). Age, sex, and reason for acceptance were found to have significance at the first visit. The younger children in this study chose the patch over gel because of appearance; the older children chose the patch over gel because of novelty and taste.

Some of the authors' findings were similar to those of other studies of the lidocaine patch or benzocaine gel. In adults, the patch had a more significant anesthetic effect than topical gel,[3] but this had not yet been found in children. In a study by Kreider et al, children made fewer sounds during injection with the patch (*P*=.003), and if they did vocalize it was not until after penetration during increased pressure of the anesthetic in the area.[5] Consistent with the findings reported by Kreider et al,[5] the Sounds value in the authors' study was higher for gel than the patch (*P*=.001). Like the Kreider study, the authors found no significant difference in reported pain (pain-eye response was not recorded in this study), but in the authors' study SEM scale composite values were higher for gel than patch.

The Whali-Wong values were similar for patch and gel; the values for SEM, however, were lower for patch than gel. The reason for the similarity in the Whali-Wong values could have been due to subjects' anxiety in trying a new mode of topical anesthesia and participating in the study. After all, the majority of subjects chose the patch as their first modality of treatment.

The change in reason for preference from visit 1 to visit 2 could be due to experience: even though appearance is important to children, taste is also an important factor. Pain reduction was not as important to the children when deciding which method of topical anesthesia was preferable.

The region that was found to be most painful in this study was the mandibular block. Unfortunately, only 3 subjects received this injection; therefore, it is difficult to ascertain if this area was most uncomfortable because of the type of patient (apprehensive vs calm) or the location. This region could be most painful because of the greater tissue depth in this area (the topical anesthesia does not penetrate the full depth of the tissue) and contact made by the needle with the periosteum.

According to Martin et al,[8] topical anesthetics are only moderately effective, and it is both technique of injection and manipulation of the oral cavity that affects patients' perception of pain upon injection. If this were truly the case, the patch with an appealing design could be a more effective topical anesthetic for operative procedures in children and help facilitate a more acceptable environment for the child.

Topical anesthetics have been utilized in dentistry to reduce pain psychologically and physiologically. Recently, different modalities of topical anesthetics other than benzocaine gel, especially the DentiPatch, have been studied in adults, but not as frequently in a younger population. In addition, neither preference nor acceptance has been studied in adults or children. In the present study, preference and acceptance as well as reduction in pain by 2 different types of topical anesthetics were considered. This study found that the lidocaine patch was more effective in reducing pain upon entrance of injection with the use of the SEM scale. Sounds and composite values were significantly lower when utilizing the patch than when utilizing the gel.

During application of the topical agents, patients were cooperative and calm. At times, however, it was difficult to ensure constant application of the lidocaine patch. It was easy to dislodge the patch from the area, and sometimes the operator had to hold the patch against the mucosa during the entire time of application. While the operator's intention was to ask children all questions regarding selec-

tion and preference in a neutral way, it is possible that they influenced the children in some unconscious way concerning which anesthetic they wanted first and deciding which they preferred.

Other limitations of the study were as follows:

1. The sample size was relatively small, but was offset by the within-subjects design that ensured that the control subjects were identical to the experimental subjects.
2. While the rater for the pain scale was not blinded to the type of topical anesthetic used and interrater reliability was not calculated, other procedures helped reduce bias: the rating was done by an assistant rather than the operator, and the assistant directly observed the child and had been trained in the rating procedure.
3. While the patch was cut in half in this study to reduce the amount of anesthetic administered, Noven does not recommend that this be done in standard clinical practice.

Conclusions

The patch was associated with some objective evidence of reduced pain compared to the benzocaine gel and was preferred by most children.

Acknowledgments

The authors would like to acknowledge Louis Siegelman, DDS, for his help with the goal and design of the study.

References

1. Noven Pharmaceuticals DentiPatch information. Available at: http://www.noven.com/proddevsvs.htm. Accessed November 1997.
2. Houpt MI, Heins P, Lamster I, Sone C, Wolff MS. An evaluation of intraoral lidocaine patches in reducing needle-insertion pain. *Compendium of Continuing Education in Dentistry.*1997;18:309-316.
3. Hersch EB, Houpt M, Cooper S, Fieldman R. Analgesic efficacy and safety of an intraoral lidocaine patch. *J Am Dent Assoc*. 1996;127:1626-1634.
4. Carr M, Horton J. Evaluation of transoral delivery system for topical anesthesia. *J Am Dent Assoc*. 2001; 132:1714-1719.
5. Kreider KA, Stratmann RG, Milano M, Agostini F, Munsell M. Reducing children's injection: lidocaine patches vs topical benzocaine gel. *Pediatr Dent*. 2001;23:19-23.
6. Tyler DC, Tu A, Douthit J, Chapman R. Toward validation of pain measurement tools for children: a pilot study. *Pain.* 1993;52:301-309.
7. Wright GZ, Weinberger SJ, Marti R, Plotzke O. The effectiveness of infiltration anesthesia in the mandibular primary molar region. *Pediatr Dent*. 1991;13:278-283.
8. Martin MD, Ramsay DS, Whitney C, Fiset L, Weinstein P. Topical anesthesia: differentiating the pharmacological and psychological contributions to efficacy. *Anesth Prog*. 1994;41:40-47.