The Effectiveness of a Needle-Free System in Reducing Injection Pain During Palatal Infiltrative Anesthesia in Children: A Randomized Clinical Study
Study Type and Sample Size

NCT Number: NCT06606587

The local clinical research ethics committee approved this prospective, clinical, randomized study (Approval number: 22-KAEK-060). The clinical trial number is NCT06606587 at clinicaltrials.gov website. This study was conducted between January 2023 and December 2023.

All procedures performed in this study were carried out according to the ethical principles described in the Declaration of Helsinki. Patients and their parents were informed about the study, and informed consent was obtained before treatment and the study was executed following CONSORT Statement 2010 guidelines [13]. The required number of participants was obtained after power analysis based on data from a previously conducted study on the subject [alpha(α)=0.05 beta(β)=0.05 and power=0.95]. It was found that 50 people should be included in the study [14].

Patient Selection and Randomization

This study included 50 children aged 7–14 years who presented to the dentistry clinic with their parents. Participants were required to have an indication for the extraction of maxillary permanent first molars under palatal infiltration anesthesia and to provide informed consent for the procedure (Fig. 1).

Included in this study were presence of a maxillary first permanent molar with an indication for extraction; absence of ankylosis, root resorption exceeding one-half of the root length, severe structural loss, root canal calcification precluding endodontic treatment, vertical root fracture, or extensive furcation lesions; systemically healthy status; and a behavioral rating of 2, 3, or 4 on the Frankl scale [15]. The primary indications for extraction included extensive

dental caries, orthodontic treatment planning, and periapical or periodontal infections affecting the maxillary first permanent molars. Frankl behavior rating scale (2,3 and 4). FBRS scores were rating 2(negative), 3(positive) and 4(definitely positive). Exclusion criteria included a Frankl score of 1, known allergy to local anesthetic agents, presence of acute infection, refusal to participate in the study, medical or developmental disorders, pathological conditions in the anesthesia area, developmental tooth defects, and limited mouth opening.

Conversely, those with medical or developmental disorders, allergies to anesthetic agents, pathological conditions in the anesthesia area, developmental tooth defect or limited mouth opening were excluded.

Participants meeting the inclusion criteria were randomly assigned to one of two groups. To ensure randomization, two sealed envelopes, each containing one of the anesthesia methods, were prepared. One envelope contained "Group 1" and the other contained "Group 2". Each participant selected an envelope, determining their assigned anesthesia technique. In Group 1, palatal anesthesia was administered using the Comfort-In™ jet injection system, while in Group 2, a dental needle injection was used. To prevent any interference with pain perception, topical anesthetics were not applied before the injections [16]. The procedure was performed by only one dentist.

Comfort-In™ Injection Group

In the experimental group, palatal infiltrative anesthesia for maxillary first permanent molars was administered using the Comfort-In™ Injection system (Mika Medical, Busan, Korea). A total of 25 patients were included in this group. Before administering anesthesia, the child was prepared using the tell–show–do behavioral guidance technique.

The Comfort-In™ system utilizes a pressurized spring mechanism and a yellow silicone cap to facilitate proper positioning on periodontal tissues during jet injection. The injection was administered 5 mm below the palatal gingival margin line, close to the free gingiva, and at a vertical angle (Figs. 2a and 3). A total of 0.3 cc of anesthetic solution was delivered by pressing the jet injection system button. The local anesthetic used was 1 ml of Articaine Hydrochloride (Ultracaine D-S forte, Hoechst, Canada) with 1:100,000 epinephrine (Figs. 2a and 3).

After the injection, a 2-minute waiting period was observed to allow for intraosseous anesthetic diffusion. The Comfort-In™ jet injection system is an intraosseous anesthesia technique, and since its effect becomes evident within a short period, a waiting time of 2 minutes was established [17]. The decision to administer an additional dose was specifically determined during clinical evaluations based on the patient's sensitivity or pain response upon gingival probing at the palatinal gingiva. To assess the adequacy of palatal anesthesia, a periodontal probe was gently inserted into the palatal mucosa at the anesthesia site, and the child's response was monitored. If the patient reported no pain or discomfort during probing, the anesthesia was considered sufficient. If any discomfort was noted, an extra dose of anesthesia was administered before proceeding.

Once palatal anesthesia was confirmed to be sufficient, buccal infiltration anesthesia was performed using a dental needle syringe. Following successful anesthesia, the tooth was extracted.

Dental Injection Group

In this group, palatal anesthesia was administered using the dental needle injection technique. A total of 25 patients were included in this group. The injection site was located approximately 5 mm below the palatal gingival margin, on the attached gingiva, and the needle

was inserted at a 45-degree angle (Figs. 2a and 3). Before administering anesthesia, the child was prepared using the tell–show–do behavioral guidance technique.

Following needle insertion, bone contact was established and then withdrawn by 3–5 mm, at which point 0.3 cc of anesthetic solution was slowly deposited. The local anesthetic agent used was 1 ml of Articaine Hydrochloride (Ultracaine D-S forte, Hoechst, Canada) with 1:100,000 epinephrine, administered with a 27G dental needle (Figs. 2a and 3).

After the injection, a waiting period of five minutes was allowed to ensure the anesthetic had taken full effect. The adequacy of palatal anesthesia was assessed clinically by gently probing the gingiva and observing the patient's response to pain or sensitivity. If no discomfort was noted, the anesthesia was considered sufficient. However, in cases where the response indicated inadequate anesthesia, an additional dose of local anesthetic was administered using the conventional dental needle technique. This supplementary injection was intended to alleviate any remaining discomfort and was interpreted as a sign of failure in the initial palatal infiltration. Once adequate palatal anesthesia was confirmed, buccal infiltration anesthesia was delivered with a dental needle syringe, and the tooth was extracted under effective local anesthesia.

Pain Assessment

Pain perception was assessed using both subjective and objective measures immediately after palatal anesthesia. For subjective evaluation, the Wong-Baker FACES Pain Rating Scale[18] (WBFPRS) was used, allowing patients to self-report their pain levels. For objective assessment, the Face, Legs, Activity, Cry, Consolability Scale (FLACC) [19] was utilized.

The WBFPRS is a visual analog scale that features a series of facial expressions ranging from a smiling face to a crying face, each corresponding to a numerical value between 0 and

10. A score of 0 represents "no pain," while a score of 10 indicates "hurts worst." Patients were asked to identify the face that best represented their pain at that moment.

The FLACC behavior scale is an observational pain assessment tool that evaluates five behavioral parameters:

1. Facial expression
2. Leg movement
3. Activity level
4. Crying
5. Consolability

Each parameter is scored on a scale from 0 to 2, with a total possible score ranging from 0 to 10. According to the FLACC behavior scale:

- 0 points indicate no pain,
- 1–3 points indicate mild pain,
- 4–6 points indicate moderate pain and discomfort,
- 7–10 points indicate severe pain and distress.

To ensure standardized evaluations, all injections were administered by a single researcher experienced in Comfort-In™ jet injection. Additionally, all injections were recorded on video for later assessment. The FLACC behavior scale scores were assigned by two pediatric dentists (BA, HA), who reviewed the video recordings to assess interobserver reliability. Meanwhile, WBFPR scores were obtained directly from the patients immediately after anesthesia.

Statistical Analysis

Data was analyzed using version 4.4.1 of the R programming language. Normality was assessed using Kolmogorov Smirnov test. Numerical data represented as mean ± standard

deviation and median (minimum-maximum). Categorical data represented as frequency and percentage.

Spearman's rho (ρ) test was used to establish intra-rater reliability. Inter-rater agreement was assessed using Kappa (κ) test, with values >0.81, 0.80–0.61, 0.60–0.41, 0.40–0.21, and <0.20 denoting perfect, substantial, moderate, fair, and slight agreement, respectively.

The differences between groups were evaluated using Spearman's correlation test, Mann–Whitney U-test, and Wilcoxon t-test. The significance level was set at $p<0.05$.

Multiple linear regression and multiple ordinal logistic regression were used to model the effects of age, gender, Frankl behavior scale scores and anesthesia methods (Comfort-In/ Dental needle) on the scores of the FLACC behavior scale and Wong-Baker FACES Pain Rating Scale, respectively.