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Materials and Methods

Ethics Approval: Ethical approval for this study was obtained from the Tokat Gaziosmanpaşa University Faculty of Medicine Clinical Research Ethics Committee (Approval No: 16-01 / Date: 14.09.2023). The study was conducted in accordance with the principles of the Declaration of Helsinki. Before the procedures, detailed information about the study's purpose and the treatment to be performed was provided to the children and their parents, and both the child assent and informed consent forms were obtained.

Determination of Sample Size: Using G*Power v.3.1.9.7, a power analysis for the planned study with 2 dependent groups indicated that, with 80% test power (1–β) and an effect size of 0.56, 28 patients (56 permanent first molars) were planned to be included (Smaïl-Faugeron et al., 2019).

Participant Selection Criteria: The study included 28 children aged between 6 and 12 years who met the following criteria: absence of systemic disease; a score of 3 or 4 on the Frankl Behavior Rating Scale; bilateral MIH in the maxilla or mandible; deep dentin caries in the permanent first molars that could be treated with vital pulp therapy; and no history of acute pain.

Study Design: The study was conducted using a split-mouth design with 28 patients and 56 teeth who met the inclusion criteria and were recruited from the Department of Pediatric Dentistry, Faculty of Dentistry, Tokat Gaziosmanpaşa University. The patients included in the study were randomly assigned to two groups:

- **Control group:** Anesthesia administered using the conventional injection technique.
- **Study group:** Intraosseous anesthesia administered with the computer-controlled anesthesia device (SleeperOne).

Teeth affected by MIH were classified according to the Molar–Incisor Hypomineralization Treatment Need Index (MIH-TNI). Those in category 2 were evaluated as “Without hypersensitivity,” while those in category 4 were assessed as “With hypersensitivity” (Figure 1).

Dental Anesthesia Methods: All procedures were performed by the same dentist in a single-unit room, and appointments were scheduled as the first of the morning (08:15). Patients were instructed to arrive with a full stomach and brushed teeth. Before the procedure, all steps were explained using the tell–show–do technique.

All treatments were planned in two sessions, scheduled 7–10 days apart. The anesthesia method to be used in the first session was determined by randomization. For this purpose, each patient was asked to randomly select one of the envelopes labeled with different anesthesia methods. In addition, to determine which tooth to begin treatment on, patients were asked to choose between blue and green cards: children who selected the blue card started with the right first molar, while those who selected the green card started with the left first molar.

In both the control and study groups, a topical anesthetic spray containing 10% lidocaine (Vemcaine® pump spray 10%, Vem Pharmaceutical Industry and Trade Co., Türkiye) was applied to the target area with a cotton pellet for 1 minute before anesthesia administration. In the control group, anesthesia was administered using a 2 ml plastic dental syringe (Berika Technology Medical Manufacturing Import Export Trade Co., Türkiye) for both infiltration and mandibular block

anesthesia. For the maxillary teeth, buccal infiltration anesthesia was administered; for the mandibular teeth, mandibular block anesthesia was administered. In the study group, anesthesia was performed using a computer-controlled local anesthesia system with 30-gauge, 9 mm Effitec extra-short needles (Dental Hi Tec, ZI de l'Appentière, Mazières-en-Mauges, France). Following topical anesthesia, half of a carpule of local anesthetic solution (Ultracaine D-S Fort, Sanofi Aventis Deutschland, Frankfurt, Germany) was administered to the designated teeth using the intraosseous anesthesia technique, in accordance with the manufacturer's instructions.

Dental Pain and Anxiety Assessment Scales: To evaluate the dental anxiety levels of the patients, the CFSS-DS (Children's Fear Survey Schedule–Dental Subscale) was administered at their first visit. This scale includes 15 questions directed to the child, each answered on a 5-point scale ranging from 1 ("not afraid at all") to 5 ("very afraid"). The total score ranges from 15 to 75. Based on the total score, children scoring between 15 and 38 were considered not to have dental anxiety, while scores of 38 and above were considered indicative of dental anxiety.

WBS, VAS, and FLACC scales were administered to the patients before anesthesia, after anesthesia, and after the treatment procedure. During the same periods, pulse rate and oxygen saturation were measured using a fingertip pulse oximeter device.

Salivary Cortisol Measurements: 15 minutes before anesthesia, 15 minutes after anesthesia and after the treatment procedure, patients were instructed to rinse their mouths with water and then spit into a saliva collection container. Since cortisol measurements were to be performed on collected saliva, water was used as the rinsing solution to prevent interference from anesthetic agents or other chemicals with hormone levels. The collected saliva samples were transferred from the collection containers into 2 ml centrifuge tubes using pipettes and centrifuged at 5000 rpm for 10 minutes. Using pipettes, the remaining saliva on top was transferred to Eppendorf tubes, and the samples were stored at -20 °C. The centrifugation process was completed within 5 minutes of sample collection. Salivary cortisol levels were measured in the Department of Medical Biochemistry, Faculty of Medicine, Tokat Gaziosmanpaşa University, using an ELISA kit (Salivary Cortisol Kit, BT LAB, Shanghai, China).

Statistical Analysis: Data were analyzed using IBM SPSS version 23. The normality of data distribution was assessed with the Shapiro–Wilk test. For normally distributed data, parametric tests (Independent Samples t-test, Paired Samples t-test, Repeated Measures ANOVA, Pearson correlation) were used; for non-normally distributed data, non-parametric tests (Mann–Whitney U test, Wilcoxon test, Friedman test, Spearman's rho) were applied. For categorical variables, Fisher's Exact test (with Monte Carlo correction), Marginal Homogeneity test, and Cochran's Q test were used. Quantitative data were presented as mean ± standard deviation or median (min–max), while categorical data were expressed as frequency and percentage. A p-value of < 0.05 was considered statistically significant.