Title:

Pain Perception Associated with Cordless Electronic local anesthetic delivery system In Children (A randomized controlled trial)

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The injection of a local anesthetic represents the greatest source of fear and anxiety, especially in children and adolescents, because it is mainly associated with pain and discomfort. Furthermore, severe anxiety and fear may increase pain perception (Garret-Bernardin et al., 2017). Although the aim of local anesthesia is to eliminate pain during dental procedures, the fear connected to the needle puncture is frequently considered a reason for not visiting the dentist**(Galeotti et al., 2016).**

Therefore, there is an urgent need to develop techniques that decrease pain during injection, preventing patients from avoiding dental treatment **(Garret-Bernardin et al., 2017).**

Recent developments have allowed introducing computerized anesthetic injection as an alternative method to classic dental anesthesia. Innovative computerized systems might be a possible solution to reduce the pain during the local anesthetic injection by automatically controlling the slow delivery of local anesthetic solution (González-Castro & Arias, 2017).

Wireless computer-controlled local anesthetic delivery (CCLADs) have emerged, with the control unit integrated into the syringe body, eliminating the need for foot pedal attachments. These devices use conventional dental needles and LA carpules. Examples include the Anaeject ®, Dentapen ®, and iCT systems ® **(Khan et al., 2025).**

Pain perception in children causes a number of changes in their emotional state. It can lead to emotions like fear, anxiety, sadness and might have an impact on day-to-day activities. Three components of pain assessment in children are self-report, behavioral observation and physiological measures. Most reliable indicator of pain is a combination of all 3, known as a multi-dimensional pain assessment **(AlRaddadi et al., 2025).**

Wong-Bakers facial pain rating scale (WB-FPS) is one of the scales used to measure self-reported pain perception. It consists of 6 faces with word descriptors and numbers from 0 to 10. The child is asked to point to the face that describes how he/she feels at the particular moment and numbers on this scale can be adjusted to a 0 to 10.This simple scale can be easily reproduced for use at the chairside with children as young as 3 years of age **(Nagarwal et al., 2022).**

Behavioral observation pain assessment tools are available for use with pre-verbal or non-verbal children and for cognitively impaired children, one such scale is Face legs activity cry and consolability (FLACC) scale. It has been found to have reasonable interrater reliability and validity as a measure of pain in children with varying degrees of cognitive impairment. This simple tool

contains five categories, each of which are scored from 0-2 to provide a total score ranging from 0-10 **(Nagarwal et al., 2022).**

Despite the assessment of many computer controlled local anesthetic delivery systems, like The Wand and Calaject, evidence concerning newer devices like Top Injector® is still few. Further, only a few studies have employed a within-subject crossover method to decrease inter-individual variability in pain perception.

This study aims to evaluate and compare pain perception and pain-related behavior during local anesthesia injections between conventional dental syringe and Star pen®, as well as to correlate the dental fear and anxiety of children with pain perception.

Methodology:

- **Study design:**

This is a split mouth randomized controlled trial, will be conducted in the outpatient clinic of pediatric dentistry, Medical and scientific Centre of Excellence, National Research Centre.

- **Sample size:**
  Based on **AlRaddadi et al (AlRaddadi et al., 2025)**mean pain perception score varied between 1.55 (±0.31) and 1.82 (±1.76) in different groups. Using G power statistical power Analysis program (version 3.1.9.4) for sample size determination **(Uttley, 2019)**, A total sample size (n=22 patients in a split mouth study) will be sufficient to detect a medium effect size (d) = 0.87, with an actual power (1-β error) of 0.8 (80%) and a significance level (α error) 0.05 (5%) for two-sided hypothesis test.
- **Sample selection:**

The sample will be selected from children who attending pediatric dental clinic at Medical and scientific Centre of Excellence, National Research Centre. and who have two primary molars that are indicated for pulpotomies or extractions. The study's protocol, risks, and benefits will be explained to the parents or legal guardians, and informed consent will be obtained from them if they agree to participate.

- **Inclusion criteria**:

  Children aged 5–12 years.
  Physically and mentally healthy children with no cognitive or emotional impairments.
  Having two contralateral primary molars need extraction or pulpotomy.
  No contraindication for the use of local anesthesia.
  Not taking any analgesic before the appointment for at least 24 h **(Bushra & Aslam, 2010).**
- **Exclusion Criteria**: History of allergy to local anesthetics, acute infection or inflammation at the injection site, significant cognitive or developmental impairments that prevent reliable pain assessment, and use of analgesics or sedatives within 24 hours of the procedure.

- **Study Objectives:**

Primary Objectives:

1- To compare the pain perception and pain behavior of children with the type of administration device (Traditional Dental Syringe vs. Top Injector®).

Secondary objectives:

1- To correlate the dental fear and anxiety of children with pain perception.

- **Randomization:**

Because of the nature of the split-mouth design, patients serve as their own controls. Each tooth fulfilling the inclusion criteria will be randomly assigned to one of two groups, the control group (traditional dental syringe) or the experimental group (Top Injector®), using a list of random numbers that will be generated online with a randomization program (http://www.randomizer.org).

During the first appointment, the patient will be given one type of the mentioned LA techniques (traditional or Top Injector®), depending on the randomization; during the second visit, the patient will be given the other technique.

- **Clinical procedure:**

1- Explaining clinical procedure and the objectives of the study to parents or Guardians and obtaining an informed consent from them. the research will be conducted in conformity with the Declaration of Helsinki (2013).
2- All children will be clinically examined and randomly assigned to one of the LA techniques (traditional or Star Pen®) in the first appointment.
3- Subjective evaluation of dental fear and anxiety of each child using The Dental Subscale of Children's Fear Survey Schedule (CFSS-DS) **(Mobin et al., 2023)**Prior any treatment.
4- Subjective evaluation of pain perception will be evaluated for each child immediately post injection using Wong-Baker FACES Pain Rating Scale (WBFPRS) **(Garra et al., 2010).**
5- Objective evaluation of pain behavior will be evaluated for each child during injection using FLACC Scale (**F**ace, **L**egs, **A**ctivity, **C**ry, and **C**onsolability) **(Nagarwal et al., 2022).**
6- Physiological parameters of pain assessment such as Heart Rate and Oxygen saturation will be measured using pulse oximeter at pre-injection and during injection.
7- Finishing the dental treatment either extraction or pulp therapy.

- **Measurement of outcomes:**

Variable	Measurement Tool	Timing of Measurement
Pain Perception (Subjective)	Wong-Baker FACES Pain Rating Scale (WBFPRS)	Immediately Post-Injection
Pain Perception (Objective)	FLACC Scale (Behavioral)	During Injection
Physiological Response	Heart Rate (HR) and Oxygen Saturation (SpO_2)	Pre-injection, during Injection
Dental fear and anxiety	Dental Subscale of Children's Fear Survey Schedule (CFSS-DS)	Prior any treatment

- This study will be self-funded.

➢ **Statistical analysis:**

Statistical analysis will be performed using a commercially available software program (SPSS Chicago, IL, USA).

Numerical data will be described as mean and standard deviation or as median and range as appropriate according to the normality of the data. Data will be compared using Mann Whitney U test or independent t test depending on normality.

The level of significance will be set at $P \leq 0.05$. All tests will be two tailed.

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