Pain Perception Due to Dental Injection by Smartject: Split Mouth Design Study

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KEY WORDS
Anesthesia, Local; Pain Perception; Injections; Visual Analogue Scale;

ABSTRACT
Statement of the Problem: Dental injection is one of the most fearful procedures in dental setting, especially for children. Many researchers have attempted to find a painless method. As computer controlled local anesthesia delivery system devices (CCLADs) allow the speed rate and pressure of injection solution to be controlled, they may cause less pain during injection in comparison to the conventional method.

Purpose: The aim of this study was to compare pain perception in dental injection by Smartject with conventional technique.

Materials and Method: The present study was a randomized single-blind crossover clinical trial. The participants consisted of 50 healthy volunteer dental students. They received a topical anesthetic agent plus injection in maxillary premolar buccal mucosa via conventional technique on one side (control) and a topical anesthetics agent plus injection in maxillary premolar buccal mucosa by Smartject on the other side (experimental). The first injection method was chosen based on block randomization table. A blind person recorded the subjects’ pain perception based on the visual analogue scale (VAS) in the two groups. Repeated measure test, independent Student t-test and Student paired t-test were used. Statistical significance was defined at p < 0.05.

Results: There was statistically significant difference in VAS score between Smartject and the conventional technique. The mean of VAS scores for Smartject and the conventional technique were 14.5±7.4 and 24±12.1, respectively.

Conclusion: It is suggested, needle penetration is not the main reason of pain during injection. Inconsistent fluid pressure created by injected anesthetic solution on nerve fibers is more impressive in pain development. Hence, Smartject as a CCLAD can be considered as an appropriate device for dental injection.

Introduction
According to many studies, the most fearful experience cited by subjects who were asked to rank the situations in dental treatment is fear of dental injection. [1-2] This fear may prevent patients from seeking dental treatment. [3]

Numerous studies have been conducted to find a painless injection, [4-6] including application of topical anesthesia, [7] prolonged injection time, [8] pre-cooling injection site, [9] pressure to injection site, [10] applying laser as pretreatment method, [11-13] warming the local anesthetic agents, [14] buffering the local anesthetics, [14-15] tactile stimulation, [16-17] and distraction technique. [18] However, more situations and techniques need to be evaluated to improve stress management in dental setting.
Traditional injection systems that uses metallic syringe do not allow the control of flow rate in a constant way and consequently, fluid pressure varies depending on manual force used by the practitioner during the injection procedure. [19] An injection into some areas in oral cavity, such as the palate that requires higher force, causes difficulty in syringe control and does not provide a comfortable injection. [6]

Recently, several researches have focused on the effectiveness of computer controlled local Anesthesia delivery system devices (CCLADs). These devices are designed to control the pain of the injection by delivering anesthetic solution at a constant pressure, volume and injection rate. [19] Several companies have improved the computer based, speed-controlled local anesthetic devices, including Comfort Control Syringe (CCS®) and the Comfort-in®, Deninjection®, No Pain III®, Meg-inject®, and Smartject®. These devices have different characteristics, such as design, weight, injection speed, shape, and possibility of aspiration, so operator can choose the device based on the convenience, depending on different situations. [20]

Smartject has been developed to provide operator convenience. Its lightweight design provides safe injection; in heavy design devices, it is difficult to control movement during needle injection, especially when a long period is needed for injection. [20] Moreover, having the possibility to use standard lidocaine carpule as well as conventional dental needle are the other advantages of Smartject. [20] Another good point of Smartject is having the possibility of aspiration; it is a facility where block injection is needed. [6]

Many studies have shown anxiety as well as pain perception in pediatric and general population could be reduced with CCLAD system. [21-27] However, some studies found no statistically significant difference in pain perception between conventional injection and a computerized device. [19, 22, 28]

It is worth mentioning, that so far no other studies have compared Smartject with the conventional technique. In addition, there is a controversial result about CCLAD efficacy in comparison with the conventional technique. [21, 28-29] The current study was designed to evaluate Smartject efficacy in comparison with conventional syringe injections on pain related with dental injection.

Materials and Method
The current study was a randomized single-blind crossover clinical trial and it was conducted in Dental School of Shiraz University of Medical Sciences, Shiraz, Iran. Fifty healthy volunteer dental school students from Shiraz University of Medical Sciences participated in this study. Their age ranged from 23 to 28 years. The sample size was determined based on a similar study. [30] The exclusion criteria were history of systemic disease, presence of abscess, redness, fistula in injection site, taking any kinds of medication that would change the pain perception, and history of allergy to lidocaine. The inclusion criteria were considered as all participants should have previously experienced the conventional syringe and none of them had ever experienced Smartject injection before.

After explaining the study procedure, a written consent form was obtained from all participants before the commencement of the trial. The Committee of Research and Ethics of university approved all the aspects and steps of this research protocol (Grant#94-01-03-9946) and it was submitted in IRCT (IRCT2015101024-445N2).

The participants received a topical anesthetic agent followed by injection by conventional technique on one side (control) and a topical anesthetic agent followed by injection by Smartject on the other side (experimental). The first injection method was chosen based on block randomization table.

The patients were explained how to report their pain perception during injection using visual analogue scale (VAS). VAS was scored on a 100-mm horizontal line with the left endpoint marked “no pain” and the right endpoint marked “pain as bad as it can be” for each patient.

Injection procedure
Buccal infiltration injection was conducted in maxillary premolar buccal mucosa aiming for the apical area of the tooth to evaluate the pain perception. On the experimental side, the injection site was dried with a cotton roll for thirty seconds and then benzocaine gel (Benzocaine USP, USA) was applied for one minute. The procedure was immediately followed by injection with mode 1 Smartject (KMG co, Saha-gu, Busan, Korea) (Figure 1) using 30 gauge short needle (DENJECT, Korea). In the same session, on the control side, injec-
tion site was dried with a cotton roll for thirty seconds and then Benzocaine gel (Benzocaine USP, USA) was applied for one minute. The procedure was immediately followed by conventional injection with 30 gauge short needles (DENJECT, Korea). In both the experimental and control sides, 1 ml of 2% lidocaine with 1:80,000 epinephrine (Lidocaine 2% E-80, Colombia) was injected. A trained examiner, blinded to the study, recorded pain perception during injection in both sides based on VAS.

Data were analyzed by SPSS software version 21. Repeated measure test was used to find out the effect of treatment sequence on results. Student paired t-test was applied to compare VAS score between Smartject and the conventional technique. Independent Student t-test was used to compare VAS score between male and female in the conventional technique as well as Smartject. Statistical significance was defined at $p<0.05$.

**Results**

In this study, the total number of participant was 50 and male to female ratio was 22 males (44%) and 28 females (56%), their age ranged from 23 to 28 (24.3±1.7) years. Repeated measure test showed that the sequence of treatment had no effect on the result. Hence, in this study we merely evaluated the pain perception of the two mentioned methods. Student paired t-test showed statistically significant difference between the mean of VAS scores for Smartject and the conventional technique (14.5±7.4 and 24±12.1 respectively), ($p=0.006$)

Student paired t-test showed statistically significant difference in the VAS score between Smartject and the conventional technique in males as well as females (Table 1).

Independent Student t-test showed no statistically significant difference in VAS score between males and females in the conventional technique as well as Smartject (Table 2).

**Table 2:** Comparison of Visual Analogue Scale in male and female in both injection methods

| Injection method         | Mean±SD VAS in Male | Mean±SD VAS in Female | $p$ Value |
|--------------------------|---------------------|-----------------------|-----------|
| Smartject                | 12.5±8.07           | 15.1±10.2             | 0.420     |
| Conventional technique   | 25.3±11.3           | 22.2±10.1             | 0.450     |

**Discussion**

Results of the current study showed the buccal infiltration injection by Smartject device caused statistically less pain in comparison with the conventional syringe in male and female, which was clinically important (more than five scores in VAS). [30] Different studies reported a range of at least 13-30 mm decrement in VAS score as clinically significant. [31-32]

Several studies showed anterior middle superior alveolar injection with computer controlled devices to be less painful than that using conventional syringe technique. [21, 33-34]

Krochak and Friedman stated that patients were able to manage their anxiety about injections successfully after applying the Wand system (a type of CCLAD). Hence, this can be a good method to decrease disruptive behaviors in children, especially in younger children. [35] Moreover, children who had experienced conventional technique were five times more likely needing be controlled for dental management than children who received injection by a computer controlled devices. [19]

Since CCLADs provide precise control of anesthetic solution flow rate, pressure and duration of injection time, the factors that are so difficult to achieve by manual injection, these results could be expected. However, some studies reported that there is no difference in pain perception during injection with conventional syringe in comparison to CCLAD devices. [22, 28-29]

As pain is a multi-factorial issue, it can be influenced by different factors such as age, gender, and situation. [36] The wide age range in the two above-mentioned studies [28-29] should be considered as their limitation for the same reason. The age range of participants in Verslout et al. [28] study and in Asarch et al. [29] study was 4-11 years and 5-13 years, respectively.
Allen et al. [19] reported after the first 15-second interval of the injection by computerized injection device, disruptive behavior developed as the time passed. In contrast to Allen et al. [19] study, Gibson et al. [37] study reported disruptive behavior diminished over time. However, in current study this parameter was not assessed, as the subjects were adult. In common belief, needle penetration into the tissue is not the main reason contributing to discomfort. Volume and pressure induced by anesthetic solution during injection results in more pain and stress. Anxiety in patients following local anesthetic injection makes the dentist nervous. [5, 21]

In current study, gender was not found to be a significant factor in pain perception in both injection methods. This result was in agreement with some other studies. [17, 38] However, in some studies gender was reported as a factor in pain perception as well as in acceptance of new method. [11, 16, 39] This discrepancy could be due to different inclusion criteria such as age and awareness level about applied procedure.

Split mouth design of this study provided results that are more reliable. The subjects for this study were adult because perception of pain in preschool children is complex and involves behavioral, physiological, psychological, and developmental factors. [19] The single blind design of the study can be considered as a limitation. In addition, limited number of Smartject cartridges (where carpules and needle are mounted) resulted in taking more time. The fact that the participants were drawn from dental students might give rise to possible bias. Evaluating different age groups, as well as different type of injection and other CCLAD devices are recommended for future studies.

Conclusion
It seems that needle insertion might not be the most important factor on pain perception during an injection. It seems that inconsistent fluid pressure and speed created by anesthetic solution on the nerve fibers is more significant in pain perception during conventional injection method. Therefore, Smartject (as a CCLAD) can be considered as an appropriate device for dental injection owing to its several options and aptitudes.

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Conflict of Interest
The authors declare that they have no conflict of interest.

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