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Efficacy of a Smart Injector for Dental Anaesthesia. A split- mouth study

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Abstract

Objectives

This study aims to evaluate the advantages of the Smart Dental Injector (SDI) compared to traditional injectors regarding anesthesia onset time, duration of effect, and pain perception.

Material and Methods

30 volunteers (11 males, 19 females; mean ages: 24.6 ± 2.2 and 23.1 ± 1.8) randomly received bilateral intraoral mental nerve blocks with 1.8 mL of 2% plain lidocaine using a smart dental injector (SDI, n = 30) or traditional syringe (control, n = 30) The vitality of the lower 1st premolar pulp was evaluated during the 1 minute and subsequently at 60-second intervals to initiate anesthesia, and then every 3 minutes for the duration of the anesthesia. with pain assessed using a visual analog scale (VAS).

Results

The smart injector significantly reduces pain perception by 61.7% ($p < 0.001$), and achieves a faster onset of anesthesia ($p = 0.002$), was not clinically significant, without affecting the duration of anesthesia ($p = 0.381$).

Conclusions

The smart dental injector device significantly reduces pain and speeds up the onset of anesthesia without affecting the duration of the anesthesia.

Clinical relevance

Smart injectior eliminate human error by controlling fluid dynamics to reduce pain and dosing inaccuracy.

Introduction

Traditional local anaesthetics are frequently used in dental practice [1]. Local anaesthesia is considered one of the most effective methods for reducing discomfort during invasive dental procedures. Anaesthesia has constituted a fundamental component of dentistry throughout its historical development and remains essential despite the proliferation of sophisticated techniques and equipment [2]. Pain during injection or prolonged numbness may cause anxiety and discomfort for patients.

Therefore, appropriate local anaesthetic delivery devices are required to minimise factors related to patient anxiety [2].

Traditional metallic syringes do not allow precise control of the flow rate and require manual force from the practitioner during the procedure [3]. Numerous devices have been developed to deliver anaesthetics with reduced pain for the patient. These devices are designed to control both pain and the injection rate [2]. For example, external cooling and vibration may be applied at the site of local anaesthesia to reduce discomfort [4]. In addition, alternative anaesthesia delivery systems include needleless jet injection methods, topical anaesthesia, and computer-controlled dental anaesthesia [2]. All these approaches aim to make the anaesthetic experience more comfortable and less unpleasant for patients [4].

The electronic dental (smart) injector was designed to make the user experience easier and more comfortable. Its lightweight design makes the injection process safer. With heavy devices, controlling the needle can be difficult, especially during prolonged injections, which can lead to tension or inaccuracy [5]. These devices were invented to relieve injection pain, as they deliver an anesthetic solution at a constant pressure, volume, and rate [3]. Another advantage of the smart injector is that it can be used with both standard lidocaine cartridges and traditional dental needles [5]. An additional feature is its suction function, which is particularly important when block injections are required [6]. Consequently, it may be considered a viable alternative to conventional local anaesthesia delivery methods [7]. Ghaderi and Ahmadbeigi suggested that Smartject™ may be considered an appropriate device for dental injections [8].

To date, few studies have directly compared smart injectors with traditional injection methods. Therefore, the present study aimed to evaluate whether smart injectors offer advantages over traditional injectors in terms of onset time, duration of action, and pain perception. A split-mouth study design was used to assess the differences in the primary outcomes in thirty patients (60 sites) receiving local anaesthesia.

Methods

This study followed the principles of the Helsinki Declaration and was registered in the clinical trials.gov registry (ID: NCT07257432), registry date 16.11.2025. Furthermore, it was approved by the Research and Ethics Committee of Al-Andalus University for Medical Sciences, Syria (approval number: 15/18, date: 15.08.2025). Written informed consent was obtained from all participants before the commencement of the trial.

Subjects and Study Design

A crossover, double-blinded (both the patient and the assessor), split-mouth study design was used. The sample consisted of 60 cases of local anaesthesia performed on 30 volunteers (11 males and 19 females); each volunteer received two injections on two different sides of the mouth. Participants were aged between 20 and 30 years The mean age of the sample members was (23.1 ± 1.8 for females and

24.6 ± 2.2 for males) in both groups, from the dental clinic patients of the Faculty of Dentistry at Al-Andalus University for Medical Sciences.

The sample size was determined based on the results of a pilot study involving 9 patients (4 males and 5 females) aged 23 to 30 years. An electric pulpometer was used to measure the onset time of anesthesia (in seconds) and to estimate the initial mean and standard deviation. The mean onset time of anesthesia for the smart injector group and the control group was 45.4 and 69.11 seconds, respectively, with standard deviations of 14.10 and 14.94 seconds, respectively. These data were entered into G*Power software (*version 3.1.9.7 Heinrich Heine University Düsseldorf, Germany*) for a preliminary statistical power analysis using the independent samples t-test to obtain a larger and more accurate sample size,. With a significance level of $\alpha = 0.05$ (95% confidence level), a power of 80% ($\beta = 0.80$), and an effect size ($d = 1.65$) calculated from the experimental data, the minimum required sample size was set at 14 patients (7 patients per group). To account for data loss or patient withdrawal, the final sample size was increased to 30 patients (15 patients per group).

Patient Selection Criteria

The inclusion criteria were vital untreated teeth ,dental integrity was verified using periapical photographs to detect any deep caries, fillings, or periapical lesions that might affect pulpometer readings, systemically healthy male and female participants (female participants not in the menstrual cycle phase), absence of allergy to local anaesthetics, no use of medications that could alter pain perception, age between 20 and 30 years, no previous experience with smart injection, and absence of smoking or alcohol consumption.

The exclusion criteria included participants with systemic diseases, allergy to local anaesthetics, bleeding disorders, dental anxiety, needle phobia, or infection at the injection site.

Random Assignment and Allocation of the Sample

In this split-mouth design, all participants received both interventions. Randomization determined which side received the smart injector and which side received the conventional injector. To reduce selection bias, patients were blinded by covering their eyes until the injection procedure was completed. Furthermore, blinding was applied to the assessor responsible for reading and recording the results.

Injection Procedures

Participants were trained to assess anaesthesia before the experiment. Vital signs were recorded before administration of the anaesthetic. Baseline pulp sensitivity thresholds were recorded for the lower first premolar using a pulp tester, which was positioned midway between the gingival margin and the occlusal edge of the tooth.

Pulp vitality was tested in the lower first premolars 10 minutes before administering anaesthesia, with two consecutive readings taken to determine individual threshold values. These baseline thresholds were used to determine when to begin measuring the study variables.

After the anaesthetic injection, the equipment was checked, and participants were monitored to ensure appropriate responses. The response was evaluated by a second clinician. Pulp vitality in the lower first premolars was assessed during the first minute and then every 60 seconds until anaesthesia was confirmed, thereby determining the onset of pulpal anaesthesia. After confirmation of anaesthesia, assessments were performed every 3 minutes until tooth sensitivity returned [9]. The tooth was tested until no response (pulsation, tingling, or pain) was observed.

During the experiment, participants received 1.8 ml of 2% plain lidocaine for the intraoral mental nerve block on both sides (smart injector and control injector), Without using a topical anesthetic gel to avoid affecting the results of the anesthesia and the sensation of pain. A conventional carpule syringe with aspiration capability and a short 30G needle was used on the control side, While the wireless smart electronic injection device with LCD screen (*anesthesia pen X, China*)was used on the experimental side. All injections were performed by a single investigator.

Clinical assessment

Three variables were evaluated:

- Onset time of action: defined as the period between the end of the injection and the first reading showing no response.
- Duration of anaesthesia: the time from administration of the local anaesthetic until the patient regained a response to the pulp vitality test.
- Visual Analogue Scale (VAS): pain perception during injection was assessed using a 100 mm VAS, where the left end (lower values) represents “no pain,” and the right end (higher values) represents the “most severe pain”. Patients were recalled after one week for a second appointment to evaluate the injection sites [10].

Statistical analysis

The collected data were analysed using SPSS (version 20.0, Chicago, Illinois, USA). "The Shapiro-Wilk test was used to assess the distribution of the data, which showed an abnormal distribution. Accordingly, the Wilcoxon signed-rank test was applied to compare pain levels, duration of anesthesia, and onset time of effect between the two groups. The probability value $P < 0.05$ was considered statistically significant. Figures were generated using the Python programming language.

Results

The mean time to achieve anesthesia was shorter in the smart injection group (143 ± 10.47 seconds) compared to the traditional injection group (148 ± 10.73 seconds) (Table 1). Although the smart injection system accelerated the onset of anesthesia by a mean difference of 5.20 seconds, this small margin is practically insignificant, the average duration of the anesthetic effect in the electronic injector group was (108.43 ± 18.93 minutes) compared to (112.17 ± 13.62 minutes) in the traditional injector group; although the duration of the effect was shorter on average by 224 seconds (3.74 minutes) with the electronic injector, this difference was not statistically significant (Table 2). The smart injection group was characterized by achieving lower and more stable pain levels on average (4.93% ± 3.71%, with a range of 1% to 15%). In contrast, the traditional injection group showed higher pain rates on average (12.87% ± 13.78%), accompanied by wide dispersion in results, with values ranging between 1% and 70% (Table 3).

The Wilcoxon signed-rank test revealed a statistically significant difference in the time to onset of anesthesia between the two groups ($W = 48.0$, $p = 0.002$; Table 4). This clinical assessment is entirely consistent with the absence of statistically significant differences in the total duration of anesthesia ($p = 0.381$; Table 4). In contrast, the intelligent system achieved a significant clinical advantage in reducing pain perception by 61.7%, with a mean paired difference of -7.93% ($p < 0.001$; Table 4).

Table 1
Sample size (N), average, standard deviation, standard error, minimum, and maximum values concerning the onset time (in seconds) for each of the study groups.

Injector type	N	Mean	Std. Dev.	Std. Err.	Min	Max
Smart	30	143	10.47	1.91	120	165
Traditional	30	148	10.73	1.96	120	168

Table 2
Sample size (N), average, standard deviation, standard error, minimum, and maximum values concerning duration of action (in minutes) for each of the study groups.

Injector type	N	Mean	Std. Dev.	Std. Err.	Min	Max
Smart	30	108.43	18.93	3.46	68	153
Traditional	30	112.17	13.62	2.49	80	140

Table 3
Sample size (N), average, standard deviation, standard error, minimum, and maximum values concerning the pain perception (as a percentage) for each of the study groups.

Injector type	N	Mean	Std. Dev.	Std. Err.	Min	Max
Smart	30	4.93	3.71	0.68	1	15
Traditional	30	12.87	13.78	2.52	1	70

Table 4
Results of the Wilcoxon signed-rank tests comparing the electronic and traditional injector methods

Interpretation	p-value	Wilcoxon Statistic (W)	Variable
Significant***	< 0.001	16.5	Pain perception during injection (%)
Not significant	0.381	190.0	Duration of action (min)
Significant*	0.002	48.0	Onset time (sec)

The electronic injector group demonstrated a 61.7% lower mean pain score compared with the traditional injector group (4.93 vs. 12.87). Error bars represent the standard error of the mean. The difference between groups was statistically significant according to the Wilcoxon signed-rank test ($W = 16.5$, $p < 0.001$). Triple asterisks (***) indicate $p < 0.001$.

Discussion

Numerous devices have been advertised for alleviating discomfort during local anaesthesia. Nonetheless, this research focused on examining the benefits of the smart dental injector compared with the traditional injector concerning the speed of onset, duration of effectiveness, and perception of pain. To assess the onset time, the duration of pulpal anaesthesia could be measured using electric pulp testing [11], and the perception of pain using the visual analogue scale [10]. Electric pulp testing is a recognised technique for assessing the onset and duration of pulpal anaesthesia in a standardised manner [9].

The results of the current study showed a statistically significant advantage for the Smart Dental Injection (SDI) system in the speed of anesthesia onset compared to traditional manual injection (143 ± 10.47 seconds vs. 148 ± 10.73 seconds, respectively; $p = 0.002$). Despite this statistical advantage, the actual time difference was extremely small (only 5 seconds), a margin that may not have significant clinical (practical) importance in a dental practice, especially since the overall comparison between the two groups did not show any substantial differences in the duration of anesthesia ($p > 0.05$). However, the smart system achieved a significant and statistically significant 61.7% reduction in pain levels compared to traditional injection ($P < 0.01$). Taken together, these data indicate that the competitive advantage of smart injection lies not in accelerating or prolonging the anesthetic's effect, but in providing a more comfortable and less painful treatment experience for the patient thanks to the calculated and stable flow of the anesthetic.

Lidocaine is available as a 2% injectable solution with or without epinephrine. The onset of action is between 1 and 2 minutes, and the duration of action ranges from 30 to 60 minutes without epinephrine and from 60 to 240 minutes with epinephrine [12]. Our study revealed that the onset time for 2% lidocaine without a vasoconstrictor was 2 minutes in both groups (Table 1). This result is in accordance with the studies conducted by Dugal *et al.* and Rebolledo *et al.*, in which the onset of action of lidocaine

was reported as 1.15 and 1.25 minutes, respectively [13, 14]. Furthermore, De Oliveira *et al.* found that the onset time of lidocaine was 2 minutes [15]. On the other hand, Tortamano *et al.* reported an onset time of 8.7 minutes for 2% lidocaine [9]. This difference may be due to the study method and injection site, as their comparison was made between two groups using a 4% articaine solution with epinephrine for the inferior alveolar nerve. Moreover, Theddeus *et al.* found that the onset time of lidocaine was 5 minutes [16], possibly because they used a low concentration of lidocaine solution (0.2%) in their study.

In our study, the mean duration of anaesthesia for the Smartject injection was 108.43 ± 18.93 minutes, whereas for the traditional injection it was 112.17 ± 13.62 minutes (Table 2). Therefore, our findings are consistent with those of Theddeus *et al.*, who reported that the duration of action of 2% plain lidocaine was 99.67 minutes [16]. Meanwhile, Moore *et al.* reported that the mean duration of pulpal anaesthesia was 61.8 ± 59 minutes and 51.2 ± 55.9 minutes [17]. In addition, Thomson and Lalonde reported that the duration of action of 2% lidocaine was 4.9 hours [18]. These differences may be due to variations in methodology, injection site, and the fact that some studies relied on patients' natural sensation to assess the duration of action. Oliveira *et al.* reported that the duration of action of 2% lidocaine mixed with epinephrine (1:100,000) ranged from 159 to 273 minutes [19]. They determined the return of normal sensation by applying a pain stimulus at the end of the anaesthetic effect. Moreover, Vinycomb and Sahhar found that the duration of anaesthesia of lidocaine mixed with epinephrine was approximately 2 hours [20]. Unfortunately, they did not specify the concentrations of lidocaine or epinephrine used in the solution, which makes comparison difficult.

On the other hand, the smart injector competitive advantage and significant clinical superiority were demonstrated by its 61.7% reduction in pain perception (Fig. 1). Our study showed a statistically significant decrease in pain levels ($p < 0.001$; Table 4), with the mean pain score decreasing from 12.87 ± 13.78 (range: 1–70) in the traditional group to 4.93 ± 3.71 (range: 1–15) in the smart group (Table 3). This positive result is consistent with the findings of Libonati *et al*, Yogesh Kumar *et al*, and Gill *et al*, all of whom confirmed that the smart injector significantly reduces pain compared to traditional injection] 21,22,23[. This strong correlation is attributed to the electronic control of the anesthetic fluid's flow and pressure. On the other hand, the study conducted by Ghaderi and Ahmadbeigi used an injection method that was most similar to ours, though not a direct comparison] 8[. Furthermore, Yeneisey *et al*. concluded that injections using computer-controlled devices are significantly less painful than injections using the traditional manual syringe technique [24].

In contrast, Ram *et al* and Asarch *et al* reported that there is no difference in pain perception during injection with a conventional syringe in comparison to Computer-Controlled Local Anesthetic Delivery (CCLAD) devices. The smart injector provides precise control of anesthetic solution flow rate, pressure, and duration of injection time; these factors are difficult to achieve by manual injection [25, 26], so it could be expected that, as pain levels were lower in the smart injector group, it may represent a viable alternative to the traditional injection method. Nevertheless, further studies are required to evaluate the impact of age groups, gender, and physiological factors on pain perception, which were not addressed in our study.

Conclusion

From our assessment of both the onset and duration of anaesthesia, it can be concluded that our findings are consistent with the broader literature. The novelty of our study centres on the evaluation of pain perception when comparing the smart and traditional injector groups. Given the meaningful reduction in pain observed in the smart injector cohort, as well as its versatile features and capabilities, the smart injector can be considered a promising device for dental anaesthetic injections.

Declarations

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Authors' contributions: Ali Rokia performed methodology, data statistics, and conceptualization, and wrote the original draft. Mouetaz Kheirallah performed project administration, supervision, validation, visualization, tables and figures, interpretation of statistical data, and review of it.

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Data Availability: The data used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics approval: The study was approved by the Research and Ethics Committee of Al-Andalus University for Medical Sciences (approval number 15/18 Date/15.8.2025).

Informed consent was obtained from all individuals participating in the study.

Competing Interests The authors declare no competing interests.

Consent for publication not applicable

Informed consent

was obtained from all individuals participating in the study.

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Figures

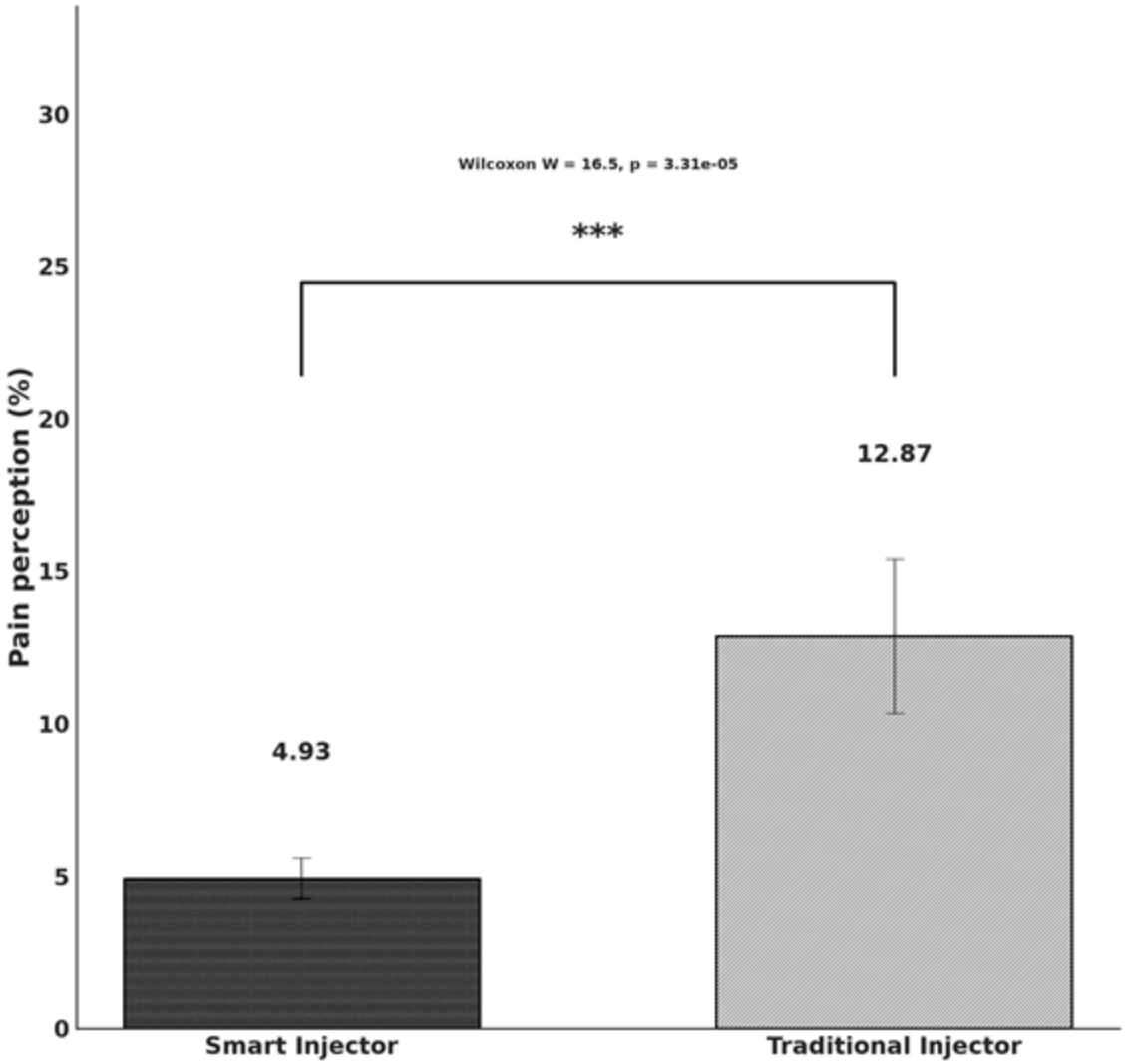


Figure 1

Bar chart showing the mean pain perception scores (VAS) for the electronic (smart) and traditional injector groups.