Metallic syringe versus electronically assisted injection system: a comparative clinical study in children

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Abstract

Aim Local anaesthesia injection necessary for pain control in paediatric dentistry may itself be painful sometimes, partly because of the pressure felt during injection; electronically assisted injection systems were developed to address this problem.

Materials and methods Study design: The present study is a clinical study in children that compared two types of devices for paediatric buccal infiltration anaesthesia: the aspirating syringe and an electronically assisted injection system, the Wand STA. A split mouth, randomised controlled clinical trial was conducted on 30 healthy six to eight-year-old patients (6.64 ± 0.803 years) requiring pulpotomies on two symmetrical primary maxillary molars. Each patient received the following types of anaesthesia, in separate, consecutive, randomly ordered sessions: conventional buccal infiltration by metallic aspirating syringe and buccal infiltration by computer-controlled local anaesthetic device (Single Tooth Anesthesia). Parameters assessed were: pain experienced during injection, patient's heart rate and behaviour, anaesthesia quantity required and onset time.

Results No statistical differences were observed between the two techniques ($p \leq 0.05$) for all assessed parameters.

Conclusions Results suggest that computer-assisted anaesthesia may represent an alternative to conventional syringes for local buccal anaesthesia in paediatric dental treatment; comparison to other types of dental infiltration anaesthesia needs further investigation.

KEYWORDS Local injection; Children; Computerised anaesthesia, STA.

Introduction

When working with young children, controlling pain with effective local anaesthesia is an essential step towards obtaining and maintaining patient cooperation. Clinical studies have proven that children can experience pain sensation at an early age and, most importantly, they can memorise the feeling [Kennedy et al., 2008]. Therefore, a negative experience at the dentist's can determine the child's apprehension for future dental treatment.

Dental fear is common amongst young children, ranging between 6% to 42% [Soares et al., 2017]. This emotional distress can alter the patient's will to cooperate and affect the treatment. To relieve this negative feeling, many techniques have been proposed, both pharmacological and non-pharmacological [Cinaetti et al., 2017].

Distracting the child can alter the pain perception by diverting his/her attention from unwanted procedures. Many distraction techniques such as the use of toys, games, audio and audio-visual distraction were described in the literature and proved to be effective in reducing anxiety and fear. Micro invasive procedures like Atraumatic Restorative Techniques, chemical elimination of caries and air abrasion have also been proposed as an alternative, less painful approach to conventional drilling and filling [Cianetti et al., 2017]. Recently, Cianetti et al. [2018] suggested a novel approach to remove caries using ultrasonic tips instead of the rotational burs, that proved to significantly reduce dental anxiety.

Dental injection is a major trigger in young children for negative behaviour. The pediatric dentist is required to give the young patient as painless an injection as possible, leading to a positive experience that will encourage the child to visit the dental office again.

William Halstead was the first to obtain effective dental anaesthesia in a patient in 1853 by introducing the metallic syringe for cocaine injection in the inferior alveolar nerve [Malamed, 1997]. Other anaesthetic molecules were later discovered, resulting in a less toxic, longer lasting and effective anaesthesia. However, the metallic syringe used in those early times has only slightly evolved into the ones used nowadays.

Computer controlled local anaesthetic devices introduced

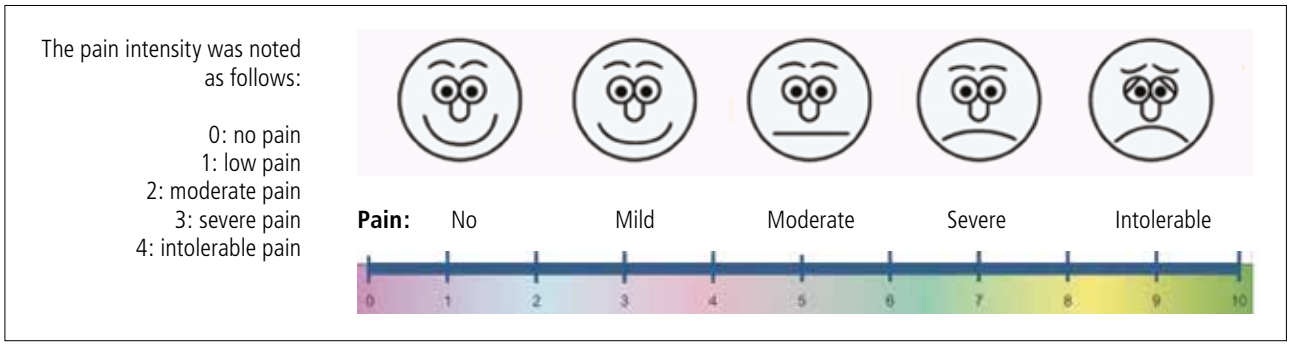

FIG. 1 Visual Analogue Scale (Wong and Baker, 1988).

in the mid-1990s can deliver the anaesthetic solution at a constant rate and pressure, using the Dynamic Pressure Sensing (DPS) technology, and promise an easy, effective and painless injection according to their manufacturers.

The aim of the present article is to report the results of a study comparing two types of anaesthetic devices for buccal infiltration anaesthesia: the traditional syringe and a computer-assisted anaesthesia delivery system (The Wand, Single Tooth Anesthesia - STA, Milestone Scientific Inc., Livingston, NJ, USA).

Materials and methods

Thirty healthy six to eight-year-old children (6.64 ± 0.803 years) with no history of previous dental injection were randomly selected from those registered for treatment at a dental school clinic (University of Saint- Joseph Beirut, Lebanon). Patients included in the study had two symmetrical primary maxillary molars at stage II of dental development, stability stage for primary teeth [McDonald, 2008] with no signs of infection, abscess, or radiolucency and requiring pulpotomy treatment. Such treatment comprises the amputation of the coronal pulp followed by hemostasis and formocresol application on the amputated pulp stumps using a cotton pellet placed for five minutes in the pulp chamber, which is then filled with a zinc oxide eugenol base material, after which the tooth is restored with a paediatric preformed crown.

The study was approved by the university's ethics committee (USJ-2014-31) and informed parental consent was obtained for all children prior to their inclusion in the study.

Materials

For both injections, 1.8 ml cartridges containing 2% mepivacaine local anaesthetic solution with 1/100 000 adrenalin (Scandicaine 2% Special, Septodont, France) were used. For the metallic syringe, 30 gauge needles (0.3 mm x 12 mm) (Monoeject USA) were chosen; the STA system includes specially designed sterile disposable handpieces, with their own 30 gauge needles (0.3 mm x 12 mm).

Methods

Each participating child received two types of buccal injections in two separate, consecutive visits, using a metallic syringe in one session, and using the STA device in the other. The technique used in the first session was randomly chosen. The following was said to the child: "I will now use a magic pen that will put your tooth to sleep". The same operator performed all injections.

Rating	Behavior	
0	Definitely negative	Refusing to play game, crying forcefully or fearfully, or any other overt evidence of extreme negativity
1	Negative	Reluctance to playing, uncooperative behaviour, and some evidence of negative attitude that is not pronounced
2	Positive	Acceptance of playing, willingness to comply with the dentist, cooperative behaviour
3	Definitely positive	Good relation with the dentist, interested in the environment, laughing and enjoying the situation

TABLE 1 Fankl behavioural scale (Frankl, 1962).

Injection rate

With the manual syringe, the injection was completed in approximately 120 seconds, at the rate of 0.01ml/sec. With the STA system, the injection started with the ControFlo rate (0.005 ml/sec), and when the machine emitted the "cruise" sound, indicating that the needle was positioned correctly and that it could be advanced in the tissue, the rate was switched to the RapidFlo mode (0.03 ml/sec). The entire injection was completed in approximately 100 seconds.

Evaluation criteria

Self-reported pain by the child: the Wong Baker Visual Analogue scale [Wong Baker, 2001) was presented to the child before initiating treatment and at the end of treatment, for pointing to the face depicting his/her status (Fig. 1).

Child's behaviour

An outside examiner assessed the child's behaviour at the beginning of the session, during the injection and treatment phases according to the Frankl scale adopted by the American Academy of Pediatric Dentistry in 1990 (Table 1).

Patient's heart rate

Using a pulse oximeter and a stopwatch, patient's heart rate was recorded three times: at rest, during the injection, and during the pulpotomy procedure, for 10 seconds each time.

Anaesthesia quantity

The number of cartridges required to obtain sufficient anaesthetic effect was noted.

Teeth	Anesthesia with metallic syringe	Anesthesia with STA system
Upper right first molar	8 (26.7%)	12 (40.0%)
Upper right second molar	4 (13.3%)	6 (20.0%)
Upper left first molar	12 (40.0%)	8 (26.7%)
Upper left second molar	6 (20.0%)	4 (13.3%)

TABLE 2 Tooth and type of anaesthesia.

Visual Analogue Scale (VAS)	N	Mean value	Standard deviation	p
Metallic syringe	30	1.33	0.711	0.763 Wilcoxon's test
STA	30	1.37	0.669	

Scores for the VAS	No pain	Minor pain	Moderate pain	Total
Metallic syringe	24 (80.0%)	2 (6.7%)	4 (13.3%)	30 (100.0%)
STA	22 (73.3%)	5 (16.7%)	3 (10.0%)	30 (100.0%)
Total	46 (76.7%)	7 (11.7%)	7 (11.7%)	60 (100.0%)

TABLE 3 The pain scores between the two techniques using the Visual Analogue Scale (VAS).

Duration of the anaesthetic effect

The operator registered the exact time of injection initiation and parents were asked to inform the operator how long afterwards the anaesthetic effect subsided by asking the child. This measurement was done in minutes.

Statistical analysis

Statistical analysis was performed using the Statistical Package Software for Social Science [SPSS for Windows, Version 18.0, Chicago, IL, USA). Parametric tests were used when the variables followed a normal distribution whereas nonparametric tests were used when the variables did not follow a normal distribution.

Results

Population description

Thirty patients aged 6 to 8 years with a mean of 6.64 ± 0.803 years were included in this study, 18 boys (mean age 6.46 ± 0.698 years) and 12 girls (mean age 6.92 ± 0.900 years) (Table 2).

Comparison between the two techniques for the average heart rate

Heart rate was measured for 10 seconds at rest, then during the injection, and during the pulpotomy. The average heart rate measurements for 10s were statistically not significantly different between anaesthesia with the metallic syringe and that with the STA at rest (p=0.742), during injection (p=0.700) and during pulpotomy (p=0.739).

Comparison of pain scores of the two techniques

The Visual Analogue Scale (VAS) results were coded as: 1) no pain, 2) mild pain and 3) moderate pain, and results indicated that:

- 80% of the subjects felt no pain with the syringe, while 73.3% had no pain with the STA;
- 6.7% of the subjects had mild pain with the syringe versus 16.7% with the STA;
- 13.3% of the subjects experienced moderate pain with the syringe and 10.0% with the STA.

For the VAS, there was no statistically significant difference between the two techniques (p=0.763) (Table 3).

Comparison of the Frankl scale scores between the two techniques

The mean value and standard deviation for each technique were calculated using the Wilcoxon test. For the metallic syringe, the mean score was 2.70 and the standard deviation was 0.535. For the STA, the mean score was 2.63 and the standard deviation was 0.615.

The number and percentage of children who exhibited scores from 1 to 3 were also noted and results showed that:

- 3.3% of the participants exhibited a score 1 on the Frankl scale for the syringe, and 6.7% for the STA;
- 23.3% of the participants exhibited a score 2 on the Frankl scale for the syringe, and 23.3% for the STA;
- 73.3% of the participants exhibited a score 3 on the Frankl scale with the syringe, and 70.0% with the STA.

For the Frankl behavioural scale, there was no statistically significant difference between the two techniques (p=0.564) (Table 4).

Comparison of anaesthesia quantity between the two techniques:

Mean score and standard deviation for the anaesthesia quantity for both groups were calculated using the Wilcoxon test. For the syringe group, the average score was 1.03 cartridges and the standard deviation was 0.183. For the STA group, the average score was 1.00 cartridge and the standard deviation was 0.000. For the average quantity of anaesthesia, there was no statistically significant difference between the two techniques (p=0.317).

Comparison of the duration of the anaesthetic effect (in minutes) for both techniques

The mean value and standard deviation for both groups were assessed using the Wilcoxon test. For the syringe group, the anaesthetic effect lasted 102.7 minutes with a standard deviation of 18.084, and for the STA group, it lasted 100.00 minutes with a standard deviation of 23.489. The difference

Frankl's behavioral scale	N	Mean value	Standard deviation	p
Metallic syringe	30	2.70	0.535	0.564 Wilcoxon's test
STA	30	2.63	0.615	

Scores for Frankl's behavioral scale	1	2	3	Total
Metallic syringe	1 (3.3%)	7 (23.3%)	22 (73.3%)	30 (100.0%)
STA	2 (6.7%)	7 (23.3%)	21 (70.0%)	30 (100.0%)
Total	3 (5.0%)	14 (23.3%)	43 (71.7%)	60 (100.0%)

TABLE 4 Comparison of the Frankl scale scores between the two techniques.

between the two techniques was not statistically significant (p=0.733).

Discussion

The present study was a split mouth, randomised clinical trial conducted on 30 patients aged between 6 and 8 years (mean age 6.64 ± 0.803 years). Each patient served as his or her own control in accordance with studies by Ram and Peretz [2003], Palm et al. [2004], Langthasa et al. [2012], and Bani et al. [2017]. For all the parameters assessed, results showed no statistically significant differences between using a metallic syringe or the STA system for a buccal periapical injection in the maxillary molar area.

This study focused on performing buccal, periapical anaesthesia injections with the STA system. The primary reason for choosing a periapical injection was that in young children, it is one of the most common infiltrations performed, sometimes associated with pain and not well tolerated. Therefore, a verification of whether a periapical buccal injection using the STA system is less painful than the traditional syringe was sought.

Comparison of the results

The results found in the present study were in accordance with those of Gibson et al. [2000], Koyutürk et al. [2009] and Langatha et al. [2012] who found no significant difference in patient's feelings, comfort and satisfaction between the administration of conventional and computer-assisted injections. Also, in a recent randomised controlled study on one hundred children aged 8–12 years, Mittal et al. [2015] found that pain perception was significantly higher during traditional palatal infiltration injection as compared to computerised palatal infiltration, while there was no difference in pain perception during buccal infiltration with both techniques.

On the other hand, several studies on the subject suggested that the use of an electronic device could reduce the pain felt during an injection. Jalevik and Klingberg [2014] in their study of 28 subjects reported significantly lower pain at the time of needle insertion and delivery of local anaesthetic using a computer-controlled device (the STA) over traditional syringes. Also, a split mouth study by Tahmassebi et al. [2009] of 30 four to nine-year-old children, presenting bilateral primary molars with similar lesions, compared injections using a traditional syringe and a computer-controlled device and concluded that electronic-assisted anaesthesia can reduce to some extent the pain caused by the injection. In a recent study, Giannetti et al. [2018] found that the efficacy of computer-assisted anaesthesia was 100% when treating primary teeth and 94% of patients gave a positive evaluation after having tried the device with STA technique.

The authors of these studies explain their results by the following arguments: injection can be painful if the needle is inserted too quickly or with great pressure; injection pressures are also very variable due to the large variation of soft tissues' elasticity. With a conventional manual syringe, the volume flow and pressure parameters cannot be accurately controlled, resulting in difficult and irregular injections. During the first symposium on electronically assisted anaesthesia devices [2008], participants agreed on the fact that the computer-controlled local anaesthesia delivery method provides a virtually painless, predictable injection, has the potential to desensitise patients towards their fears of injection, and therefore can reduce anxiety.

Results about pain perception using computer-controlled local anaesthesia delivery systems are not conclusive. Children should be taught how to overcome strong emotions and to calm down, including the dental situation and specially during local anaesthetic injections. Professional communication boosts skills to manage pain perception and child behaviour [Goetterms et al. 2019]. Nevertheless, all authors agree on the necessity to conduct more clinical studies using various types of computer-controlled injection devices, hoping to find a novel method to control pain during local injection in young children.

Comparison of the selected criteria

The present study evaluated and analysed several measurements, including patients' heart rate. Monitoring this physiological parameter is in accordance with studies by Thoppe-Dhamodhara et al. [2015], and Bensal et al. [2014]. Results of the present study indicate that all patients demonstrated a higher heart rate at rest in the second session no matter the injection technique received first. In fact, an elevation in the heart rate is the first mechanism of cardio-vascular response to stress in young children [Angelovski et al., 2016].

Other criteria can be used to assess the pain associated with an oral injection in children. Versloot et al. [2008] chose to videotape the injections given to 147 children aged between 4 and 11 years and to evaluate their behaviour on software; results indicated no statistical difference between an injection with a computer-assisted device and the traditional technique for the self-reported pain and distress reaction. In another study by Quieroz et al. [2015], the level of cortisol in saliva after an injection was examined in 20 children, with no statistically significant difference found between conventional and computerised anaesthesia (p=0.34). In the present study, parental cooperation for testing salivary enzymes was difficult to obtain due to the perception that it was unnecessary to the dental treatment of the child. It would certainly be interesting to conduct such a study because salivary enzymes are released faster than any other body fluid and do not require invasive or cumbersome procedures such as the collection of blood or urine tests.

The opinions are divided around the STA device. An ergonomic evolution (the machine is somewhat cumbersome), a decreased financial burden (the device is costly and needles are expensive) and a faster and less complex method of administering intraligamentary anaesthesia might convince reluctant practitioners to adopt this mode of anaesthesia.

It must be noted that other similarly operating devices have been marketed. Among them, the "Accupal" (Hot Springs, AR, USA) offers the possibility to generate vibration and controls the injection pressure. Also, the "Med-jet" (Medical International Technologies, Montreal, QC, Canada) relies on a compressed air system to administer anaesthesia. The device is placed firmly against the mucosa and the solution is delivered by painless pressure. It would be interesting in future studies to compare these devices with the STA and among them, to find which, if any, can provide the patient with the best possible anaesthesia experience.

Conclusions

The present study assessed the following parameters: pain

experienced during injection, patient's heart rate and behaviour, anaesthesia necessary quantity and onset time. There was no statistical difference for all the parameters examined between a periapical buccal dental injection at the maxillary primary molar area using a traditional metallic syringe and an electronically assisted injection system.

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Conflict of interest

All authors declare no conflict of interest

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Ethical approval

The ethical committee of the Saint Joseph University (USJ-2014-31) approved the study.

Compliance with ethical standards.

Informed consent

Formal consent was obtained prior to the study by all participants.

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