Available online at www.sciencedirect.com
ScienceDirect
British Journal of Oral and Maxillofacial Surgery xxx (2017) xxx–xxx
BRITISH Journal of Oral and Maxillofacial Surgery
www.bjoms.com

Dental anaesthesia for children – effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial☆

R. Patini, E. Staderini*, M. Cantiani, A. Camodeca, F. Guglielmi, P. Gallenzi

A. Gemelli Teaching Hospital Foundation IRCCS, Rome, Catholic University of Sacred Heart, Institute of Dentistry and Maxillofacial Surgery. Largo Agostino Gemelli, 1, 00135 Rome, Italy

Accepted 8 August 2018

Abstract

Local anaesthesia in dentistry is usually given by conventional injection through a syringe. In this randomised, single-blind, split-mouth clinical study we evaluated the perception of pain and changes in heart rate in children being given dental local anaesthesia using a computer-controlled device compared with that given using a traditional syringe. Participants were in good general health with no contraindications to local anaesthetics. One half of each maxilla was anaesthetised using each technique, the order having been randomly selected according to a computer-generated sequence. The hypothesis was that the controlled anaesthetic flow rate results in virtually imperceptible injections. The outcomes were the perception of pain and the heart rate. Seventy-six children aged from 5–12 years old participated in this study. The mean (SD) pain score of the conventional injection was 5.51 (2.46) and the mean (SD) heart rate was 2.72 (6.76), which were significantly higher than those of the computerised delivery system, which were 4.74 (2.8) and 0.34 (7.3) ($p = 0.04$). More patients anaesthetised with the traditional syringe technique required a second injection ($n = 21$). These results suggest that dental anaesthesia given to children with a computer-controlled delivery system reduced pain better than that given with a conventional syringe.

Keywords: Child; Heart Rate; Dental Anesthesia; Anesthesiology; Pain; Tooth Extraction

Introduction

The number of children who attend the dentist prophylactically has decreased as a consequence of parental carelessness, poor economic conditions, or both, and children now attend the dentist with conditions such as pulpitis or a dental abscess, which make the sessions more stressful. Local anaesthesia and control of pain and stress are among the most challenging elements for such children, as fear of injections is common.[1–4] Pain arises from the mechanical trauma of insertion of a needle into the site of an injection as the tissues suddenly distend,[5–7] but local infiltration by conventional syringe injection is still the most common way of giving a dental anaesthetic.

A precision-metered dental injection system called Wand® (Milestone Scientific) has now become available (Fig. 1), which is a computer-controlled local anaesthetic delivery system that provides a precise flow-rate of injection regardless of the resistance of the tissues. The flow of anaesthetic is

☆ Protocol registration number: NCT03348800 (ClinicalTrials.gov).

* Corresponding author at: A. Gemelli Teaching Hospital Foundation IRCCS, Rome, Catholic University of Sacred Heart, Institute of Dentistry and Maxillofacial Surgery. Largo Agostino Gemelli, 1, 00135 Rome, Italy. Tel.: +39 3334154329.

E-mail addresses: romeo.patini@unicatt.it (R. Patini), edoardo.staderini@unicatt.it (E. Staderini), monicacantiani@hotmail.it (M. Cantiani), andrecamo@tiscali.it (A. Camodeca), fe.guglielmi@gmail.com (F. Guglielmi), patrizia.gallenzi@unicatt.it (P. Gallenzi).

https://doi.org/10.1016/j.bjoms.2018.08.006
0266-4356/

Fig. 1. The computer-controlled local anaesthetic delivery system.

computer-controlled, and initiated by exerting pressure on a foot pedal.[5,7] Continuous positive pressure yields a constant anaesthetic drip that precedes the needle during its insertion. All techniques of local intraoral anaesthesia are possible with the Wand®, and while there is considerable evidence of the benefits of using computer-controlled delivery systems in adults, only moderate evidence exists regarding its use in children.[8–11]

Our hypothesis was that, as with adults, a controlled flow rate would result in a virtually pain-free injection, so the aim of this single-blind, split-mouth study was to compare the traditional syringe technique with the computer-controlled Wand® anaesthetic system to evaluate perception of pain (assessed with Numerical Visual Rating Scale (NVRS)),[12] and heart rate, in children who required at least two teeth to be extracted from opposite sides of the maxilla.

Patients and Methods

We designed a parallel, single-centre, single-blind, split mouth, active control study that was stratified according to age (5–12 years, with balanced randomisation) and was done in the Paediatric Dentistry Unit of the Catholic University of the Sacred Heart, Rome, Italy, from March 2016 – March 2017. The participants were in good general health and had no contraindications to local anaesthesia. Exclusion criteria were: any patients with a medical condition that could alter the perception of pain, or any patient who had taken an antibiotic or antinflammatory drug during the month immediately preceding the procedures.

The study was done in accordance with the declaration of Helsinki and it was approved by the local Ethics Committee. A detailed informed written consent form was signed by each patient's parent or guardian before every procedure. Patients were informed that both a computer-controlled, and traditional syringe, techniques would be used for their dental procedures. No patient had previously experienced the Wand® injection technique.

Measurements

The NVRS was shown to the patients and explained before the injections. It is a 10-point pain scale (in which 0 means no pain and 10 means the worst pain possible) based on the Visual Rating Scale and Numerical Rating Scale that were used for adults in a previous report.[12] It was easier for the children to understand and for this reason was preferred to other scales. Heart rate was assessed using a pulse oximeter before and after the injection.

Procedures

The sample size was calculated from a power analysis based on the results of previous studies[12,13] to detect at least a one grade difference on the NVRS with an SD of 0.85, and a difference in heart rate of at least 4 bpm with an SD of 3 bpm between groups. The α and β values were set as 0.05 and 0.90, respectively, and the sample size was calculated to be 30 subjects for each group. One half of the maxilla of each patient was anaesthetised with the Wand® system, and the other half by a conventional syringe, in two different sessions to avoid lasting effects. In both sessions patients were blindfolded with a sleeping mask so that they could not see which anaesthetic delivery system was being used. The anaesthetic was given by the same trained operator (RP), and the order in which the techniques were used had been randomly selected.

Simple randomisation was used taken from a random computer-generated sequence. The number generated indicated the technique that was to be used at the first session: odd numbers for the traditional technique and even numbers for the computer-controlled technique. Generation of the random numbers, enrolment of participants, and their assignment to the intervention was done by an author not involved in the clinical procedures (AC).

In both halves the intraligamentary technique, and the same amount of anaesthetic (one cartridge), were used. In both techniques pressure was applied using the handle of the dental mirror as distraction for palatal injections, before

Please cite this article in press as: Patini R, et al. Dental anaesthesia for children – effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial. *Br J Oral Maxillofac Surg* (2017), https://doi.org/10.1016/j.bjoms.2018.08.006

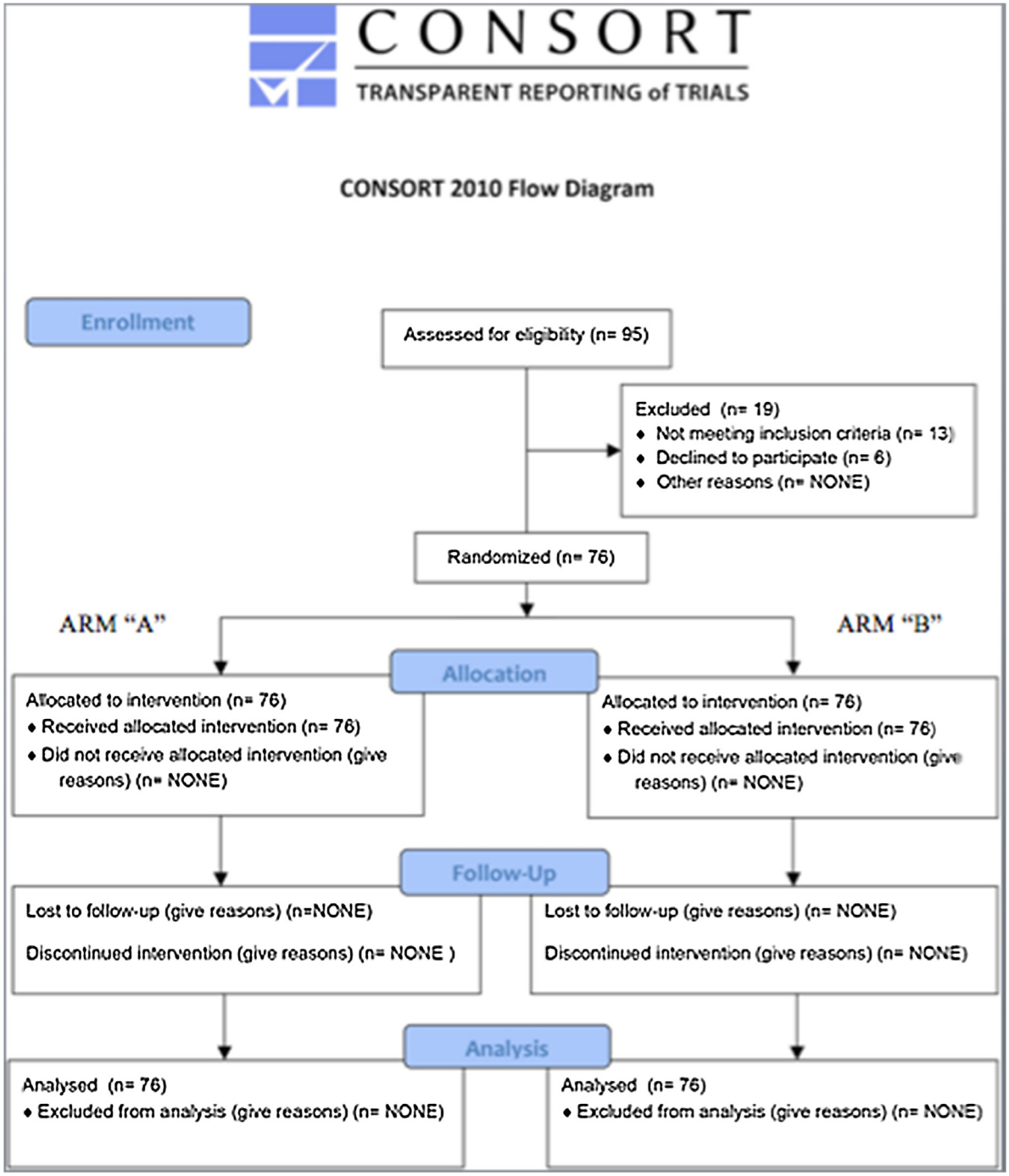

Fig. 2. Consort 2010 flow diagram. In the first arm (A) patients were given anaesthesia using the Wand® first, and in the second arm (B) they were given anaesthesia using the conventional technique first.

insertion of the needle. The needle was inserted parallel to the long axis of the tooth into the sulcus of each root and some drops of local anaesthetic were given before the needle entered the tissue. After a few seconds the needle was advanced to penetrate the tissue, and an additional amount of solution given. The Wand® was set on a pre-programmed injection mode named "STA" (speed mode 0,005 ml/second). The computer-controlled system produces audible beeps that were deactivated. Once anaesthesia had been achieved, the tooth was extracted. Immediately after the local anaesthetic, children were asked to remove their masks and rate the pain felt while the anaesthetic was being given. This was recorded by an author (FG), who was unaware of which type of anaesthesia had been used.

All patients were given 2% mepivacaine hydrochloride (Carboplyina 20 mg/ml with epinephrine 1:100.000,

Please cite this article in press as: Patini R, et al. Dental anaesthesia for children – effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial. *Br J Oral Maxillofac Surg* (2017), https://doi.org/10.1016/j.bjoms.2018.08.006

Table 1
Results (n = 76 in each group).

	Syringe Mean (SD)	Computer-controlled Mean (SD)	Difference (95% CI)	p value
Pain after injection (0–10)	5.51 (2.46)*	4.74 (2.8)*	0.77 (0.04 to 1.5)	0.04
Changes in heart rate after injection (bpm)	2.72 (6.76)*	0.34 (7.3)*	2.38 (0.15 to 4.61)	0.04

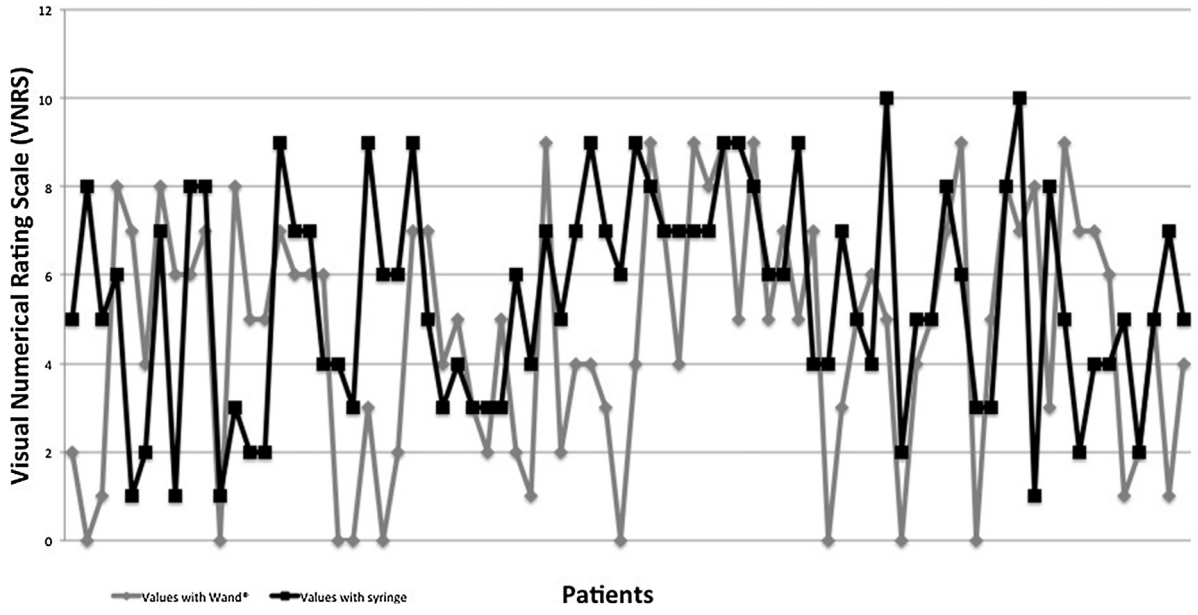

Fig. 3. Perception of pain with the Wand® and with a dental syringe.

Dentsply), ands a 1.8 ml anaesthetic cartridge was used for both types of anaesthetic. The local anaesthetic was injected with an extra-short 30 gauge dental needle for the Wand® (30 G handpiece and needle, Milestone Scientific), and with a traditional 30 gauge needle (Trend Ject 0.30 × 21 mm) for conventional anaesthesia.

The patient's age, sex, score on NVRS after injection, and variation in heart rate after injection were recorded on a structured form.

Statistical analysis

All analyses were made by an assessor (ES) who was unaware of the anaesthetic used, with the aid of the software program IBM SPSS Statistics for Windows (version 20.0, IBM Corp). Exploratory analysis showed that all variables were normally distributed with equality of variances. Perception of pain and changes in heart rate during injection were evaluated, and the paired *t* test was used to assess the significance of each difference. Probabilities of less than 0.05 were accepted as significant.

Results

Ninety-five children were enrolled from December 2015 to February 2016, and 19 were excluded; 13 did not match the inclusion criteria and in six cases parents did not give the consent. This left 76 children (38 boys and 38 girls), age range 5–12 years (mean (SD) 8 (2) years), who participated from March 2016 to March 2017. The two techniques are shown in Fig. 1, the design of the trial in Fig. 2, and numerical results in Table 1. Data about perception of pain are shown in Fig. 3, and variations and differences in sensation between the two techniques are shown in Figs. 4 and 5. Both perception of pain and heart rate were significantly better with the Wand® than with the traditional injection (p = 0.04 in each case). Twenty-one patients required a second injection after the traditional anaesthetic, whereas only five required one after injection with the Wand® system.

Discussion

We have shown that the Wand® system resulted in a significant reduction in the perception of pain compared with traditional injections (p = 0.04), during induction of local anaesthesia. These results are interesting as they provide useful information on the management of fear and anxiety associated with anaesthesia in children. The use of a computer-controlled local anaesthetic delivery system eliminates the emotional tension in the child that is usually associated with a dental syringe, so the many treatments that require local anaesthetic can be done more easily.

Please cite this article in press as: Patini R, et al. Dental anaesthesia for children – effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial. *Br J Oral Maxillofac Surg* (2017), https://doi.org/10.1016/j.bjoms.2018.08.006

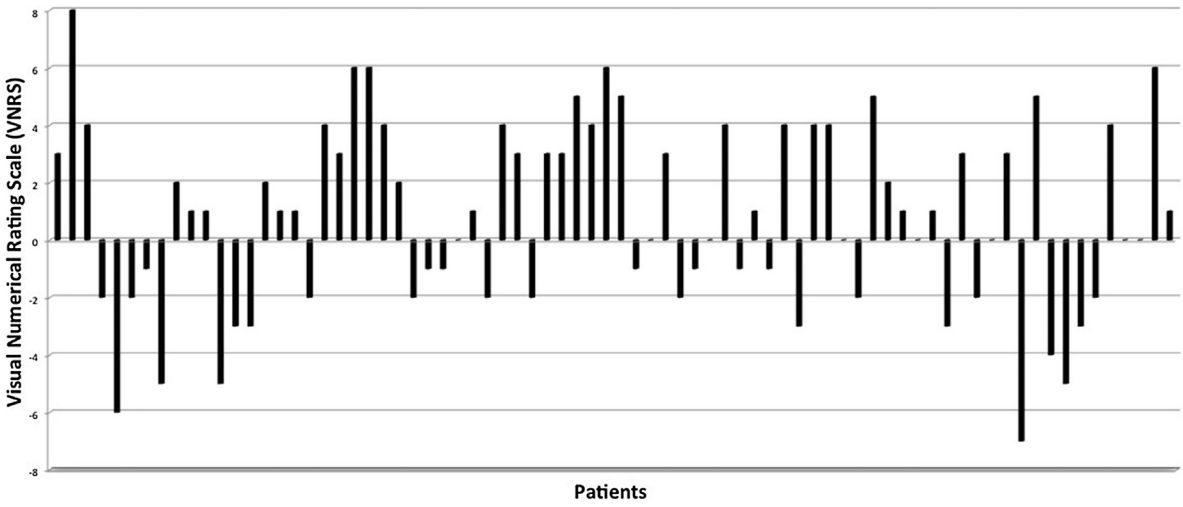

Fig. 4. Differences in the perception of pain between the Wand® and the traditional local anaesthetic technique.

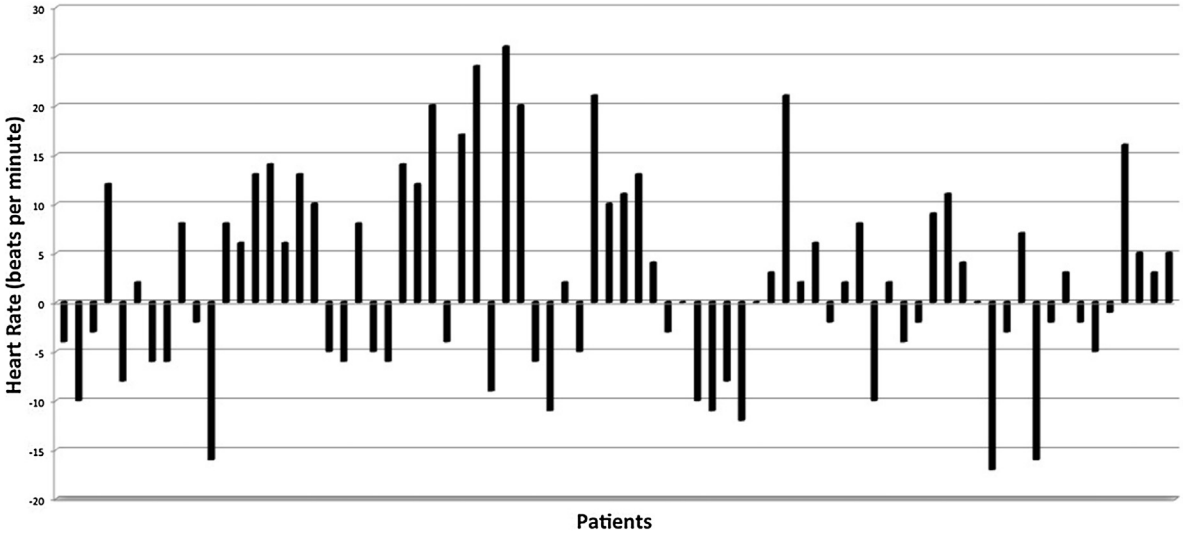

Fig. 5. Variation in heart rate between the Wand® and the traditional local anaesthetic technique.

The use of computer-controlled injection systems has been extensively investigated and compared with the conventional syringe injection technique. Most published trials, however, have been conducted in adults and reported contradictory results: either describing the potentially lower perception of pain using the Wand®;[14–18] or no differences between the two techniques, [19] or negative results.[4]

To the best of our knowledge there is only limited information about children. In particular, our good results confirm those of Langhtasa et al and of San Martin-Lopez et al who reported significantly less pain when the anaesthetic was injected with the Wand® compared with the traditional technique.[20–21]

Tahmassebi et al, on the other hand, found no significant differences in the perception of pain from anaesthetic injections between the traditional syringe and Wand® system.[22] Such results should be considered in light of the fact that children were randomly assigned to the test group (Wand® system) or to the control group (traditional technique), so they were unable to make a differential evaluation of the outcome. In addition, the mean age of the children that they studied was considerably lower than that in other reports, which suggests a possible reporting bias as a result of uncooperative behaviour.

As far as evaluation of heart rate was concerned, 40 of the 76 patients showed a greater increase after the traditional syringe injection technique than after the Wand®. The reduction in beats/minute was significant ($p = 0.04$). Some authors found similar results,[21] but there has been no general agreement, as shown by Langthasa et al.[20]

Even though it was not one of our outcomes, it is interesting that 21 of the patients anaesthetised with the traditional injection technique required a second injection while only five of the test group required one.

Please cite this article in press as: Patini R, et al. Dental anaesthesia for children – effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial. *Br J Oral Maxillofac Surg* (2017), https://doi.org/10.1016/j.bjoms.2018.08.006

The findings of the present study should be interpreted with caution because, even if the study was powered to detect a minimal difference of 1 and the sample size far exceeded the number required, the significant results indicate that the difference did not exceed this threshold.

Other limitations include the fact that although the pulse oximeter was left on throughout the procedure, and it was switched on a few minutes before the start of the anaesthetic, the preoperative recording of the heart rate was made when the child was already seated on the dental chair. This may have introduced a bias connected to the typical tension that precedes dental procedures. Secondly, the study group comprised children who were to have at least two teeth extracted from opposite sides of the maxilla, and this may have caused fear of the dentist. Such children may have a greater perception of pain as a consequence of their fear. Another confounding factor is the anxiety that often precedes dental extractions, and that can be transmitted to children even by their parents. For these reasons it is possible that in a group of children without fear or anxiety the differences between the two systems may not be so obvious.

Conclusions

In view of the many efforts made to ensure painless procedures in dentistry in children, the findings of this study should be considered by dentists who deal with children. The computer controlled anaesthetic delivery system did successfully reduce stress and pain, and could be a viable alternative to the conventional dental syringe, which is usually associated with uncooperative behaviour.

Protocol registration number: NCT03348800 (ClinicalTrials.gov ID).

The complete protocol can be accessed using the above protocol registration number at https://www.clinicaltrials.gov/ct2/search.

Conflict of interest

We have no conflicts of interest.

Ethics statement/confirmation of patient permission

Approved by the local Ethical Committee. Patient permission obtained.

References

1. Kleinknecht RA, Klepac RK, Alexander LD. Origins and characteristics of fear of dentistry. *J Am Dent Assoc* 1973;**86**:842–8.
2. Milgrom P, Weinstein P, Getz T. *Treating fearful dental patients. A patient management handbook*. 2nd ed. Seattle: University of Washington; 1995.
3. Kroeger R. *Managing the apprehensive dental patient*. Cincinnati: Heritage Communications; 1987.
4. Goodell GG, Gallagher FJ, Nicoll BK. Comparison of a controlled injection pressure system with a conventional technique. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2000;**90**:88–94.
5. Ballard BE. Biopharmaceutical considerations in subcutaneous and intramuscular drug administration. *J Pharm Sci* 1968;**57**:357–78.
6. Hutchins HS, Young FA, Lackland DT, et al. The effectiveness of topical anesthesia and vibration in alleviating the pain of oral injections. *Anesth Prog* 1997;**44**:87–9.
7. Yenisey M. Comparison of the pain levels of computer-controlled and conventional anesthesia techniques in prosthodontic treatment. *J Appl Oral Sci* 2009;**17**:414–20.
8. Oztaş N, Ulusu T, Bodur H, et al. The wand in pulp therapy: an alternative to inferior alveolar nerve block. *Quintessence Int* 2005;**36**:559–64.
9. Ran D, Peretz B. Assessing the pain reaction of children receiving periodontal ligament anesthesia using a computerized device (Wand). *J Clin Pediatr Dent* 2003;**27**:247–50.
10. Fukayama H, Yoshikawa F, Kohase H, et al. Efficacy of anterior and middle superior alveolar (AMSA) anesthesia using a new injection system: the Wand. *Quintessence Int* 2003;**34**:537–41.
11. Ram D, Kassirer J. Assessment of a palatal approach-anterior superior alveolar (P-ASA) nerve block with the Wand in pediatric dental patients. *Int J Paediatr Dent* 2006;**16**:348–51.
12. Patini R, Coviello V, Raffaelli L, et al. Subjective pain response to two anesthetic systems in dental surgery: traditional syringe vs. a computer controlled delivery system. *J Biol Regul Homeost Agents* 2012;**26**:89–97.
13. Garret-Bernardin A, Cantile T, D'Antò V, et al. Pain experience and behaviour management in pediatric dentistry: A comparison between traditional local anesthesia and the Wand computerized delivery system. *Pain Res Manag* 2017;**2017**:7941238.
14. Lee S, Reader A, Nusstein J, et al. Anesthetic efficacy of the anterior middle superior alveolar (AMSA) injection. *Anesth Prog* 2004;**51**:80–9.
15. Nicholson JW, Berry TG, Summitt JB, et al. Pain perception and utility: a comparison of the syringe and computerized local injection techniques. *Gen Dent* 2001;**49**:167–73.
16. Nusstein J, Berlin J, Reader A, et al. Comparison of injection pain, heart rate increase, and postinjection pain of articaine and lidocaine in a primary intraligamentary injection administered with a computer-controlled local anesthetic delivery system. *Anesth Prog* 2004;**51**:126–33.
17. Versloot J, Veerkamp JS, Hoogstraten J. Computerized anesthesia delivery system vs. traditional syringe: comparing pain and pain-related behavior in children. *Eur J Oral Sci* 2005;**113**:488–93.
18. Nusstein J, Claffey E, Reader A, et al. Anesthetic effectiveness of the supplemental intraligamentary injection, administered with a computer-controlled local anestheticdelivery system, in patients with irreversible pulpitis. *J Endod* 2005;**31**:354–8.
19. Nusstein J, Lee S, Reader A, et al. Injection pain and postinjection pain of the anterior middle superior alveolar injection administered with the Wand or conventional syringe. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* 2004;**98**:124–31.
20. Langthasa M, Yeluri R, Jain AA, et al. Comparison of the pain perception in children using comfort control syringe and a conventional injection technique during pediatric dental procedures. *J Indian Soc Pedod Prev Dent* 2012;**30**:323–8.
21. San Martìn-Lopez AL, Garrigos-Esparza LD, Torre-Delgadillo A, et al. Clinical comparison of pain perception rates between computerized local anesthesia and conventional syringe in pediatric patients. *J Clin Pediatr Dent* 2005;**29**:239–43.
22. Tahmassebi JF, Nikolaou M, Duggal MS. A comparison of pain and anxiety associated with the administration of maxillary local analgesia with Wand and conventional technique. *Eur Arch Paediatr Dent* 2009;**10**:77–82.

Please cite this article in press as: Patini R, et al. Dental anaesthesia for children – effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial. *Br J Oral Maxillofac Surg* (2017), https://doi.org/10.1016/j.bjoms.2018.08.006