

ORIGINAL ARTICLE

Effectiveness of the “pain-free dental injection” (PaFein) teaching model in reducing children’s pain: A randomized, controlled study

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Abstract

Purpose: This study explores the effectiveness of a comprehensive structured teaching model – the “PaFein” – for instructing postgraduate pediatric dental residents in the provision of pain-free local anesthesia to children.

Methods: Ten postgraduate pediatric dental residents and 172 children between the ages 5 and 13 participated in the study following ethical approval. The previously measured baselines guided the randomization of study and control groups. The study group (five residents) attended the PaFein course (9 hours). Based on power calculations, residents performed dental injections (8 mandibular block, 8 palatal/lingual and 14 buccal infiltrations) in randomly assigned child patients. Demographic data of residents/children, parental and self-report anxiety scores and Visual Analogue Scale (VAS) pain scores were noted to examine children’s anxiety and pain during dental injections.

Results: Children’s mean anxiety score did not differ significantly between groups; however, VAS pain reports during dental injections (a, b, c, d) were found lower in the PaFein study group than the control group ($p < 0.05$). VAS pain reports for (a) buccal injections were 1.08 and 1.9 ($p = 0.02$); (b) inferior alveolar nerve blocks were 1.58 and 3.37 ($p = 0.0002$); (c) palatal/lingual injections were 1.34 and 3.02 ($p < 0.0001$); (d) total means were 1.28 and 2.59, respectively ($p = 0.0001$). VAS pain reports of anxious and non-anxious children in the PaFein study group (1.63 and 1.17) were also lower than the control group (3.33 and 2.39) ($p < 0.0001$ and $p = 0.005$).

Conclusion: The “PaFein” teaching model was found to be effective in training dental residents to reduce dental injection pain in children, including the anxious ones.

KEYWORDS

anxiety, dental anesthesia, education, pain, pediatric dentistry

1 | INTRODUCTION

The “Profile and Competences for European Dentist” document emphasizes humane and compassionate care for patients, values providing local anesthesia (LA) for pain control and declares these as required competencies for graduating dentists.¹ Today it is believed that delivering painless LA to children is the key to developing a long term/nurturing relationship and potential cooperative child patients. For this purpose, numerous scientific studies have been conducted to determine and overcome several dependent factors (e.g., related to equipments, techniques and practitioners) that may cause pain perception during dental injections.²

In the service of pain free dentistry, a recent review by Monteiro et al.³ evaluated the interventions for increasing acceptance of local anesthetic injections in children and adolescents. They reported inconclusive evidence when (i) audiovisual distraction, (ii) the Wand (iii) counter-stimulation/distraction and (iv) hypnosis were compared to conventional management techniques. Additionally, precooling of the injection site, the use of a camouflage syringe, an electrical counter-stimulation device, and video modeling acclimatization were also reported insufficiently convincing for increased LA acceptance by children.

Effective pain control is also mandatory in cancer treatments and is provided by analgesic medicines in addition to chemo and radiotherapies. Nevertheless, epidemiological studies inform of persistent, untreated and severe pain reports from cancer patients.⁴ Therefore, in order to overcome suboptimal cancer pain management, researchers focused on educational interventions, which were provided either for professionals, or patients or both.⁵ Trials, which study educational interventions for professional training on an agreed guideline for cancer pain management, reported not only superior results but also practices that reduced pain intensity compared to usual care.^{4,6}

Within this perspective, in the search for pain free LA delivery in children, the present study investigates the effectiveness of an educational intervention which we call the PaFein teaching model. To our knowledge, the present study is the first trial to evaluate the effectiveness of an educational intervention for preparing caregivers to reduce dental injection pain. For pain free injections, previous studies^{2,3} evaluated a variety of interventions and equipment, especially local anesthetic syringes. In this study only the conventional syringe was used in all cases. The PaFein is a comprehensive structured teaching model developed to train postgraduate pediatric dental residents (though is also suitable for undergraduate students) in how to provide pain-free dental injections for children by combining conventional and modern strategies of pain and anxiety management.

PICO research question in this study is “Do children report lower pain scores when the postgraduate pediatric dental residents who attended the ‘PaFein’ course administer dental injections compared to injections given by residents who did not attend?” In the PICO research question, (P) represents patient: children who need a dental injection. (I) stands for intervention: postgraduate residents who attended the PaFein course before administering dental injections to the intervention group children. (C) represents control: postgraduate residents who did not attend the PaFein course before administering dental injections to the control group children (O) stands for outcome: the primary outcome is the reduction in pain scores of children during dental injections in the intervention group and the secondary outcome is to observe pain reductions also for the anxious children.

Therefore, the present study explores the effectiveness of a comprehensive structured teaching model – the “PaFein” – for instructing postgraduate pediatric dental residents in the provision of pain-free local anesthesia in children. And, the null hypothesis is that no difference in pain scores is anticipated between intervention and control group.

2 | MATERIALS AND METHODS

This parallel randomized, controlled, single blind, prospective trial was conducted in the Pediatric Dentistry Department at Marmara University, between November 2018 and January 2020. The study protocol was approved by the Clinical Research Ethics Committee, School of Dentistry, Marmara University, Istanbul, Turkey; (Decision number: 2018/177, April 26th 2018). Informed consent from graduates and parents was obtained. Clinical Trial Registry ID was obtained from UMIN (The University of Tokyo Hospital, Medical Information Network Centre, CTR 36405, 08.10.2018).

2.1 | Participants

Children, aged between 5 and 13, who were registered for dental treatment ($n = 191$) and 10 postgraduate pediatric dental residents, who were enrolled as first-year residents in the Pediatric Dentistry Department, School of Dentistry, Marmara University, Istanbul, Turkey participated in the study.

2.1.1 | Pilot study

A pilot study was conducted to establish equivalent study and control groups. After bio-statistical counseling each postgraduate resident performed 12 local anesthetic

TABLE 1 Baseline demographic data, self-efficacy, and empathy scores of postgraduate residents and baseline anxiety and dental injection pain scores of children in the pilot study groups

	Age (mean ± sd)	Experience (Year) (mean ± sd)	Self-efficacy score (mean ± sd)	Empathy score (mean ± sd)
Group A (<i>n</i> = 5)	25.2 ± 0.83	0.6 ± 0.89	69.4 ± 3.04	89.8 ± 4.76
Group B (<i>n</i> = 5)	25.4 ± 0.89	0.7 ± 0.67	70.2 ± 2.86	88.6 ± 8.53
	CFSS-DS pv (mean ± sd)	FIS (mean ± sd)	VPT (mean ± sd)	VAS pain score (mean ± sd)
Group A (<i>n</i> = 5)	28.48 ± 4.11	0.36 ± 0.05	0.98 ± 0.75	2.53 ± 0.61
Group B (<i>n</i> = 5)	28.81 ± 3.95	0.34 ± 0.05	0.99 ± 0.70	3.01 ± 1.14

Note: Unpaired *t*-test, *p* > 0.05 in all group comparisons.

Abbreviations: CFSS-DS pv, Child Fear Survey Schedule-Dental Subscale parental version; FIS, Facial Image Scale; VAS, Visual Analog Scale; VPT, Venham Picture Test.

injections, when pain control was an essential part of the actual treatment plan for their patients (three inferior alveolar nerve blocks [IANBs], three palatal/lingual infiltrations, six buccal infiltrations). Based on the demographic data of the postgraduate residents (age, experience, year after graduation, empathy, and self-efficacy scores), and the average anxiety and pain perception scores obtained from patients during injections, two equivalent groups, Group A and Group B were formed. Each postgraduate resident drew “study” or “control” group lots to randomly determine their group. Postgraduate residents in Group A, who drew more “study” group lots, were assigned the “PaFein” study group (Table 1).

2.1.2 | Main study

Children aged 5–13 who had been registered for routine dental treatment were assessed according to eligibility for inclusion and exclusion criteria (*n* = 191). Healthy, co-operative children who needed non-urgent dental treatment under LA were included while those who had systemic or psychological problems and/or were unwilling to participate were excluded (Figure 1). Dental Hospital Electronic Medical Record System randomly allocated eligible subjects to 10 postgraduate residents, who were either in the study or control group, based on ten sets of 30 Unique Registration Number per set, ranging from 1 to 300.

The study was single blind because subjects (children) were blind to the study. However, due to the nature of the study, postgraduate residents could not be blinded whether they attended the PaFein course or not.

Power analysis was performed ($\alpha = 0.05$; power = 0.8; $P_0 = 0.25$; $P_1 = 0.00001$; $M = 1$), and a minimum of 26 injections were calculated, in order to have a minimum of eight injections for the IANB and Palatal Injection subgroups. In order to allow for any possible dropouts, 30 injections were decided for each

postgraduate resident. P_0 value (anticipated pain reduction) was decided as a mean value of 25% which was obtained from a previous study.⁷

2.2 | Measurements

The General Self-Efficacy Scale-Turkish Version’s validity and reliability tests were performed by Yıldırım and İlhan.⁸ Likert’s scale format was preferred. Responses to the question “How much does this define you?” ranged from “no” to “very good” in five grades. The score for each question ranges from 1 to 5. Opposite scored items were the 2nd, 4-7th., 10-12th., 14th, 16th., and 17th items of the scale. The total score obtained from the scale varies between 17 and 85. Higher scores on the scale indicate increased self-efficacy perceptions.

In the present study, the student version of Jefferson Scale of Physician Empathy (JSPE S-version) was preferred, which was adapted to Turkish by Gönüllü and Öztuna.⁹ The actual version was developed for medical students. Empathy characteristics of medical students were determined in a doctor-patient relationship. Ten positively and 10 negatively worded statements were answered from 1 (strongly disagree) to 7 (strongly agree) on a 7-point Likert’s scale. A minimum score of 20 and a maximum 140 score can be obtained from the scale. The increase in scores indicates higher empathetic consistency.

For the study of primary and secondary outcomes, children’s pain and anxiety levels were assessed by various tests designed to purpose. The Visual Analogue Scale (VAS), a self-reporting scale, was preferred to evaluate children’s experience of pain. The scale displayed a colored spectrum on the front side ranging from no pain (white) to severe pain (red), which indicates relevant pain scores ranging from 0 to 10 on the reverse side.¹⁰

The Dental Subscale of Children’s Fear Survey Schedule parental version (CFSS-DS pv), which consists of

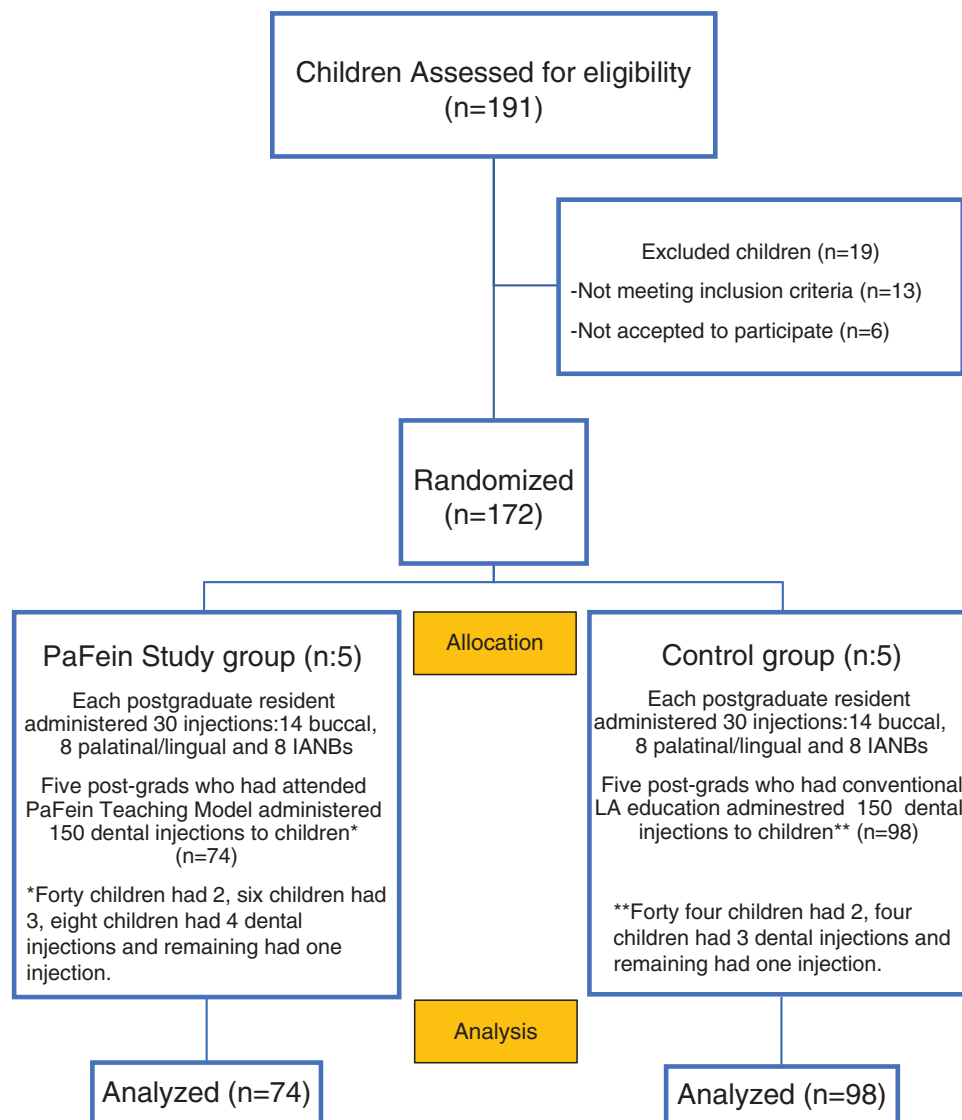


FIGURE 1 Study flow

15 articles, was developed in 1982 by Cuthbert and Melamed.¹¹ The answers are given by parents on a Likert-type scale, ranging from 15 to 75. For children with moderate and severe dental fear levels, threshold values are set as 32 and 38 points, respectively.

In the present study, the Venham Picture Test (VPT), a self-reporting scale, was used to evaluate children's situational anxiety. It consists of 16 illustrations in pairs. Among the pairs, one represents the presence of anxiety and the other represents absence of anxiety. Children's anxiety scores were calculated between 0 and 8, according to the illustration they chose, representing themselves. Higher scores indicate the presence of anxiety and its level.¹²

A secondary self-report scale used in the study to evaluate children's state of anxiety was the Facial Image Scale (FIS). It displays nine faces showing emotions ranging from "non-anxious" to "very anxious." Chil-

dren were requested to indicate the face that represents their actual feelings. The scores range between 0.04 (positive/nonanxious) and 0.97 (negative/very anxious), demonstrating the state anxiety.^{13,14}

2.3 | Materials

Conventional plastic syringes (Beybi Sterile Dental Injector; Beybi Plastik Fab. San., İstanbul, Turkey) were preferred for buccal, lingual and palatal injections, with 13 mm needles and 30 G (BD Microlance 3, Becton, Dickinson and Company Limited, Louth, Ireland). For IANB injections traditional plastic syringes with 27G and 50 mm needles were used (Beybi Sterile Dental Injector; Beybi Plastik Fab. San., İstanbul, Turkey). Lidocaine 10% spray for topical anesthesia (Vemcaine spray; Vem ilaç

Sanayi, Tekirdağ ili, Türkiye) and Articaine 80 mg/2 ml with 0.01-mg epinephrine (Maxicaine ampule; Vem İlaç Sanayi, Tekirdağ, Türkiye) were used as anesthetic solutions.

2.4 | Procedure and the PaFein teaching model

Following the pilot study as outlined in Section 2.1, study and control groups were formed with five postgraduate residents in each. The study group participated in 9 hours of the PaFein teaching model course. The PaFein teaching model targets development in cognitive, effective, and psychomotor domains of postgraduate residents.

In light of the guidelines and textbooks, didactic, pre-clinical, and clinical courses were designed to improve postgraduate residents' knowledge, understanding, and skills in the mentioned domains.^{7,15-18} In the didactic section, techniques and theoretical infrastructure for pain-free LA were taught. These lessons included topics such as management of dental anxiety and pain in children, communication with child patients, psychological fundamentals of behavioral guidance, encouraging stimulus control freedom, and developing self-efficacy skills in children. In the preclinical section, psychomotor skill development was aimed for. Steps for the pain-free injection technique, injection before insertion, and to open an analgesic pathway, were practiced on chicken legs. In the clinical section, postgraduate residents practiced behavior management techniques, self-efficacy development and stimulus control freedom in role plays. Residents also administered LA injections on each other, such as buccal infiltration and indirect palatal/lingual anesthesia, so that they could practice details of the technique. They experienced stimulus control freedom with each other, provided instant feedback, and follow-up feedback afterwards in group discussions about the pain-free injection techniques practiced during clinical training. All PaFein courses were given and supervised by one researcher who remained the same (OOK).

The control group did not attend any course and was advised to provide treatments with the routine anesthesia application. A thorough explanation was given to the groups, advising them not to talk or discuss the techniques used in the study group, nor should the control group observe colleagues in the PaFein study group. Study group residents were advised to carry out treatments in line with the training they had received in the PaFein course and not to apply any pre-training routines. Some fundamental key points were emphasized such as not performing LA in the first session, and if possible, administering the first injection

as a buccal infiltration in the upper jaw, rather than an IANB or palatal injection.

Postgraduate pediatric dental residents performed a total of 30 injections with eight mandibular blocks, eight palatal/lingual injections, and 14 buccal infiltrations based on power calculations. Prior to treatment, children's demographic data, previous LA experience, CFSS-DS-pv, FIS, VPT and VAS scores were noted. All scales prior to treatment were presented to the children by the postgraduate resident performing the injection, and scales after dental injections (VAS pain and FIS anxiety scale) were applied by the same, single researcher (SMO) who was independent of the postgraduate residents. Children who needed more than one treatment under LA were scheduled for a further appointment and treated by the same postgraduate resident.

The descriptive statistics were given as mean \pm standard deviation for continuous random variables and as frequency (%) for discrete random variables. Distributions of continuous random variables were tested with the Kolmogorov-Smirnov test. All continuous random variables were normally distributed in groups; therefore, unpaired *t*-test was preferred as appropriate. X^2 test was used to compare discrete random variables. To analyze further for the secondary outcome, subjects who were anxious (CFSS-DS > 32) and/or relatively anxious (FIS > 0.3 and VPT > 0) were compared with the nonanxious children by unpaired *t*-test. SPSS 16.0 was used to analyze the data and significance level was set at $p < 0.05$ level.

3 | RESULTS

The demographic data and previous LA experience of children exhibited no difference between groups ($p > 0.05$), and findings are presented in Table 2.

No difference was observed in preinjection CFSS-DSpv, FIS and VPT anxiety scores. However, after the injections, the study group reported lower anxiety scores than the control group (FIS-2: 0.37 and 0.47, $p < 0.002$). Anxiety scores are presented in Table 2.

3.1 | Primary outcome

The study group reported significantly lower pain scores than the control (c) group [VAS 1.28 (study) and 2.59(c), $p < 0.0001$] (Table 2). For different injection sites pain scores for study and control groups are buccal infiltrations [1.08 (study) and 1.9(c), $p < 0.05$], IANBs [1.58 (study) and 3.37(c), $p < 0.0001$] and palatal/lingual injections [1.34 (study) and 3.02(c), $p < 0.0001$]. Pain scores regarding injection sites are presented in Figure 2.

TABLE 2 Comparison of demographic data^(a), previous local anesthesia experience^(a), pre^(b) – post^(c) injection anxiety and local anesthesia VAS pain scores of children in the research groups

		PaFein group (n = 74)	Control group (n = 98)
Gender n (%) ^(a)	Girls	32 (43%)	44 (45%)
	Boys	42 (57%)	54 (55%)
Age ^{(a),(#)} (mean ± sd)		9.06 ± 2.13	8.34 ± 2.14
Previous LA experience ^(a) n (%)	No	18 (24%)	16 (16%)
	Yes	56 (76%)	82 (84%)
Parents' education ^(a) n (%)	Mother	Elementary or less	52 (70%)
		High school	14 (19%)
		University or higher	8 (11%)
Father	Elementary or less	36 (49%)	
	High school	24 (32%)	
	University or higher	14 (19%)	
Family income ^(a) n (%)	<2500 TL	4 (5%)	16 (16%)
	2500–5000 TL	28 (38%)	45 (46%)
	>5000 TL	13 (18%)	15 (15%)
	No comment	29 (39%)	22 (23%)
		PaFein Group (mean ± sd)	Control Group (mean ± sd)
	p-Value		
CFSS-DS pv. ^(b)	0.941	26.36 ± 8.24	26.29 ± 7.22
FIS-1 ^(b)	0.938	0.30 ± 0.22	0.30 ± 0.23
VPT ^(b)	0.644	0.92 ± 1.80	0.82 ± 1.69
VAS	0.0001	1.28 ± 1.51	2.59 ± 2.44
FIS-2 ^(c)	0.002	0.37 ± 0.26	0.47 ± 0.28

Note: Chi-square test, ^(#) unpaired *t*-test; *p* > 0.05 in all demographic data^(a) comparisons.

Abbreviations: CFSS-DS pv, Child Fear Survey Schedule-Dental Subscale parental version; FIS, Facial Image Scale; VAS, Visual Analog Scale; VPT, Venham Picture Test.

3.2 | Secondary outcome

Both anxious and nonanxious children in the study group reported significantly lower pain scores [VAS 1.63 (study) and 1.17 (study)] than the children in the control group [VAS 3.33(c) and 2.39(c)] (*p* < 0.01). Pain reports of children who were grouped as anxious (CFSS-DS > 32), and/or relatively anxious (FIS > 0.3 and VPT > 0) can be seen in Table 3.

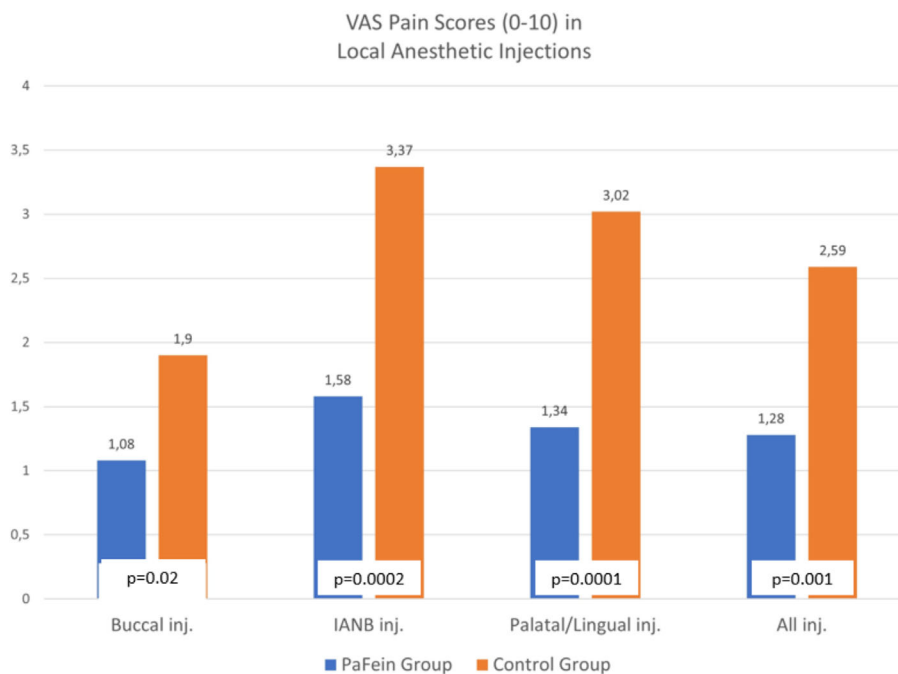
The null hypothesis is rejected, and children who were treated by postgraduate residents who had attended the “PaFein” course reported significantly lower pain scores during dental injections.

4 | DISCUSSION

In pediatric dentistry, pharmacologic and/or nonpharmacologic techniques are used to manage pain and anxiety. No single technique is as yet reported to be best. There-

fore, knowledge of several techniques, to be individually selected as appropriate for a particular patient, are advised for pediatric dentists.^{3,19} However, Coxon et al.²⁰ reported that pediatric dentists do feel that they have limited control and knowledge of nonpharmacological behavior guidance and dental fear. As these studies inform of limited success-control and knowledge of behavior guidance and pain control, the present study aims to explore the effectiveness of an educational intervention, the PaFein teaching model, for training dentists to provide pain-free local anesthesia for children.

Participants were included based on the findings of a previous study,⁷ which reported experienced students having some difficulties in adapting their actual knowledge of pain-free injections, which is based on traditional LA education. Some participants found it difficult to alter their injection technique. Therefore, the study group in the present study consisted of ten inexperienced, novice postgraduate residents. Prior to the main research, a pilot study was carried out, and pain scores for preliminary injections



Unpaired t-test, $p < 0.05$

FIGURE 2 Comparison of Visual Analogue Scale (VAS) pain scores reported by children in various dental injections in the groups (primary outcome)

TABLE 3 Comparison of local anesthesia VAS pain scores (0–10) reported by anxious and non-anxious children in the research groups (secondary outcome)

Anxiety scales (Range)		PaFein group VAS pain score (mean ± sd)	Control group VAS pain score (mean ± sd)	p-Value
CFSS-DS pv. (15–75)	Anxious (CFSS ≥ 32)	1.63 ± 1.86	3.33 ± 2.95	0.005
	Nonanxious (CFSS-DS < 32)	1.17 ± 1.37	2.39 ± 2.26	0.0001
FIS (0.04–0.097)	Anxious (FIS ≥ 0.3)	1.38 ± 1.59	2.93 ± 2.63	0.0001
	Nonanxious (FIS < 0.3)	1.17 ± 1.41	2.23 ± 2.19	0.001
VPT (0–8)	Anxious (VPT > 0)	1.76 ± 1.50	3.20 ± 2.53	0.002
	Nonanxious (VPT = 0)	1.02 ± 1.45	2.33 ± 2.37	0.0001

Note: Unpaired t-test, $p < 0.01$ in all comparisons.

Abbreviations: CFSS-DS pv, Child Fear Survey Schedule-Dental Subscale parental version; FIS, Facial Image Scale; VAS, Visual Analog Scale; VPT, Venham Picture Test.

were recorded to provide baseline data when constructing equivalent study and control groups. The experience level, mean self-efficacy and empathy scores, age of participants and children's pain reports during preliminary injections were noted. Equivalent groups were then formed ($p > 0.05$) (Table 1).

Anxiety is a major confounding factor when pain is anticipated, and research reports high correlations between anxiety and pain.^{21–23} Therefore, in the present randomized clinical trial, before interventions were started, the demographic information and anxiety scores of children in the study and control groups were eval-

uated. No differences were observed between groups, that confirmed successful randomization ($p > 0.05$) (Table 1).

Regarding the primary outcome, pain scores in the study group were found to be lower than those in the control group for every injection type (Table 2). Differences in pain scores were more evident for IANB and palatal/lingual injections, which were considered more traumatic for children compared to buccal injections ($p < 0.0001$). Pain scores for these traumatic injections (VAS 1.58 and 1.34) in the study group were also lower than those recorded for the buccal injections (VAS 1.9) administered in the control

group. If this finding can be supported by future studies, then IANB and palatal/lingual injections should no longer be considered more traumatic for children.

In the search for increased acceptance of local anesthetics in pediatric dentistry, several studies compared conventional syringes with new injection devices, new equipment and/or new dentist interventions.^{22,24–40} Findings in the literature regarding VAS pain reports of children during buccal, palatal, and IANB injections with traditional syringes compared to devices/equipment other than traditional syringes (e.g., CCLAD, vibration devices, and other) are presented in Figure 3. For standardization purposes, only studies on children and using the VAS pain scale were included in the summary regarding injection sites. Studies cited were either performed by a single, same operator or 2–3 experienced pediatric dentists. Some included a limited age range and/or older age children. In the present study, five different first year postgraduate residents, who were relatively inexperienced operators, performed all the injections in a relatively wide age range, of 5 to 13 years old. Therefore, regarding postgraduate residents' experience levels, the reported pain scores for all injection sites in the study group were evaluated as relatively low, and this is promising for the future of pain free dental injections in children.

Regarding the secondary outcome, pain perception of anxious and non-anxious children was evaluated sensitively in the study. Three different anxiety scales were used prior to injections, two of which were self-reported by the children, and one was answered by parents (Table 2). For all anxiety scales, anxious children reported lower pain scores in the study group than in the control group. Furthermore, anxious children in the study group also perceived less pain than the nonanxious children in the control group.

The findings of this preliminary study report statistically significant pain reductions (>1 point on a 1–10 scale) for various injection types and represent around a 40% improvement in injection pain reduction, which also includes injections for highly anxious children. In the field of pediatric dentistry, LA guidelines, behavior management guidelines and textbooks on atraumatic/pain free injections and behavior management are available.^{7,15–18} The present study compiled the existing information related to pain free injections for children into the PaFein teaching model and trained postgraduate residents in nine hours of didactic, preclinical, and clinical courses. Therefore, further studies are required to develop the PaFein educational intervention and improve its effects for the future of pain free dentistry.

The present study possesses some limitations. The operators were all the same gender (female) and also the experiment employed a limited number ($n = 5$) of

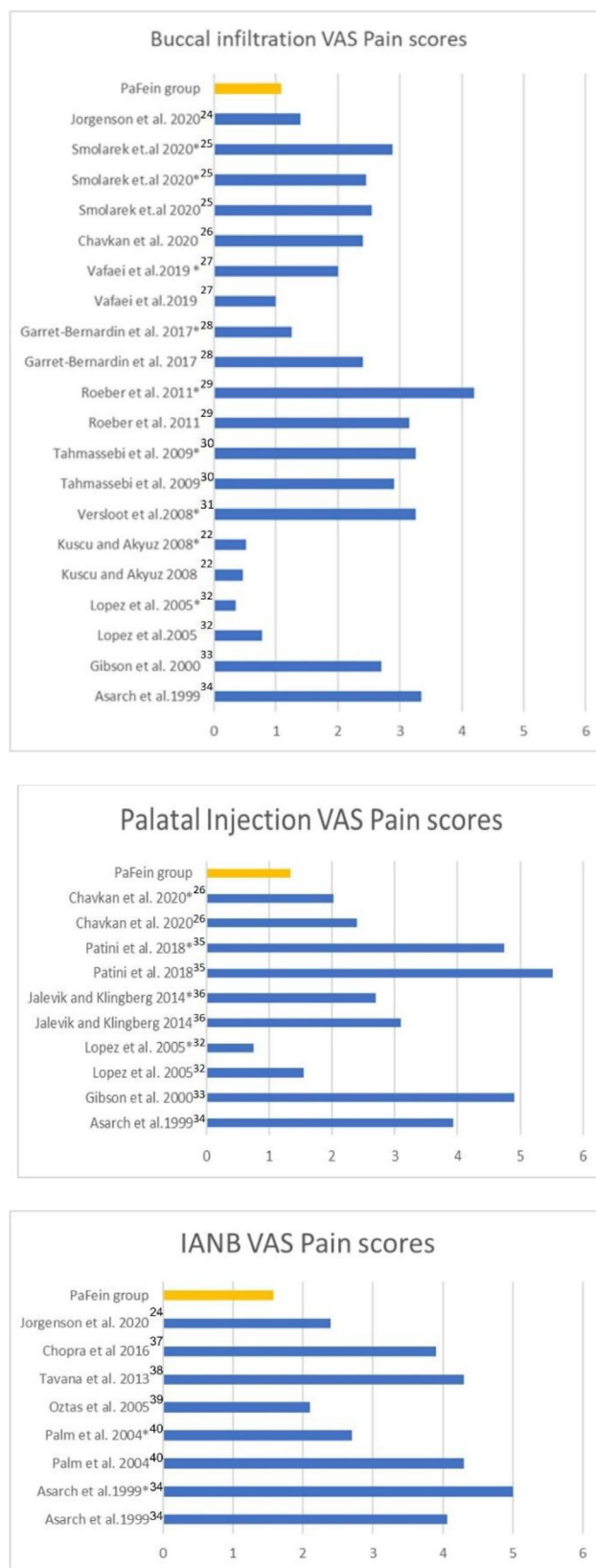


FIGURE 3 (A, B, and C) Literature summary: Reported mean Visual Analogue Scale (VAS) pain scores (0–10) of children during buccal, palatal, and inferior alveolar nerve blocks (IANB) injections with traditional syringes and devices/equipment other than traditional syringes*

postgraduate residents. If possible, a multicenter study design, with the participation of more postgraduate residents of both genders and children from different countries and cultures, will more precisely evaluate the effectiveness of the PaFein teaching model. Therefore, academic readers of the present article are kindly invited to contact the corresponding author with ideas for a multi-center research design to improve the PaFein teaching model.

5 | CONCLUSION

The “PaFein” teaching model was found to be effective in training dental residents to reduce dental injection pain in children (primary outcome), including the anxious ones (secondary outcome). Future studies with larger sample sizes are required to make more comprehensive assessments of the PaFein teaching model’s effectiveness.


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CONFLICT OF INTEREST

Authors had no financial, economic or professional interests that may have influenced the design, execution or presentation of this scholarly investigation.

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