Original Article

Determination of the Effect of Two Different Methods of Dental Anesthesia on Pain Level in Pediatric Patients: A Cross-Over, Randomized Trial

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Abstract

Background: In dentistry, needles are the most feared and anxiety-causing tool, making anesthetic injection a worrying practice for patients. **Aim:** To evaluate the effect of intraosseous anesthesia (IOA) and needle-free dental anesthesia (NFA) on pain levels in systemically healthy 8–10-year-old patients. **Patients and Methods:** Twenty patients aged 8–10 years were included in this cross-over study. Specifically, the pain was measured by Wong Baker, pulse rate (PR), and salivary opiorphin levels (SOL). In addition, the Frankl Behavioral scale was used to measure behaviors and face, legs, activity, cry, consolability (FLACC) was utilized to measure pain and discomfort. To determine the patients' anxiety levels Spielberger State-Trait Anxiety Scale (SSAS-SAAS) was used. The Friedman and Wilcoxon signed-rank tests were used. $P < 0.05$ was considered significant. **Results:** According to FLACC scores, IOA and NFA exhibited significantly pain alteration patterns in during local and topical anesthesia, respectively ($p = 0.004$, 0.001; $P < 0.01$). Also, only NFA showed significantly decreased SOL values in 5- and 10-min after local anesthesia periods compared to the before levels ($p = 0.004$, $P = 0.001$; $P < 0.01$). **Conclusion:** Patients feel similar pain perceptions during local anesthesia application in both injection systems. According to the SOL values, NFA may provide more higher anesthetic efficiency than IOA.

Keywords: *Anesthesia, injections, opiorphin, saliva, scales*

Highlights

- It is the first study that compares needle-free and intraosseous systems.
- Intraosseous and needle-free systems have similar results for felt pain levels.
- Opiorphin levels may have shown technique that provides higher anesthetic efficiency.

Introduction

Dental treatments are often associated with pain but their patient acceptance has been facilitated by hypodermic injection of procaine and lidocaine amide as anesthetic agents. However, many patients associate pain with injection due to mechanical trauma of needle insertion or the sudden stretching of tissues by anesthesia during rapid release of the anesthetic.[1]

According to the American Dental Association, fear of pain can prevent patients from visiting their dentists also local anesthetic injection is the most anxiety-inducing procedure for patients.[1] Painless anesthesia is a critical issue in terms of increasing the patients' trust in the physician during any procedure. However, a child's feeling of anxiety during dental treatment may lead to maladaptive behaviors that may hinder and delay the treatment.[2,3] Therefore, especially in pediatric dentistry, ways to avoid the invasive and often painful nature of injection are being investigated.[4] Different measures

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to reduce discomfort associated with an injection have been tried like that using of topical anesthetic, warming anesthesia solution to body temperature using of low-level laser or another local anesthetic delivery methods.[1,5]

Computer-controlled local anesthetic delivery systems (CCLAD), including, SleeperOne™, Wand,[6] and Comfort-In™, which provide anesthesia using pressure, can be regarded as new systems that have been developed to perform local analgesic injection while overcoming the shortcomings of traditional infiltration procedures. SleeperOne™ is a new type of CCLAD that apply intraosseous anesthesia (IOA) with a persistent resistance system analysis that regulates injection according to tissue density.[4] Unlike traditional needle syringe injection methods, it was indicated that the Comfort-In™ provides local anesthesia by penetrating below the periosteum.[7]

Although previous studies have generally compared traditional techniques and CCLAD systems using behavioral and pain scales,[8,9] a comparative study of Comfort-In™, a new needle-free anesthesia (NFA) method, and SleeperOne™, a CCLAD method, is not available in the literature. In addition, in the literature review, no study was found in which the effect of anesthesia methods on pain sensation was compared using a *'cross-over'* research design by obtaining both biological, physiological, and observational data from the patients with the aim of evaluating the effect of IOA and NFA on pain levels in systemically healthy 8–10-year-old patients. Therefore, the project we designed is innovative compared to other studies.

Hypothesis

No difference in pain levels of systemically healthy 8–10-year-old patients will be observed during local anesthesia performed as the IOA or NFA anesthesia methods.

Methods

Ethics

After obtaining the ethics committee approval from Karadeniz Technical University Faculty of Medicine Clinical Research Ethics Committee for the study (approval number 2019/699), the approval of the Turkish Medicines and Medical Devices Agency of the TR Ministry of Health was obtained (approval number 71146310-511.06-E.204453). It is registered at (NCT05002673). All the patients included in the study subjects have given their written informed consent.

Sample size determination

The sample size was determined based on the study conducted by Campanella *et al*.[1] with an effect size = 0.5, alpha error = 0.05, and beta error = 0.20, it was determined that a total of 35 samples were needed and considering possible losses, a total of 40 patients were found to be sufficient. Since the study was designed as a *'cross-over'* study, 20 patients were included in the study.

Patient selection

Patients aged 8–10 years, who were systemically healthy, without any physical or psychological disorders, did not use any medication, had undergone dental treatment (except for extraction) previously but with at least one week passed since then, had never tried IOA and NFA anesthesia techniques before, were not undergoing any orthodontic or ongoing dental treatment (e.g., root canal therapy), were compatible enough to undergo therapy in the clinic in a sitting position, had infection between the roots with a rate over 1/3, had 2/3 root formation, had been indicated for extraction of the maxillary primary molar teeth (55/65 No. teeth),[10] and did not have acute and/or subacute infection of the related or other teeth or mouth and surrounding tissues were included in the study. Further, patients who scored above 41 in the state anxiety subscale and above 44 in the trait anxiety subscale[11] of the Spielberger State-Trait Anxiety Scale (SSAS-SAAS) were not included in the study.

In this study, 40 patients' legal representatives that suitable for including criteria and coming university dental hospital pediatric clinic between September 2020 and January 2020 were interviewed. Among them, nine patients did not accept to attend study. After the procedures were started, five patients were withdrawn from the study voluntarily, while four patients were excluded due to cooperation problems. In addition, although the patients were excluded from the study due to data loss in the video recordings of two patients, the study was completed patients with a number suitable for the sample size (n = 20) [Figure 1].

Randomization

Twenty patients who presented to the clinic, met the inclusion criteria and agreed to participate in the study were assigned numbers from 1 to 20, respectively. Subsequently, patient numbers were randomly distributed using a computer-assisted randomization[12] programme. According to the sequence number of the patients, envelopes containing details about the application group (i.e., which anesthesia method would be applied first) were chosen by each patient in a blinded manner.

Accordingly, the first procedure to be applied to that patient was decided.

Study design

A cross-over design that in which two or more treatments are applied to the same patient within the framework of a plan was used in this study.[13] An informed consent form was obtained from all patients included in the study and their parents before the procedure. Patients included in the study were taken to isolated single rooms around 9–10 am. The patients were asked to feed and brush their teeth approximately 1 hour before the dental procedure.

SSAS-SAAS was administered by the principal investigator to determine the patients' state and trait anxiety levels before the procedure. The SSAS-SAAS scale consisted of two separate scales included of 20 questions each, state and trait, and each question was scored from 1 (not at all) to 4 (completely). The scales included direct and reversed statements like "I am currently calm" and "I usually get tired quickly".[14]

Subsequently, like in every patient who presented to the pediatric dentist clinic, the tell-show-do behavior guidance technique was used and unstimulated saliva samples were passively taken three times from the floor of the mouth of each patient using a Pasteur pipette: 15 min before dental anesthesia, 5 min after dental anesthesia and 10 min after dental anesthesia.[15,16] A pulse metre (Yonker Fingertip Pulse Oximeter, Prolinx GmbH, Germany) was attached to the patient's right index finger 15 min before the procedure as an indicator showing the relationship of heart rate (measured as pulse rate (PR)) with pain. PR measurements were made in 15 min before local anesthesia, during topical anesthesia, during local anesthesia, and during extraction.

During dental anesthesia with two systems, 4% articaine 1/100.000 (Ultracain DS Forte Ampul, Articaine HCl 40 mg/ml Epinephrine HCl 0.012 mg/ml, PharmaVision San. ve Tic. A.Ş., Turkey)[17] in ampoule and carpule forms were used. All anesthesia procedures and tooth extraction treatments were performed by the same researcher who had one month of experience using Comfort-In™ (Mika Medical; Busan, Korea) and SleeperOne™ (DHT, Cholet, France) injection systems.

The Frankl and the Face, Legs, Activity, Cry, Consolability (FLACC) scores (15 min before local anesthesia, during topical anesthesia, during local anesthesia, and during extraction) were determined by the two calibrated pediatric dentists, who did not perform the procedure, to objectively evaluate the patient's behaviors and pain levels before the treatment, during the administration of local anesthesia, and during and after the treatment, based on the video recordings of the patients. Before the study, these two pediatric dentists evaluated FLACC and Frankl scales on 10 patients that independent of the study group, and the interobserver agreement was found to be good ($\kappa = 0.729$). In addition, the Wong-Baker Faces Pain Rating Scale (WB) that included faces describing pain from 0 (no pain) to 10 (unbearable pain) was used before the procedure, immediately after anesthesia, immediately after extraction and 15 min after the procedure to analyze the subjective pain felt by the children.[18] The FLACC scale graded five pain-related behaviors with 0, 1, or 2 points, and an increase in the score indicated the presence of pain. The Frankl Behavioral Scale rated children's behavior in dental treatments from 1 (absolutely negative) to 4 (absolutely positive). However, all scales (SSAS-SAAS, FLACC, Frankl, WB) were used in the study were used in other studies in Turkish validated format.[14,18]

The same parameters were tested one week later while performing the left/right upper tooth extraction using the dental anesthesia technique that had not been applied in the first session based on randomization in each patient [Figure 1].

IOA anesthesia procedure

The installation of the SleeperOne™ (DHT, Cholet, France) anesthesia device (needle diameter and length, 30 Gauge/9 mm, a double row needle that provides better penetration into the bone)[19] was made in accordance with the manufacturer's instructions. Before local anesthesia, 1–2 drops of articaine solution was applied to the buccal region after superficially passing the epithelium for topical purposes, and then the IOA method was used. IOA was performed directly on the interproximal bone between the two teeth. By approaching from the buccal part, the needle was gently pushed into the cortical bone under the interdental papilla at an angle of 45° with clockwise and counter clockwise movements,[4] and a total of half carpule (1 cc) of the anesthetic was administered [Figure 2].

NFA anesthesia procedure

Likewise, the installation of the Comfort-In™ (Mika Medical; Busan, Korea) anesthesia device was performed in accordance with the manufacturer's instructions. Before anesthesia, 1 shot of 0.1 ml was applied to the buccal and palatal regions for topical purposes, and after 10–15 seconds of anesthesia, 2 shots of 0.3 ml each to the buccal region and 2 shots of 0.1 ml each to the palatal region were administered (total 1 cc)[7] [Figure 3].

Obtaining saliva samples

Saliva samples were taken from the individuals in the patient group in a biochemistry tube with separator gel. Consent forms were collected along with the saliva samples. The tubes were centrifuged at 1800× g for 10 min. After centrifugation, the supernatants were carefully transferred to capped microfuge tubes and stored at −80°C until analysis. The saliva samples were brought to room temperature and thawed before analysis. The thawed samples were homogenised by vortexing and the biochemical parameters were measured.

Determining opiorphin levels

SOL was determined using the enzyme-linked immunosorbent assay (ELISA) kit (Cusabio, Cat No: CSB-EQ027423HU, Wuhan, China)[20] in accordance with the manufacturer's instructions. The opiorphin standards (40–0.625 ng/mL) were prepared according to the kit-specified procedure. Absorbances of the samples and standards were measured at 450 nm using a microplate reader spectrophotometer (Versamax, Molecular Devices, California, USA). Each sample was analyzed in duplicate, and their results were averaged and presented in ng/mL units. The intra-assay repeatability (%CV) of the ELISA kit used was calculated as 3.2% (n = 20).

Statistical analysis

A statistical data program was used for statistical analyses. Descriptive values were assigned to sex and age. Descriptive values were expressed as mean ± standard deviation, median (minimum–maximum) or % values. Cohen's Kappa value was calculated for inter-observer agreement. Normal distribution of the data was evaluated using the Shapiro–Wilk test. The Friedman and Wilcoxon signed-rank tests and Bonferroni correction were applied for both continuous (SOL, PR, and SSAS-SAAS scores) and categorical variables (WB, Frankl, and FLACC scores). In all analyses, a *P* value of <0.05 was considered statistically significant.

Blinding

The Frankl Behavioral Scale and the FLACC Scale data were scored from the video recording images of the procedure by two other pediatric dentist researchers who were independent to each other. The researchers who determined the levels of opiorphin in the collected saliva and performed the statistical analyses blinded to the grouping of the patients. Although the patients had partial awareness of the technique applied, since all evaluations were performed on video recordings, the risk of subjective results during the pain scoring of the patients was avoided and objective blinding could be established.

Results

In the study, there were 2 patients aged 8 years, 7 patients aged 9 years and 11 patients aged 10 years. Further, 8 (40%) of the patients were girls and 12 (60%) were boys [Table 1].

SOL, PR, and SSAS-SAAS scores

According to SSAS-SAAS scores, there were not statistically significant difference in state and trait anxiety of patients between two sessions. (p = 0.636; $P > 0.05$) [Table 2]. According to the statistically significant decreases, PRs suggested that patient may have felt more comfortable with NFA than IOA method during extraction (p = 0.002; $P < 0.01$) [Table 3]. For the NFA method, the significant decrease in the SOL at 5- and 10-min anesthesia showed the effectiveness of anesthesia (p = 0.004, $P = 0.001$; $P < 0.01$) [Table 4].

Wong-Baker, Frankl, and FLACC scale scores

Significant increases in FLACC during local anesthesia showed the presence of pain during local anesthesia for the IOA method (p = 0.004; $P < 0.01$). For the NFA method, the increase in the FLACC scores during topical anesthesia showed that the pain during topical anesthesia (p = 0.001; $P < 0.01$). In addition, for the NFA method, a significant increase in the WB value in immediately after the extraction showed the presence of pain during the extraction (p = 0.002; $P < 0.001$). In addition, there was seen that the decrease in the Frankl score during anesthesia (p = 0.003; $P < 0.05$) for the IOA method and during topical anesthesia (p = 0.004; $P < 0.05$) for the NFA method [Tables 5,6,7].

Discussion

One of the most important factors affecting success in pediatric dentistry is pain control.[21,22] In the literature,

Table 1: Age and gender distributions of patients

		n (%)	
Age			
Median (min-max) 10 (8-10)	8	9	10
Mean±SD 9.45±0.686	2 (10)	7 (35)	11 (55)
Gender	Girl	Boy	
	8 (40)	12 (60)	

Table 2: Time-dependent changes in Spielberg trait-state anxiety scale scores

Anesthesia Type	Spielberg State score	Spielberg Trait score	*P*
	Median (min-max)	Median (min-max)	
Intraosseous	34 (28-41)	[a]28.5 (20-41)	
Needle-free	34 (28-41)	[b]31 (20-41)	[a-b]*P*=0.636

P>0.05 Wilcoxon signed ranks test

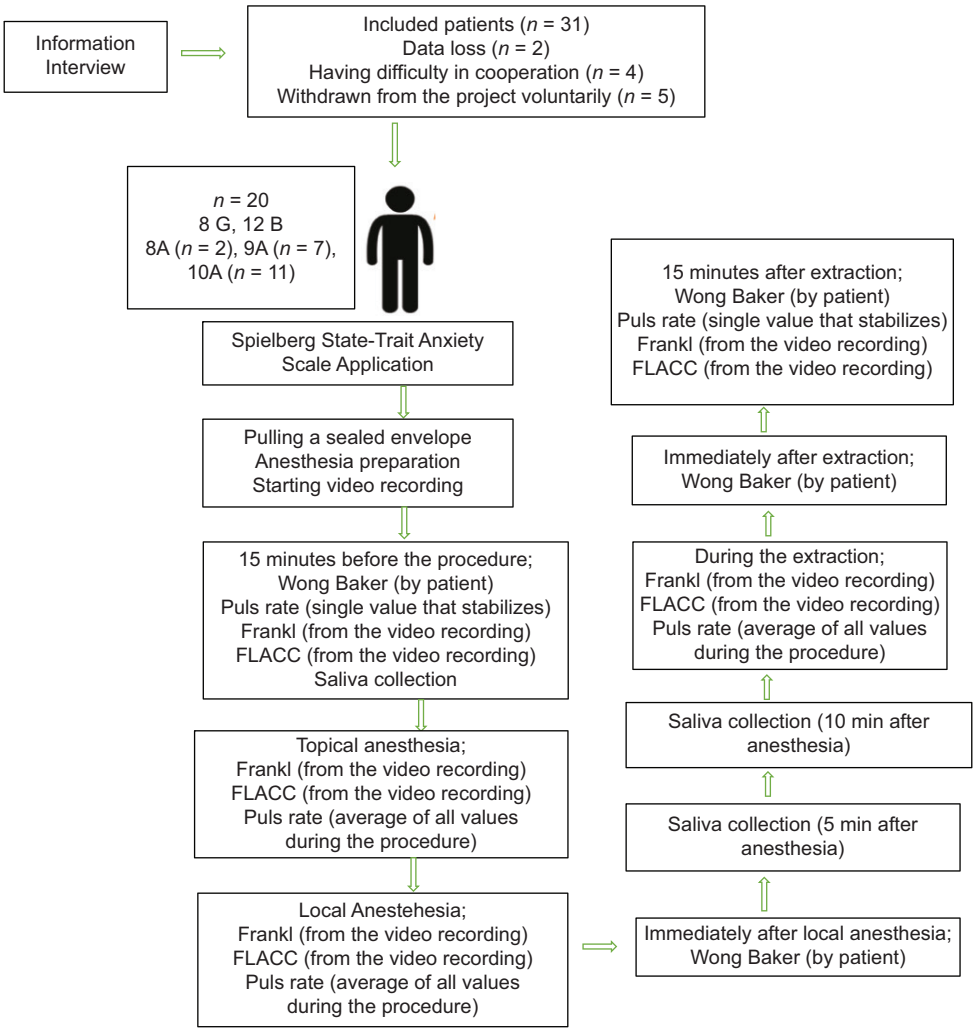

Figure 1: Patient selection and applications during treatment

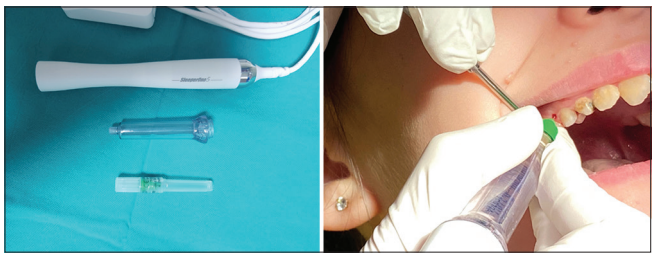

Figure 2: Intraosseous anesthesia device and its intraoral application

Figure 3: Needle-free anesthesia device and its intraoral application

methods such as the use of computer-controlled anesthesia delivery systems, modern devices, and new NFA systems have been investigated to reduce anesthesia-induced pain.[22,23] However, according to our knowledge, no study has evaluated the effects of IOA and NFA methods on patients' pain levels. Therefore, this study was designed and conducted to eliminate this research gap and to compare two different advanced dental anesthesia devices.

In this study, the cross-over design was preferred as it eliminates subject variability and allows greater biological homogeneity.[13] The reason for choosing children aged 8–10 years was that there are studies[18,22,23] reporting that the scales used herein are reasonable and reliable for children in this age group.[17,24,25] In addition, the tooth extraction treatment was chosen in this study because of it was most painful procedure for children.[26,27] Also, patients who had previous tooth extraction experience were not included in the study

Table 3: Time-dependent changes in pulse rate values for two different anesthesia type

Anesthesia Type	Puls rate 15 min before local anesthesia Median (min-max)	Puls rate During topical anesthesia Median (min-max)	Puls rate During local anesthesia Median (min-max)	Puls rate During extraction Median (min-max)	Puls rate 15 min after extraction Median (min-max)	*P*
Intraosseous	107 (87-144)	99.4 (71.5-133.1)	[b]101.15 (80.3-142.4)	99.05 (80.8-205.4)	[a]96 (80-130)	[a-b]*P*=0.002
Needle-free	[g]106 (89-134)	[j]109 (84.5-137.8)	[k]109.75 (80.8-129)	[h]96.85 (76.3-130.3)	[f]97.5 (69-112)	[f-g]*P*=0.002
						[h-j]*P*=0.002
						[f-j]*P*=0.002
						[h-k]*P*=0.002
						[f-k]*P*=0.001

*$P<0.01$ Friedman Wilcoxon signed ranks test, Bonferroni Correction

Table 4: Time-dependent changes in opiorphine values

Anesthesia Type	Opiorphin value 15 min before local anesthesia Median (min-max)	Opiorphin value 5 min after local anesthesia Median (min-max)	Opiorphin value 10 min after local anesthesia Median (min-max)	*P*
Intraosseous	17.85 (7.4-36.50)	15.10 (3-40)	19.05 (7.6-39.7)	
Needle-free	[d]23.1 (5.1-42.6)	[c]15.7 (2.7-28.8)	[e]16.55 (4.4-34)	[c-d]*P*=0.004
				[e-d]*P*=0.001

*$P<0.01$ Friedman Wilcoxon signed ranks test, Bonferroni Correction

because of the thought that experience with extraction treatment might change the pain and anxiety levels of the study.

WB, which was developed for the subjective assessment of pain, is an easy-to-use scale with adequate psychometric properties.[18] FLACC, one of the scales used in pain measurement, has been shown to have excellent validity and reliability for the objective assessment of pain in young or cognitively sound children.[28] In this study, WB and FLACC were used to evaluate children's pain behaviors both subjectively and objectively, taking advantage of both these scales. The general anxiety level of the individuals may affect the specific anxiety level related to the procedure.[14] Baygin *et al*.[14] evaluated the relationship between pre-procedural anxiety level and perceived pain level during the procedure in children undergoing tooth extraction and reported that the measured anxiety levels were correlated with each other.[14] In this study, SSAS-SAAS was used to determine state and trait anxiety levels of the patients when they came to the clinic. While the trait anxiety subscale scores of the patients included in the study did not change due to the cross-over study design, the absence of a statistically significant difference between the state anxiety subscale scores between sessions ($p = 0.636$; $P > 0.05$) suggested that the initial anxiety levels of the patients were similar. This outcome may have simplified to compare the anesthesia methods during the study period.

In addition to the pain and anxiety scales used in the study, PR[1,29] and SOL, which are physiological and biological markers[27] that indirectly measure pain and anxiety,[15,30] were used to obtain measurements independent of observer bias or subjective reporting of the patient.[1] Similarly, there are studies in the literature that have used PR[1,27] and SOL[15,16,30] to analyze pain and anxiety.

The hypothesis of the study that there would be no difference in felt pain during local anesthesia between IOA and NFA systems is partially accepted. According to increases in FLACC scores during local and topical anesthesia, IOA and NFA systems produced pain during local and topical anesthesia, respectively. However, the increase in FLACC during local and topical anesthesia with IOA and NFA systems may also have occurred owing to the fear of injection.[26] Although it was not statistically significant, two methods showed similar patterns of change according to the Frankl, WB and PRs.

According to our knowledge as there is no study in the literature that compares IOA and NFA systems, it may not be appropriate to compare the results of this study entirely. In general, studies in the literature have compared traditional injection and CCLAD, they report that CCLAD to be more advantageous.[2,31,32] However, there are also studies that did not find a statistical difference between the two injection methods.[17,24,33]

IOA has high efficacy rates, but it is rarely used in young patients.[34] In previous studies conducted on adults that compared IOA with conventional syringes and computerized devices, pain ratings were found to be higher in the early stages of the traditional procedure than in the computerized procedure.[34] Pain due to

Table 5: Time-dependent changes in Wong Baker scores for two different anesthesia type

Anesthesia Type	WB score 15 min before local anesthesia (0/2/4/6/8/10)			WB score After local anesthesia (0/2/4/6/8/10)			WB score Right after extraction (0/2/4/6/8/10)						WB score 15 min after extraction (0/2/4/6/8/10)						*P*
Intraosseous	*n* (%)			*n* (%)			*n* (%)						*n* (%)						
	0	2	4	0	2	4	10	0	2	4	6	8	0	2	4	6			
	17 (85)	1 (5)	2 (10)	8 (40)	8 (40)	3 (15)	1 (5)	1 (5)	8 (40)	7 (35)	3 (15)	1 (5)	8 (40)	6 (30)	5 (25)	1 (5)			
	Median (min-max)			Median (min-max)			Median (min-max)						Median (min-max)						[b-a]*P*<0.001
	[a]0 (0-4)			2 (0-10)			[b]4 (0-8)						2 (0-6)						
Needle-free	*n* (%)			*n* (%)			*n* (%)						*n* (%)						[c-d]*P*<0.001
	0	2	0	2		10	0	2	4	6	10	0	2	4	6				[c-d]*P*=0.004
	18 (90)	2 (10)	10 (50)	9 (45)		1 (5)	2 (10)	9 (45)	7 (35)	1 (5)	1 (5)	8 (40)	8 (40)	3 (15)	1 (5)				[c-f]*P*=0.002
	Median (min-max)			Median (min-max)			Median (min-max)						Median (min-max)						
	[d]0 (0-2)			[f]1 (0-10)			[c]2 (0-10)						[e]2 (0-6)						

*P<0.01 Friedman Wilcoxon signed ranks test, Bonferroni Correction

osseous perforation was mild to moderate in 8–78% and severe in 0–15% of patients.[34,35] In a study by Sixou *et al*.,[35] in which they compared IOA and conventional anesthesia, they noted symptoms of pain/discomfort during mucosal anesthesia and bone perforation, but these findings were not associated with high pain scores. The findings of pain/discomfort during IOA in patients can be considered as a result similar to the patient's feeling of pain during local anesthesia in this study. Because of the device used in the study by Sixou *et al*.[35] was an advanced model of SleeperOne™, it can be assumed that their results are not entirely comparable with the results of this study.

A study by Versloot *et al*.[36] found that using CCLAD (Wand) did not provide any benefit compared to traditional injection as it creates additional discomfort for the child owing to the long injection time in extremely anxious children. Wand is one of the CCLAD similar to SleeperOne™.[4] Nieuwenhuizen *et al*.[4] compared Wand and SleeperOne™ in their study. They found no significant difference in pain between two devices but the duration of anaesthesia injection for SleeperOne™ was shorter than that for Wand. Although no measurements were made in this study, it can be thought that the longer duration of anesthesia injection in the SleeperOne™ injection method[37] may have been affected the patient's feeling of pain during local anesthesia.

In this study, the statistically significant decrease in the SOL for the NFA system, both 5 min and 10 min after anesthesia, was accepted as important biological data showing the effectiveness of anesthesia. Similar results were obtained in a study by Parida *et al*.[15] evaluating the relationship between SOL and the use of different local anesthetic techniques. They found that SOL increased, although not statistically significantly, during anesthesia techniques that cause more pain compared to other techniques. In a study by Ozdogan *et al*.[30] evaluating toothache due to endodontic dental diseases and SOL concentrations, it was reported that SOL increased significantly in toothache due to inflammation and a strong correlation was observed between the reported pain level and SOL. The significant decrease in the SOL in this study can be explained that local anesthetics control pain or the element of psychological relief after the onset of lethargy is involved.[15]

In the literature, in studies where NFA method was evaluated, high patient and operator acceptance has been reported.[38,39] There is one study in the literature evaluating the Comfort-In™ system also the study in question used injection for topical anesthesia. In the study, Yıldırım *et al*.[22] reported that the NFA system significantly

Table 6: Time-dependent changes in FLACC scores for two different anesthesia type

Anesthesia Type	FLACC score 15 min before local anesthesia (0-10)							FLACC score During topical anesthesia (0-10)							FLACC score During local anesthesia (0-10)						
Intraosseous	*n* (%)							*n* (%)							*n* (%)						
	0	1						0	1	2	3				0	1	3	4	6		
	17 (85)	3 (15)						13 (65)	4 (20)	1 (5)	2 (10)				8 (40)	4 (20)	3 (15)	4 (20)	1 (5)		
	Median (min-max) [b]0 (0-1)							Median (min-max) 0 (0-3)							Median (min-max) [a]1 (0-6)						
Needle-free	*n* (%)							*n* (%)							*n* (%)						
	0	1	2					0	1	2					0	1	2				
	15 (75)	4 (20)	1 (5)					4 (20)	8 (40)	8 (40)					6 (30)	12 (60)	2 (10)				
	Median (min-max) [f]0 (0-2)							Median (min-max) [e]1 (0-2)							Median (min-max) [j]1 (0-2)						

Anesthesia Type	FLACC score During extraction (0-10)							FLACC score 15 min after extraction (0-10)	*P*
Intraosseous	*n* (%)							*n*(%)	[a-b]*P*=0.004
	0	2	3	4	5	6		0	[c-b]*P*=0.001
	7 (35)	3 (15)	1 (5)	5 (25)	3 (15)	1 (5)		20 (100)	[d-a]*P*=0.002
	Median (min-max) [c]2.5 (0-6)							Median (min-max) [d]0 (0-0)	[d-c]*P*=0.001
Needle-free	*n* (%)							*n* (%)	[e-f]*P*=0.001
	0	1	2	3	4	5	6	0	[g-f]*P*=0.004
	6 (30)	6 (30)	2 (10)	3 (15)	1 (5)	1 (5)	1 (5)	20 (100)	[h-e]*P*<0.001
	Median (min-max) [g]1 (0-6)							Median (min-max) [h]0 (0-0)	[h-j]*P*<0.001
									[h-g]*P*=0.001

*$P<0.01$ Friedman Wilcoxon signed ranks test, Bonferroni Correction

Table 7: Time-dependent changes in Frankl scores for two different anesthesia type

Anesthesia Type	FRANKL score 15 min before local anesthesia (1-4)		FRANKL score During topical anesthesia (1-4)		FRANKL score During local anesthesia (1-4)		FRANKL score During extraction (1-4)		FRANKL score 15 min after extraction (1-4)		*P*
	n (%)		*n* (%)		*n* (%)		*n* (%)		*n* (%)		
Intraosseous	3	4	3	4	3	4	2	4	4		[a-b]*P*=0.004
	4 (20)	16 (80)	4 (20)	16 (80)	9 (45)	11 (55)	1 (5)	12 (60)	7 (35)	20 (100)	[c-a]*P*<0.001
	Median (min-max)		Median (min-max)		Median (min-max)		Median (min-max)		Median (min-max)		
	4 (3-4)		[b]4 (3-4)		[e]4 (3-4)		[a]3 (2-4)		[c]4 (4-4)		
Needle-free	*n* (%)		*n* (%)		*n* (%)		*n* (%)		*n* (%)		[d-f]*P*=0.004
	3	4	2	3	4	2	3	4	4		[d-g]*P*=0.002
	4 (20)	16 (80)	1 (5)	8 (40)	11 (55)	2 (10)	4 (20)	14 (70)	1 (5)	9 (45)	10 (50)	20 (100)	
	Median (min-max)		Median (min-max)		Median (min-max)		Median (min-max)		Median (min-max)		
	4 (3-4)		[f]4 (2-4)		4 (2-4)		[g]3.5 (2-4)		[d]4 (4-4)		

*p<0.01 Friedman Wilcoxon signed ranks test, Bonferroni Correction

decreased the pain scores compared to traditional topical anesthesia methods, but did not significantly affect patient preferences. In our study, for the NFA system, statistically significant increases in scores of the FLACC suggested that the patients were more incompliant and felt more pain during topical anesthesia. This situation can be supported that NFA requires the use of pressure to rapidly apply the anesthetic solution to the tissue, indicated by Yıldırım *et al*.[22] Hence, a sharp popping sound and a feeling of pressure are experienced during the administration of the anesthetic solution. Yıldırım *et al*.[22] also stated that the negative relationship they reported in their study may be related to the discomfort that younger children felt from the pressure sensation from the Comfort-In™ injection system, and they may have interpreted this as a higher level of pain.

Further, for NFA system, according to the WB scores showed that the patients felt pain during tooth extraction. However, in contrast to WB scores, PRs have decreased during tooth extraction statistically significant for NFA method. In addition, the decrease in SOL, which shows the effectiveness of anesthesia, was statistically significant in NFA method. Considering these findings, it can be considered valid because of that physiological and biological marker such as SOL results as their measurements are not subject to observer bias or not based on the subjective reporting of the patient.[1]

The limitations of this study are that the injection systems used in the study were not compared in terms of post-operative discomfort and patient preferences, and that a conventional dental injection group was not established as a control group. In future studies, these limitations should be addressed with larger patient populations, mostly on the basis of biological and physiological markers.

Conclusion

1. The results showed that IOA and NFA systems are similar effect of pain during local anesthesia.
2. Further, decreases the SOL, which is a robust biological marker, suggested that the NFA system may have provided higher anesthetic efficiency.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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