Original Article

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Effect of the new needle-free injection system on pain perception and dental anxiety during anesthesia: randomized controlled split-mouth study

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Backgrounds: Pain management is one of the most important factors affecting the success of pediatric dentistry. Therefore, new needle- and pain-free local anesthesia techniques have been developed in parallel with technological advancements. The purpose of this study is to compare the pain perception and dental anxiety levels associated with a needle-free injection system (Comfort-in™) and the classic needle method during treatment-required infiltration anesthesia in children.

Methods: This randomized controlled crossover split-mouth clinical study included 94 children who required dental treatment with local anesthesia using a dental needle or needle-free injection system for the bilateral primary molars. The Wong-Baker Scale (WBS) was used to measure pain perception at different times, and the Modified Child Dental Anxiety Scale (MCDAS) was used to measure the anxiety level of the child. A statistical software package was used to process the data. Statistical significance was set at $P < 0.05$.

Results: There was no significant difference between the needle-free injection system and dental needle method during the induction stage for filling and pulpotomy ($P > 0.05$). "Pain on postoperative 1st day" was similar in both types of anesthesia ($P = 0.750$).

Conclusions: The needle-free injection system was as effective as the dental needle method. The Comfort-in™ system was an acceptable alternative for patients during the postoperative period. Understanding how pain management may be provided during local anesthesia administration and a child's fear and anxiety regarding the dentist may lead to better dental compliance.

Keywords: Children; Dental Anxiety; Jet Injection; Local Anesthesia; Pain Assessment.

INTRODUCTION

Pain management is one of the most important factors affecting treatment success in pediatric dentistry. Painful dental procedures cause fear, and anxiety increases the intensity of the perceived pain. A decrease in pain sensation during dental procedures may develop trust by increasing the relationship between the patient and dentist, providing relief from fear and anxiety, and allowing the patient to exhibit positive attitudes towards dental interventions [1].

Administration of local anesthesia with a dental needle can cause an improvement in dental anxiety and fear among children. Therefore, needle-and pain-free local anesthesia techniques have been developed. Along with

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the development of needle-free jet systems, the patient's needle phobia and dental anxiety that may occur as a result of injection are prevented.

Comfort-in™ system, which is one of the new dental devices developed to administer local anesthesia by using a needle-free jet system. The Comfort-in™ system is a patented "liquid jet" system for injecting anesthetic solutions quickly (in one-third of a second), at a high pressure. Few studies have investigated the effectiveness of the Comfort-in™ system on primary molars in children.

In this study, we aimed to compare the intensity of pain perceived after the infiltration anesthesia was administered with Comfort-in™ System and dental needle method in dental cases requiring anesthesia. Moreover, we investigated whether the colors chosen by the children to express their pain status was a predictive factor in determining the intensity of the pain they felt during treatment.

METHODS

This study was approved by the Clinical Research Ethics Committee of the Medicine University of Gaziosmanpasa University (No. 18-KAEK-089). All clinical trials involving the assignment of patients to treatment groups were registered before patient enrollment. Written consent was obtained from all the parents. The study protocol was registered at ClinicalTrials.gov (NCT04682080).

This was a randomized controlled, crossover, split-mouth clinical study conducted in children aged 4 to 10 years. The minimum required sample size was determined to be 94 children (188 bilateral primary molars) with a study power of 80%, a margin of error of 5%, and an effect size of 0.275 (G*Power Ver:3.1.9). A total of 120 children (240 bilateral primary molars) were included in the study to compensate for possible data loss due to various reasons. Fig. 1 shows the CONSORT flow diagram of this trial.

Children who were healthy (ASA I), cooperative, and required dental treatment of bilateral primary molars were included. Patients who had any systemic disease, allergy, disability, or syndrome; those with insufficient mouth opening; and those whose parents did not agree to their participation in the study were excluded.

1. Randomization and masking

Sealed opaque envelopes were drawn to ensure randomization during selection of the first treatment side. In this study, all anesthesia procedures and dental treatments were performed by the same dentist (MB) with 2 years of experience using the Comfort-in™ system (MK Global CO., Gangseo-gu Busan, Rep. of Korea). All dental equipment were introduced using the "tell-show-do" technique.

Vemcaine spray (Vemcaine, Turkey) was used as the topical anesthetic agent and was applied to the relevant area for approximately 1 min using a cotton applicator.

2. Dental needle group

Initially, the children were informed about anesthesia; “We need to put your tooth to sleep so that it doesn't hurt while washing the tooth. I'm going to use a minty sleeping water to numb your teeth. You may feel like a tiny ant is biting.”

After topical anesthesia was achieved, infiltration anesthesia was induced using a disposable 2 ml plastic dental syringe (Genject, Turkey) with a 50 mm long and 0.40 mm thick 27-gauge needle while keeping the tissues taut. Ultracaine DS Forte™, the active ingredient of which is 4% articaine and 1/100000 epinephrine, was used as the anesthetic solution in both types of anesthesia. The anesthetic solution (0.3 mL) was stored for approximately 20 seconds, and care was taken to avoid bubble formation in the tissues during injection.

3. Needle-free group (Comfort-in™ system)

In the second appointment of patients, after topical anesthesia, the children were informed that another tool would be used, this time to put their teeth to sleep, this

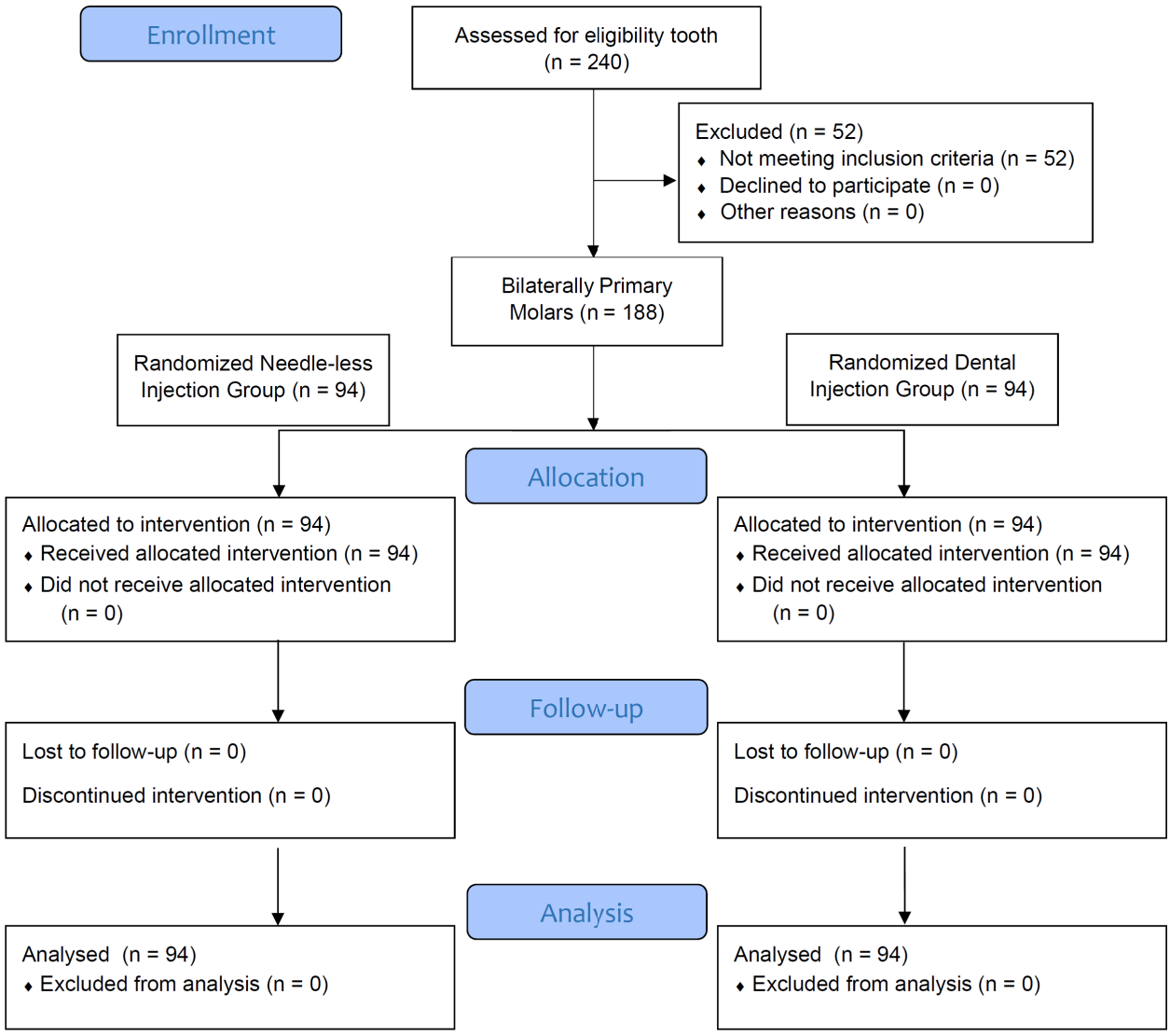

Fig. 1. The CONSORT flow diagram of the randomized clinical trial. n, number.

device would make a "pop" sound, and they would feel as if their gum were punched. A dose of 0.3 ml (3 units) of Ultracaine DS Forte™ was injected with a needle-free injection system, which enabled the anesthetic solution to be delivered with a pressure of 2000 psi through a 0.15 mm hole in less than 2 seconds.

4. Treatment protocol

Infiltration anesthesia was administered using the needle-free injection system or the dental needle method. Subsequently, filling or pulpotomy was performed. The pain perception and anxiety levels of the patients were determined using scales.

The facial expressions rating (Wong Baker) scale (WBS) consists of 6 facial expressions that are rated from 0 to 10 according to the intensity of pain. The children were asked to choose the face they thought represented their pain status. The pain intensity represented “Injection Pain.”

The dentist waited for 5 min, and during the cavity preparation process in filling and during pulp extirpation in pulpotomy, the children were asked to choose the face from the scales based on whether they perceived pain. The selected pain intensity represented “Treatment Pain.”

At end of dental treatment, the selected pain intensity represented "Post Treatment Pain."

The parents of patients were given a copy of the Wong-Baker Scale and instructed to ask about their child's pain at the anesthesia site. The children were asked to choose the expression they thought was closest to their pain status on the first postoperative day. The selected pain intensity represented "1st Day Post Treatment" values of the patients. The dentist (MB) reached the patients to record the pain values.

At the end of the second session, the patients were asked which method they preferred for anesthesia, and their answers were recorded.

The Modified Children's Dental Anxiety Scale (MCDAS), which assesses dental anxiety related to specific dental procedures, includes eight items [2].

5. Statistical analysis

Continuous variables are presented as mean ± standard deviation and categorical variables are presented as n (%). The Significance Test of the Difference Between Two Means and One-Way Analysis of Variance (ANOVA) was used to compare the mean values of the quantitative variables between groups. Cross-tables and chi-squared tests were used to evaluate whether there was a relationship between the qualitative variables. Repeated-measures ANOVA was used for analyzing repeated measurements. P values smaller than 0.05 were considered statistically significant. A statistical software package (IBM SPSS Statistics 19, SPSS Inc., IBM Co., Somers, NY) was used for the calculations.

RESULTS

In our study, a total of 94 patients, consisting of 39 girls and 55 boys, in the 4-10 (6.96 ± 1.43) age group, were evaluated using the split-mouth design (Table 1). All patients were ASA I according to the ASA classification.

1. Assessment of pain intensity

The arithmetic mean and standard deviation of the pain values according to anesthesia type are presented in Table 2. There was no difference between the needle-free

Table 1. Patient and teeth distribution according to the evaluation parameters

Variables		n	%
Gender	Girl	39	41.5
	Boy	55	58.5
Type of injection	Comfort-in system	94	50.0
	Dental needle method	94	50.0
Frankl behavioral scale	Positive	18	19.1
	Definitely positive	76	80.9
Number of teeth injected with anesthesia	54	17	9.0
	55	29	15.4
	64	17	9.0
	65	29	15.4
	74	22	11.7
	75	26	13.8
	84	22	11.7
	85	26	13.8
Dental treatment type	Filling	102	54.3
	Pulpotomy	86	45.7
Jaw	Maxilla	92	48.9
	Mandible	96	51.1
MCDAS	Low anxiety (0-25)	172	91.5
	High anxiety (26-40)	16	8.5

MCDAS, modified Children's Dental Anxiety Scale; n, number.

Table 2. Pain comparison of two anesthesia types used in the two dental procedures

	Filling			Pulpotomy			Total		
	Comfort-in Mean ± SD	Dental needle Mean ± SD	P_2	Comfort-in Mean ± SD	Dental needle Mean ± SD	P_2	Comfort-in Mean ± SD	Dental needle Mean ± SD	P_2
Injection	4.00 ± 2.56 (a)	4.51 ± 3.12 (a)	0.383	4.28 ± 3.04 (a)	3.30 ± 3.05 (a)	0.126	4.128 ± 2.779 (a)	3.957 ± 3.131 (a)	0.419
Treatment	2.94 ± 2.81 (a)	2.55 ± 2.34 (b)	0.438	2.56 ± 2.44 (b)	2.14 ± 2.56 (a)	0.447	2.766 ± 2.641 (a)	2.362 ± 2.436 (a)	0.305
Post-treatment	1.29 ± 1.83 (b)	1.22 ± 1.84 (c)	0.830	1.30 ± 1.95 (c)	0.74 ± 1.75 (b)	0.161	1.298 ± 1.871	1.000 ± 1.802	0.166
P_1	< 0.001	< 0.001		< 0.001	< 0.001		< 0.001	< 0.001	

Three-way analysis of variance was used for repeated measurements. (abc): comparison between pain. P_1, Intra-group comparison; P_2, Intergroup comparison; SD, standard deviation.

Table 3. Jaw pain comparison between anesthesia and within groups

Jaws		Comfort-in system	Dental needle method	P
		Mean ± SD	Mean ± SD	
Maxilla	Injection	3.957 ± 2.616	3.957 ± 3.252	0.593
	Treatment	2.913 ± 2.623	2.087 ± 2.346	0.122
	Post treatment	1.304 ± 1.987	1.044 ± 1.873	0.422
	P	< 0.001	< 0.001	
Mandible	Injection	4.292 ± 2.946	3.958 ± 3.045	0.525
	Treatment	2.625 ± 2.679	2.625 ± 2.515	0.899
	Post treatment	1.292 ± 1.774	0.958 ± 1.750	0.245
	P	< 0.001	< 0.001	

SD, standard deviation.

Table 4. Pain degree comparison according to MCDAS between low and high anxiety groups

	Total (n = 188)	MCDAS		F	P_1
		Low anxiety (0-25) (n = 172)	High anxiety (26-40) (n = 16)		
		Mean ± SD	Mean ± SD		
Injection	4.04 ± 2.95 (a)	3.84 ± 2.76 (a)	6.25 ± 4.06 (a)	10.250	0.002
Treatment	2.56 ± 2.54 (b)	2.38 ± 2.41 (b)	4.5 ± 3.14 (a)	10.672	0.001
Post treatment	1.15 ± 1.84 (c)	1.06 ± 1.67 (c)	2.13 ± 3.05 (b)	5.038	0.026
1st day post treatment	0.61 ± 1.37 (d)	0.59 ± 1.3 (d)	0.75 ± 2.05 (c)	0.191	0.663
F; P_2	83.566; < 0.001	74.463; < 0.001	22.385; < 0.001		

(abcd): A common letter as a colon indicates statistical insignificance. MCDAS, modified Children's Dental Anxiety Scale; n, number; P_1, comparison between groups (significance test of the difference between two means); P_2, comparison within groups (repeated measures analysis of variance); SD, standard deviation.

injection system and the dental needle method during injection, treatment, and post-treatment in the filling and pulpotomy treatment. The "1st day post treatment pain" value was similar for both the needle-free injection system and the dental needle method (P = 0.750). There was no significant difference between the maxilla and mandible in terms of the intensity of injection, treatment, and post-treatment (P > 0.050) (Table 3).

2. Assessment of anxiety levels

Children with high levels of anxiety had higher pain scores than those with low anxiety during injection, treatment, and post treatment. The mean values of injection, treatment, and post treatment pains differed, the "1st day post treatment pain" did not different according to MCDAS score categories (Table 4).

3. Assessment of anesthesia preferences

While 41 of the 94 patients (43.62%) preferred the needle-free injection system (Comfort-in™), 53 patients (56.38%) preferred the dental needle method.

DISCUSSION

Our study is one of the few studies that had a split-mouth design comparing the effectiveness of infiltration anesthesia delivered using the dental needle method and Comfort-in™ system in primary teeth.

Previous studies have compared various types of jet injection systems and infiltration anesthesia to the dental needle method. Makade et al. [3] and Ocak et al. [4] reported that the value of injection pain was higher in infiltration anesthesia induced with the dental needle method than in anesthesia induced with a jet injection system. In a study comparing injection pain, infiltration anesthesia using the dental needle method, and a jet injection system (Injex™), it was found that a higher level

of pain occurred with the jet injection system [5]. Oliveira et al. [6] compared the needle-free injection system (Comfort-in™) and infiltration anesthesia with the dental needle method in adults and reported that the pain values of the two types of injections were similar. In our study, although the value of injection pain with the Comfort-in™ system was higher than that with infiltration anesthesia using the dental needle method, the difference was not significant.

There are different opinions regarding the success of the jet injection system in providing pulpal anesthesia. Munshi et al. [7] reported that a jet injection system (Madajet™) could be used for all clinical procedures involving primary teeth. There are studies showing that the jet injection system Injex™ cannot provide sufficient pulpal anesthesia [5,8]. Oliveira et al. [6] observed that the basal electrical stimulation thresholds of teeth under the dental needle method anesthesia and needle-free injection system (Comfort-in™) anesthesia were similar.

According to our results, there was no significant efficacy differences between the two types of injections, and no additional anesthesia was required in the patients. The measurement of similar pain values in both filling and pulpotomy suggested that an adequate depth of anesthesia was achieved with the Comfort-in™ system. The pain values in the mandible and maxilla were significantly similar showing that effective anesthesia was achieved as the anesthetic solution spread through the tissues by diffusion with both the local dental needle method and the Comfort-in™ system anesthesia in the mandible in children as a result of the mandible not having a cortical structure as dense as that in adults.

Yıldırım et al. [9] and Ocak et al. [4] reported that younger children may interpret the intensity of the pain they perceive as higher than the actual intensity due to the noise and sensation of pressure created by a jet injection system. In our study, we believe that the sound produced by Comfort-in™ system and the feeling of pressure it created, negatively affected the children's perception of pain and anesthesia method preferences.

In our study, the finding that the post treatment pain value was similar in both types of anesthesia may be attributed to the similar duration of action of both methods. However, post treatment pain may have varied depending on the type of treatment performed, tissue damage, or the interpretation of numbness as pain, caused by the ongoing effect of the anesthetic effect. The patients' first post-treatment day pain with the dental needle method and Comfort-in™ system anesthesia were similar. Although Comfort-in™ system causes bruising and hemorrhage in the tissue caused by the high-pressure during administration, we consider that the levels of bruising and hemorrhage are acceptable for children in the postoperative period. Previous studies reported that the Madajet™ and Injex™ systems caused more discomfort in the postoperative period than the dental needle method [3,5].

In our study, 56.38% of the children preferred infiltration anesthesia using the dental needle method, while 43.62% preferred Comfort-in™ system. In previous studies conducted using different jet injection systems, patients preferred infiltration anesthesia with the dental needle method [5,8]. In other studies, it was reported that anesthesia administered using a jet injection system was preferred [3,7,10]. It was observed that the preferences of the children were not concentrated on a single type of anesthesia, but varied according to the individual. In our study, we consider that the children's preference for infiltration anesthesia with the dental needle method to the Comfort-in™ system was caused by the noise of the Comfort-in™ device during injection and the feeling of pressure it produced among the patients.

Dental anxiety is affected by age, sex, and socio-demographic factors. Dental anxiety occurs at a young age and but decreases with age [11]. Similar to the literature, the anxiety levels of the patients included in our study were higher among those of higher ages. Other studies have reported that dental anxiety is not related to sex [12-14]. In our study, boys had higher anxiety levels than girls, according to their MCDAS scores, but the difference was not significant.

It has been reported that injection pain varies according

to the level of anxiety, and there is a positive correlation between anxiety levels in children and their perceived pain levels [15]. In our study, injection, treatment, and post treatment pain levels measured in patients with low anxiety were significantly lower than those in patients with high anxiety.

The limitations of this study were the impossibility of blinding the methods used while administering the anesthetic solution to the participants, no distinction based on the children's characteristics, and the exclusion of patients with negative attitudes towards dentists.

In summary the Comfort-in™ system can be used as an alternative to dental needle method to reduce injection pain in children. There was a positive correlation between children's anxiety levels and the intensity of pain they perceived.

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AUTHOR CONTRIBUTIONS

Melek Belevcikli: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing - original draft, Writing - review & editing
Halenur Altan: Conceptualization, Investigation, Methodology, Project administration, Writing - original draft, Writing - review & editing
Osman Demir: Data curation, Formal analysis, Methodology, Software, Validation, Writing - original draft

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REFERENCES

1. Holmes RD, Girdler NM. A study to assess the validity of clinical judgement in determining paediatric dental anxiety and related outcomes of management. Int J Paediatr Dent 2005; 15: 169-76.
2. Wong HM, Humphris GM, Lee GT. Preliminary validation and reliability of the modified child dental anxiety scale. Psychol Rep 1998; 83: 1179-86.
3. Makade CS, Shenoi PR, Gunwal MK. Comparison of acceptance, preference and efficacy between pressure anesthesia and classical needle infiltration anesthesia for dental restorative procedures in adult patients. J Conserv Dent 2014; 17: 169-74.
4. Ocak H, Akkoyun EF, Çolpak HA, Demetoğlu U, Yücesoy T, Kılıç E, et al. Is the jet injection effective for teeth extraction? J Stomatol Oral Maxillofac Surg 2020; 121: 19-24.
5. Arapostathis KN, Dabarakis NN, Coolidge T, Tsirlis A, Kotsanos N. Comparison of acceptance, preference, and efficacy between jet injection INJEX and local infiltration anesthesia in 6 to 11 year old dental patients. Anesth Prog 2010; 57: 3-12.
6. Oliveira ACA, Amorim KS, Nascimento Júnior EMD, Duarte ACB, Groppo FC, Takeshita WM, et al. Assessment of anesthetic properties and pain during needleless jet injection anesthesia: a randomized clinical trial. J Appl Oral Sci 2019; 27.
7. Munshi AK, Hegde A, Bashir N. Clinical evaluation of the efficacy of anesthesia and patient preference using the needle-less jet syringe in pediatric dental practice. J Clin Pediatr Dent 2001; 25: 131-6.
8. Dabarakis NN, Alexander V, Tsirlis AT, Parissis NA, Nikolaos M. Needle-less local anesthesia: clinical evaluation of the effectiveness of the jet anesthesia Injex in local anesthesia in dentistry. Quintessence Int 2007; 38: E572-6.
9. Yıldırım S, Tokuç M, Aydın MN. The effect of pre-anesthesia with a needle-free system versus topical anesthesia on injection pain of the inferior alveolar nerve block: a randomized clinical trial. Clin Oral Investig 2020; 24: 4355-61.
10. Saravia ME, Bush JP. The needleless syringe: efficacy of anesthesia and patient preference in child dental patients. J Clin Pediatr Dent 1991; 15: 109-12.
11. Folayan MO, Idehen EE, Ufomata D. The effect of sociodemographic factors on dental anxiety in children seen

in a suburban Nigerian hospital. Int J Paediatr Dent 2003; 13: 20-6.
12. Wogelius P, Poulsen S, Sørensen HT. Prevalence of dental anxiety and behavior management problems among six to eight years old Danish children. Acta Odontol Scand 2003; 61: 178-83.
13. Akbay Oba A, Dülgergil CT, Sönmez IS. Prevalence of dental anxiety in 7-to 11-year-old children and its relationship to dental caries. Med Princ Pract 2009; 18: 453-7.
14. ten Berge M, Veerkamp JS, Hoogstraten J, Prins PJ. Childhood dental fear in the Netherlands: prevalence and normative data. Community Dent Oral Epidemiol 2002; 30: 101-7.
15. Arntz A, van Eck M, Heijmans M. Predictions of dental pain: the fear of any expected evil, is worse than the evil itself. Behav Res Ther 1990; 28: 29-41.