

# Postoperative Pain After the use of Sodium Hypochlorite gel and Solution Forms: A Randomized Clinical Study

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# ABSTRACT

**Objective:** The present study aimed to compare the effect of sodium hypochlorite (NaOCI) gel and solution forms on postoperative pain level.

**Methods:** Fifty-two patients were divided into two groups according to the root canal irrigation solution. In the NaOCI solution group, the root canals were irrigated with 2 mL of 5.25% NaOCI between each pecking motion. In the NaOCI gel group, 5.25% NaOCI gel was used according to the manufacturer's instructions. The root canal treatments were completed and the participants were given instructions to record postoperative pain levels on 24, 48, and 72 hours and 1 week after treatment using VAS.

**Results:** Intergroup analyses revealed that the NaOCI gel group resulted in significantly less postoperative pain than the NaOCI solution group on day 1.

**Conclusion:** It can be concluded that using NaOCI gel during root canal preparation results in less postoperative on day 1 when compared with the NaOCI solution.

Keywords: NaOCl gel, NaOCl solution, postoperative pain

# HIGHLIGHTS

- This the first study comparing NaOCI gel and solution forms in terms of postoperative pain
- It has been revealed that NaOCI gel during root canal preparation results in less postoperative on day 1.
- This is the first study revealing the beneficial effect of NaOCI gel in lowering postoperative pain

### INTRODUCTION

Irrigation of the root canals is an essential part of endodontic treatment because the complete elimination of microorganisms from the root canal system is impossible only with instrumentation (1). Sodium hypochlorite (NaOCI) is the most common irrigant used in endodontics because of its physicochemical and antibacterial properties (2), and its unique ability to dissolve necrotic tissue

remnants (3). However, accidental injection of the solution into the periapical tissues can result in some serious complications such as; hemolysis, ulceration, allergic reaction and tissue necrosis (4). To avoid complications associated with extrusion of the solution, gel form of the NaOCl solution can be proposed. Previously, it has been reported that the gel and solution both did not interfere in the EDTA solution's action (5). Additionally, Garcia et al. (6) have evaluated the effect of several forms of NaOCl on the microhardness of root canal dentin and reported that the NaOCl gel and solution forms have a similar effect on dentinal microhardness. Moreover, the antibacterial effectiveness of NaOCl gel and solution forms were compared and it has been reported that the antibacterial efficacy of the NaOCl gel and solution forms were similar (7). However, the tissue dissolution capacity of the NaOCl solution was higher than the gel form (7).

Another complication is postoperative pain that occurs when the solution extruded into the periapical tissues (8). Several strategies have been recommended to reduce postoperative pain include medication (9), intracanal cryotherapy (10), low-level laser therapy (11), occlusal reduction (12), and glide-path application (13). However, to date, the effect of using NaOCI gel for root canal disinfection during root canal preparation on postoperative pain has not been studied. Thus, the present study aimed to compare the effect of NaOCI gel and solution forms on postoperative pain

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This work is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License. level. The null hypothesis was that there would be no difference between the NaOCI gel and solution groups in terms of postoperative pain.

# MATERIALS AND METHODS

The Ethical Committee of the Faculty of Dentistry, University of A approved the study protocol with a decision number of 2017-91. All the participants included in the study signed an informed consent form before undergoing the treatment. The sample size calculation, which was made by a program (GPower; Franz Faul, University of Kiel, Germany) according to the data obtained from a previous study (11), indicated that 18 patients were sufficient for per group with an error of alpha=0.05, effect size of 0.84 and power of 0.8. However, considering the possible loss of the participants and to increase the statistical power, 30 patients for each group were included. Randomisation of the participants was performed by using a web program (www.randomizer.org) and all the patients were blinded to the groups.

Healthy patients (American Society of Anesthesiology [ASA] I) having molar teeth diagnosed with a periapical diagnosis of symptomatic apical periodontitis and a pulpal diagnosis of symptomatic irreversible pulpitis without radiolucency and with a preoperative pain of more than 50 on 10 cm visual analog scale (VAS) were included to the study. Electric pulp tester (EPT) (Digitest, Parkell, Edgewood, NY, USA) and cold test (Roeko Endo Frost, Coltene, Langenau, Germany) were used to test the sensibility of the teeth. Also, a percussion test was performed using finger and end of an instrument. Exclusion criteria were as follows: teeth having previous root canal treatment, root fracture, swelling, pathological mobility, a pocket depth of more than 3 mm and patients who are older than 65 years old or younger than 18, and taking antibiotics or analgesic within one month prior to the study. Teeth having radiographic lesions were excluded. Only teeth having healthy or widened periodontal ligament were included.

All the teeth had been anaesthetised using 1.8 ml 4% articaine with 1:100.000 epinephrine (Ultracaine DS Forte; Aventis, Istanbul, Turkey) before the isolation of the teeth with rubber dam. For maxillary molars, local infiltration anaesthesia was performed and for mandibular molars, mandibular anaesthesia was performed. Access cavities were prepared and the coronal thirds of the root canals were instrumented using Reciproc R25 files (VDW GmbH, Munich, Germany). Following root canal irrigation with 2 mL of 5.25% NaOCI (Chloraxid, Cerkamed, Poland), the working lengths were determined using an apex locator (Raypex 6,VDW). Then, all the root canals were prepared using Reciproc instruments according to the manufacturer's instructions at full working length.

NaOCI solution group: During preparation, the root canals were irrigated with 2 mL of 5.25% NaOCI (Chloraxid, Cerkamed) between each three pecking motion.

NaOCl gel group: During preparation, 5.25% NaOCl gel (Chloraxid, Cerkamed) was used according to the manufacturer's instructions. The NaOCl gel was applied directly into the canal by using the applicator and root canal preparation was performed. The root canals were then flushed with 2 mL of saline. The amount of NaOCI gel applied into the root canal between each pecking motion was 2 mL. This procedure was repeated between each three pecking motion until the root canal preparation was completed.

The root canals were then irrigated with 6 mL of 17% EDTA for the final irrigation once the root canal preparation was completed. The root canals were dried with paper points and obturated with gutta-percha cones and sealer (Sealapex, Kerr Corporation, Orange, CA) using cold lateral condensation technique. Then the permanent restorations were performed with resin composite (3M ESPE, St Paul, MN). The participants were given instructions to record postoperative pain levels on 24, 48, and 72 hours and 1 week after treatment using VAS and analgesic taken on the questionnaire. In case of the patient was referred to an unscheduled appointment, it was also recorded.

# **Statistical analysis**

All the statistical analyses were conducted by using IBM<sup>®</sup> SPSS<sup>®</sup> Statistics 20 software (IBM SPSS Inc., Chicago, IL, USA) at a significance level of 5% (P=0.05). Since the data were not normally distributed, the Mann-Whitney U test was used to compare the pre- and postoperative pain values between the groups. Linear regression analyses were carried out to determine the confounding effects introduced by covariates (tooth number, gender, treatment group, age, analgesic intake, and preoperative pain level). Chi-square test was used to analyze nominal data (gender, analgesic intake, and tooth number).

# RESULTS

Five participants from the solution group and 4 participants from the gel group were lost during follow-up. Statistical analyses revealed that there was no significant difference between the groups in terms of demographic data (P>0.05) (age, gender, tooth number, and analgesic intake) (Table 1). The distribution of the teeth was as follows; first upper molars were 11 and 11, second upper molars 6 and 7, first lower molars were 7 and 6, and second lower molars were 1 and 2 for the solution and gel groups respectively.

**TABLE 1.** Distribution of patients according to age, gender, tooth number and analgesic intake

	NaOCI solution	NaOCI gel	P value
n	25	26	
Mean age	34.36±15.1	39.62±16.5	0.262
Gender			0.683
Female	12	11	
Male	13	15	
Tooth number			0.856
#2	3	5	
#3	5	3	
#14	6	8	
#15	3	2	
#19	4	2	
#30	3	4	
#31	1	2	
Analgesic intake	9	4	0.091

**TABLE 2.** Linear Regression findings for group, gender, age and tooth number on the dependent variable "postoperative pain level on day 1"

	В*	Standard Error	Beta	P value
Group	-13.193	5.225	-0.358	0.015
Gender	0.499	5.362	0.014	0.926
Age	0.098	0.151	-0.89	0.521
Preoperative pain level	-0.346	0.247	-0.202	0.168
Tooth number	-0.357	0.264	-0.191	0.183
Analgesic intake	-0.133	6.019	-0.003	0.983

**TABLE 3.** Pre and postoperative pain levels according to the groups

	NaOCI solution	NaOCI Gel	P value
Preoperative	74.0±10.5	76.12±11.2	0.492
1 <sup>st</sup> day	34.4±19.2	20.77±15.4	0.018
2 <sup>nd</sup> day	12.8±17.8	4.81±10	0.077
3 <sup>rd</sup> day	3.8±8.9	1.92±6.7	0.381
7 <sup>th</sup> day	0	0	-

Linear regression analyses showed that the postoperative pain level on the 1<sup>st</sup> day was only affected by the type of the NaOCI (P<0.05). Preoperative pain level, age, gender, tooth number, and analgesic intake did not affect the postoperative pain level on day 1 (P>0.05) (Table 2).

Intergroup analyses revealed that both groups were comparable with regard to preoperative pain levels (P>0.05). The Na-OCI gel group resulted in significantly less postoperative pain than the NaOCI solution group on day 1 (P<0.05). However, there was no statistically significant difference between the groups in terms of postoperative pain levels on the 2<sup>nd</sup>, 3<sup>rd</sup>, and 7<sup>th</sup> days (P>0.05) (Table 3).

# DISCUSSION

According to the result of the present study, it has been revealed that using NaOCI gel for root canal disinfection resulted in less postoperative pain on day 1 when compared with the NaOCI solution group. Thus, the null hypothesis that no differences existed between the NaOCI gel and solution groups in terms of postoperative pain was rejected. As it was previously mentioned, there is no study evaluating the effect of NaOCI gel on postoperative pain, therefore present results cannot be compared with previous studies.

Endodontic postoperative pain is affected by several factors such as preoperative pain level (14), the number of appointments (15), irrigation method (16), the method of the determination of the working length (17), type of the tooth (18), type of the instrument (19), movement kinematic of the instrument (20), extrusion of root canal filling material (21) and apically extruded debris (22). In the present study, all these factors were standardized except for the amount of apically extruded debris. Thus, the result of the present study can be explained by the difference in the amount of apically extruded debris between the groups. Because there could be a positive correlation between the amount of apically extruded debris and the risk of flare-ups (23). Similarly, Siqueira et al. (24) have stated that one of the principal causes of postoperative pain is apical extrusion of contaminated debris into the periapical tissues. Although the present study did not assess the amount of apically extruded debris, it has been mentioned that the risk of extrusion of NaOCI solution into periapical tissues can be reduced with the use of the gel form of the NaOCI (5). Therefore, it can be speculated that the amount of apically extruded debris was higher in the NaOCI solution group and this resulted in more postoperative pain in this group. Moreover, extrusion of the solution into the periapical area migth have been resulted in pain regardless of the amount of apically extruded debris. Since the NaOCI is cytotoxic (25), inflammatory reactions could be induced by the NaOCI solution in the periapical area (26) which resulted in more postoperative pain in the solution group.

Seltzer et al. (22) stated that the most common cause of postoperative pain is microbial injury, which is caused by microorganisms and their products, to the pulp or periradicular tissues which are induced (or) exacerbated during root canal treatment. Thus, another explanation of the present results could be that NaOCI gel exhibited better antibacterial activity than the NaOCl solution during the preparation of the root canals. In contrast, Zand et al. (27) have reported that the antibacterial efficacy of the NaOCI gel was less than that of the NaOCI solution. It is well known that the antibacterial efficacy of the NaOCI increases with its concentration (28). In contrast, previous studies demonstrated that the antimicrobial effectiveness of NaOCI is not affected by its concentration (29-31). However, further in-vivo studies evaluating the antibacterial efficacy of NaOCI gel and solution are needed to verify our explanations.

It was shown by Peters et al. (32) that the use of a gel during preparation negatively affects torque on NiTi instruments and torque values were significantly reduced by the EDTA solution. In the present study, while NaOCI gel and solution forms were compared, Peters et al. compared EDTA solution and gel forms during preparation. It is well known that the chelating action of EDTA leads to reduced torgue that occurs during preparation (33). Therefore, a direct comparison cannot be performed. Additionally, in the present study, the root canals were irrigated with 2 mL saline between each pecking motion in the gel group, to reduce the torque during preparation. In the present study, periapical radiographs were used to assess the number of root canals. However, it is well known that CBCT imaging is better than periapical radiography for assessing the number of root canals (34). Without CBCT evaluation it is possible to miss an extra root canal during endodontic treatment. The number of root canals may contribute to the level of postoperative pain (35). Therefore, this might be one of the limitations of the present study.

# CONCLUSION

Within the limitations of the present study, it can be concluded that using NaOCI gel during root canal preparation results in less postoperative on day 1. This is the first study revealing the beneficial effect of NaOCI gel in lowering postoperative pain. Thus, further studies are needed.

#### Disclosures

Conflict of interest: There are no any conflict of interest.

**Ethics Committee Approval:** The Ethical Committee of the Faculty of Dentistry, University of A approved the study protocol with a decision number of 2017-91.

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