COMPARATIVE EVALUATION OF APICAL EXTRUSION OF SODIUM HYPOCHLORITE GEL AND SOLUTION IN PRIMARY MOLARS USING TWO DIFFERENT INSTRUMENTATION TECHNIQUES: AN *IN-VITRO* STUDY

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ABSTRACT

Introduction: Sodium hypochlorite solution apical extrusion leads to life-threatening sequelae. Gel-type has been suggested as a safer alternative during intra-canal irrigation due to its' higher viscosity.

Objectives: To compare the apical extrusion of three sodium hypochlorite viscosities in primary molars prepared with two different instrumentation techniques.

Material and methods: This was an *in-vitro* crossover study. Sixty human primary molar roots were divided into two groups (n = 30), depending on physiological root resorption, and each group was further divided into two sub-groups (n = 15) based on instrumentation technique. Manual instruments (K-file) and rotary files (ProTaper) were used for root canal instrumentation. Each group was irrigated with 5 ml of sodium hypochlorite solution and two different viscosities of sodium hypochlorite gel after preparation. The extruded volume was collected and calculated using Myers and Montgomery model. Statistical analysis was performed by applying Kolmogorov-Smirnov test and Kruskal-Wallis test.

Results: A statistically significant difference was found between sodium hypochlorite solution and gel in manual instrumentation groups. No statistically significant difference was observed between the extruded volumes in the rotary instrumentation groups.

Conclusions: Sodium hypochlorite gel is a safer alternative for primary molars prepared by stainless steel K-file. Preparation technique used in primary molars affects extruded irrigant volume more compared with physiologic root resorption.

Key words: sodium hypochlorite, pediatric endodontics, primary pulpectomy, rotary files, hand files.

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INTRODUCTION

Sodium hypochlorite has become the most used endodontic irrigant owing to its' highly effective antimicrobial properties and its' efficacy to dissolve pulp tissue and debris [1]. In addition, it is a very effective disinfectant toward *Enterococcus faecalis* that is the most isolated micro-organism in the root canal, associated with post-treatment disease in both permanent [2-5] and primary teeth [5]. However, cytotoxicity is a common disadvantage of sodium hypochlorite that may lead to severe injury if it extrudes to the periapical tissues [6].

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Sodium hypochlorite accident is characterized by sudden pain, swelling, profuse bleeding [6, 7], secondary infection, and paresthesia [7]. Sodium hypochlorite extrusion is mainly related to misuse of the compound, irregularities of the root canal system, wide apical foramen diameter [8], and using liquid form [9].

Endodontic treatment of deciduous teeth is different from that of permanent teeth due to primary pulp morphology and physiological root resorption [10]. There is an increased risk of sodium hypochlorite extrusion beyond the apex in primary teeth due to physiological root resorption [11, 12]. This resorption leads to a change of apical foramen continually [13]. Sodium hypochlorite extrusion causes damage to permanent tooth bud; therefore, continued observation of the successor permanent bud is mandatory [11, 12]. Endodontic rotary system for deciduous teeth was first introduced by Barr *et al.* in 2000 [14]. NiTi rotary files are more efficient in pediatric patient as they reduce the chairside time needed for endodontic treatment compared with stainless steel K-files [14, 15].

Zand *et al.* suggested that the adverse effects of sodium hypochlorite solution can be prevented by using NaOCl gel [9]. In addition, NaOCl solution cannot be used as an irrigant in immature teeth, thus gel form was a safe alternative for immature teeth irrigation with an open apex up to 2.5 mm [16]. Furthermore, gel form demonstrated better behavior than solution form on deciduous molars dentin [17]. However, NaOCl gel was less effective than its' solution type against *Enterococcus faecalis* [2].

OBJECTIVES

This study aimed to compare the extrusion of sodium hypochlorite gel and solution during irrigation. To the best of our knowledge, it is the first *in-vitro* study that compared the volume of extrusion between sodium hypochlorite gel and solution in primary molars with two different instrumentation techniques.

MATERIAL AND METHODS

This was an *in-vitro* crossover study. Sample size was determined using G* Power 3.1.7 software (Heinrich-Hein-Universität-Düsseldorf, Germany; http://www.gpower.hhu.de/). Effect size f = 0.9435816/α err prob = 0.05/ Power (1-β err prob) = 0.99/Number of groups = 12. This research was performed on sixty human primary molar roots extracted due to serial extraction and periapical pathology. The roots were cleaned out of residual soft tissue and debris, then stored in a saline solution at room temperature. Selection criteria were as follows: lack of fractures, cracks, or caries, with physiologic resorption of no more than 1/3 root length, and lack of internal and external pathological root resorption.

STUDY GROUPS

Sixty human primary molar roots were collected and divided into two equal groups based on physiologic root resorption:

- group A: no physiologic root resorption has occurred (*n* = 30);
- group B: physiologic root resorption has started < 1/3 root length (*n* = 30).

Then each group was further divided into two subgroups, depending on instrumentation technique:

- group 1: manual preparation was performed using stainless steel K-files (Dentsply Maillefer) (*n* = 15);
- group 2: rotary instrumentation was done using ProTaper Universal files (Dentsply Maillefer) (*n* = 15) (Table 1).

The roots in each group were irrigated with 5 ml of 3 viscosities of sodium hypochlorite after preparation:

- sodium hypochlorite solution 5.25% (Carmel®; Akka Brothers Co., Carmel Detergent, Damascus, Syria) (ν = 0.563 cSt) [16];
- sodium hypochlorite gel 2.25% (Harpic®; Reckitt Benckiser, PLC, Slough, UK) (ν = 226.666 cSt) [16];
- sodium hypochlorite gel 2.25% (WC Net Bleach®; Bolton Manitoba, Milan, Italy) (ν = 190 cSt) [16].

ROOT CANAL INSTRUMENTATION

A 2 mm round bur (Dentsply Maillefer) was used for the access cavity preparation, the final outline of access cavity was performed using endo Z bur (Dentsply Maillefer). A 10 K-file size (Dentsply Maillefer) was placed into the root canal to verify its' patency, then the working length was calculated to be less than 2 mm of the apical foramen. Manual preparation was performed with stainless steel K-files 0.02 taper, starting with 15 K-file size and finishing with 25 K-file size. Rotary instrumentation was done using ProTaper Universal (PTU), and PTU files were applied in the following order: Sx (size 19, taper 0.035), S1 (size 17, taper 0.02),

TABLE 1. Groups, physiologic root resorption stage, and instrumentation technique used

Group	Physiologic root resorption	Instrumentation technique	Sample size
A1	No physiologic root resorption	Manual instrumentation*	15
A2	No physiologic root resorption	Rotary instrumentation†	15
B1	Physiologic root resorption < 1/3	Manual instrumentation*	15
B2	Physiologic root resorption < 1/3	Rotary instrumentatio[n]†	15

*Stainless steel K-file. †ProTaper Universal file (PTU).

S2 (size 20, taper 0.04), F1 (size 20, taper 0.07), and F2 (size 25, taper 0.05).

IRRIGATION PROTOCOL

The Institutional Review Board of the Oregon Health & Science University (Portland, USA) irrigation protocol was applied in this study. Starting with irrigation with NaOCl for 30 seconds, then waiting for 60 seconds, and finally applying further irrigation for 30 seconds, with constant needle movement from 1-2 mm away from the working length every 6 seconds. The flow rate was 5 ml/60 sec [18]. A 27-gauge side-vented needle (Endo-Top; CERKAMED, Stalowa Wola, Poland) was used for irrigation and placed 5 mm away from the apical foramen. The canals were rinsed after complete preparation.

COLLECTING THE EXTRUDED IRRIGANTS

This study was performed using Al Nesser *et al.* [16] experimental protocol, and Myers and Montgomery [19] model was also applied. A plastic lid was drilled at the center, and each molar was fixed at the level of the cemento-enamel junction with a composite (Tetric N-Ceram®; Ivoclar Vivadent, Zurich, Switzerland). To equalize the air pressure inside and outside the plastic vial, a 22-gauge needle was placed into the plastic lid. An empty plastic vial was weighed, then the weight of 5 ml of each irrigant type was determined by subtracting the weight of empty plastic vial. The extruded irrigant weight was calculated using the previously applied method. After each root irrigation, the plastic container was replaced with a new one. Different investigators performed this procedure to accomplish researcher blinding. Extruded irrigants volumes (ml) were calculated by transforming the previous weights (g), using the following equation:

$$\text{Volume of extruded irrigant} = \frac{\text{Weight of extruded irrigant} \times 5}{\text{Weight of 5 ml of irrigant}}$$

STATISTICAL ANALYSIS

IBM SPSS software version 22 (IBM Corp., Armonk, USA) was applied for statistical data analysis. Kolmogorov-Smirnov test was used to verify the normality of data, and Kruskal-Wallis test was used to analyze the differences between study groups. Significance level (*p*-value) was adjusted at 0.05.

RESULTS

In total, four groups were assessed (Table 1). Data were presented as mean, standard deviation (SD), standard error (SE), maximum (Max.), and minimum (Min.) values in each group. Our data indicated that the least extrusion volume was noted for NaOCl gel Harpic, followed by NaOCl gel WC Net Bleach. Conversely, NaOCl Carmel solution had the highest volume of extrusion (Table 2).

A significant difference was observed in extruded volumes between the three types of irrigants in the group A1 ($p = 0.010$) and the group B1 ($p = 0.0002$). However, no statistically significant differences were noted between the three types of NaOCl irrigants in the group A2 and the group B2, with $p = 0.052$ and $p = 0.992$, respectively (Table 2 and Figure 1).

TABLE 2. Descriptive analysis of the extruded irrigant volumes (ml)

Group	NaOCl type	*n*	Mean	SD	SE	Min.	Max.	*p*-value
A1	NaOCl solution Carmel	15	2.8297	1.19277	0.30797	0.34	4.78	0.010*
	NaOCl gel Harpic	15	1.1772	1.05963	0.27360	0.00	2.81	
	NaOCl gel WC Net Bleach	15	1.4048	1.74457	0.45045	0.09	4.27	
A2	NaOCl Solution Carmel	15	2.9052	2.03089	0.52437	0.06	4.97	0.059
	NaOCl gel Harpic	15	1.4008	1.91198	0.49367	0.01	4.97	
	NaOCl gel WC Net Bleach	15	2.3884	1.86690	0.48203	0.02	4.99	
B1	NaOCl Solution Carmel	15	4.8013	0.18869	0.04872	4.33	4.99	0.00002***
	NaOCl gel Harpic	15	1.7435	1.49660	0.38642	0.00	3.76	
	NaOCl gel WC Net Bleach	15	2.9491	1.93357	0.49924	0.03	4.96	
B2	NaOCl Solution Carmel	15	4.8800	0.06658	0.01719	4.78	4.99	0.992
	NaOCl gel Harpic	15	4.8155	0.21702	0.05603	4.21	4.99	
	NaOCl gel WC Net Bleach	15	4.8636	0.10795	0.02787	4.67	4.99	

Group A1 – manual instrumentation for primary molar roots without physiologic resorption. Group A2 – rotary instrumentation for primary molar roots without physiologic root resorption. Group B1 – manual instrumentation for primary molar roots with physiologic resorption < 1/3 root length. Group B2 – rotary instrumentation for primary molar roots with physiologic root resorption < 1/3 root length.

*n – sample size, SD – standard deviation, SE – standard error, Min. – minimum, Max. – maximum, * – statistical significance (p < 0.05); *** – highly statistical significance (p < 0.001)*

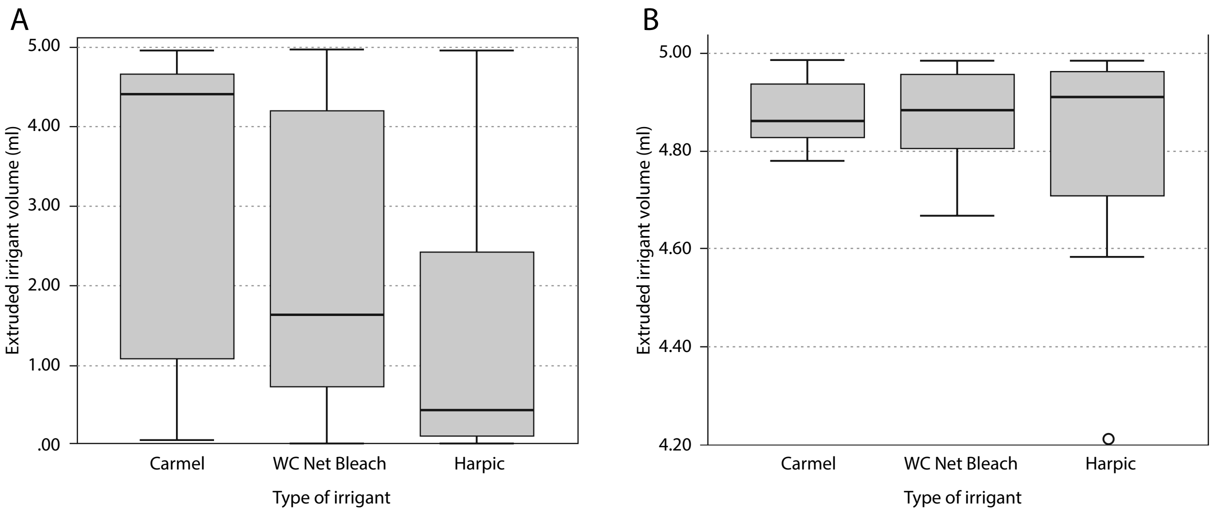

FIGURE 1. Box plots of the volume of extruded irrigants showing median, interquartile range, minimum, and maximum in the A2 and B2 groups (ml). Group A2 – rotary instrumentation for primary molar roots without physiologic root resorption; Group B2 – rotary instrumentation for primary molar roots with physiologic root resorption

TABLE 3. Pairwise comparison between the three types of sodium hypochlorite in group A1 and group B1 (ml)

Group	Comparison	Mean difference	SE	*p*-value
A1	NaOCl gel Harpic vs. NaOCl gel WC Net Bleach	–0.2276	4.795	1.000
	NaOCl solution Carmel vs. NaOCl gel Harpic	1.6525	4.795	0.025*
	NaOCl solution Carmel vs. NaOCl gel WC Net Bleach	1.4249	4.795	0.027*
B1	NaOCl gel Harpic vs. NaOCl gel WC Net Bleach	–1.2056	4.795	0.145
	NaOCl solution Carmel vs. NaOCl gel Harpic	3.0578	4.795	0.00001***
	NaOCl solution Carmel vs. NaOCl gel WC Net Bleach	1.8522	4.795	0.025*

Group A1 – manual instrumentation for primary molar roots without physiologic resorption. Group B1 – manual instrumentation for primary molar roots with physiologic resorption < 1/3 root length.
*SE – standard error; * – statistical significance (p < 0.05); *** - highly statistical significance (p < 0.001)*

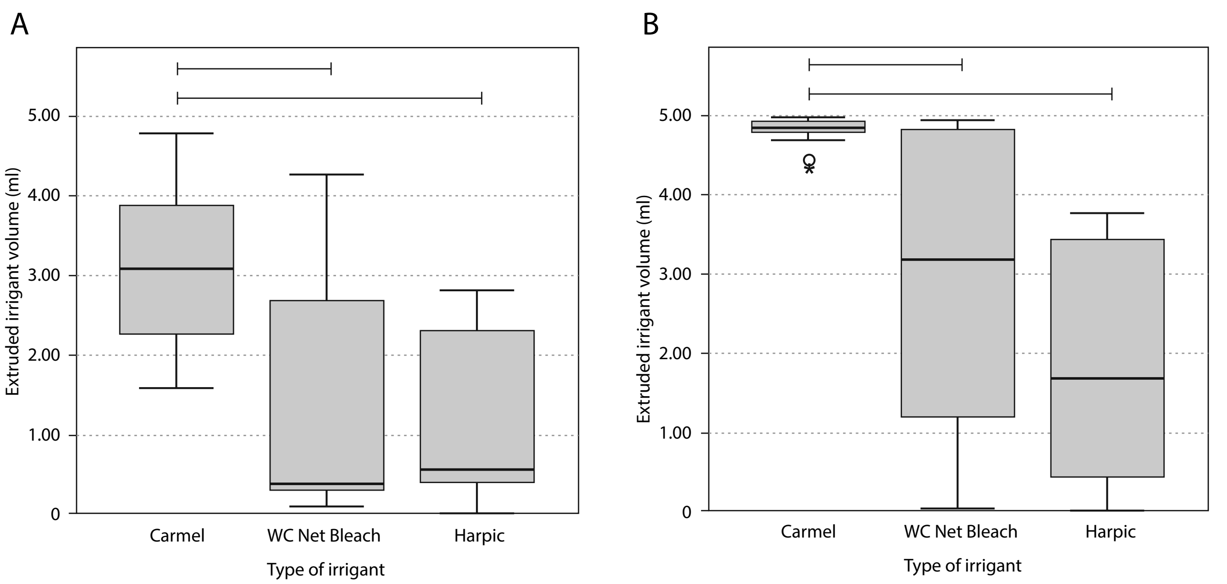

FIGURE 2. Box plots of the volume of extruded irrigants showing median, interquartile range, minimum, and maximum in the A1 and B1 groups (ml). Group A1 – manual instrumentation for primary molar roots without physiologic resorption; Group B1 – manual instrumentation for primary molar roots with physiologic resorption < 0.001

A pairwise comparison test in the group A1 showed a significant difference between NaOCl Carmel solution and NaOCl Harpic gel ($p = 0.025$), and a significant difference between NaOCl Carmel solution and NaOCl WC Net Bleach gel ($p = 0.027$). However, no significant difference was noted between NaOCl WC Net Bleach gel and Harpic gel ($p = 1.000$) (Table 3 and Figure 2). Similar results were obtained by pairwise comparison test in the group B1, with $p = 0.00001$, $p = 0.025$, and $p = 0.145$, respectively (Table 3 and Figure 2). Bonferroni correction for multiple tests was applied to adjust significance values. Multiple comparisons were not performed in the A2 and B2 groups, because the overall test did not show significant differences across the samples (Table 2).

DISCUSSION

The cyto-toxic effect of sodium hypochlorite is a well-known shortcoming. Sodium hypochlorite extrusion to periapical tissues is known as the sodium hypochlorite accident, which may result in life-threatening sequelae [6]. One survey reported that almost half of dental practitioners experience at least one sodium hypochlorite accident throughout their clinical practice [20]. In addition, the extruded irrigant poses a threat to the permanent tooth germ [11, 12]. Therefore, the aim of this study was to compare the extrusion of three viscosities of sodium hypochlorite through primary molar roots. Sodium hypochlorite solution was compared with gel-type because it has better properties than solution-type. According to several studies, gel-type is harder to extrude to periapical tissues [9, 16, 21, 22], has a better effect on primary molars dentin [17], and provides easier handling and management [3, 23]. These are crucial necessities in pediatric dentistry practice and minimize post-operative pain [24]. However, gel-type is less effective toward *Enterococcus faecalis* [2] and does not present the same dissolution capacity as solution-type [25].

Primary molars were chosen for this study because deciduous dentin is thinner [26]. Therefore, primary molar roots are brittle and more prone to perforations during endodontic instrumentation, which results in a higher irrigants extrusion. In addition, primary teeth roots resorb immediately, as the root growth completes [13].

The accepted protocol of Myers and Montgomery was applied to compare sodium hypochlorite different irrigants. The main disadvantage of this protocol is the lack of mechanical back pressure provided by the vital periapical area [27]. Study groups were irrigated using side-vented needles instead of using regular open-ended needles, as they can reduce the extrusion of irrigants [28].

ProTaper universal (PTU) system was chosen because is the most commonly rotary system used amongst dentists [29]. Furthermore, PTU system is well accepted for primary teeth endodontic treatment [30]. To the best of our knowledge, no study has compared the extrusion of three various viscosities of sodium hypochlorite by comparing the manual K-file to ProTaper universal system at different stages of physiologic root resorption in deciduous teeth. This study showed a significant difference between NaOCl Carmel solution and the two viscosities of NaOCl gel in the groups A1 and B1. This result is in line with the viscosity test done by Al Nesser *et al.* [16], who demonstrated that NaOCl Carmel solution presented the lowest viscosity (0.563 cSt), while the highest viscosity was reported for NaOCl Harpic gel (226.666 cSt), followed by WC Net Bleach gel (190 cSt). The pairwise comparison test for the group B1 demonstrated a highly significant difference between NaOCl Carmel solution and NaOCl Harpic gel. This finding is in agreement with a research done by Gunor *et al.* [31]. In his study, it was declared that as a result of physiologic root resorption, deciduous teeth have an open apical foramen, which allows rapid extrusion of irrigants beyond the apex. In addition, no statistically significant difference was observed between the three viscosities of sodium hypochlorite in the groups A2 and B2, since rotary instrumentation leads to lateral perforation in primary roots, according to several studies [32-35]. Therefore, irrigant extrusion would occur regardless of sodium hypochlorite viscosity.

Musale and Mujawar [32] stated that NiTi rotary protocols usage for primary teeth, which are suitable for permanent teeth, would cause lateral perforation. Accordingly, Mudale *et al.* [33] study declared that the unavailability of files designed for primary teeth leads to lateral perforation because of anatomical variations. Similarly, Sowmiya *et al.* [34] found that the increased risk of lateral perforation while using rotary instruments is due to the thin dentinal walls in primary teeth. Furthermore, Manker *et al.* [35] concluded that PTU system removes a high volume of dentine in primary roots. In contrast, Barr *et al.* [14] and Nagaratna *et al.* [15] suggested that rotary systems make endodontic treatment more efficient and reduce the errors that usually occur during the usage of stainless steel K-file.

The laboratory setting was the main limitation of this research, where the measurement of extruded irrigant would not be the same as in the oral cavity, owing to the absence of mechanical back pressure of the periapical area. For these reasons, it would be appropriate to conduct clinical trials to match the oral cavity environment. Moreover, further studies on other rotary systems would be beneficial.

CONCLUSIONS

Based on our findings, the preparation technique used in the primary molars affects extruded irrigant volume more than the physiologic root resorption. In addition, sodium hypochlorite gel is a safer alternative during intra-canal irrigation in the primary molars prepared by stainless steel K-file. The use of stainless steel K-file is a safer alternative for primary molars preparation due to the high risk of the irrigant extrusion when using Pro Taper Universal files. This is mainly where physiologic root resorption has advanced.

CONFLICT OF INTEREST

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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