



# Efficacy of Different Irrigation Techniques in Removing Ledermix Paste from Simulated Root Canal Irregularities

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## ABSTRACT

**Introduction:** Root discoloration is reported after using Ledermix paste for prevention of external inflammatory root resorption in traumatically injured teeth. Therefore, it seems necessary to remove Ledermix completely from the root canal prior to root canal filling. The aim of this study was to evaluate the efficacy of sodium hypochlorite or alcohol with or without passive ultrasonic irrigation in removing Ledermix from standardized grooves in coronal and apical root canal thirds. **Methods and Materials:** Root canals of ten extracted single-rooted teeth were prepared to size 35 and split longitudinally. Standardized grooves were cut in the coronal and apical part of the root canal and filled with Ledermix paste. The reassembled specimens were irrigated with 1% NaOCl or 80% alcohol delivered with a size 30 syringe or with an ultrasonic device. The amount of remaining Ledermix paste was evaluated by three calibrated observers under 30× magnification using a four-grade scoring system. The data was analysed with a nonparametric ANOVA-type method for longitudinal data in factorial experiments. Pairwise comparisons were adjusted by using the Bonferroni corrections ( $P=0.05$ ). **Results:** For the coronal groove, no statistical difference between passive ultrasonic irrigation with NaOCl or alcohol was found ( $P=0.089$ ). Irrigation with ultrasonically activated alcohol was significantly more effective than manual irrigation irrespective of the irrigant ( $P=0.0118$ ). Ultrasonic activation of alcohol removed Ledermix paste significantly better from the apical groove than the other irrigation procedures ( $P<0.05$ ). **Conclusion:** This *in vitro* study showed that ultrasonic activation of alcohol was the most effective irrigation technique for removal of Ledermix paste, especially in the apical third of the root canal.

**Keywords:** Alcohol; Irrigation; Ledermix Paste; Passive Ultrasonic Irrigation; Ultrasonics

## Introduction

The antibiotic-corticoid compound paste, marketed as Ledermix has been proposed as an intracanal medicament to relieve postoperative pain associated with acute apical periodontitis or to prevent external inflammatory root resorption in traumatically injured teeth [1-5]. Ledermix paste contains a tetracycline antibiotic, demeclocycline-hydrochloride (3.2%) and a corticosteroid, triamcinolone acetonide (1%), in a polyethylene glycol base.

It is known that remnants of calcium hydroxide may interact with root canal filling materials [6, 7] resulting in an increased apical leakage [6, 8] or in a potential reduction of sealer adaptation to the root canal wall [9]. Although it is unclear if remnants of Ledermix paste alter the setting reaction of root canal sealers, they do act as a physical barrier preventing a close contact between root canal dentine and filling material. Moreover, root discoloration has been reported after use of Ledermix paste [10, 11]. Chen *et al.* [10] showed that even under zero light conditions, root

discoloration following short-term application of Ledermix can still occur within 2 weeks, indicating non-light-based chemical reactions in the staining process. Therefore, it seems necessary to remove inter-appointment dressings from the root canal prior to root canal filling [12] to maintain the sealing and bonding efficacy of the permanent root filling or biomaterials and to prevent tooth staining [5]. Several studies showed that remnants of intracanal medication still remain despite the use of different irrigation techniques and solutions [13, 14].

Usually, the removal of the medicament is accomplished by irrigation in combination with hand instrumentation. Different activation techniques have been proposed to improve the mechanical flushing action of the irrigant [15, 16] with conflicting results regarding the effectiveness in removing calcium hydroxide [17, 18]. Van der Sluis *et al.* [17] demonstrated that enhancement of the flushing action of the irrigant with passive ultrasonic irrigation (PUI) removed calcium hydroxide significantly better from inaccessible areas in the apical third of the root canal compared to syringe irrigation. In contrast, no difference was found between manual irrigation and PUI in removing calcium hydroxide from the apical area [18, 19].

Only two studies compared the efficacy of different irrigation techniques using sodium hypochlorite (NaOCl) for removal of calcium hydroxide and Ledermix paste and it was concluded that Ledermix paste was significantly easier to be removed [14, 20, 21]. However, these studies used NaOCl as an irrigant, which was applied to the root canal with either manual irrigation [14] or different activation systems such as RinsEndo (Dürr Dental, Bietigheim-Bissingen, Germany) or EndoActivator (Dentsply Sirona, Ballaigues, Switzerland) [20]. None of these studies investigated the effect of different irrigation solutions when removing Ledermix paste.

According to the manufacturer, demeclocycline hydrochloride, which is also responsible for the yellow color of Ledermix paste, is soluble in alcohol. No data on the effectiveness of the removal of Ledermix paste with alcohol is available.

The purpose of this study was to compare the efficacy of sodium hypochlorite or alcohol with or without passive ultrasonic activation in removing Ledermix paste from mechanically not accessible regions of the root canal. The null hypothesis was that alcohol and NaOCl show no significant difference in cleaning root canal irregularities from Ledermix paste irrespective of the irrigation method.

## Materials and Methods

### Preparation of specimens

At the time of the experimental procedures, an approval by the Ethic Committee was not mandatory at the University of Göttingen. Ten extracted human mandibular premolars with straight root canals, intact apices and no previous endodontic treatment were selected and stored in thymol solution throughout the study. After preparation of the access cavity, a size 10 stainless-steel K-file was inserted into the root canal until the tip was just visible at the apical foramen. All teeth were shortened to a length of 17 mm with a working length of 16 mm, and root canal preparation was performed with FlexMaster rotary NiTi instruments (VDW, Munich, Germany) to size 35/0.02 taper. After each instrument change, the root canals were irrigated with 2 mL of 1% NaOCl using a syringe and a 30-gauge needle (NaviTip; Ultradent, South Jordan, UT, USA). Subsequently, two grooves were cut along the long axis of each tooth using a diamond disc (Horico, Berlin, Germany) without penetration of the root canal. Subsequently, the roots were split longitudinally using a waxing instrument (Le Cron; Aesculap, Tuttlingen, Germany).

One standardized groove was prepared in each root half with a modified round bur (Hager & Meisinger, Neuss, Germany) to simulate mechanically not accessible root canal extensions [22]. The grooves had a standardized size of 4 mm in length, 0.2 mm in width and 0.5 mm in depth. The locations of the grooves were 2-6 mm from the apical foramen in one half of the tooth (apical section) and 10-14 mm from the apex in the opposite part (coronal section). This method was used in a previous study for removal of calcium hydroxide and Ledermix paste from root canals [14].

The specimens were embedded in acrylic resin (Paladur; Heraeus Kulzer, Hanau, Germany) to seal the apex and to allow tight reassembly of the root halves. Using a toothbrush, the grooves were cleaned, and specimens inserted into silicone (Silaplast; Detax GmbH, Ettlingen, Germany) to take digital pictures with the MOTIC Ergonomic Trinokular Zoom Stereo Microscope (Motic, Wetzlar, Germany) under 30× magnification and a digital camera (Moticam 1300, Motic Instrument Inc, Richmond, BC, Canada) with a resolution of 1.3 megapixel. Digital images were taken before and after the application of the intracanal medication and after irrigation.

Following, the grooves were filled with Ledermix paste (Riemser, Greifswald, Germany) using a size 10 Reamer, and the root halves were reassembled and fixed using a clamp. Subsequently, the root canals were completely filled with Ledermix paste using a Pastinject filler size 40 (Micro-Mega, Besançon,

France), and the access cavities were sealed with a cotton pellet and Cavit (3M ESPE, Neuss, Germany). All specimens were stored at 37°C and 100% humidity for seven days in an incubator.

### Irrigation procedures

A preliminary study confirmed the possibility of reusing single specimens up to at least five times without visible damage of the root canal walls during irrigation [23]. Therefore, ten teeth were reused for different irrigation techniques and irrigants in four experimental groups, consecutively and in a random sequence of the specimens. In groups 1 and 2, the irrigant was delivered by using a 10-mL syringe and a 30-gauge needle (NaviTip; Ultradent, South Jordan, UT, USA). In groups 3 and 4, the solutions were simultaneously delivered and activated with an ultrasonic device (Piezon Master 400; EMS, Nyon, Switzerland) and a stainless-steel K-file size 15 (Endosonore, Dentsply Maillefer, Ballaigues, Switzerland), with its power set at the ¼ of the scale. The irrigant was either 1% NaOCl (group 1 and 3) or 80% alcohol (group 2 and 4). In all groups, the volume of irrigant was 20 mL and time for irrigation/activation was 3 min. The tip of the needle as well as the ultrasonically activated file was inserted to 1 mm short of the working length without binding. After irrigation, the root canals were dried using size 35 paper points. The root halves were separated, and digital photographs of the grooves were taken. Prior to reutilization of the specimens, the root canals were cleaned with a tooth brush to remove the remaining intracanal medication from the grooves and root canals, followed by a complete refilling with Ledermix paste before the next irrigation procedure.

### Scoring procedure

The amount of remaining Ledermix paste in the grooves was scored under the microscope with 30× magnification by three calibrated dentists. The scoring system used in this investigation was previously described by van der Sluis *et al.* [17]: score 0: the groove is empty; score 1: less than half of the groove is filled with Ledermix paste; score 2: more than half of the groove is filled with Ledermix paste; score 3: the entire groove is filled with Ledermix paste (Figures 1A to D).

For calibration of the observers, three dentists scored and discussed 150 root halves using reference photographs until agreement. After five days, the three investigators scored another 50 root halves. Intra observer reproducibility and inter observer agreement were calculated.

### Statistical analysis

Statistical analysis was performed by using nonparametric analysis of variance procedures for longitudinal ordinal data in factorial designs [24]. Results were regarded as significant if  $P < 0.05$ . Pairwise comparisons were adjusted by using the Bonferroni corrections.

### Results

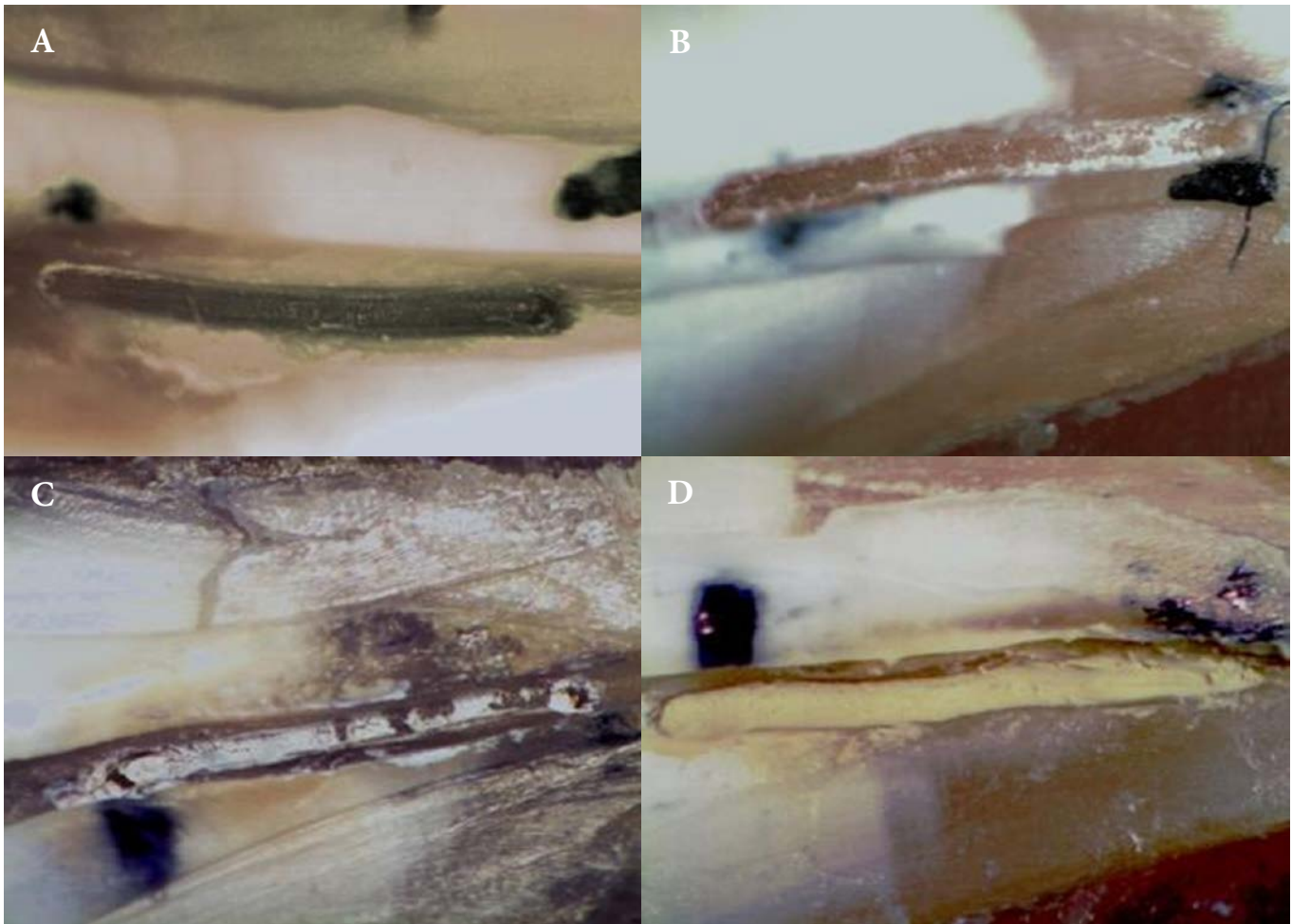
Intra observer reproducibility was 94% for the first investigator, 95% for the second and 95% for the third investigator. The inter observer agreement was 94% (95% confidence interval: [89%; 100%]), thus the difference among the three observers was not significant ( $P = 0.9181$ ).

The statistical analysis showed a significant effect for irrigation procedure ( $P < 0.0001$ ). Thus, the null hypothesis was not confirmed. Moreover, the interaction between the irrigation procedure and the location of the groove was significant ( $P < 0.0001$ ). Therefore, coronal and apical grooves were evaluated separately. Nevertheless, there were no significant differences regarding cleanliness between the coronal and apical groove ( $P = 0.5294$ ). The results of the scoring procedures are represented in Table 1.

For the coronal groove, irrigation with ultrasonically activated alcohol was significantly more effective than manual irrigation irrespective of the irrigant ( $P = 0.0118$ ). No significant difference between the irrigants was detected for manual irrigation ( $P = 1$ ). Ultrasonic activation of NaOCl showed no significant difference compared to manual irrigation with alcohol or NaOCl ( $P > 0.05$ ). The ultrasonic groups were equally effective irrespective of the irrigant ( $P = 0.089$ ).

**Table 1.** Frequency distribution of Ledermix remnants score by experimental groups and location of the groove. The readings were pooled for both observers

Irrigation	Location of the groove	Irrigant	Score			
			0	1	2	3
Syringe	coronal	NaOCl	0	8	22	0
		Alcohol	0	8	22	0
	apical	NaOCl	3	9	18	0
		Alcohol	0	12	18	0
Ultrasonics	coronal	NaOCl	0	24	6	0
		Alcohol	3	27	0	0
	apical	NaOCl	0	4	26	0
		Alcohol	15	14	1	0



**Figure 1.** A) Score 0 (the groove is empty); B) Score 1 (less than half of the groove is filled with Ledermix paste); C) Score 2 (more than half of the groove is filled with Ledermix paste); D) Score 3 (the entire groove is filled with Ledermix paste)

Pairwise comparisons of the different irrigation procedures for apical groove demonstrated a significantly better performance for ultrasonic activation of alcohol than all other groups ( $P < 0.035$ ). Ledermix paste was completely removed after PUI with alcohol in 50% of the specimens. The differences between groups 1-3 were not significant ( $P > 0.171$ ).

## Discussion

The null hypothesis that alcohol and NaOCl show no significant difference in cleaning root canal irregularities from Ledermix paste irrespective of the irrigation method was not confirmed.

The results indicated that PUI with alcohol performed significantly better in the coronal part of the root canal than manual irrigation. Moreover, passive ultrasonic irrigation

with alcohol removed Ledermix paste significantly better from the apical groove than PUI with NaOCl or manual irrigation. Overall, the superior cleaning efficiency of PUI for removal of debris [22, 25] or calcium hydroxide [17, 26] compared to syringe irrigation has been demonstrated. This finding may be attributed to the higher streaming velocity of the irrigant generated by PUI [27], thereby flushing out remnants of an intracanal medicament through its displacing motion [13]. In addition, shear stresses created during PUI by high-velocity jets can enhance the cleaning of lateral grooves [28]. A study examining manual irrigation, sonic activation, ultrasonic activation and EndoVac showed no significant difference in the coronal and apical part of the root canal; and apically, none of the irrigation methods were able to completely remove smear layer, but EndoVac was significantly better than other irrigation methods [19]. Another study examining smear layer removal after



preparation of deciduous teeth with two different NiTi-instrument systems and irrigation with and without passive ultrasonic activation showed no improvement in smear layer removal after ultrasonic activation [29].

Also, it is important to investigate apical extrusion of intracanal dressing when trying to remove it using ultrasonic activation or other methods of activation. A study by Huiz Peeters *et al.* [4] showed in immature teeth with apical periodontitis no extrusion of intracanal dressing after ultrasonic and laser activation.

Observation of either manual or ultrasonic irrigation showed that there was no significant effect of the irrigation solution, *e.g.* NaOCl and alcohol removed comparable amounts of Ledermix paste from the coronal third. In contrast, PUI with alcohol was significantly more effective than ultrasonic irrigation in combination with NaOCl in the apical third. In this apical area, the percentage of complete Ledermix paste removal (Score 0) were 50% for PUI with alcohol *vs.* 10% for PUI with NaOCl. The cleaning efficacy of an irrigation technique depends not only on mechanical agitation but also on the chemical ability of the irrigant to dissolve an intracanal medicament [22]. Ledermix paste is composed of a synthetic corticosteroid (triamcinolone acetonide) and demeclocycline hydrochloride, which is soluble in alcohol. According to the manufacturer, irrigation with alcohol is recommended to remove Ledermix paste from the root canal. Therefore, the ability of alcohol to dissolve Ledermix paste was compared to NaOCl, which is the main irrigant during root canal treatment [30]. Only two studies investigated the removal of Ledermix paste from the root canal. Rödig *et al.* [14] compared the efficacy of ultrasonic irrigation and RinsEndo for removal of calcium hydroxide or Ledermix paste using root canals with standardized grooves in the apical root canal wall. The percentages of complete removal of medication (score 0) were 51.7% for Ledermix paste and 11.7% for calcium hydroxide. Irrespective of the irrigation technique, Ledermix paste removal was significantly more effective than the removal of calcium hydroxide [14]. Chou *et al.* [20] investigated the removal of Ledermix paste, Odontopaste (Australian Dental Manufacturing, Brisbane, Queensland, Australia), DoxyPaste (Ozdent, Castle Hill, New South Wales, Australia) and a calcium hydroxide paste (Pulpdent Paste; Pulpdent, Watertown, MA, USA) from the root canal using different irrigation techniques. These medicaments were removed

with ethylenediaminetetraacetic (EDTA) and NaOCl, which were delivered using syringe irrigation and a conventional 27-gauge open-ended notched needle tip or a side-vented Max-I-Probe (Dentsply Rinn, Elgin, IL, USA) or activated using a sonic device (EndoActivator; Dentsply Sirona, Ballaigues, Switzerland). The roots were also split in halves and digital pictures were taken to calculate the percentages of remaining medicament. Calcium hydroxide was significantly more difficult to be removed than the steroid antibiotic pastes, with an average of 27% of the root canal surface covered after irrigation regardless of the irrigation technique. Removal of the steroid antibiotic pastes was significantly enhanced with EndoActivator compared to conventional irrigation [20].

Controversy exists regarding the removal of medicaments from different parts of the root canal. Several authors observed remnants of calcium hydroxide mainly in the apical region irrespective of the irrigation technique used [13, 31, 32]. Nevertheless, some of these studies evaluated medicament removal from the complete root canal wall unrelated to root canal third [12, 31] or information on the apical preparation size and insertion depth of the irrigation device was lacking [12, 31]. Overall, comparison of these results is complicated due to different experimental designs.

In the present study, no significant difference regarding the removal of Ledermix paste between the coronal and the apical part of the root canal was detected. A study on the removal efficacy of conventional manual irrigation with different solutions (1% NaOCl, 10% citric acid and 20% EDTA) for the removal of calcium hydroxide used a similar experimental set-up with standardized grooves in the coronal and apical third [21]. Chelating agents such as citric acid and EDTA were significantly more effective than NaOCl for removing calcium hydroxide. Moreover, the cleanliness in the apical groove was superior to that of the coronal groove. The authors speculated that hydrodynamic effects had an impact on the results of their study, because the irrigation needle was introduced 1 mm short of working length and the needle opening was adjacent to the apical groove [21]. There are no additional data in the literature that compared medicament removal from standardized grooves in the coronal and apical third.

The experimental design is based on the study by Lee *et al.* [22] and has been used in several studies on the removal of debris [33], calcium hydroxide [17], Ledermix paste [14],

sealer [34] and triple antibiotic paste [35]. Advantages of the groove model are the standardized size of the artificial grooves and their location as well as the comparable amount of medicament before irrigation. These grooves simulate mechanically not accessible root canal areas where remnants of intracanal medication may accumulate. Prior to refilling the grooves with Ledermix paste all grooves were carefully cleaned to allow reusing the same specimens in each group. This method was adopted from previous studies [17, 23] in order to eliminate differences of grooves among groups and to facilitate comparison of different irrigation techniques. Overall, a major disadvantage of this study design is the lack of representing the clinical complexity of the whole root canal anatomy. This shortcoming may be overcome with micro-computed tomography, which allows three-dimensional quantitative evaluation of residual medication in the root canal [13]. The four-grade scoring system was first described by van der Sluis *et al.* [17]. After a thorough calibration, an inter observer reproducibility of 94% and intra observer agreement of 94% and 95% was achieved. The differences in scoring never exceeded one score and statistical analysis confirmed no significant effect of the observers.

Since many of the samples showed remnants of Ledermix paste, further research is necessary to establish a more effective irrigation protocol for the removal of this intracanal medicament.

## Conclusion

PUI with alcohol was significantly more effective than manual irrigation in removing Ledermix paste from grooves in the coronal part of the root canal. Moreover, PUI with alcohol was the most efficient method to remove Ledermix paste from the apical root canal third.

Conflict of Interest: 'None declared'.

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