

Smear Layer Removal with Herbal Preparation and 17% edta as a Root Canal irrigant

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ABSTRACT :

INTRODUCTION : Root canal treatment aims to eliminate all the microbial loads from the root canal system and prevent the infection

Aim : To compare and evaluate smear layer removal of smear layer removal with herbal preparation and 17% EDTA as a root canal irrigant in human root dentin”

Objectives :

- 1) To evaluate smear layer removal after irrigation with 17%EDTA,
- 2) To evaluate smear layer removal after irrigation with herbal preparation,
- 3) To compare the smear layer removal after irrigation with 17%EDTA, herbal preparation, combination of both in extracted single rooted teeth

Conclusion: Irrespective of technique used, EDTA as compared to NEW HERBAL FORMULATION was more efficiently removed in [SEP]coronal and middle third as compared to apical third of the root canals. [SEP] [SEP]

Introduction: For the successful endodontic treatment, it is necessary to obtain a sterile root canal. The vital part of this process is to remove all the contents of the root canal

mechanically. Root canal treatment aims to eliminate all the microbial loads from the root canal system and prevent the infection. Although cleaning and shaping have been shown to greatly reduce the number of bacteria in infected canals, complete disinfection of canals is difficult to achieve.

Rationale: The smear layer occludes the orifices of the dentinal tubules and also hinders the penetration of intracanal medications and sealers into the dentinal tubules. So, the removal of the smear layer is important for fluid tight seal and success of the root canal treatment.

Aim : To compare and evaluate smear layer removal of smear layer removal with herbal preparation and 17% EDTA as a root canal irrigant in human root dentin”

Objectives :

Primary objective :

- 4) To evaluate smear layer removal after irrigation with 17%EDTA,
- 5) To evaluate smear layer removal after irrigation with herbal preparation,

Other objective :

- 1) To compare the smear layer removal after irrigation with 17%EDTA, herbal preparation, combination of both in extracted single rooted teeth

Primary Research question:

Is herbal preparation with and without 17 % EDTA can remove smear layer from the apical third of human root dentin as a root canal irrigant?

Hypothesis:

The Herbal preparation with and without 17% EDTA will be effective in smear layer removal in apical third of canal in human root dentin as a root canal.

Focused PICO question / PICO format :

P- Human single rooted teeth

I- Herbal preparation for irrigation with and without 17% EDTA

C-17% EDTA

O- smear layer removal in apical third of root canal

In the present systematic review, population is Human single rooted teeth; the intervention is Herbal preparation for irrigation with and without 17% EDTA; the comparison is 17% EDTA; and the outcomes is smear layer removal in apical third of root canal.

Method

Inclusion and exclusion

INCLUSION CRITERIA:-

- Freshly extracted teeth
- Single root teeth
- Caries free
- Absence of cracks

EXCLUSION CRITERIA:-

- Endodontic treated
- Grossly carious
- Fractured teeth

SEARCH STRATEGY

For identification of studies included or considered for this review, detailed search strategy was developed for the database searched. Search was initiated with the combination of controlled vocabulary-free text terms. The keyword employed in this search was broadly classified into five categories describing population, intervention, comparison, outcome, and the type of study.¹

The electronic searches have been made into four databases viz., Medline through PubMed, The Cochrane Central Register of Controlled Trials, Google Scholar, and Sci-hub.

The article published in the period between the dates of inspection of each database was considered, by using various combination of following MeSH terms and keywords.

The search terms are AND, OR ((17% EDTA) OR (Smear layer removal) OR Herbs, OR Herbal, ((17% EDTA) AND ((smearlayer removal in apical third of root canal))).

COCHRANE search strategy:

The search terms used are AND, OR ((17% EDTA) OR (Smear layer removal) OR Herbs, OR Herbal, ((17% EDTA) AND ((smearlayer removal in apical third of root canal))).

PUBMED search strategy:

The search terms used are AND, OR ((17% EDTA) OR (Smear layer removal) OR Herbs, OR Herbal, ((17% EDTA) AND ((smearlayer removal in apical third of root canal))).

GOOGLE SCHOLAR search strategy:

The search terms used are AND, OR ((17% EDTA) OR (Smear layer removal) OR Herbs, OR Herbal, ((17% EDTA) AND ((smearlayer removal in apical third of root canal))).

SCI-HUB search strategy:

The search terms used are AND, OR ((17% EDTA) OR (Smear layer removal) OR Herbs, OR Herbal, ((17% EDTA) AND ((smearlayer removal in apical third of root canal))).

STUDY SELECTION

A title identified from the search was screened by one reviewer with a subsequent duplicate independent checking of their abstracts/full-texts retrieved by the electronic search against the eligibility criteria by another reviewer.¹

Substantial agreement between reviewers in the study selection process was obtained. After the same reviewers independently reviewed the full-text articles of the previous included studies, and studies which did not present any of the exclusion criteria were selected.²

Additionally, all references of the selected studies were manually screened for potentially relevant additional studies. Any possible discrepancies encountered during this process that is, inclusion or exclusion criteria, were resolved by discussion between the reviewers who selected the included studies. If a disagreement persisted, the judgment of a third reviewer was considered decisive.

DATA EXTRACTION AND DATA ITEMS

Information on authors' names, year of publications, study design, sample, inclusion criteria, groups of intervention, type of treatment, follow-up period, method of dentin hypersensitivity stimulation and method of pain assessment and result was independently extracted by two reviewers.³ Data regarding the included studies was also independently extracted by the reviewers based on a previously defined protocol in a specific form in the Microsoft Office Excel 2007 software (Microsoft Corporation, USA).

RISK OF BIAS IN INDIVIDUAL TRIALS

To evaluate the risk of bias in individual studies, different tools were used for randomized controlled trials (RCTs). The risk of bias of the included trials was assessed using Cochrane's risk of bias tool (33). It was used for RCTs after initial calibration. A main risk of bias assessment was included in the systematic review pertaining to each trial's primary outcome.

Risk of bias within studies:

Risk of bias within the studies was evaluated independently by two review researchers. The Cochrane risk of bias tool was used for randomized controlled trials (RCTs) and the studies were classified as low risk of bias, unclear and high risk bias. The following domains were assessed.

Cochrane Risk of Bias Tool for Randomized Controlled Trials:

1. Reaching risk of bias judgements for bias arising from the randomization process

Low risk of bias	Allocation was adequately concealed. AND There are no baseline imbalances across intervention groups at baseline appear to be compatible with chance. AND An adequate (random or otherwise unpredictable) method was used to generate allocation sequence. OR There is no information about the method used to generate the allocation sequence.
Some concerns	Allocation was adequately concealed. AND There is a problem with the method of sequence generation. OR Baseline imbalances suggest a problem with the randomization process. OR No information is provided about concealment of allocation. AND Baseline imbalances across intervention groups appear to be compatible with chance. OR No information to answer any of the signalling questions.
High risk of bias	Allocation sequence was not concealed. OR No information is provided about concealment of allocation sequence.

	AND Baseline imbalances suggest a problem with the randomization process.
2. Reaching risk of bias judgements for bias due to deviations from intended intervention (effect of assignment to intervention)	
Low risk of bias	Participants, carers and personnel were unaware of intervention groups during the trial. OR Participants, carers or personnel were aware of intervention groups during the trial but any deviations from intended intervention reflected usual practice. OR Participants, carers or personnel were aware of intervention groups during the trial but any deviations from intended intervention were unlikely to impact on the outcome. AND No participants were analyzed in the wrong intervention groups (that is, on the basis of intervention actually received rather than of randomized allocation).
Some concerns	Participants, carers or personnel were aware of intervention groups and there is no information on whether there were deviations from usual practice that were likely to impact on the outcome and were imbalanced between intervention groups. OR Some participants were analyzed in the wrong intervention groups (on the basis of intervention actually received rather than of randomized allocation) but there was little potential for a substantial impact on the estimated effect of intervention.
High risk of bias	Participants, carers or personnel were aware of intervention groups and there were deviations from intended interventions that were unbalanced between the intervention groups and likely to have affected the outcome. OR Some participants were analyzed in the wrong intervention groups (on the basis of intervention actually received rather than of randomized allocation), and there was potential for a substantial impact on the estimated effect of intervention.
3. Reaching risk of bias judgements for bias due to missing outcome data	
Low risk of bias	No missing data. OR Non-differential missing data (similar proportion of and similar reasons for missing data in compared groups). OR Evidence of robustness of effect estimate to missing data (based on adequate statistical methods for handling missing data and sensitivity analysis).
Some concerns	An unclear degree of missing data or unclear information on proportion and reasons for missing in compared groups.

	AND There is no evidence that the effect estimate is robust to missing data.
High risk of bias	A high degree of missing data. AND Differential missing data (different proportion of or different reasons for missing data in compared groups). AND There is no evidence that the effect estimate is robust to missing data.

4. Reaching risk of bias judgements for bias in measurement of the outcome

Low risk of bias	The outcome assessors were unaware of the intervention received by study participants. OR The outcome assessors were aware of the intervention received by study participants, but the assessment of the outcome was unlikely to be influenced by knowledge of the intervention received.
Some concerns	There is no information available to determine whether the assessment of the outcome is likely to be influenced by knowledge of the intervention received.
High risk of bias	Reported outcome data are likely to have been selected, on the basis of the results, from multiple outcome measurements (e.g. scales, definitions, time points) within the outcome domain, or from multiple analyses of the data (or both).

Thresholds for Converting the Cochrane Risk of Bias Tool to AHRQ (Agency for Healthcare Research and Quality) Standards (Good, Fair, and Poor)

Good quality: All criteria met (i.e. low for each domain).

Using the Cochrane Risk of Bias tool, it is possible for a criterion to be met even when the element was technically not part of the method. For instance, a judgment that knowledge of the allocated interventions was adequately prevented can be made even if the study was not blinded, if EPC team members judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding.

Fair quality:

One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was unlikely to have biased the outcome, and there is no known important limitation that could invalidate the results.

Poor quality:

One criterion not met (i.e. high risk of bias for one domain) or two criteria unclear, and the assessment that this was likely to have biased the outcome, and there are important limitations that could invalidate the results.

Following studies selected for the present systematic review shown low risk of bias in randomization process, missing outcome data, measurement of outcome and reported results. Good and fair quality obtained in quality assessment with unclear intended interventions.⁴

STUDY FINDING'S

RAMA S KALLURU, N DEEPAK KUMAR, SHAFIE AHMED, EMANUEL SOLOMON SATHISH, THUMU JAYAPRAKASH, ROOPADEVIA GARLAPATI, BUTTI SOWMYA, K NARASIMHA REDDY in 2014² evaluated the microhardness of human dentin by using four irrigating solutions. In the present study a total of 40 extracted mandibular premolars were selected and sectioned horizontally in the middle third of the root. Forty specimens of 4 mm thickness were embedded in acrylic resin and polished.⁵ Four test groups, each group containing ten specimens were immersed in respective irrigating solution and subjected to vicker's microhardness test at T0, T2 and T5min.² The data obtained were analyzed using the one way ANOVA followed by Tukey HSD method with $\alpha=0.05$ as the level for statistical significance. There was no statistically significant difference in mean values between four experimental irrigating solutions. And the Authors concluded that mixture of Tetracycline isomer i.e. Doxycycline, Citric acid and a Detergent (Tween 80) MTAD not altered the microhardness of root canal dentin significantly and seems to be an appropriate irrigating solution, because of its harmless effect on the microhardness of the root canal dentin.

HEBATALLA E. KANDIL, AHMED H. LABIB, HATEM A. ALHADAINY B IN 2014 Studied¹ the effect of different irrigants on root dentin microhardness and smear layer removal. In the present study a total of 50 roots were equally divided into two halves to measure dentin microhardness and to evaluate the amount of smear layer. One hundred root halves were divided into five equal groups 20 sample each according to the final irrigants used: Group 1: 2.5% NaOCl, Group 2: 2.5% sodium hypochloride (NaOCl) followed by 7% malic acid (MA), Group 3: 2.5% NaOCl followed by 17% ethylenediamine tetraacetic acid (EDTA), Group 4: 2.5% NaOCl followed by mixture of tetracycline, acid and detergent (MTAD) and Group 5: saline. Ten root halves from each group were prepared to measure dentin microhardness at baseline measurement and after treatment to determine the change in microhardness, while the remains 10 root halves were prepared for scanning electron microscope to evaluate the amount of smear in the coronal, middle and apical thirds. Data were analyzed using one-way ANOVA and Student's t-test for microhardness and Kruskal–Wallis and Mann–Whitney for smear layer. Malic acid showed the greatest significant reduction in dentin microhardness ($P < 0.05$), followed by EDTA, MTAD, NaOCl and saline (control). EDTA, malic acid and MTAD efficiently removed smear layer, respectively, in the coronal and middle thirds of root canal. However, in the apical region, malic acid showed more efficient removal of the smear layer than the other irrigants. Authors concluded Malic acid showed the greatest significant reduction in dentin microhardness ($P < 0.05$), followed by EDTA, MTAD, NaOCl and saline (control).

NAVEEN CHHABRA, HITESH GYANANI, AND LAXMIKANT KAMATAGI IN 2015 studied the effectiveness of the combination of two natural extracts in varying ratios for removal of smear layer either alone or supplemented with sonic agitation. In the

present study a total Fifty extracted single-rooted teeth were collected, disinfected and decoronated below the cemento-enamel junction to obtain standardized root length of 10 mm.⁴ Root canals were instrumented using rotary files at working length 1 mm short of the apex. Specimens were divided into six groups according to the irrigation protocol as follows: Group A – Distilled water, Group B – 17% ethylenediaminetetraacetic acid, Group C – Herbal extracts in 1:1 ratio, Group D – Herbal extracts in 1:1 ratio supplemented with sonic agitation, Group E – Herbal extracts in 2:1 ratio, Group F – Herbal extracts in 2:1 ratio supplemented with sonic agitation.⁵ Specimens were longitudinally sectioned and evaluated under scanning electron microscope for smear layer removal efficacy. Obtained scores were statistically analyzed using one-way analysis of variance and post-hoc test. Among all, Group B showed the best results followed by Group F. Remaining other groups showed inferior outcome ($P < 0.05$). And the Authors concluded that the combination of two extracts in 2:1 ratio was slightly better than 1:1 ratio and the smear layer removal efficacy was further improved when accompanied with sonic agitation.⁵

Eick et al (1970)⁶ were the first who identified the smear layer using scanning electron microscope (SEM) and found that smear layer is made from different size of particles ranging from <0.5 to $15\ \mu\text{m}$. The presence of smear layer on instrumented root canals was first reported by McComb and Smith⁷ in (1975). They showed that this layer is made of remnants of dentin, odontoblastic processes, necrotic or viable pulp tissues, and bacteria. Lester and Boyde (1977) reported that smear layer is a mineralized collagen matrix made up of entrapment of organic matter within inorganic dentin.⁷

Şen BH, Wesselink PR, Türkün M (1995)⁸ discussed that smear layer should be removed or not from the instrumented root canals, are still controversial. It has been shown that, this layer is not a complete barrier to bacteria and it delays but does not abolish the action of endodontic disinfectants. Endodontic smear layer also acts as a physical barrier interfering with adhesion and penetration of sealers into dentinal tubules. In turn, it may affect the sealing efficiency of root canal obturation. When it is not removed, the durability of the apical and coronal seal should be evaluated over a long period. If smear layer is to be removed, EDTA and NaOCl solutions have been shown to be effective, among various irrigation solutions and techniques, including ultrasonics, that have been tested. Once this layer is removed, it should be borne in mind that there is a risk of re-infecting dentinal tubules if the seal fails. They also emphasized that, further studies are needed to establish the clinical importance of the absence or presence of smear layer.

Violich DR, Chandler NP (2010)⁹ overviewed on the articles on the smear layer, focusing on its relevance to endodontics. The PubMed database was used initially; the reference list for smear layer featured 1277 articles, and for both smear layer dentin and smear layer root canal revealed 1455 publications. Smear layer endodontics disclosed 408 papers. Data obtained suggests that smear layer removal should enhance canal disinfection. They concluded that if smear is to be removed, the method of choice seems to be the alternate use of EDTA and sodium hypochlorite solutions. Conflict remains regarding the removal of the smear layer before filling root canals, with investigations required to determine the role of the smear layer in the outcomes of root canal treatment.

Li, D., Jiang, S., Yin, X., Chang, J.W.W., Ke, J. and Zhang, C. (2015)¹⁰ conducted study to use high-resolution micro-computed tomography (micro-CT) and scanning electron microscopy (SEM) to compare the efficacy of four irrigation techniques (needle, ultrasonic, Endoactivator, and photon-induced photoacoustic streaming (PIPS)) in removing calcium hydroxide from the root canal and isthmus of maxillary premolars. PIPS and ultrasonic irrigation more effectively removed calcium hydroxide from the main canal and isthmus in maxillary premolars than did Endoactivator or needle irrigation.^{11,13}

Researchers have different opinion regarding the importance of removing or leaving this smear layer. Some investigators advocated the importance of maintaining the smear layer after canal preparation, and some studies provide strong evidence to prove that smear layer acts as a seal to the dentinal tubules and minimizes bacterial and its toxin from invasion by altering dentinal permeability.^{12,13} **Pashley** (1985)¹⁴ reported that the presence of a smear layer may limit bacteria present in the infected canal to enter the dentinal tubules in case of inadequate canal disinfection or recontamination of the canal between treatment sessions. However, a study by **Williams and Goldman** (1985)¹⁵ reported that this layer cannot act as a complete barrier and its presence could only delay bacterial invasion.

Madison and Krell (1984)¹⁶ using a chelating agent, ethylenediaminetetraacetic acid (EDTA) solution, found no difference in the leakage properties regardless of the presence of smear layer. However, a major disadvantage of these studies is that the experiments did not mimic the clinical condition and were undertaken using cross-sectional root models or dentin discs. This limitation was overcome by a study of **Drake et al** (1994)¹⁷ and they suggested that smear layer formed during mechanical instrumentation can prevent bacterial colonization of root canals as it limits bacterial penetration into dentinal tubules.

Some authors advocated the significance of removing the smear layer since it contains necrotic tissue, bacteria, and its by-products. Smear layer can act as a reservoir for further microbial irritants and may serve as a substrate for microorganisms to survive, multiply, and then proliferate deeply inside the dentinal tubules.^{18,19,20} **Brännström** (1984)²¹ advocated that these microorganisms inside the dentinal tubules can easily be destroyed once the smear layer is removed. In addition, the smear layer can minimize the ability of disinfecting agents to penetrate the dentinal tubules. Other studies showed that it can also minimize the ability of intracanal medicaments to penetrate deeply. Therefore, smear layer can delay but did not completely eliminate the effect of disinfectant agent or intracanal medicament.²²

The advantages and disadvantages of smear layer removal are still controversial. The need and the importance of smear layer removal are connected to the root content (live or necrotic pulp). **De Deus** (2011)²³ found that in case of treating vital teeth where there is no contamination and the aseptic chain is maintained, removal of the smear layer may not be required. However, if treatment of a necrotic tooth is due, the smear layer will become infected, and the clinician should consider the importance of its removal.²⁴

Limitations of the study : The influence of various variables suggests necessity of further studies on larger number of samples under strictly controlled experimental conditions. As this is vitro study this cant be totally correlated with vivo environment. Large size sample required.

CONCLUSION:

Irrespective of technique used, EDTA as compared to NEW HERBAL FORMULATION was more efficiently removed in ^[SEP]coronal and middle third as compared to apical third of the root canals. ^[SEP] ^[SEP]

Conflict of Interest:

All the authors associated with present manuscript declared no potential conflicts of interest with respect to research, authorship or publication of this article.

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