The Effect of Smear Layer Removal on Endodontic Outcomes

by
Susan E. Hinman, LCDR, DC, USN

A thesis submitted to the Faculty of the
Endodontics Graduate Program
Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
in partial fulfillment of the requirements for the degree of
Master of Science
in Oral Biology

June 2012

Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
Bethesda, Maryland

CERTIFICATE OF APPROVAL

MASTER'S THESIS

This is to certify that the Master's thesis of

Susan E. Hinman

has been approved by the Examining Committee for the thesis requirement
for the Master of Science degree in Oral Biology at the June 2012 graduation.

Thesis Committee:

Patricia A. Tordik, DMD
CAPT, DC, USN
Associate Dean, Graduate Dental Program
Navy Medicine Professional Development Center

Terry D. Webb, DDS, MS
CAPT, DC, USN
Chairman, Endodontics Dept.

Kathleen McNally, DDS
COL, DC, USA
Assistant Program Director, Endodontics Dept.

Glen M. Imamura, DDS, MS
CAPT, DC, USN
Chairman, Dental Research Dept.

Glenn A. Munro, DDS, MS
CAPT, DC, USN
Dean, Naval Postgraduate Dental School

The author hereby certifies that the use of any copyrighted material in the thesis manuscript entitled:

"The Effect of Smear Layer Removal on Endodontic Outcomes"

is appropriately acknowledged and, beyond brief excerpts, is with the permission of the copyright owner.

Susan E. Hinman, DDS, MS
Endodontics Department
Naval Postgraduate Dental School
Uniformed Services University of the Health Sciences
01/01/2013

The Effect of Smear Layer Removal on Endodontic Outcomes

Susan E. Hinman, DDS, MS

ABSTRACT: Introduction: In endodontics, a smear layer is created during mechanical shaping of the root canal system. Smear is a surface film of debris consisting of dentin particles, tissue remnants and bacteria. The combined use of ethylene diamine tetraacetic acid (EDTA) and sodium hypocholorite (NaOCl) irrigants has been shown to effectively remove smear layer during canal instrumentation. However, removal is not universally practiced by all clinicians. To date, the only evidence supporting smear layer removal is based upon *in vitro* studies or empiricism. **Objective:** A prospective, randomized, double-blinded, clinical trial investigated the effect of smear layer removal from the root canal system on healing outcomes. A secondary analysis assessed the influence of covariant factors on healing. **Materials and Method:** Subjects were selected from the Endodontic Clinic population at Naval Postgraduate Dental School (NPDS), Bethesda, MD. Patients who agreed to participate in the study were consented and randomized into one of two experimental groups. All subjects received a standardized evaluation and treatment regimen with the exception of the irrigants used. In one group, the root canals were irrigated using a 17% EDTA solution to remove the smear layer. In the remaining group, 0.9% sodium chloride was used which did not remove smear layer. A standardized follow-up radiographic and clinical evaluation to establish periapical healing was conducted one year after root canal treatment. An interim primary data analysis was performed using Fischer's exact chi-square ($\alpha \leq 0.05$) on 41 of 137 subjects enrolled to date. **Results:** No significant association was detected between irrigant and radiographic healing, $p=0.540$. Using logistic regression modeling, no covariant factors were found to influence healing. **Conclusion:** This preliminary evaluation indicated that smear layer removal does not affect periapical outcomes.

KEY WORDS: Smear layer, smear layer removal, smear layer creation, EDTA, Sodium hypochlorite, Periapical index

INTRODUCTION: The presence of bacteria in the dentinal pulp causes irreversible damage and apical pathosis (1) precipitating the need for endodontic treatment to remove the diseased pulpal tissue and associated bacteria. The process of shaping root canals during root canal therapy has been shown to leave behind a smear layer (2). This smear layer is made up of bacteria, dentin, cytoplasmic and organelle enzymes, lamina limitans and organic and inorganic constituents of dentin of 1-2 microns (3). Smear plugs created by pushing smear into dentinal tubules up to 40 microns deep (4), can entomb bacteria and prevent complete cleaning of the canal system. The decision to remove the smear layer in endodontic treatment has proponents and detractors. Many in-vitro studies have shown that removal of the smear layer increases dentin permeability (6) and its removal has been the subject of many investigations of how it may affect the quality of root canal seal (7). One controversy in endodontics is whether the removal of the smear layer has any effect on the healing outcome of nonsurgical root canal treatment (8).

Debate regarding removal of the smear layer exists and many in-vitro studies have identified the most efficient process for removal of the smear layer. Normal saline and sodium hypochlorite (NaOCl) have been shown not to remove smear layer as described by Yoshida et al. in the Journal of Endodontics in 1995. The use of NaOCl has been shown to remove pulpal remnants on the uninstrumented parts of the canal wall, however, the smear layer with a large surface-to-mass ratio is susceptible to acids and chelating agents. The use of 17% EDTA alone will demineralize smear but leaves a fibrous layer on canal walls. A combination of 17% EDTA and NaOCl will effectively remove pulpal remnants and the smear layer (9, 10). The use of 1cc 17% EDTA in contact with dentin for one minute followed by a 3 cc flush of 6% NaOCl is effective in removal of the smear layer (3). To date, no in-vivo studies to investigate the intentional removal of the smear layer in a root canal system and its effect on healing outcomes of nonsurgical endodontic treatment has been completed. The purpose of this study is to investigate, 1) the effect of smear layer removal from the root canal system on healing outcomes and 2) the impact of factors other than the methodology of nonsurgical treatment on healing outcomes.

MATERIAL and METHODS: This prospective randomized double-blinded clinical trial was approved by the National Military Medical Center Institutional Review Board at Bethesda, Maryland and was open to all patients requiring root canal treatment in the Endodontic Department of the Naval Postgraduate Dental School (NPDS). To participate, subjects must have been 18 years of age or older, able to consent and referred for endodontic therapy. Patients were excluded if they had previously initiated therapy or treatment, a documented allergy to the dental materials used in the study or were taking antibiotics at the time of treatment.

A power analysis was conducted. The healing rate in the control group with potential covariant factors was accepted at approximately 80%. The sample size was based on point estimation rather than a hypothesis perspective, and anticipated a healing rate in the experimental EDTA sample would increase (85% estimate). To be able to estimate the true rate of healing to within five percentage points, a sample size of 200 teeth per group was required. To account for loss to

follow up or other treatment complications 220 subjects will be enrolled in both the experimental and control groups for a total of 440 subjects.

A standardized protocol was followed for all treatments and was completed by first and second year endodontic residents. To minimize variables a single appointment visit was specified. Those patients who were not completed in a single visit were completed and the data collected. However, their information was not included in the final analysis. Standardized preoperative, intraoperative and postoperative treatment forms were used for data collection.

Treatment was rendered under local anesthesia (2% lidocaine with 1:100,000 epinephrine) with rubber dam isolation. Caries removal and straight-line access into pulp chamber was achieved. All canal orifices were located with the aid of an endodontic explorer and ultrasonic instruments when applicable. Patency length was determined with a 0.02 taper #10 stainless steel FlexoFile (Dentsply Maillefer, Tulsa, OK) on all canals using a Root ZX (J Morita, Irvine,CA) apex locater. Working length (WL) was set 1mm short of patency and confirmed radiographically. Coronal flaring using Profile orifice openers (Dentsply Maillefer, Tulsa,OK) was completed and the apical one third was instrumented sequentially with 0.02 taper #10, #15, and #20 FlexoFiles (Dentsply Maillefer, Tulsa, OK). Rotary instrumentation was completed in a crown down fashion using 0.04 Profile (Dentsply Maillefer, Tulsa,OK) to WL to a minimum master apical file size of #35. Irrigation of 6% sodium hypochlorite (NaOCl) during instrumentation was delivered with a 1 inch, 30 gauge, Max-I-Probe syringe (Dentsply Maillefer, Tulsa, OK) and did not exceed 2mL per canal. Sterile paper points (Henry Schein, Melville, NY) were used to dry the canals.

Each subject was randomly assigned (random.org) to either the experimental or control group. The provider and patient were blinded as to the irrigant used and were provided either 1 mL per canal of 17% EDTA or 0.9% sterile saline. The test irrigants were delivered over 1 minute period per canal. The canals were again dried with sterile paper points (Henry Schein, Melville, NY), and a final rise of 3mL 6% NaOCl for each canal was completed. The canals were then dried with sterile paper points (Henry Schein, Melville, NY) in preparation for obturation with gutta percha cone (Diadent, Burnaby, BC, Canada) and a mixture of eugenol and Grossman Type 801 Root Canal Cement Powder (Roth International LTD, Chicago, IL) using the continuous wave technique. The sealer was delivered into the canal using a lentulospiral (Dentsply Maillefer, Tulsa, OK); the canal space was backfilled be delivery of thermoplastizied gutta percha. The chamber was cleaned with an alcohol soaked cotton pellet and the tooth was temporized with a sterile cotton pellet and Fuji IX GI® (GC America Inc., Alsip, IL) packable glass-ionomer cement. Post-operative periapical radiographs were taken with Rinn XCP (Dentsply Rinn, Elgin, IL) positioning device and Blu-Mousse (Parkell, Edgewood, NY). The bite registration material was used to create a positioning index for the postoperative film. This index was used later to capture follow-up radiographs at the same angle and location. Patients were informed of the completed treatment and returned to their referring dentist for definitive restorations. Patients were contacted by phone and e-mail to schedule a 12 month follow up

appointment. Clinical signs and symptoms were recorded and radiographs taken using the one year follow up treatment visit. All films were taken with size 2 Kodak Insight (Carestream Dental, Rochester, NY) double film packets and processed with the Peri Pro III (Air Techniques Melville, NY).

After follow ups were completed, the immediate postoperative films, one year follow up films were collected, coded and randomized for viewing by two of the study investigators (S.E.H. and J.L.S.). The films were evaluated by three board certified endodontists who were blinded to the status of the film and to the coronal restoration. The evaluators were calibrated on grading the images using the Periapical Index (PAI) scoring system as adapted from Orstavik (19). The radiographs were projected on a screen in a darkened room and scored by forced consensus. Scores we identified and comparison was made between the immediate postoperative and the follow up PAI scores. Clinical signs and symptoms were included in the evaluation and subjects reporting pain or had symptoms on percussion or palpation were considered not healed for the evaluation. Scores of 1 or 2 were considered healed while scores of 3 ,4 or 5 were considered not healed(19).

The primary objective of this study was to determine the effect of EDTA on healing of pulpal and periapical disease. This was based on radiographic evaluation, clinical signs and symptoms after one year. Statistical analysis was completed to compare two groups using the Fisher's exact chi-square. Logistic regression modeling was used to calculate the effect of other factors on healing after one year as collected on the standardized data collection sheets.

RESULTS: This interim analysis reviewed one hundred and one subjects who met the inclusion criteria and consented for participation in the study. Twenty-nine subjects withdrew or were withdrawn due to protocol deviations to include multiple appointments. Forty-two patients were evaluated at one year both clinically and radiographically (Figure 1.), 23 in the experimental group (EDTA) and 19 subjects in the control group (saline). Twenty-nine subjects have been lost to follow up for a recall rate of 58 percent. Two subjects presented with clinical symptoms and were classified as non-healed one from each of the EDTA and Saline groups. Radiographic healing was found in 24 subjects (13 EDTA, 11 Saline) while 18 subjects were non-healed (10 EDTA, 8 Saline). Fisher's exact chi square analysis showed no statistically significant difference in the percentage of healed teeth at 12 months between the control and experimental groups ($p>0.95$). Logistic regression analysis of covariate variables (age, gender, presence of pre-operative radiolucency, patency, diabetes and hypertension) showed no statistically significant differences.

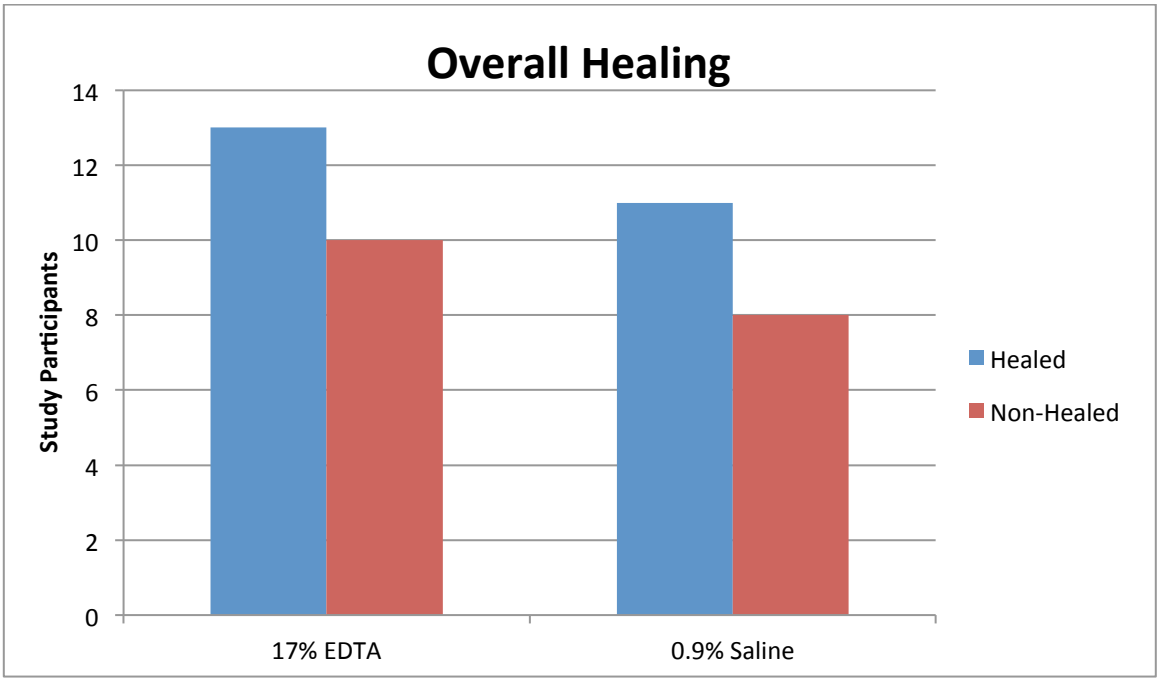

Figure 1

DISCUSSION: A Report on the practice of endodontic smear layer removal was published in 2001 (25), acknowledging a variation in the practice and teaching in regards to smear layer across the endodontic community. A 2012 web based survey of endodontic irrigation techniques, with a 28% response rate, reported 77% of respondents were intentionally removing the smear layer (32). From 2001 to 2012 there have been no clinical investigations to predict the outcome of root canal therapy when the smear layer has been intentionally removed compared to a control. In-vitro investigation have been conducted to look at and identify the presence of and ability to remove bacteria (7, 10, 22, 29), increase root canal seal (13, 15, 27) all with the implication that removing or not removing the smear layer will imply a better outcome. The use of EDTA in combination with NaOCl has been shown to increase dentinal erosion (21). The introduction of adhesion based root canal filling materials in which smear plugs are removed to allow for the formation of a resin based hybrid layer have not shown an increase in endodontic outcome compared to a systematic review of endodontic outcomes (11, 30). This prospective randomized double-blinded study has been undertaken to evaluate radiographic healing with removal of the smear layer. The study follows a standardized treatment protocol to evaluate the use of different irrigation regimens and there effect on outcome. This interim analysis showed no statistically significant difference in the healed rate of root canal treatment and the removal of the smear layer. Factors unique to individual subjects that could not be controlled such as history of hypertension, diabetes and treatment factors such as preoperative diagnosis or presence of apical pathosis were evaluated for effect on outcome with no statistical differences. The ability to control the variables in the study is what gives the study power over other research available. The randomization was completed by assigning the number of subject determined by

the power analysis to either group A or group B prior to enrollment. The subjects and the providers were blinded to the irrigation regimen used during the treatment. The data analyzed was for subjects for whom the protocol had no deviation and follow up was completed. Two patients had clinical symptoms to include reported pain and pain on palpation and percussion, one from each group. The statistical analysis of this small sample size showed a high p-value at 85 with 0.05 confidence interval indicates that increasing the sample size by continued follow up or increasing to a higher confidence interval will show little decrease in p-value and significance may never be found.

CONCLUSION: Based on this randomized double-blinded controlled clinical trial there is no statistically significant difference when the smear layer is removed on endodontic outcomes.

REFERENCES:

1. Kakehashi S, Stanley HR, Fitzgerald RJ. The effects of surgical exposures of dental pulps in germ-free and conventional laboratory rats. Oral Surg Oral Med Oral Path 1965; 20: 340-9.

2. McComb D, Smith DC. A preliminary scanning electron microscopic study of root canals after endodontic procedures. J Endod 1975; 1: 238-42.

3. Pashley D. Smear layer: overview of structure and function. Proc Finn Dent Soc 1992; 88: 215-24.

4. Mader CL, Baumgartner JC, Peters DD. Scanning electron microscopic investigation of the smeared layer on root canal walls. J Endod 1984; 10: 477-83.

3. Crumpton BJ, Goodell GG, McClanahan SB. Effects on smear layer and debris removal with varying degrees of 17% REDTA after rotary instrumentation. J Endod 2005; 31: 536-8.

4. Mjor IA, Nordhal I. The density and branching of dentinal tubules in human teeth. Arch Oral Biol 1996;41:401-12.

5. Gambarinin G, Laszkiewicz J, A scanning electron microscopic study of debris and smear layer remaining following use of GT rotary instruments. Int Endod J 2002;35:422-7.

6. Pashley D, Michelich V, Keht T. Dentin permeability: effects of smear layer removal. J Prosthet Dent 1981; 46: 531-7.

7. Shahraven A, Haghdoost A-A. Effect of smear layer on sealing ability of canal obturation: a systemic review and meta-analysis. J Endod 2007; 33: 96-105.

8. Torabinejad M, Handysides R, Khademi AA, Bakland LK. Clinical implications of the smear layer in endodontics: A review. Oral Surg Oral Med Oral Path Oral Radio Endod 2002; 94: 658-66.

9. Baumgartner JC, Mader CL. A scanning electron microscope evaluation of four root canal regimens. J Endod 1987; 13: 147-57.

10. Bystrom A, Sundqvist G. The antibacterial effect of sodium hypochlorite and EDTA in 60 cases of endodontic therapy. Int Endod J 1985;18:35-40.

11. Conner DA, Caplan DJ, Teixeira FB, Trope M. Clinical outcome of teeth treated endodontically with a nonstandardized Protocol and root filled with Resilon. J Endod 2007; 33: 1290-2.

12. Drake DR, Wiemann AH, Rivera EM, Walton RE. Bacterial retention in canal walls in vitro: effect of smear layer. J Endod 1994;20:78-82.

13. Avramovich A, Goldberg F. The relationship of the root canal sealer to the dentine wall. An in vitro study using scanning electron microscope. J Br Endod Soc 1976;9:81-6.

14. Orstavik D, Haapasalo M. Disinfection by endodontic irrigants and dressings of experimentally infected dentinal tubules. Endod Dent Traumatol 1990; 6: 142-9.

15. Saleh IM, Ruyter IE, Haapasalo MP, Orstavik D. Adhesion of endodontic sealers: scanning electron microscopy and energy dispersive spectroscopy. J Endod 2003;29:595-601.

16. Foster KH, Kulild JC, Weller RN. Effect of smear layer removal on the diffusion of calcium Hydroxide through radicular dentin. J Endod 1993; 19:136-40.

17. Mor C, Rotstein I, Friedman S. Incidence of interappointment emergency associated with endodontic therapy. J Endod 1992;18:509-11.

18. Trope M. Flare up rate of single-visit endodontics. Int Endod J 1991; 24: 24-6.

19. Orstivik D., Kerekes K, Eriksen HM. The periapical index: a scoring system for radiographic assessment of apical periodontitis. Endod Dent Traumatol 1986; 2: 20-34.

20. Hulsmann M, Heckendorff M, Lennon A. Chelating agents in root canal treatment: mode of action and indications for their use – a review. Int Endod J 2003; 36: 810-30.

21. Qian W, Shen Y, Haapasalo M. Quantitative analysis of the effect of irrigant solution sequences on dentin erosion. J Endod 2011; 37: 1437-41.

22. Soares JA, de Carvalho MAR, Santos SMC, Mendonca RMC, Ribeiro-Sobrinho AP, Brito-Junior M, Magalhaes PP, Santos MH, Farias LM. Effectiveness of chemomechanical preparation with alternating use of sodium hypocholorite and EDTA in eliminating intracanal *enterococcus faecalis* Biofilm. J Endod 2010; 36:894-98.

23. Chugal NM, Clive JM, Spangberg LSW. A prognostic model for assessment of the outcome of endodontic treatment: effect of biologic and diagnostic variables. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2001; 91: 342-52.

24. Gharib SR, Tordik PA, Imamura GM, Baginski TA, Goodell GG. A confocal laser scanning microscope investigation of the epiphany obturation system. J Endod 2007; 33: 957-61.

25. Moss HD, Allemang JD, Johnson JD. Philosophies and practices regarding the management of the endodontic smear layer: results from two surveys. J Endod 2001; 27: 537-9.

26. Molander A, Warfvinge J, Reit C, Kvist T. Clinical and radiographic evaluation of one- and two-visit endodontic treatment of asymptomatic necrotic teeth with apical periodontitis: a randomized clinical trial. J Endod 2007; 33: 1145-8.

27. Timpawat S, Vongsavan N, Messer HH. Effect of removal of the smear layer on apical microleakage. J Endod 2001; 27: 351-3.

28. Sen BH, Wesselink PR, Turkun M. The Smear layer: a phenomenon in root canal therapy. Int Endod J 1995; 28: 141-8.

29. Clark-Holke D, Drake D, Walton R, Rivera E, Guthmiller JM. Bacterial penetration through canals of endodontically treated teeth in the presence or absence of the smear layer. J Dent 2003; 31: 275-81.

30. Ng YL, Mann V, Rahbaran S, Lewsey J, Gulabivala K. Outcome of primary root canal treatment: systematic review of the literature – part 1. Effects of study characteristics on probability of success. Int Endod J 2007; 40: 921-39.

31. Penesis VA, Fitzgerald PI, Fayad MI, Wenckus CS, BeGole EA, Johnson BR. Outcome of one-visit and two-visit endodontic treatment of necrotic teeth with apical periodontitis: a randomized controlled trial with one-year evaluation. J Endod 2008; 34:251-7.

32. Dutner J, Mines P, Anderson A. Irrigation trends among american association of endodontists members: a web-based survey. J Endod 2012; 38: 37-40.