

THE EFFECT OF SMEAR LAYER REMOVAL ON ENDODONTIC OUTCOMES

by

Grant Ronald Layton, D.M.D.
Lieutenant Commander, Dental Corps
United States Navy

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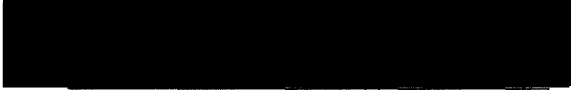
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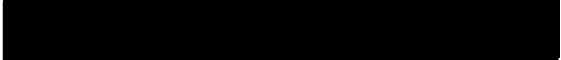
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Research Committee:


Glen M Imamura, DDS, MS
Research Committee Chair


Calvin B. Suffridge, DDS, MS
Chairman, Endodontics Dept

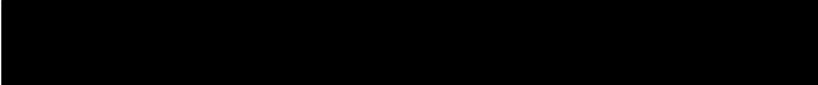

John J. Neal, DDS, MS
Program Director, Endodontics Dept


CDR Andrea Lisell, DMD, MS
Research Mentor

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Grant Ronald Layton
Endodontic Graduate Program
Naval Postgraduate Dental School
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ABSTRACT

THE EFFECT OF SMEAR LAYER REMOVAL ON ENDODONTIC OUTCOMES

GRANT RONALD LAYTON
D.M.D., ENDODONTICS DEPT, 2019

Directed by: LCDR ANDREA LISELL, ENDODONTIC STAFF

Introduction: A layer of organic and inorganic debris referred to as the smear layer is produced during mechanical instrumentation of root canal system. Effectively removing this layer is accomplished with the use of Ethylenediaminetetraacetic acid (EDTA) and sodium hypochlorite (NaOCl). Recommendation to remove or retain the smear layer has not been supported based on a controlled outcome study. This remains a topic of discussion within the endodontic community. This randomized, prospective, double-blinded clinical trial compared the outcomes of teeth in two groups; which either had the smear layer removed or where the smear layer was left intact. Covariate factors and the possible influence on outcomes was analyzed. **Materials & Methods:** Following inclusion criteria compliance and subject's enrollment, random assignment to one of two (group A or B) irrigation protocols was made. Standardized instrumentation followed by assigned final irrigation protocol was completed for each subject. Group A received 1ml/minute/canal of 17% EDTA with Group B receiving 1ml/minute/canal of .9% saline. 3ml/canal of 6% NaOCl was then rinsed regardless of assigned group. Clinical and radiographic evaluations completed no earlier than 12 months post treatment to assess outcome differences. Modified periapical index (PAI) score (1-5) used for radiographic analysis using Fisher's Exact test ($p < 0.05$). **Results:** An interim analysis of 192 subjects revealed no significant difference between the irrigation protocol groups ($p = .30$). Pre-operative apical lesion was found as the

only covariate affecting healing rates ($p=.0001$). **Conclusion:** Within the limitations of this *in-vivo* clinical study, removal of the smear layer did not affect endodontic outcomes.

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REVIEW OF THE LITERATURE

Endodontic therapy continues to evolve with a goal to reduce the presence of bacteria and diseased tissue within the root canal system. Without the presence of bacteria, pulpal and periapical disease is not found [1]. Mechanical instrumentation of the canal to facilitate removal creates what is known as the smear layer. As researchers looked closely within the canal to assess the effects of chemomechanical debridement, the layer was further described and analyzed. Composed of the inorganic and organic material from within the tooth this layer of pulp remnants, dentinal debris and bacteria remaining on and within the dentinal wall [2, 3]. Composed particles ranging in size from less than .5 to 15 μ m with layer thickness ranging from 2-5 μ m thick and extending up to 110 μ m into the dentinal tubules [4-6]. Understanding the properties and the effect it has on the coronal and apical seal whether present or absent has been studied and reported[7, 8]. Bacteria and tissue encased within the dentinal tubules by the smear layer has been shown though what effect on endodontic outcomes it possesses is yet to be determined[9].

Rinsing with saline or sodium hypochlorite (NaOCl) alone does not remove the smear layer as it is firmly embedded along the canal wall and into the dentinal tubules[10] Chelators such as acetic acid or ethylenediaminetetraacetic acid (EDTA) have been shown to remove the smear layer effectively when utilizing a combination of 17% EDTA along with a final rinse of 5.25% NaOCl to achieve the best results[10]. To further dial in the procedure for successful removal of the smear layer studies were conducted to refine the volume and time needed to efficiently remove the smear layer. Using 1ml of 17% EDTA over a 1-minute time frame with a final rinse of 3ml of 5.25% NaOCl. Concentration, volume and time listed based on literature has been show to produce the desired effect of removal of the smear layer with minimal deleterious

effects on the erosion of the dentin[11, 12]. Continued research with new products and techniques to remove the smear layer have also been found to be successful with no reported study showing increased efficacy over the above reported protocol. Among such reports are the use of hydrogen peroxide, mild acids such as citric acid, BioPure® MTAD®, Omix®, ultrasonics and lasers[2, 10, 13-18].

To date, no *in-vivo* outcome study has been reported evaluating the removal of the smear layer as part of initial nonsurgical endodontic therapy and the effects on outcomes in permanent teeth. Evaluation of the literature for recommendation on whether the smear layer should be removed is controversial. Removal to eliminate trapped bacteria[2], decrease bacterial leakage[19], and increase the quality of the seal[20] are among some of the reasons that a clinician might advocate for the removal of the smear layer. On the other hand for reasons such as increasing dentin permeability, decreasing apical seal[21] or bacterial leakage[3] the clinician may choose to not remove the smear layer. A study theorized that not removing the smear layer may prevent bacteria from being able to penetrate into dentinal tubules[22]. The conflicting information only provides evidence for specific reasons while not addressing any possible effect on healing directly. This interim analysis of a prospective double blind randomized clinical trial investigating, 1) the effect of smear layer removal on endodontic outcomes and 2) the impact of covariate factors on outcomes.

MATERIALS AND METHODS

Patient selection. The Institutional Review Board (IRB) at the Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD approved this study. Funding was provided by WRNMMC, Bethesda, MD. The Endodontics Department at the Naval Postgraduate Dental School (NPDS) is a referral-based clinic serving an active and retired military population,

their family members and other eligible beneficiaries. Prior to receiving any treatment, all patients received a comprehensive endodontic evaluation. Patients were asked to participate in this study if they were 18 years or older and had the ability to consent, were in good health (American Society of Anesthesiology health status classification I or II) and required initial NSRCT without any prior treatment and could be completed in a single visit. Additionally, all participants agreed to return for a 1-year follow-up examination. Patients with a history of periodontal disease, previously initiated or previously treated, on antibiotic therapy or presenting with an acute apical abscess were ineligible to participate. Those patients allergic to any medication or dental material used in the study, including latex or gutta percha, and subjects who reported being pregnant were not asked to participate in the study.

Treatment protocol. Once enrolled, subjects were randomly assigned to one of two treatment groups (A or B). Two pre-operative periapical radiographs were taken, one straight on and one angled. Medical conditions, clinical symptoms and diagnostic and treatment information were collected on standardized data collection forms. All treatment was provided by NPDS endodontic residents using dental operating microscopes and verified by endodontic staff. Except for the test irrigant being either 17% EDTA or 0.9% sterile saline, a standardized treatment protocol was utilized for all subjects regardless of group assignment. Subjects were anesthetized and the tooth being treated was isolated with rubber dam and Oraseal® caulking adhesive (Ultradent Products, South Jordan, UT). Straight-line access was established using #2 round or #557 carbide burs (Henry Schein, Melville, NY) and EndoZ burs (Dentsply Maillefer, Tulsa, OK). Coronal flaring was created using #2, #3, and #4 Gates Glidden drills (SybronEndo Corporation, Orange, CA). Canal working lengths were established using a Root ZX® (J Morita, Irvine, CA) and confirmed radiographically. A glide path was created using 0.02 taper

#10, #15, #20 FlexoFile® stainless steel files to working length. The canals were cleaned and shaped with 0.04 Profile (Dentsply Maillefer, Tulsa, OK) rotary files using a crown down technique to at least a master apical file size #35 with .04 taper. Recapitulation was performed with 0.02 taper #10 FlexoFiles to working length and irrigated with 6% NaOCl, delivered from a 30-gauge side vented irrigation tip between all file sizes for a total intraoperative irrigation volume not exceeding 2ml. The canals were then dried with sterile paper points (Henry Schein, Melville, NY).

In order to blind the clinician to the final irrigation protocol, the provider was handed a syringe containing one of the two irrigating solutions labeled “irrigant A” or “irrigant B”. Group A received a rinse with 17% ETDA and group B with 0.9% saline. The clinician delivered 1ml of the test irrigant 1mm short of working length over 1 minute per canal, after which identical treatment for all subjects resumed.

A final rinse of 3ml of 6% NaOCl per canal was performed and the canals were dried with sterile paper points. A System B® (SybronEndo, Orange, CA) plugger was selected that bound within the canal 5-7 mm short of working length. Working length was confirmed using a 0.04 taper master gutta percha cone (Diadent, Burnaby, BC, Canada). Roth 801 sealer (Roth International LTD, Chicago, IL) was delivered into the canal and walls coated. The master cone was seated to working length and the canal was obturated with gutta percha using a continuous wave technique. The canal was backfilled using an Obtura II™ (Obtura Spartan, Earth City, MO). Alcohol-soaked cotton pellets were used to clean the chamber prior to temporizing the access with a sterile cotton pellet and Fuji Triage® (GC America Inc., Alsip, IL) or Cavit™ Temporary Filling Material (3M ESPE Dental, St Paul, MN). A post-operative radiograph was taken using a XCP® (Dentsply Rinn, York, PA) device with Blu-Mousse® (Parkell inc, Edgewood, NY) bite registration material in order

to reproduce the vertical and horizontal angles of the radiograph at the follow-up appointment. The subject was instructed to return to the referring dentist for the permanent restoration.

A follow-up examination, conducted no less than 12 months following treatment, was completed. Providers reviewed health history and recorded clinical data including results from diagnostic testing on standardized follow-up data collection forms. A periapical radiograph was taken using the positioning device previously created at the treatment appointment. A pulpal and apical diagnosis was made based on diagnostic testing conducted during the follow-up exam.

Outcomes assessment. Data from the treatment and follow-up exam were utilized to determine the endodontic outcome. Subjects that were classified as “Healed” were defined as asymptomatic and absence of radiographic lesion at the time of follow-up, while “non-healed” subjects were defined as either symptomatic and/or presence of a radiographic lesion.

PAI scoring. The PAI scoring, described by Ørstavik (**Error! Reference source not found.**), was conducted by 3 calibrated, board certified endodontists. The coronal restorations of the immediate post-operative and 1-year follow-up radiographs were masked to eliminate reviewer bias. Radiographs were coded, randomized and individually projected onto a screen in a dark room. After conventional film were converted into digitized images, they were randomized and individually viewed on a single laptop with the ability to adjust the density and contrast. Radiographs were scored individually, and when there was disagreement, forced consensus was used. A PAI score of 1 or 2 was considered healed while a PAI score of 3, 4 or 5 was considered non-healed. All data were entered into SPSS Statistics (IBM, Armonk, NY).

Statistical analysis. To establish sample size, a power analysis was performed estimating an 80% healed rate at 12 months. In order to estimate the true healed rate to within 5 percentage points, a sample size of 440 subjects will be evaluated for significance using the fisher’s exact test.

RESULTS

This interim analysis reports that a total of 287 subjects enrolled in the study, 50 subjects enrolled since the last interim analysis. 11 subjects did not complete the NSRCT at NPDS, resulting in 218 subjects who were eligible for follow-up. 192 subjects completed the follow-up examination for a follow-up rate of 88%. A total of 34 subjects with a completed follow-up were unable to be analyzed due to extraction (n=15) or deviation from protocol (n=19). The most common protocol deviation was due to multiple appointment treatments but also included surgical root canal treatment, missed canal, use of sealer not per protocol and known use of EDTA. The remaining 158 subjects were analyzed. As shown Figure 1 63% of subjects assigned to the .9% Saline group healed while 71% of subjects assigned to the 17% EDTA group healed. The comparison of the two irrigation protocols at this time shows no statistical significance ($p = 0.30$).

Figure 1. *The Healed Rates of the Irrigation Protocols*

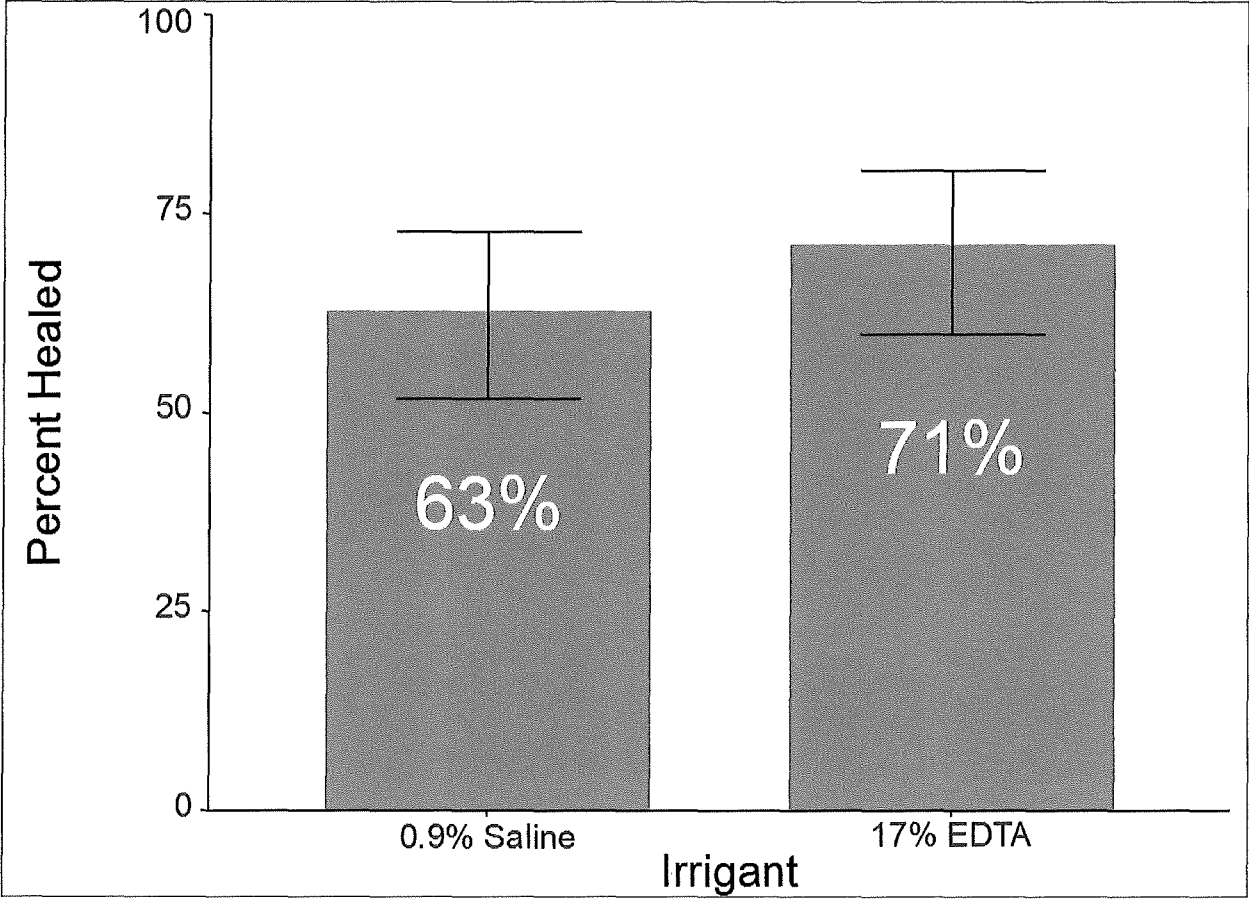
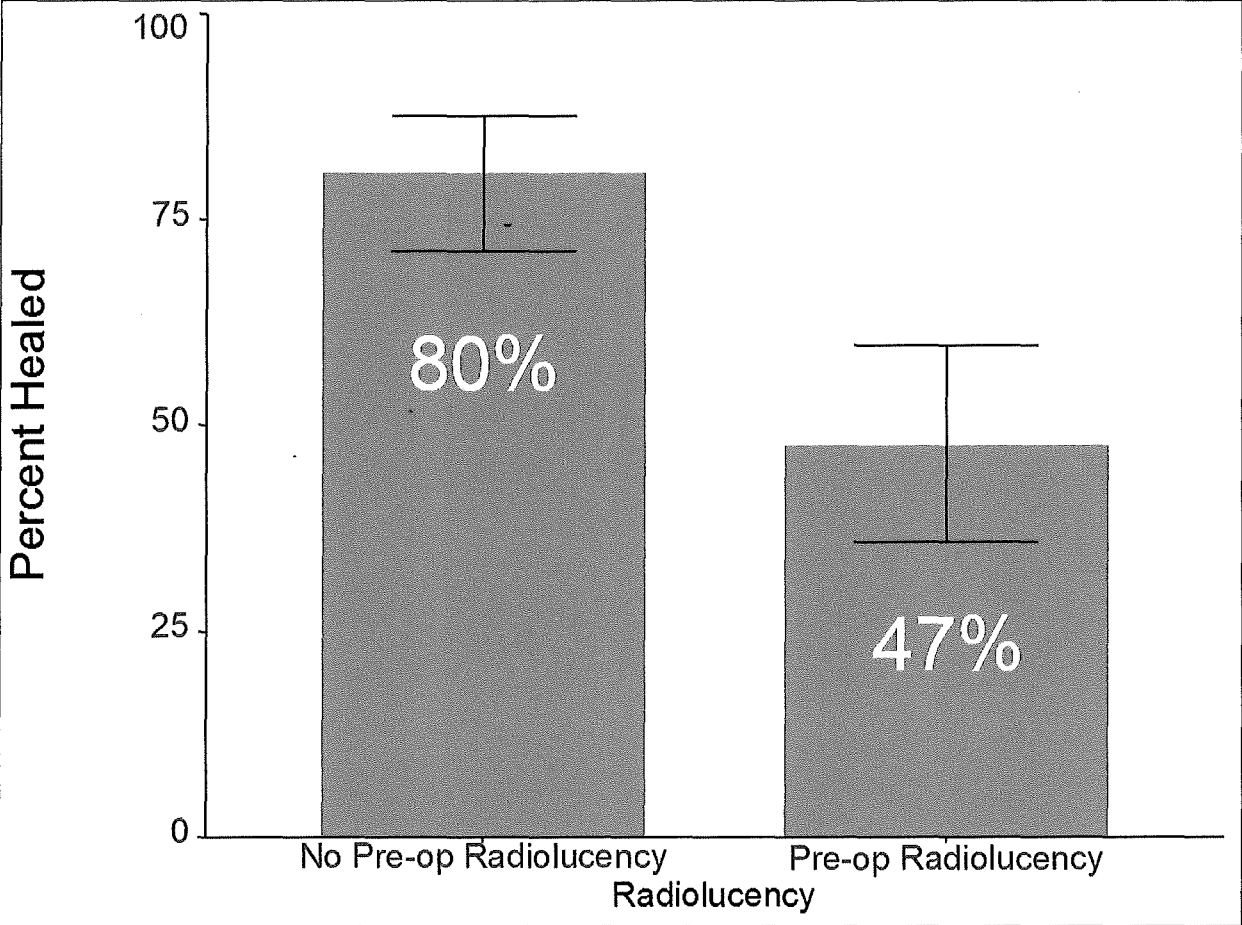


Figure 2 contains a list of covariate factors that were analyzed. The presence of a pre-operative radiolucency was the only covariate that demonstrated a significant influence on healed rates. As shown in Figure 3, 47% of those subjects with a pre-operative radiolucency healed, whereas 80% of those subjects without a pre-operative radiolucency healed ($p < .001$).

Figure 2. Covariate Factors Evaluated

Gender	History of ortho treatment	Pre-op/Post-op lamina dura
Tooth position	History of external resorption	Presence of pre-op radiolucency
Tooth type	History of bleaching	Pre-op pulpal diagnosis
Pre-op/Post-op diabetes	History of internal resorption	Pre-op apical diagnosis
Pre-op/Post-op HTN	Pre-op/Post-op post	Patency
Pre-op/Post-op smoker	Pre-op/Post-op caries	Procedural complications
Pre-op/Post-op coronary heart disease	Pre-op/Post-op cold sensitivity	Intra orifice barrier
Pre-op/Post-op pain	Pre-op/Post-op mobility	Obturation fill length
Pre-op/Post-op EPT results	Pre-op/Post-op bleeding on probing	Post treatment apical diagnosis
Pre-op/Post-op palpation	Pre-op/Post-op restoration	Post treatment pulpal diagnosis
Pre-op/Post-op percussion	Pre-op/Post-op probing depths	Time lapsed between initial treatment and permanent restoration
Pre-op/Post-op sinus tract	Pre-op/Post-op open margin	Follow-up apical diagnosis
Pre-op/Post-op swelling		

Figure 3. Pre-Operative Radiolucency and Healed Rates



DISCUSSION

With no previous studies in which to compare the assessed single variable of smear layer removal in a double blind prospective randomized clinical trial on permanent teeth there exists a gap in knowledge in regards to this question. Studies that assess the effects of smear layer removal have focused on singular effects within the limitations of in vitro studies. Such studies in favor of the removal report the releasing of trapped bacteria within and under the smear layer[2], increased ability to seal obturation material[20], or to decrease microleakage[19] and enhances the ability of intracanal medicaments to diffuse through the dentin[23]. The opposing in vitro studies in favor of not removing the smear layer report an increase in apical microleakage[21] or dentinal erosion increased through the combined use of EDTA and sodium hypochlorite[24]. Bacterial leakage has been shown to increase [3] and bacterial count within dentinal tubules was found to be lower when the smear layer was left intact. [22]

The purpose of this prospective double blind randomized clinical study was to investigate the influence of smear layer removal on endodontic outcomes during single-visit initial NSRCT. In an effort to minimize variability a standardized protocol was established and followed by all providers treating enrolled subjects. Exact materials and techniques laid out as part of the protocol maintain consistency between treated subjects. Calibration of endodontic providers was completed prior to participation in the study via PowerPoint presentation and written instructions were made available to practitioners during treatment for reference and guidance.

This interim analysis determined that removing the smear layer using a combination of 17% EDTA and 6% NaOCl did not lead to improved healed rates. The results of this study are in agreement with a prospective study though methodology differed and comparison may not be accurate[25]. Smear layer removal has been evaluated on a primary tooth model with findings

advocating for the removal of the smear layer[26], and a reported no significant difference[27]. Differences noted between the studies and the current include: primary vs. permanent teeth, citric acid vs. EDTA as the smear layer removal irrigant, multi-visit vs. single visit treatment, use of an intra canal medicament vs. no medicament, obturation with zinc-oxide eugenol vs gutta percha, and multi-year vs. one-year follow-up. Due to the number of additional variables and methodologies a comparison is very difficult to make.

The presence or absence of the smear layer was not found to be a statistically significant variable. Based on previous studies that have shown that apical pathosis is caused by intracanal bacteria[1] and the reduction of intracanal bacteria when utilizing rotary instrumentation[28] and 6% NaOCl [29] may overshadow the effects of the smear layer. Reduction of bacterial load from the canal both in the planktonic state and as part of a biofilm without a way to quantify how much of a smear layer is produced may indeed overshadow what potential minimal smear layer is being produced and its effect on healing. It has been reported that 35-56% of a canals surface remains untouched during mechanical instrumentation[30] which could result in a low production of smear layer covered surfaces within the canal. These factors may lend credit to this study's findings that removing the smear layer may not be significant when evaluating outcomes.

In addition to the primary objective, covariate factors were analyzed to determine statistical influence on endodontic outcomes. Of those evaluated the presence of a pre-operative radiolucency was found to be statistically significant in effecting healing rates. This is in agreeance with such studies by Ng et al[25], Marquis et al[31], and Imura et al [32]. These studies found decreases in healed rates when a pre-operative lesion was present and an increased healed rate when the pre-operative lesion was not present.

The limitations of this interim analysis include current sample size at this time, length of follow-up and the use of a strict criteria during outcomes assessment. A power analysis was completed prior to protocol approval in order to determine sample size. This analysis was completed assuming an 80% healed rate based on a previously published outcome study[25]. For this interim analysis, the sample size (187 analyzed subjects) is well below the sample size needed to have a sufficient power (440) and therefore the results of this study could potentially change as more subjects are enrolled and analyzed.

Orstavik reported that at 12 months following completion of NSRCT approximately 90% of teeth that will heal will show signs of healing[33]. Healing was noted to continue past the 12-month mark and noted within the study it could take four years for complete healing to be recorded. Due to the transient military population and the relatively high capture rate based on that study the recall examination was set at no earlier than 12 months from completion of initial NSRCT though a longer recall time should result in an increased healed rate[34]. Loose healed rate was not considered for this study which would reduced the overall healed rate and places it lower than other published studies that did not use strict criteria during PAI scoring[25]. This study's classification of "healed" or "non-healed" without a "healing" category is a limitation. Additional scoring systems have been compared against the PAI scoring system with higher intra- and inter-observer agreement values with other indexing assessments for periapical health assessed radiographically[35].

CONCLUSION

The interim analysis of this prospective double blind randomized clinical trial reveals that the healed rate of single-visit initial non-surgical root canal treatment was not significantly altered by the presence or absence of the smear layer in permanent teeth at this time. Additionally, the presence of a pre-operative radiographic lesion was the only covariate factor determined to impact endodontic outcome.

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