THE EFFECT OF SMEAR LAYER REMOVAL ON ENDODONTIC OUTCOMES

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ABSTRACT

THE EFFECT OF SMEAR LAYER REMOVAL ON ENDODONTIC OUTCOMES
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Introduction: During mechanical instrumentation of root canals, a thin layer of organic and inorganic debris is created along the canal referred to as the smear layer. Ethylenediaminetetraacetic acid (EDTA), in conjunction with sodium hypochlorite (NaOCl), has proven to be effective in removing the smear layer. There are differing views as to whether the smear layer should be removed, however there are no adult endodontic outcome studies supporting the need for smear layer removal. This randomized clinical trial compared the outcomes of teeth where the smear layer was removed with teeth where the smear layer remained, evaluated the influence of covariate factors on endodontic outcomes and assessed the difference between radiographic analysis of conventional film versus digitized images.

Materials & Methods: Once subjects were enrolled, a standardized endodontic treatment protocol was followed with the exception of the final irrigation regimen. One group received 1ml/canal of 17% EDTA while the other group received 1ml/canal of 0.9% saline. At a minimum of 12 months post treatment, a follow-up clinical and radiographic exam was performed. Radiographic analysis was performed using a modified periapical index (PAI) score (1-5) on both conventional films and digitized images of the same films. Data were analyzed using Fisher's Exact test and Cohen's Kappa ($p<0.05$). **Results:** An interim analysis of 132 subjects revealed no significant difference between the irrigation protocol groups *($p=0.139$)*. The presence of a pre-operative apical lesion negatively impacted the outcome (OR=4.88, 95%

CI: 2.13-11.60, $p<0.001$). Radiographic analysis revealed a conversion of 25 unsure conventional films to healed of the same digitized images (Kappa=.61, 95% CI: .52-.70, $p<.001$). Smear layer removal did not affect the outcome, however the presence of a periapical lesion negatively influenced the outcome. There was a good level of agreement, but the radiographic assessment differed when comparing conventional film and digitized images.

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REVIEW OF THE LITERATURE

Studies have shown that mechanical instrumentation of root canals leaves a smear layer covering the dentinal walls as first described by McComb and Smith 1975. The smear layer is comprised of organic and inorganic substances, including fragments of odontoblastic processes, microorganisms, and necrotic materials (Peters and Barbakow, 2000). It appears as an amorphous layer on the walls of the root canal that obstructs the dentinal tubules (Yamada *et al.* 1983). The thickness of the superficial layer was estimated at 1-2 μm (Mader et al., 1984) with reports of penetration of up to 90-110 μm into the dentinal tubules (Aktener et al., 1989).

It has been advocated that effective disinfection the root canal system requires complete removal of the smear layer as it may contain bacteria and also protects bacteria within the dentinal tubules (Torabinejad et al., 2002). Irrigation utilizing EDTA and NaOCl promoted the elimination of *E.faecalis* biofilms (Soares et al., 2010). This layer has been shown to inhibit the penetration of intracanal disinfectants into the tubules (Ørstavik and Haapasalo, 1990) as well as compromise the seal of obturating materials (Shahravan et al., 2007). In contrast to this view, some found that removal of the smear layer resulted in more apical microleakage (Timpawat et al., 2001). The smear layer can be regarded as a natural cavity liner. Once removed it increases dentin permeability creating an additional avenue for pathogenic bacteria to leak into the dentinal tubules (Pashley et al., 1981, Pashley, 1992). This is supported by Drake et al., who found less bacteria in teeth where the smear layer was not removed. Additionally, dental erosion was detected when EDTA was used prior to sodium hypochlorite (Qian et al., 2011).

Different methods and solutions have been proposed to remove the smear layer, of which ethylenediaminetetraacetic acid (EDTA) has garnered the most attention. EDTA is a chelating agent frequently used in conjunction with sodium hypochlorite (NaOCl) solutions. EDTA acts

on the inorganic components of the smear layer, causing decalcification of dentin and exposure of collagen fibrils. The subsequent use of NaOCl dissolves the collagen leaving the entrances to the dentinal tubules open and exposed (Baumgartner and Mader, 1987, Goldman et al., 1982). It has been suggested that this erosion could adversely affect dentin and the tooth (Torabinejad et al., 2003).

EDTA is frequently used in conjunction with NaOCl; this combination provides antimicrobial activity along with dissolving and cleaning actions (Yamada et al, 1983). The effectiveness of this combination is confirmed in other studies; 17% EDTA and NaOCl will effectively remove pulpal remnants as well as the smear layer (Baumgartner and Mader, 1987), (Bystrom and Sundqvist, 1985). Although EDTA is effective in removing the smear layer, there are concerns of dentin erosion. It was found that irrigation with 2.5% NaOCl followed by 17% EDTA removed smear layer with no significant alteration to dentin structure when the chelating agent was applied for seven minutes. Three and five minute application times resulted in partial removal of smear layer; whereas at one minute, negligible removal of smear layer was achieved (Poudyal et al., 2014). In contrast, another study evaluated the effect of EDTA on smear layer removal and the structure of dentin after one minute and ten minute applications, followed by 10 mL of 5% NaOCl. They found that one minute of EDTA effectively removed the smear layer, leaving open tubules and a clean dentin surface. A ten-minute application of EDTA resulted in excessive peritubular and intertubular dentinal erosion and larger tubule openings (Calt and Serper, 2002). Additionally, the effective and efficient volume of EDTA per canal was studied: It was concluded that 1 ml of 17% EDTA with a contact time of one minute followed by a final rinse of 3 ml of 6% NaOCl is just as effective as 10 ml 17% EDTA in removal of the smear layer (Crumpton et al., 2005).

EDTA initiated dentin erosion has encouraged the study of other chemical irrigants. Doxycycline (DOX), a hydroxy derivative of tetracycline, was tested for its capacity to simultaneously act on both the organic and inorganic components of the smear layer. DOX used alone was effective in the cervical and middle thirds of instrumented tooth roots but less effective in the apical third of the root when compared to the combination of EDTA and NaOCl solutions in removing the smear layer. The use of NaOCl after DOX was partially effective in removing the smear layer in the cervical and middle thirds but ineffective in the apical third (Santos et al., 2010).

As EDTA weakens dentin, affecting its mechanical integrity (Saleh and Ettman, 1999), a continuous chelating irrigation protocol was introduced in an attempt to solve the issue. Etidronic acid (HEBP), the tetrasodium salt of EDTA, mixed with NaOCl, was used as a single irrigating solution. It was found that the mixture, had comparable effectiveness in reducing smear layer formation, as the conventional use of NaOCl followed by EDTA (Morago et al., 2016). Additionally, Morago et al., endorsed the removal of the smear layer to enhance the antimicrobial irrigants activity, obtaining a tighter seal of sealers.

Maleic acid is a mild organic acid found to possess a smear layer removing quality when used as an acid conditioner in restorative dentistry (Wieczowski et al., 1992). A study compared the efficacy of 17% EDTA and 7% maleic acid followed by 2.5% NaOCl as final irrigants in the removal of the smear layer. There was no significant difference between the irrigants in the coronal and middle third of instrumented canals, both combinations efficiently removed the smear layer. However, in the apical third, maleic acid performed significantly better, completely removing the smear layer on the root canal walls leaving the tubules wide open. In EDTA-treated specimens, moderate amounts of smear layer remained and in some areas peritubular

dentinal erosion was observed. Final irrigation with 7% maleic acid was more efficient than 17% EDTA in the removal of smear layer from the apical third of the root canal system, a crucial area for disinfection (Ballal et al., 2009). In contrast, a different study observed under scanning electron microscope found that 17% EDTA more efficiently removed the smear layer than 7% maleic acid at all root levels (Attur et al., 2016).

An in vitro scanning electron microscope study revealed two natural extracts (*Citrus aurantifolia* and *Sapindus mukorossi*) removed the smear layer. Although the efficacy of removal was further improved when accompanied with sonic agitation, 17% EDTA remained superior to the two extracts (Chhabra et al., 2015). Smear Clear and QMiX have been shown as effective as 17% EDTA in removing instrument debris and the smear layer (Aranda-Garcia et al., 2013).

Another study compared the efficacy of BioPure MTAD, 17% EDTA, and 42% citric acid in smear layer removal in the apical third of instrumented canals. Scanning electron microscopy revealed the efficacy of BioPure MTAD and 17% EDTA was significantly greater than 5.25% NaOCl (control). None of the protocols applied completely removed the smear layer in the apical region of prepared root canals (Mancini et al., 2009).

When comparing different techniques for removing smear layer, apical negative pressure irrigation (EndoVac system) showed lower scores of remaining smear layer when compared to the conventional 30-gauage open ended syringe pump alone as well as with the brush which activated the irrigating solution with a medium sized rotary attached to a 600 RPM low sleep handpiece. The irrigants used in this study was 1% NaOCl and 17% EDTA (Mendonca et al., 2015). Using a different technique in which the rotary Canal Brush (a flexible microbrush) in canals prepared with WaveOne produced the cleanest canal walls, and the WaveOne system gave

superior results compared with the ProTaper system when irrigating with 5.25% NaOCl (Kamel and Kataia, 2013).

Elevating the temperature has been reported to increase the efficacy of smear layer removal (Sirtes et al., 2005). A study compared the efficacy in smear layer removal of four different irrigation techniques combined with 60°C 3% NaOCl and 17% EDTA and found no significant differences among the NaviTip FX group, EndoActivator group and control group (no agitation), however each of these groups showed greater effectiveness in removing the smear layer than that of Ultrasonic Irrigation group. However, regardless of different types of irrigation technique applied, complete removal of the smear layer was not achieved, particularly in the apical third (Guo et al., 2014).

Lasers have been used in endodontics for the following therapeutic applications; dentin desensitization, pulp capping, pulpotomy, root canal sterilization and preparation, apicoectomy, and smear layer removal (Takeda et al., 1998). Kalyoncuoglu and Demiryurek compared the efficacy of smear layer removal from teeth following canal instrumentation using erbium-doped yttrium aluminium garnet (Er:YAG) and neodymium-doped yttrium aluminium garnet (Nd:YAG) lasers, 5.25% NaOCl, 17% EDTA, and MTAD. Scanning electron microscopy (SEM) suggested that neither laser is as effective as application of EDTA followed by NaOCl solutions to remove the smear layer (Kalyoncuoglu and Demiryurek 2013).

However a different study found a synergistic effect using a final Er:YAG laser irradiation in wet canals with EDTA irrigation. This combination resulted in significantly better debridement of the root canal walls and a higher quantity of open tubules in comparison to traditional irrigation. It was proposed that the smear layer and debris were removed by photon induced photoacoustic streaming (PIPS) which contributes to an improvement in treatment

efficacy. Irrigation with chelating agents following the current conventional instrumentation procedure requires more time to initiate a satisfactory debridement (DiVito et al., 2012).

There are numerous in vitro studies regarding smear layer removal, however none are able to provide evidence that smear layer removal results in better outcomes after root canal treatment in adult teeth. A recent systematic review was published on the outcomes of primary tooth pulpectomy based on smear layer removal. It included only two studies, and they had contradicting conclusions (Pintor et al., 2016). Barcelos and others (2012) found an improved outcome in pulpectomies with smear layer removal whereas Tannure and others (2010) found comparable results in pulpectomy outcomes whether smear layer was removed or when it remained intact.

A survey in 2001 reported that 51% of practicing endodontists removed the smear layer prior to obturation (Moss et al., 2001). However, a more recent study in which the questions were worded similarly, found an increase in practicing endodontists removing the smear layer prior to obturation, 77% (Dutner et al., 2012). Although the literature remains inconclusive as to whether the smear layer should be removed prior to obturation, there appears to be an increase in endodontists removing the smear layer based on in vitro studies and empiricism.

To date, there have been no in-vivo studies investigating the intentional removal of the smear layer in a root canal system in adult teeth and its effect on healing outcomes of non-surgical endodontic treatment. The purpose of this double blinded randomized controlled clinical trial 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 non-surgical treatment on healing 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 DRP (Department of Research Programs), 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 all other beneficiaries eligible for treatment at the Endodontic clinic. 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 unable or not willing to participate, who have an existing non-surgical root canal treatment, previously initiated but uncompleted root canal treatment, canals medicated with calcium hydroxide or other dental medicament were excluded from the study. Additionally, patients less than 18 years of age, allergic to any medication or dental material used in the study, on antibiotic therapy, with periodontal disease or acute periradicular abscess were not asked to participate in the study.

Treatment protocol. All procedures and variations are accepted by the American Dental Association, the American Association of Endodontists and considered standard of care. All patient treatment began with data collection in a Subjective, Objective, Assessment, Plan (S.O.A.P) format. Medical conditions, clinical symptoms and diagnostic and treatment information were collected on standardized data collection forms. A diagnosis was made taking

all appropriate measurements and using all appropriate armamentarium that is standard of care in the endodontics specialty.

Once enrolled, the subject was de-identified and assigned a subject number in chronological order. Subjects were randomly assigned to one of two treatment groups (A or B). Two pre-operative periapical radiographs were taken. The first radiograph was taken with the x-ray beam perpendicular to the long axis of the tooth and perpendicular to the floor. The second radiograph was taken with the x-ray tube head shifted 15° to the mesial of the tooth in the horizontal plane. The vertical angulation remained at zero. The radiographs were be saved under the subject number in the Endodontics Research Share Drive, maintained on a secure government server for later use in the study.

Endodontic residents at the NPDS performed the procedures. Root canal irrigation with 1 ml 17% EDTA over one minute followed by 3 ml 6% NaOCl per canal for intentional removal of the smear layer versus root canal irrigation with 1 ml 0.9% saline over one minute followed by 3ml 6% NaOCl per canal as a negative control. With the exception of the test irrigant or the negative control irrigant, a standardized treatment protocol was utilized for all subjects regardless of group assignment.

Adequate dental anesthesia was provided followed by isolation of the operative area using rubber dam and caulking. Straight-line access into pulp chamber was achieved. All of the following procedures will be accomplished with the aid of a dental operating microscope and as many additional dental radiographs as needed for good endodontic treatment, but no more than necessary. The location of all canal orifices were identified with the aid of an endodontic explorer and ultrasonics (when applicable) and 0.9% saline irrigation. Determination of patency length was performed with a 0.02 taper #10 stainless steel FlexoFile® (Dentsply Maillefer,Tulsa,

OK) of all root canals using a apex locator. Working length was set 1 mm short of patency length and confirmed radiographically. Coronal flaring was achieved with a Profile orifice opener (Dentsply Maillefer, Tulsa, OK). Instrumentation of the apical one third of the canal was completed with an 0.02 taper #10, #15, #20 FlexoFile® stainless steel Flex-O file to working length while irrigating with 6% NaOCl not to exceed 1 ml per canal, during hand instrumentation. All irrigation will be delivered with a 30 gauge Max-i-probe syringe (Dentsply Maillefer, Tulsa, OK). The canal was instrumented with 0.04 Profile (Dentsply Maillefer, Tulsa, OK) in a crown down manner to an appropriate apical size. Recapitulation was achieved using a 0.02 taper #10 FlexoFile to working length while irrigating with 6% NaOCl, not exceeding 1 ml per canal, for a total intraoperative irrigation volume of 2 ml. All canals were dried with sterile paper points (Henry Schein, Melville, NY).

The provider was given a syringe containing either 1 ml of 17% EDTA (experimental group) or 1 ml of 0.9% sterile saline (control). Both the patient and the provider were blinded as to which irrigant was used. The decision to treat with EDTA or saline was based on the group to which the patient number was assigned using a random integer generator (random.org). The 1 ml of 17% EDTA or 1 ml of 0.9% sterile saline irrigation per canal was delivered over 1 minute per canal.

Prior to completing treatment on all patients, all canals were dried with sterile paper points (Henry Schein, Melville, NY) and a final rinse with 3 ml 6% NaOCl per canal was performed. All canals were dried with sterile paper points (Henry Schein, Melville, NY). A heated plugger that best matched the individual canal size and taper was chosen, a pre-fit plugger with a binding point (5-7mm short of length) was selected and marked with a rubber stopper. The appropriate master gutta percha cone (Diadent, Burnaby, BC, Canada) was placed in the

canal and confirmed to be at working length. The canal walls were lightly coated with a mixture of eugenol and Grossman Type 801 Root Canal Cement Powder (Roth International LTD, Chicago, IL). The heating unit was set at 200° C and the gutta-percha cone was seared at the orifice with the heated plugger and excess gutta-percha was removed. The plugger was drive activated to within 3mm of binding point (over 1.5-3.5 seconds) then deactivated and apical pressure was maintained until the plugger reached binding point. Once the plugger was inactivated, firm apical pressure was maintained at binding point for 10 seconds. Apical pressure was maintained, the heating unit was activated for 1 second and the plugger was quickly withdrawn. After confirmation with the plugger that the apical mass of gutta-percha was not dislodged the canal was backfilled with the appropriate thermoplasticised gutta percha set at 200° C. The chamber was cleaned with an alcohol-soaked cotton pellet. The access was temporized with a sterile cotton pellet and glass-ionomer.

Two post-operative periapical radiograph were taken. Intraoral placement of the sensor were aided by a Rinn XCP (Dentsply Rinn, Elgin, IL) customized for the patient with a bite registry for better duplication of the position of the sensor one year later. The first radiograph was made with the x-ray beam perpendicular to the long axis of the tooth and perpendicular to the floor utilizing digital radiography. The second radiograph was taken with the x-ray tube head shifted 15° to the mesial of the tooth in the horizontal plane. The vertical angulation remained at zero. Radiographs were saved under the subject number on the Endodontics Research Share Drive, maintained on a secure government server for later use in the study for PAI assessment.

A clinical and radiographic exam was completed no less than one year after the non-surgical root canal treatment. The follow-up data was collected; providers reviewed health history and recorded clinical data including results from diagnostic testing on standardized

follow-up data collection forms. Two periapical radiographs taken with digital radiographic sensors, one of which 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. Film radiographs were digitally converted utilizing an Epson 1600 EU-35 Transparency Unit scanner set at 1200 dpi.

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 with a PAI score of 1 or 2, at the time of follow-up, while "non-healed" subjects were defined as either symptomatic with a PAI score of 3, 4, or 5.

PAI scoring. The PAI scoring, described by (Ørstavik et al., 1986), was conducted by three 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 in the previous scoring of the conventional film. After the 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. 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. The comparison in the assessment of radiographic outcomes between conventional film and digitized images were evaluated using Cohen's Kappa. Alpha was set at .05 for all analyses.

RESULTS

This interim analysis reports a total of 237 subjects enrolled in the study, 24 subjects were enrolled less than 12 months ago, 11 subjects did not complete the NSRCT at NPDS, resulting in 202 subjects who were eligible for follow-up. 175 subjects completed the follow-up examination for a follow-up rate of 87%. A total of 43 subjects with a completed follow-up were unable to be analyzed due to extractions (n=12), deviation from protocol (n=16), and not analyzed (n=15). The most common protocol deviation was due to multiple appointment treatments but also included surgical root canal treatment, missed canal and known use of EDTA. Fifteen subjects were not analyzed in this interim analysis as the previous data was not entered in to the SPSS Statistics, however they will be included in the next analysis. The remaining 132 subjects were analyzed. Following the digital conversion, each image was re-scored, and the new dataset was used to analyze outcomes. As shown in Figure 1, 47/68 (69.1%) subjects assigned to 17% EDTA healed while 41/64 (64.1%) subjects assigned to the 0.9% saline group healed. When comparing subjects in either of the two irrigation protocols, no significant difference in healed rates was noted (p=0.139).

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

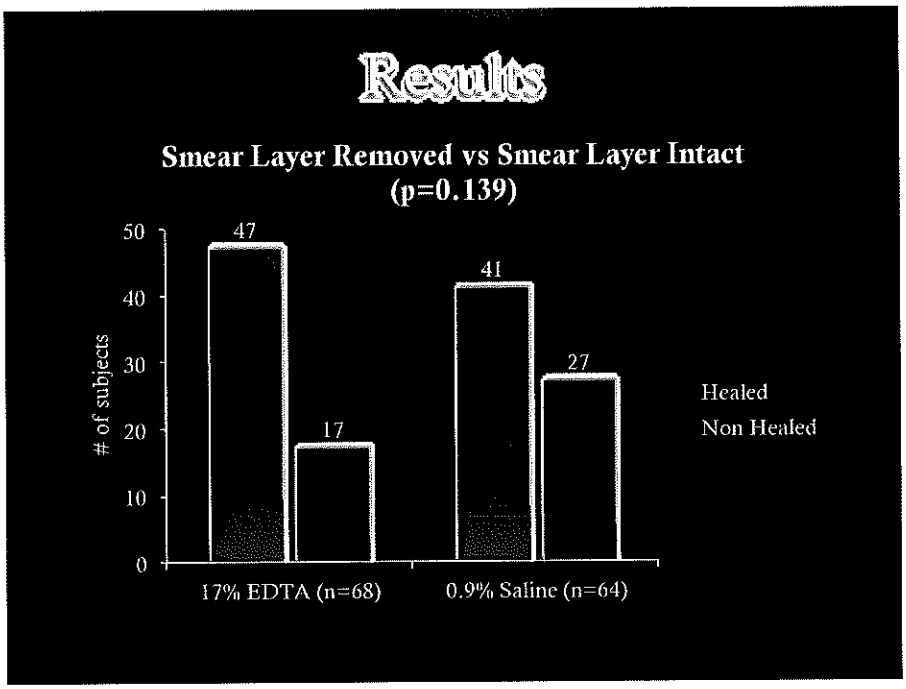
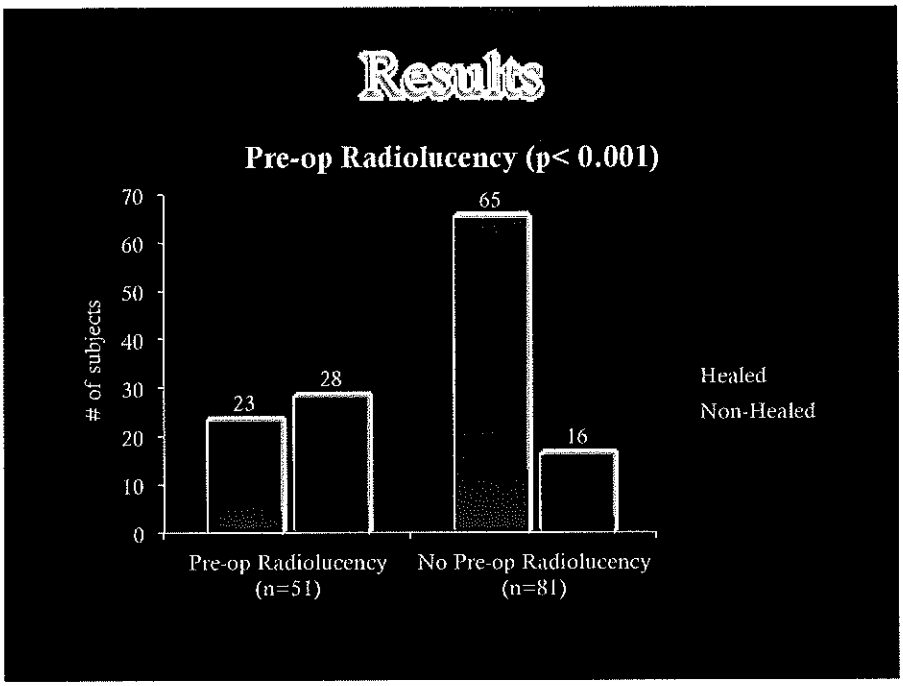


Figure 2 contains a list of covariate factors that were analyzed. The presence of a pre-operative radiolucency was the only covariate that demonstrated a significant influence on healed rates. As shown in Figure 3, 23/51 (45.1%) of those subjects with a pre-operative radiolucency healed, whereas (65/81) 80.2% of those subjects without a pre-operative radiolucency healed ($p<.001$).

Figure 2. Covariate Factors Evaluated

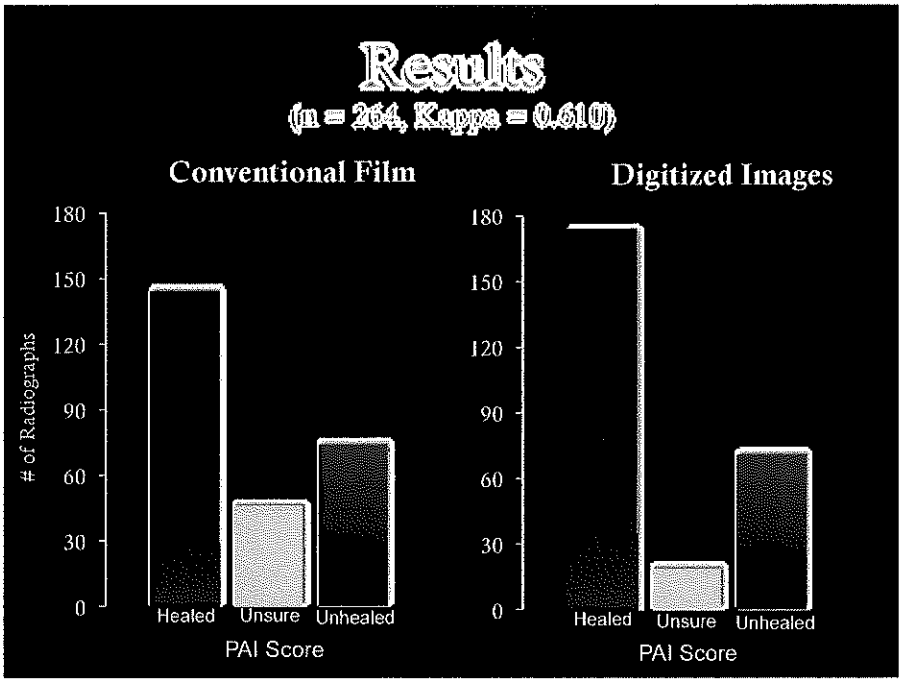
Gender	History of ortho treatment	Pre-op/Post-op lamina dura
Tooth position	History of external resorption	Presence of pre-op radiolucency
Tooth type	History of bleaching	Pre-op pulpal diagnosis
Pre-op/Post-op diabetes	History of internal resorption	Pre-op apical diagnosis
Pre-op/Post-op HTN	Pre-op/Post-op 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*



The assessment of radiographic outcomes between conventional film and the digitized images are in good agreement, however there are some differences (Kappa = 0.610) as seen in Figure 4. The largest shift occurred in which 25 unsure PAI scores in the conventional film's assessment moved to a healed PAI score.

Figure 4. *Comparison of Conventional Film and Digitized Images on PAI Scoring*



DISCUSSION

This interim analysis does not reveal a significant difference in radiographic outcomes with smear layer removal in intial non-surgical root canal treatment. The results of this study agrees with other prospective outcome studies (Ng et al., 2001). Reasons for this may include the effectiveness of 6% sodium hypochlorite alone; it eradicates not only planktonic bacteria, but also disrupts and destroys the tenacious biofilm known to protect bacteria. Six percent sodium hypochlorite was the most effective irrigant when compared to chlorhexidine and BioPure MTAD. Additionally, it was the only irrigant that rendered the bacteria nonviable and it physically removed the biofilm (Clegg et al., 2006).

Chemomechanical cleaning in endodontics involves the mechanical action of instruments along with the chemical cleaning with irrigants. Ferrer-Luque and others (2014) reported a 95.9% to 100% reduction in bacteria with rotary instrumentation in both distilled water and

5.25% NaOCl irrigant groups. The effectiveness in the mechanical instrumentation with rotary instrumentation, as used in our current study, has proven to be very effective in removing bacteria. Therefore, the use of both NaOCl and rotary instrumentation in all cases in this current study may render the removal of the smear layer unnecessary.

Although mechanical instrumentation has proven successful in removing bacteria (Ferrer-Luque et al., 2014), Zhou and others (2014) reported that 35-56% of canal surface remains untouched during mechanical instrumentation. Wide canals, such as mandibular distal canals, had significantly more uninstrumented areas than the narrower mesial canals (Zhou et al., 2014). This agrees with previous studies that evaluated Profile .04, the rotary files used in the current study. Profile .04, was not able to prepare all parts of the root canal system, leaving areas of uninstrumented canal walls (Versumer et al., 2002). As the canal walls remain untouched, a smear layer could not be created on these surfaces. This lends support to the current study's findings that removing the smear layer may not be significant.

The only covariate factor determined to have a statistical significance on healed rates was the presence of a pre-operative radiolucency. This finding agrees with multiple other previously published outcomes studies (Ng et al., 2008), Imura et al., (2007), reported a nearly a 10% drop in success rates in the presence of a periapical lesion. Marquis et al., (2006), found only one statistically significant association with a higher healed rate. They found a healed rate of 94% in teeth without a preoperative radiolucency, whereas in teeth with a preoperative radiolucency, only 77% healed (Marquis et al., 2006), supporting the current study.

Technological advances have allowed the dental practitioner an opportunity to shift from conventional film to digital radiography. Advantages include the removal of processing chemicals, decreased operative time and a reduction in radiation. To further support the current

study's protocol update from conventional film to digital radiography, studies have suggested the superior accuracy of digital radiographs in comparison to conventional film. The diagnostic accuracy of a single digital periapical radiograph was significantly better than a single film peripical radiograph. These findings were confirmed, using histopathological findings as a standard, on unclaimed cadaver bodies (Kanagasingam,et al., 2017).

Previous radiographic analysis was performed using conventional film projected on a screen using a Kodak carousel. However, Antrim (1983) found that a conventional film is more accurately assessed with a light box rather than displayed through a projector. Based on the work by Almanei and others (2017) which reported a similar diagnostic quality of digitized images to conventional film, the original conventional film were digitized. This provided the evaluators the ability to adjust the contrast and density of the digitized images. The conversion of conventional film to digitized images, allowed for the comparison in the assessment of radiographic outcomes between these two modalities. The assessment of radiographic outcomes between conventional film and the digitized images are in good agreement, however there are some differences. The largest shift occurred in which 25 unsure PAI scores in the conventional film's assessment moved to a healed PAI score in the digitized images. The ability to enhance the digitized images likely allowed the evaluators to more confidently assert that a case was radiographically healed.

In this study, a loose healed rate was not considered. Follow up examinations were completed no sooner than 12 months following the completion of non-surgical root canal treatment. However some of the lesions may be in the process healing, and may take longer than a year to be radiographically categorized as healed. Although 89% had visible signs of healing, it could take four years for complete healing (Orstavik, 1996).

CONCLUSION

The interim analysis of this prospective randomized double-blinded clinical trial revealed that smear layer removal does not affect the healed rate of endodontic outcome of single-visit initial non-surgical root canal treatment. In regards to covariate factors, teeth with a pre-operative radiolucency negatively impacted healed rates. Additionally, the assessment of radiographic assessment differed when comparing conventional film and digitized images.

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