Radiographic Healing after a Root Canal Treatment Performed in Single-rooted Teeth with and without Ultrasonic Activation of the Irrigant: A Randomized Controlled Trial

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Abstract

Introduction: The aim of this study was to compare the outcome of a root canal treatment with and without additional ultrasonic activation of the irrigant.

Methods: Single-rooted teeth with radiographic evidence of periapical bone loss were randomly assigned to 2 treatment groups. In both groups syringe irrigation was performed, and in one group the irrigant was also activated by ultrasound. Ten to 19 months after treatment, the teeth were examined by using periapical radiography (PA) and cone-beam computed tomography (CBCT). Area and volume of the periapical lesions were measured, and the outcome was presented in 4 categories: absence, reduction or enlargement of the radiolucency, or uncertain. Lesions were classified as reduced or enlarged when the change in size of the radiolucency was 20% or more.

Results: The recall rate was 82%, and 84 teeth were analyzed. CBCT detected significantly more post-treatment lesions than PA (P = .038), but the percentages of absence and reduction of the radiolucency together revealed by CBCT and PA were similar (P = .383). The CBCT results showed that absence of the radiolucency was observed in 16 of 84 teeth (19%) and reduction of the radiolucency in 61 of 84 teeth (72.6%), but there was no significant difference between the results of the 2 groups (P = .470). Absence and reduction of the radiolucency together were observed in the ultrasonic group in 39 of 41 teeth (95.1%) and in the syringe group in 38 of 43 teeth (88.4%).

Conclusions: Root canal treatments with and without additional ultrasonic activation of the irrigant contributed equally to periapical healing. (J Endod 2013;39:1218–1225)

Key Words

Cone-beam computed tomography, irrigation, radiographic healing, root canal treatment, ultrasonic

Apical periodontitis is defined as an oral inflammatory disease caused by a reaction of the host immune system to the presence of microorganisms (planktonic state or biofilm) or their products. The microorganisms are found close to or in the root canal system or at the outside around the root apex (1). The goal of a root canal treatment is to prevent or to heal apical periodontitis; therefore, the microorganisms in both planktonic and biofilm state should be removed from the root canal system (1). We try to reach this goal by chemomechanical treatment of the root canals.

Instrumentation of the root canal is associated with disadvantages such as smear layer and dentin debris production, iatrogenic errors, weakening of the root structure, and apical crack formation (2–6). Furthermore, the instruments do not touch the whole surface of the root canal wall (7), impeding complete mechanical biofilm disruption. However, instrumentation creates space in the root canal system, facilitating the delivery of disinfection solutions or medicaments that could disrupt the remaining biofilm there where the instruments did not reach the root canal wall.

Irrigation procedures could disrupt the remaining smear layer, dentin debris, and biofilm from the root canal wall (8). For an effective irrigation procedure, both the chemical dissolution or disruption and the mechanical detachment and removal of pulp tissue, dentin debris, smear layer, and microorganisms out of the root canal system are important. These aspects are related to the duration of the irrigation procedure and the flow of the irrigant that can be controlled by irrigant activation systems such as lasers and sonically or ultrasonically vibrating instruments (9, 10). Ultrasonic activation improves both the mechanical and chemical aspects of the irrigation procedure, as
has been shown by in vitro research (10, 11). Acoustic streaming and cavitation of the irrigant have been considered to be the working mechanisms (12, 13).

Until now, no randomized controlled trials (RCTs) evaluating the effect of irrigation procedures on endodontic outcome have been performed. Therefore, the aim of this study was to compare the effectiveness of root canal treatments with and without additional ultrasonic activation of the irrigant by evaluating the endodontic outcome.

Materials and Methods

Patient Selection

In total, 105 patients with a noncontributory medical history, treated between September 2010 and September 2011 in the Department of Cariology and Endodontics of Peking University School of Stomatology were selected according to the following criteria. All selected teeth were single-rooted maxillary and mandibular incisors, canines, or premolars that did not respond to sensitivity testing, had not received any endodontic treatment previously, and showed radiographic evidence of periapical bone loss. Only 1 tooth per patient was included. Pregnant women, teeth with canal curvature >25°, or periodontal pockets >3 mm were excluded. All patients were informed before the treatment, and their consent was obtained.

This study protocol was approved by the ethics board of Peking University Health Science Center (no. IRB00001052-10077).

Radiographic Technique

The included teeth were examined clinically and radiographically by using periapical radiography (PA) and cone-beam computed tomography (CBCT) at first visit and at recall.

Straight projection intraoral PA was obtained with the digital imaging system Digora Optime (Soredex, Helsinki, Finland) by using a parallel technique. A MinRay dental x-ray unit (Soredex) was used by operating at 60–70 kV and 7 mA and obtaining exposures of 0.12 seconds. After exposure, the phosphor plates were immediately scanned by using the proprietary software (Dfw v.2.5; Soredex). The scanning resolution was 400 dpi.

CBCT scans of the patients were acquired with a 3DX-Accuitomo CBCT scanner (J. Morita Mfg Corp, Kyoto, Japan), with a 4 × 4 cm field of view selection, operating conditions of 80 kVp, 4 to 5 mA, and an exposure time of 17.5 seconds. The CBCT data were reconstructed by using the system’s proprietary software.

Root Canal Procedure

All treatments were performed in a single visit by 4 dentists who had limited their work to operative dentistry and endodontics for at least 5 years. The included teeth were divided into 2 treatment groups by using random allocation software (http://www.randomization.com/) according to a standardized procedure. In both groups syringe irrigation was performed, and in one group the irrigant was also activated by ultrasound.

After local anesthesia and rubber dam isolation, coronal access was prepared. Working length (WL) was determined by using an apex locator (Root ZX, J. Morita Corp), 0.5 mm short of the “0” reading and confirmed with PA. Canals were first prepared with a #15 Flexofile (Dentsply Maillefer, Ballaigues, Switzerland) to the full WL. A crown-down preparation technique was performed by using nickel-titanium rotary instruments (FKG Dentaire, La Chaux-de-Fonds, Switzerland) #40/0.6, #35/0.8, #25/0.2, #25/0.04 until #25/0.06 reached WL. Between the use of each instrument, recapitulation of WL was performed with a #10 K file (Dentsply Maillefer). Apical enlargement was completed with S-Apex instruments with a slightly inverted taper (FKG Dentaire) #30, #35, and #40 at WL. Size 40 was the biggest size instrument used for all the root canals also when the original canal size was bigger. The rationale for this decision is that from size 40 a 30-gauge needle can easily be placed in the apical area to allow full delivery of the irrigant solution.

In both groups, 2 mL 5.25% sodium hypochlorite (NaOCl) solution was used as irrigant between each instrument. All syringe irrigation procedures were performed with a syringe and a 30-gauge needle (Navitip; Ultradent, South Jordan, UT). Needle penetration depth was 2 mm short of its binding point or WL. The flow rate was approximately 0.2 mL/sec.

In the ultrasonic group, after every other instrument, the irrigant was also activated by ultrasound for 10 seconds. Ultrasonic activation was performed with an ultrasonic device (P5 Newton; Satelec Acteon, Merignac, France) at setting “Yellow 8” dry mode by using a #20 stainless steel parallel-shaped noncutting instrument (IrriSafe; Satelec Acteon) 2 mm short to its binding point or WL.

After completion of the instrumentation, the root canals were irrigated by using a final irrigation protocol. First, the canals were irrigated with 2 mL 15% EDTA solution for 1 minute. Thereafter, in the syringe group, canals were finally flushed 3 times with 2 mL 5.25% NaOCl at a flow rate of 0.2 mL/sec. After every irrigant delivery, the irrigant was left for 10 seconds in the canal. In the ultrasonic group, 2 mL 5.25% NaOCl was delivered 3 times into each canal with a syringe, after which the irrigant was ultrasonically activated for 10 seconds. The final irrigation time (60 seconds) was identical for both groups. The total preparation and irrigation time of all the teeth included was 30 minutes.

Each canal was dried with paper points and filled with gutta-percha cones (Dentsply Maillefer) and AH Plus sealer (Dentsply, De Trey, Konstanz, Germany) by using a warm vertical compaction technique (2 in 1; VDW, Munich, Germany). Sealer was introduced into each canal twice by using a bidirectional spiral (EZ-Fill; Essential Dental System Inc, South Hackensack, NJ) for 30 seconds 2 mm short to WL. The largest gutta-percha cone that reached WL without resistance was used as master gutta-percha cone, and tug-back was established by shortening the master cone apically. Permanent coronal restorations with composite resin or core build-up (3M Filtek P60; 3M ESPE, St Paul, MN) were placed within 2 weeks after root canal treatment. Temporary restorations were filled with glass ionomer cement (Fuji; GC America Inc, St Alsip, IL).

Evaluation

Much care was taken to reach a high recall rate. The dentists who treated the patients encouraged them for follow-up by multiple telephone calls. Furthermore, financial compensation was offered for the transportation.

At recall examination, sinus tract, pain, swelling, tenderness to percussion, gingival palpation, and the quality of coronal restorations were recorded.

Two observers, an endodontist and a radiologist, examined individually and blindly the PA images and CBCT scans. A periapical lesion was diagnosed when lamina dura disruption was detected and a radiolucency associated with the radiographic apex was at least twice the width of the periodontal ligament space for both PA and CBCT (14, 15). The same 2 observers also measured the area and volume twice with a 1-month interval, and the average values of the first measurements were used as the lesion area on PA or lesion volume on CBCT scans. The lesion area on PA was measured in square millimeters by using Image J 1.28 software (National Institutes of Health, Bethesda, MD) as previously described (16). Measurement of
lesion volume on CBCT data in DICOM format (Digital Imaging and Communication in Medicine) was performed by using Amira 5.4.3 (Visage Imaging GmbH, Berlin Germany) software. Local threshold-determining algorithm (17) with manual tracing intervention was used to plot out the border of the lesion and calculate the volume (18). The length and density of root canal filling were determined as previously described (19, 20).

The lesion area and volume at the first visit were compared with those at recall. The outcome was presented in 4 categories: absence, reduction or enlargement of the radiolucency, or uncertain. Reduction and enlargement of the radiolucency were determined only when the change in size of radiolucency was 20% or more (18).

**Statistical Analysis**

Intraclass correlation coefficient (ICC) was used to test the interobserver and intraobserver agreement of the lesion area and volume measurements. The difference between the 2 groups in volume of lesion pretreatment and size of master cone were analyzed by using independent-samples $t$ test and $\chi^2$ test. The outcome determined by CBCT and PA was compared by using McNemar test. Multivariate logistic regression analysis was performed on the pooled data from CBCT to identify factors affecting treatment outcome.

The statistical analyses were performed by using SPSS software (version 16.0; SPSS Inc, Chicago, IL). The level of significance was set at $\alpha = 0.05$.

**Results**

Eighty-six of 105 patients (82%) were reexamined 10–19 months after treatment. Two teeth had been extracted for reasons unrelated to the root canal treatment.

The intraexaminer ICC values for the CBCT volumetric measurements and the PA area measurements were 0.971, 0.998 and 0.998, 0.993, respectively, for 2 examiners. The interexaminer ICC was 0.998 for the area measurements and 0.991 for the volumetric measurements.

There was no significant difference between the 2 treatment groups in the volume of the periapical lesions ($P = .148$) or the size of master cones ($P = .862$). The 2 treatment groups were comparable in all other clinical factors (Table 1). The CBCT data for the 2 groups are presented in Table 2. Absence and reduction of the radiolucency were observed in 39 of 41 teeth (95.1%) in the ultrasonic group and 38 of 43 teeth (88.4%) in the syringe group ($P = .470$).

The percentage of teeth without radiolucency determined by CBCT scans (19%) was significantly lower than that by PA (32.1%) ($P = .038$). However, the percentages of absence and reduction of the radiolucency together were similar ($P = .383$ (Table 3). From the 27 teeth without radiolucency on PA, 16 had no radiolucency and 11 had a reduced radiolucency on CBCT.

The volume of the radiolucencies varied from 1.5–375.4 mm$^3$ before treatment (Table 4). At recall, the volume of the radiolucencies had reduced by 80%–100% in 54 of 84 teeth (64%), as revealed by CBCT (Table 4) (Figs. 1 and 2).

The influence of the potential factors gender, volume of lesion pretreatment, irrigation method, length and density of root fillings, and size of master cones on the outcome was analyzed. The volume of lesion and the size of master cone influenced the treatment outcome significantly ($P < .05$). The influence of the other factors examined was not significant ($P > .05$). Absence of the radiolucency was observed in 16 of 62 teeth (25.8%) with smaller lesions, but in no teeth with larger lesions. Absence of the radiolucency was observed in 13 of 57 teeth

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Median (range) of lesion volume (mm$^3$)</th>
<th>Median (range) of lesion volume (mm$^3$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasonic</td>
<td>41</td>
<td>31 (18–76)</td>
<td>31 (18–76)</td>
</tr>
<tr>
<td>Syringe</td>
<td>43</td>
<td>33 (18–76)</td>
<td>33 (18–76)</td>
</tr>
<tr>
<td>Total</td>
<td>84</td>
<td>31 (18–76)</td>
<td>31 (18–76)</td>
</tr>
</tbody>
</table>
(22.8%) with a master cone of ≤#45, but only 3 of 27 teeth (11.1%) with a master cone of #50–#120.

At recall, 3 teeth were considered as treatment failures, 2 from the ultrasonic group and 1 from the syringe group. Two teeth were symptomatic; one had an enlarged lesion, and the other showed uncertain outcome. One asymptomatic tooth had recurrent caries with enlarged lesion on CBCT.

**Discussion**

To our knowledge, this is the first RCT investigating the effects of different irrigation protocols on endodontic outcome by using both PA and CBCT. In both irrigation groups the percentage of absence and reduction of the radiolucency was high, 95.1% for the ultrasonic group and 88.4% for the syringe group.

One of the limitations of clinical research is that many factors, including those related to the root canal treatment itself, can influence endodontic outcome (21). Therefore, standardization of the treatment procedure is of utmost importance. Molar treatments are more difficult to standardize than single canal treatments because of root canal curvature, anatomic differences of the isthmuses, treatment time, procedural errors, complete access, etc. Consequently, including molars would increase the possibility of bias, and we therefore decided to use only single-rooted teeth. This enabled us to standardize the treatment procedure as much as possible, thus limiting bias.

It could be argued that the root canal anatomy of single-rooted teeth is not challenging enough to show a difference between the 2 irrigation protocols. However, many studies, including those using micro-CT, have shown the complexity of the root canal system of single-rooted teeth especially in the apical part where oval extensions and fins are present (3, 7, 22). Furthermore, the diameter of the apical canal is often larger than the master apical file, emphasizing the importance of the irrigation procedure (23, 24).

Although ultrasonic activation improves both the mechanical and chemical aspects of the irrigation procedure in *in vitro* research, it did not influence endodontic outcome in this clinical study. This can be related to a variety of reasons, including the statistical power of the study, the clinical relevance of the *in vitro* models, the fact that improved cleaning does not automatically result in a better outcome, and the typical irrigation protocols used in this study. Furthermore, other complicating factors such as the details of the root canal anatomy (apical delta and dentinal tubules), the structure of the biofilm, the external biofilm around the root apex, root filling, or the effect of instrumentation could have been more influential than the irrigation procedures used (1).

To disinfect the root canal by irrigant flow, the irrigant should reach the biofilm to mechanically disrupt it and exert its chemical effect. However, the production of dentin debris and its accumulation in uninstrumented regions like isthmuses and fins could be more important than expected. Consequently, its subsequent removal is more difficult than anticipated (25, 26) because a direct contact of the irrigant with the biofilm is hindered. Furthermore, both dentin debris and smear layer inactivate root canal medicaments and irrigants (27).

We instrumented the root canals not farther than instrument size 40, also when the original size was bigger. This also allowed us to evaluate whether the irrigation procedure itself can disrupt biofilm where the instruments did not touch the root canal wall. From size 40, the 30-gauge needle can easily reach the apical root canal, and the irrigant solution can be delivered effectively (28). However, the percentage of teeth with absence of radiolucency in root canals larger than size 50 was significantly less than for root canals smaller than size 50. This indicates that both irrigation protocols probably could not compensate for the reduced biofilm disruption by instruments in the bigger size canals. In larger canals, irrigant exchange improves, but shear stress on the root canal wall decreases (29). Probably the same holds for ultrasonic activation of the irrigant, and higher shear stress on the root canal wall by increasing the ultrasonic intensity is needed (23). Furthermore, in a larger canal there may be more substrate area available to react with the irrigant, and perhaps a larger volume of irrigant or longer irrigation time is needed for the chemical reaction. Shear stresses on the root canal wall during irrigation procedures have recently been quantified, but the cohesion or adhesion forces of the biofilm to the root canal wall are unknown (12, 28). Also because the properties of endodontic biofilm are not sufficiently known, the volume, concentration, and application time of NaOCl needed to disrupt the biofilm are not known. Because adequate biofilm models are lacking for endodontic research, it is difficult to predict the effect of irrigation protocols on biofilm disruption. Furthermore, we cannot exclude that a larger root canal size could have influenced leakage of the root canal fillings.

For the first time in clinical research, the periapical radiolucencies on the CBCT images were volumetrically analyzed to determine the outcome. Although in *in vitro* studies the linear regression coefficient was 96.9%, thereby demonstrating a high reliability of the volumetric measurements with CBCT data, the percentage of deviation was up to 18% (17, 29). Therefore, in this study, reduction and enlargement of

**TABLE 2.** Number of Teeth with Different Radiographic Outcomes in Two Groups as Determined by CBCT

<table>
<thead>
<tr>
<th>Group</th>
<th>Absence of radiolucency</th>
<th>Reduction of radiolucency</th>
<th>Uncertain</th>
<th>Enlargement of radiolucency</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultrasonic</td>
<td>7</td>
<td>32</td>
<td>1</td>
<td>1</td>
<td>41</td>
</tr>
<tr>
<td>Syringe</td>
<td>9</td>
<td>29</td>
<td>4</td>
<td>1</td>
<td>43</td>
</tr>
<tr>
<td>Total</td>
<td>16</td>
<td>61</td>
<td>5</td>
<td>2</td>
<td>84</td>
</tr>
</tbody>
</table>

**TABLE 3.** Number of Teeth with Different Radiographic Outcomes as Determined by PA and CBCT

<table>
<thead>
<tr>
<th>PA</th>
<th>Absence of radiolucency</th>
<th>Reduction of radiolucency</th>
<th>Uncertain</th>
<th>Enlargement of radiolucency</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>CBCT</td>
<td>16</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>16</td>
</tr>
<tr>
<td>Reduction of radiolucency</td>
<td>11</td>
<td>48</td>
<td>2</td>
<td>0</td>
<td>61</td>
</tr>
<tr>
<td>Uncertain</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Enlargement of radiolucency</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>52</td>
<td>4</td>
<td>1</td>
<td>84</td>
</tr>
</tbody>
</table>
the radiolucency were determined when the volume of the radiolucency had been reduced or enlarged by 20% or more.

The recall rate in this study was very high (82%), in part because the follow-up period was only 10–19 months, and typically the recall rates in clinical studies drop over time. In a study by Ørstavik (30), the follow-up period was only 10–19 months, and typically the recall rate dropped from 71% after the first year of evaluation to 33% after the fourth year. The median recall rate in previous outcome studies was 52.7% (31). We thereby exclude the outcome of nearly half the treated teeth, knowing that a decrease in the recall rate is correlated to an increase in the success rate because the failure rate of the treated teeth, knowing that a decrease in the recall rate is correlated to an increase in the success rate because the failure rate could be almost completely reduced (Fig. 2), whereas some small lesions were only slightly decreased, indicating that time was not the main responsible factor (Table 4).

The percentage of teeth with absence of radiolucency was 32.1% as revealed by PA, which is lower than the average success rate by using strict radiographic criteria (absence of radiolucency at recall), as reported by Ng (31). In most previous outcome studies, the periapical index (PAI) scoring system of Ørstavik et al (34) was used, and PAI score 2 (small post-treatment lesion) was included in the success category (30, 31, 34, 35). Therefore, it is likely that many cases with small post-treatment lesions were included in the success category (36). In a study by Ørstavik et al (32), the PA-determined success rate was 79% including PAI scores of 2, but only 26% if only PAI scores of 1 were included. PAI score 1 is defined as the absence of radiolucency or resolution of radiolucency by PAI score 2.

A disadvantage of a short follow-up is that the percentage of teeth with absence of radiolucency was 19% as determined by CBCT, significantly lower than that determined by PA (P = .038). Interestingly, CBCT detected fewer teeth with absence of radiolucency and more teeth with reduction of radiolucency than PA (Table 3). The percentage of both groups together was 94% as determined by PA and 91.7% as determined by CBCT, which were not significantly different (P = .383).

The percentage of CBCT-determined teeth with absence of radiolucency in this study was lower than that recently reported by Patel et al (37). There are several explanations for this difference. In the study of Patel et al, the definition of absence of radiolucency was when there was no radiolucency detected on CBCT images, whereas in this study, teeth with radiolucency were excluded if there was any radiolucency on CBCT images.
was an intact lamina dura with a maximum widening of 2 mm immediately adjacent to any flush or extruded root filling material. Therefore, many post-treatment radiolucencies smaller than 5 mm³ could have been missed in the study of Patel et al. If we include 22 radiolucencies smaller than 5 mm³ (Table 4) in the group of teeth with absence of radiolucency, this percentage would be 45.2%, a value comparable to that in the study of Patel et al. In this study 26% of the teeth had pretreatment periapical lesions of >65 mm³, and in 27 of 84 teeth (32%) the master gutta-percha cone was larger or much larger than the master apical file. As explained above, this could have negatively influenced the outcome. Although in this study the percentage of teeth with absence of radiolucency was lower, the observed radiolucency was already reduced by 80% or more in 54 of 84 teeth (64%) as shown in Table 4 and Figures 1 and 2. The percentage of absence and reduction of the radiolucency together as revealed by CBCT was 91.7%, comparable with the success rate of 86.1% (absence and reduction of the radiolucency together) as reported by Patel et al. The high percentages of CBCT-determined absence and reduction of the

Figure 1. (A and B) Area measurements of periapical radiolucencies on preoperative (A) and 12-month follow-up PA (B) of 45 revealed significant reduction of radiolucency (arrows). (C-H) 3-dimensional (C, at first visit; D, at recall) and multiplanar reformatted CBCT images (E and F, at first visit; G and H, at recall) rendered a reduced radiolucency (arrows) in volume size (G and D) on tooth 45.
radiolucency reported in this study and the study by Patel et al showed that current root canal procedures can reduce the clinical problems related to root infection and the severity of the periapical inflammation.

In several but not all outcome studies, lesions >5 mm were associated with a reduced success rate (21). By calculation, the volume of a spherical lesion with a diameter of 5 mm is 65 mm$^3$, a value that was used in this study to distinguish large and small lesions. In 22 of 84 teeth (26%), the lesion was >65 mm$^3$, and absence of the radiolucency was not observed in this group.

It was not possible to perform reliable power statistics because there were no data available on the effect of irrigation procedures on endodontic outcome evaluated by PA or CBCT. In addition, because CBCT detects the lesion size more accurately, differences in outcome would be easier to detect.

Figure 2. (A–F) Multiplanar (A–D) and 3-dimensional reformatted (E and F) CBCT images at first visit (A, B, E) and 15-month follow-up (C, D, F) of 42; volume measurements (E and F) of periapical lesions (arrows) revealed significant reduction of radiolucency.
We can conclude that root canal treatments with and without additional ultrasonic activation of the irrigant equally contributed to periapical healing and resulted in a high percentage of absence and reduced lesions. More RCTs are needed to better understand the influential factors on endodontic outcome.

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References