Outcome of One-visit and Two-visit Endodontic Treatment of Necrotic Teeth with Apical Periodontitis: A Randomized Controlled Trial with One-year Evaluation

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Abstract
The choice of one-visit versus two-visit root canal therapy for necrotic teeth with apical periodontitis is a source of current debate. The primary objective of this randomized controlled clinical trial was to compare radiographic evidence of periapical healing after root canal therapy completed in one visit or two visits with an interim calcium hydroxide/chlorhexidine paste dressing. Ninety-seven patients met the inclusion criteria and consented to participate in this study. Patients were randomly assigned to either the one-visit or two-visit group, and root canal therapy was performed with a standardized protocol. Patients in the two-visit group received an intracanal dressing of calcium hydroxide/chlorhexidine paste. Sixty-three patients, 33 in the one-visit group and 30 in the two-visit group, were evaluated at 12 months. The primary outcome measure was change in apical bone density by using the periapical index (PAI). Secondary outcome measures were proportion of teeth healed or improved in each group. Both groups exhibited equally favorable periapical healing at 12 months, with no statistically significant differences between groups. (J Endod 2008;34:251–257)

Key Words
Apical periodontitis, calcium hydroxide, chlorhexidine, one-visit root canal treatment, periapical healing, periapical index

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The role of bacteria in the development and persistence of apical periodontitis is well-established (1–3). It is equally well-accepted that the prognosis for complete healing of endodontically treated teeth with the pretreatment diagnosis of apical periodontitis is approximately 10%–15% lower than for teeth without apical periodontitis (4–7). Mechanical instrumentation, including adequate apical preparation size, and chemical control through use of an antimicrobial irrigating solution are the 2 key elements that lead to effective reduction in intracanal microbial load (8, 9). Whether adequate microbial control can be obtained in one appointment is an ongoing source of controversy (2, 10, 11). Although there might be a reasonable biologic argument to prefer multiple appointment root canal therapy for infected teeth with apical periodontitis, clinical research to date has been equivocal (12).

Calcium hydroxide paste is one of the most commonly used intracanal medications for multiple appointment root canal therapy; however, there is a growing body of evidence that questions the effectiveness of calcium hydroxide against several microorganisms commonly associated with persistent apical periodontitis (13, 14). In addition, although some studies have demonstrated improved healing when calcium hydroxide is used in multiple appointment treatment as an intracanal medication (15, 16), others have found little or no benefit (17–19). A recent systematic review and meta-analysis by Sathorn et al. (12) identified only 3 clinical studies that met the standards for highest level of evidence (15, 17, 18) and concluded that there was no statistically significant difference in healing between one-visit and two-visit root canal therapy.

Because calcium hydroxide has limited effectiveness in eliminating all microbiorganisms from the root canal system, especially those commonly associated with treatment failure (13, 20), the addition of other antimicrobial agents has been suggested (13, 21). During the past decade, chlorhexidine has received much attention as a potential root canal irrigant and intracanal medication (22–26). Although the combination of calcium hydroxide and chlorhexidine as an intracanal medication is relatively untested in well-controlled clinical trials, preliminary research suggests that this might be a rational combination and should provide antimicrobial activity equal or superior to either of the ingredients used alone (21, 27–31).

The primary objective of this randomized controlled clinical trial was to compare radiographic evidence of periapical healing after root canal therapy completed in one visit versus two visits with an interim calcium hydroxide/chlorhexidine paste dressing. We hypothesized that necrotic teeth with apical periodontitis treated in two appointments with calcium hydroxide/chlorhexidine paste as an intracanal medication would demonstrate superior healing at 1 year when compared with teeth treated in one appointment.

Materials and Methods
Subject Enrollment and Sample Size Calculation
This study was approved by the University of Illinois at Chicago Institutional Review Board. Study subjects were recruited from the pool of patients referred to the Postgraduate Endodontics Clinic for initial nonsurgical root canal treatment between August 2003 and May 2006. The primary inclusion criteria were radiographic evidence of

Endodontic Treatment of Necrotic Teeth with Apical Periodontitis
apical periodontitis (minimum size, ≥2.0 mm × 2.0 mm) and a diagnosis of pulpal necrosis confirmed by negative response to cold and electric pulp tests. Pulp testing was performed by an endodontic resident, and radiographic interpretation was verified by the supervising faculty member. Patients were excluded if they were younger than 18 years old, pregnant, had a positive history of antibiotic use within the past month, needed antibiotic premedication for dental treatment (including infective endocarditis or prosthetic joint prophylaxis and immunocompromising disorders), diabetic, or if the tooth had been previously accessed. Once eligibility was confirmed, the study was explained to the patient by the endodontic resident, and the patient was invited to participate. Initial treatment was not subsidized (ie, patients were responsible for the usual root canal treatment fee); however, a financial incentive was offered for patients to return for follow-up clinical and radiographic examination. All patients were advised that root canal treatment would be performed regardless of participation in the study. After written and verbal informed consent was obtained, the patient was randomly assigned to either the one-visit or two-visit group by using a block of random numbers generated by one of the investigators (B.R.J.). Neither the postgraduate clinician nor the patient was aware of the group assignment before agreeing to participate in the study and completing the consent process.

Sample size was determined with the method described by Walters (32) for comparing means of ordinal data when the samples are presumed to display a relatively normal distribution. Radiographic evaluation of change in apical bone density at 12 months was the primary outcome measure. The minimum sample size per group was determined to be 32, on the basis of power = 0.80, \( P < 0.05 \), and the minimum clinically significant mean difference between groups was set at 0.5 units (standard deviation = 1.0 unit) by using the periapical index (PAI) scale described by Orstavik et al. (33). To ensure a minimum sample size of at least 32 subjects at the 12-month follow-up examination, the goal was to enroll 50 subjects in each group.

Clinical Procedures

All treatment sessions were approximately 3 hours in length to allow for adequate time for completion of treatment in one visit for those patients assigned to the one-visit group. The protocol specified that patients assigned to the one-visit group who could not be completed in one visit would be completed in a second visit but would not be included in the primary data analysis with either group. All treatment was performed by second-year endodontic residents following a standardized treatment protocol.

Local anesthesia (2% lidocaine with 1:100,000 epinephrine) was administered as needed for patient comfort. Initial caries excavation was performed, rubber dam isolation was obtained, and a standard access cavity was prepared. Coronal shaping and enlargement was performed with low speed Gates-Glidden drills (Dentsply Maillefer, Tulsa, OK) to obtain straight-line access to the apical third of each root. Canals were then irrigated with 2.0 mL 5.25% sodium hypochlorite. Initial canal working length was established by using the Root ZX electronic apex locator (J Morita, Irvine, CA) and a #15 stainless steel file. Working length was confirmed and adjusted as needed by using straight and angled radiographs. Canal instrumentation was performed with 0.06 taper Kt nickel-titanium rotary files (Sybron Endo, Orange, CA), size #40 to #20, in a crown-down technique with RC Prep (Premier Dental Product Co, King of Prussia, PA) as a lubricant. The master apical file size for each canal was set at 3 sizes larger than the first file to bind at the working length (after coronal enlargement with Gates-Glidden drills), with a minimum file size of #55 for all two-canal premolars and mandibular anterior teeth, mesial canals of mandibular molars, and facial canals of maxillary molars (minimum #30 for MB2 canals). A minimum master apical file size of #40 was required for the distal canal(s) of mandibular molars, palatal canals of maxillary molars, and single-canal anterior and premolar teeth. The final canal taper was 6%, with canal finishing done by circumferential hand filing with a #50 stainless steel file. Canals were irrigated with 5.0 mL 5.25% sodium hypochlorite after each instrumentation cycle, and canal patency was maintained by passing a #10 stainless steel file approximately 0.5–1.0 mm beyond the working length. After completion of canal instrumentation, all canals were irrigated with 5.0 mL 17% ethylenediaminetetraacetic acid (Roth International Ltd, Chicago, IL) for 1 minute followed by a final irrigation with 5.0 mL 5.25% sodium hypochlorite. Canals were then dried with sterile paper points. Teeth in group 1 were obturated at the same appointment by using a warm vertical condensation technique with gutta-percha (Dentsply Tulsa Dental) and Kerr EWT sealer (Kerr Sybron Endo). For teeth assigned to group 2, a lentulo spiral was used to fill all canals with a paste made by mixing calcium hydroxide powder (Roth International Ltd, Chicago, IL) and 2% chlorhexidine liquid (Balas Dental Products, Chicago, IL). Patients in group 2 were scheduled for a second appointment to complete root canal therapy at least 2 weeks but no more than 4 weeks after the initial appointment. At the second appointment, the calcium hydroxide/chlorhexidine paste was removed by using circumferential filing with Hedstrom-type files and copious irrigation with 5.25% sodium hypochlorite followed by 5.0 mL 17% ethylenediaminetetraacetic acid and a final rinse of 5.0 mL 5.25% sodium hypochlorite. Complete removal of the calcium hydroxide/chlorhexidine paste was confirmed by visual inspection with a dental operating microscope. The canals were dried with sterile paper points, and obturation was performed with the same technique described for group 1.

Access cavities of anterior teeth were etched and restored with Fuji IX (GC Corp, Tokyo, Japan). For posterior teeth, a buildup restoration was placed by using the same etching technique and Fuji IX. For the two-visit group, a pretreatment buildup of Fuji IX was placed after caries excavation, and the access cavity was sealed with Cavit (3M ESPE Dental Products, St Paul, MN). After completion of treatment, the teeth were restored with a Fuji IX buildup. Patients were instructed to return to their referring dentist or dental student for definitive restoration as soon as possible. A polyvinylsiloxane (Regisil PB; Dentsply Caulk, Milford, DE) bite registration was made and used as a positioning index on a digital extension cone paralleling sensor holder before the immediate postoperative (final fill) radiograph (Fig. 1). Radiographic exposure settings were recorded for each tooth. Follow-up radiographs were

Figure 1. A custom polyvinylsiloxane bite registration index was created for each tooth.
made with the individual custom index and recorded exposure settings. All radiographs were obtained by using the same digital imaging system (Schick Technolgies Inc, Long Island City, NY).

**Outcome Measures and Data Analysis**

The primary outcome measure for this study was change in apical bone density at 12 months. The PAI was used to evaluate radiographic healing (33). Secondary outcome measures were the presence of clinical symptoms or abnormal findings at 12 months (spontaneous pain, presence of sinus tract, swelling, mobility, periodontal probing depths greater than baseline measurements, or sensitivity to percussion or palpation) and proportion of teeth in each group that could be considered improved (decreased PAI score) or healed (PAI ≤2). The clinical and radiographic examination was performed by an endodontic resident unaware of the patient’s group assignment or baseline presentation. Clinical findings were recorded and compared with preoperative diagnostic records. The digital radiograph was made by using the individual patient’s bite registration and the same exposure settings used for the immediate postoperative image.

Radiographic images were coded and stored by 2 of the investigators (V.A.P. and P.I.F.). Images were evaluated blindly and independently by 3 experienced endodontists (B.R.J., C.S.W., and M.I.F.). Before evaluation of the study images, each examiner graded a series of 26 radiographic images not associated with the study sample and representing a wide range of periapical bone densities. Instructions for grading images with the PAI scoring system were adapted from Orstavik et al. (33) and are presented in Fig. 2. Digital images were evaluated in a random order in a darkened room on a high-resolution 17-inch flat screen LCD monitor. The examiners then met as a group and reviewed all scores to enhance calibration and inter-rater agreement. Consensus was reached on cases that did not receive unanimous agreement on the PAI score. Consensus was reached on all images. The consensus score for each image was considered the true score and was used for statistical analysis. The identifying code for each image was not broken until after the consensus score was determined. The Mann-Whitney U test was used to evaluate differences between groups at baseline (immediate postoperative) and at the 12-month follow-up evaluation. Change in PAI score for each group from baseline to 12-month follow-up evaluation was tested with the Wilcoxon signed rank test. The secondary outcome measures, proportion of teeth in each group that could be considered improved (decreased PAI score) or healed (PAI ≤2), were assessed with the χ² test. Clinical symptoms and abnormal findings at the 12-month follow-up examination were recorded but not subjected to statistical analysis.

**Results**

Ninety-seven patients met the inclusion criteria and consented to participate in the study. Sixty-three patients were examined at the 12-month follow-up, 33 in the one-visit group (group 1) and 30 in the two-visit group (group 2). There were 3 treatment failures before the 12-month examination (2 in the one-visit group and 1 in the two-visit group), and 31 additional patients were lost to follow-up (Fig. 3). Demographic characteristics for each group (age, gender, and tooth type) are listed in Fig. 4.

The mean PAI score for group 1 was 3.61 at the immediate postoperative examination and 2.27 at the 12-month follow-up, a decrease of 1.34. The mean PAI score for group 2 was 3.53 at the immediate postoperative examination and 2.30 at the 12-month follow-up, a decrease of 1.23. Both groups exhibited a statistically significant decrease with the single measure ICC (SPSS 13 for Windows; SPSS Inc, Chicago, IL), and inter-rater agreement was measured with the average measure ICC (also known as the inter-rater reliability coefficient). The criteria for strength of agreement proposed by Landis and Koch (34) were used for this study: 0.00–0.20, slight agreement; 0.21–0.40, fair agreement; 0.41–0.60, moderate agreement; 0.61–0.80, substantial agreement; and 0.81–1.00, almost perfect agreement.

After the second independent scoring session, the examiners met as a group to reach consensus on cases that did not receive unanimous agreement on the PAI score. Consensus was reached on all images. The consensus score for each image was considered the true score and was used for statistical analysis. The identifying code for each image was not broken until after the consensus score was determined. The Mann-Whitney U test was used to evaluate differences between groups at baseline (immediate postoperative) and at the 12-month follow-up evaluation. Change in PAI score for each group from baseline to 12-month follow-up evaluation was tested with the Wilcoxon signed rank test. The secondary outcome measures, proportion of teeth in each group that could be considered improved (decreased PAI score) or healed (PAI ≤2), were assessed with the χ² test. Clinical symptoms and abnormal findings at the 12-month follow-up examination were recorded but not subjected to statistical analysis.

<table>
<thead>
<tr>
<th>PAI Score</th>
<th>Description of radiographic findings</th>
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<tbody>
<tr>
<td>1</td>
<td>normal periapical structures</td>
</tr>
<tr>
<td>2</td>
<td>small changes in bone structure</td>
</tr>
<tr>
<td>3</td>
<td>changes in bone structure with some mineral loss</td>
</tr>
<tr>
<td>4</td>
<td>periodontitis with well-defined radiolucent area</td>
</tr>
<tr>
<td>5</td>
<td>severe periodontitis with exacerbating features</td>
</tr>
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Instructions for scoring using the PAI:

1.) Find the reference radiograph where the periapical area most closely resembles the periapical area you are studying (Orstavik, 1986, Fig 1). Assign the corresponding score to the observed root.
2.) When in doubt, assign higher score.
3.) For multirooted teeth, use the highest of the scores given to the individual roots.
4.) All teeth must be given a score.

**Figure 2.** PAI with verbal descriptors and instructions for scoring (adapted from Orstavik et al., 1986; Orstavik et al., 2004; and Huumonens et al., 2005).
in PAI score between the immediate postoperative examination and 12-month evaluation \((P < .05)\). There was no statistically significant difference between groups at either the immediate postoperative examination \((P = .74)\) or the 12-month evaluation \((P = .95)\) (Fig. 5). In group 1, 67% of the teeth could be considered healed (PAI ≤ 2) at 12 months, 85% were improved (lower PAI score), 12% were unchanged (same PAI score), and 3% were worse (higher PAI score). In group 2, 70% of the teeth could be considered healed at 12 months, 80% were improved, 17% were unchanged, and 3% were worse. There was no statistically significant difference between groups \((P = .86)\) (Fig. 6).

With the exception of the 3 treatment failures, no abnormal clinical findings were recorded in either group at the 12-month follow-up examination. We defined failure as the need for any additional treatment before or at the 12-month follow-up evaluation. Two patients (one in each group) presented with persistent draining sinus tracts at 6 months (both had sinus tracts present at the initial treatment appointment) and

<table>
<thead>
<tr>
<th></th>
<th>male</th>
<th>female</th>
<th>age</th>
<th>anterior</th>
<th>premolar</th>
<th>molar</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-visit RCT ((n=33))</td>
<td>18</td>
<td>15</td>
<td>mean=58 (range: 20 to 91 y/o)</td>
<td>14</td>
<td>13</td>
<td>6</td>
</tr>
<tr>
<td>2-visit RCT ((n=30))</td>
<td>11</td>
<td>19</td>
<td>mean=55 (range: 18 to 86 y/o)</td>
<td>14</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>treatment failure</td>
<td>2</td>
<td>1</td>
<td>(31, 61, &amp; 75 y/o)</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>lost to follow-up</td>
<td>15</td>
<td>16</td>
<td>mean=45 (range: 20 to 80 y/o)</td>
<td>12</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>totals</td>
<td>46</td>
<td>51</td>
<td>mean=54 (range: 18 to 91 y/o)</td>
<td>42</td>
<td>31</td>
<td>24</td>
</tr>
</tbody>
</table>

Figure 3. Consolidated Standards of Reporting Trials (CONSORT) flow chart.

Figure 4. Demographic characteristics and tooth type by group.
received nonsurgical re-treatment followed by apical surgery when the sinus tracts did not resolve 3 months after re-treatment. The third failure (group 1) presented 3 months after initial treatment with a new draining sinus tract and radiographic evidence of increased periapical radiolucency. Because this tooth had been restored with a new post and crown, surgical treatment was performed. The 3 treatment failures were not included in the primary data analysis.

Before the consensus scoring meeting, intrarater reliability scores ranged from 0.84 – 0.92, and the overall inter-rater agreement was 0.95.

**Discussion**

When this protocol was developed in 2002, the use of a combination calcium hydroxide/chlorhexidine paste as an intracanal medication was a relatively novel concept. The limited effectiveness of calcium hydroxide paste against several common endodontic pathogens has caused some investigators to question its use in multiple appointment root canal therapy (13, 14, 20, 35), although there is no commonly accepted alternative. The addition of chlorhexidine to calcium hydroxide is supported by several current studies (21, 27, 30), although other investigators have found no benefit with this combination (28, 29, 31). The expectation that teeth treated in two visits with an interappointment dressing of calcium hydroxide/chlorhexidine paste would result in improved healing when compared with one-visit root canal therapy was not supported by our results. Our findings are consistent with the majority of well-controlled clinical studies with single-ingredient calcium hydroxide paste in two-visit therapy; no statistically significant differences were observed between one-visit and two-visit treatment (15, 17–19).

Sixty-three patients from an original sample of 97 were examined at the 12-month follow-up, 33 in the one-visit group and 30 in the two-visit group. Although the sample size in this study was small, it is typical when compared with similar high-quality clinical trials (15, 17–19). Patients were randomly assigned to treatment groups, and root canal therapy was performed according to a standardized protocol that represented the authors’ consensus opinion of current best clinical practices. The preoperative PAI score was not used as an initial inclusion criterion for this study, although the requirement that all teeth must have a visible periapical radiolucent area at least 2.0 × 2.0 mm assured an initial PAI score ≥3. There was an approximately equal distribution of immediate postoperative PAI scores between the 2 groups. The only known independent variable was number of visits. Nevertheless, the sample and operators might not accurately represent the true population of patients and clinicians. Results can be influenced by many unknown and uncontrolled variables. For example, we excluded diabetic patients from our study because of concerns about possible delayed healing but did not exclude smokers, even though there is evidence to suggest that both groups experience poorer treatment outcomes (7). We also did not attempt to equalize the number of multi-rooted teeth in each group, although multi-rooted teeth with apical periodontitis have a lower probability of complete healing when compared with single-rooted teeth (5). Fortunately, the number of teeth in each group was reasonably evenly distributed by tooth type, so we do not believe this was a significant source of bias. The basic demographic characteristics (age, gender, and tooth type) of the 2 study groups were similar, and neither group varied significantly from the study dropouts, except that the mean age of dropouts was approximately 10 years younger than the overall mean age. The clinicians for this study were second-year endodontic residents, arguably more skilled than many general dentists but probably less skilled than an experienced endodontist. Treatment was performed under faculty supervision, with the opportunity for consultation and assistance as needed. Therefore, the treatment environment

<table>
<thead>
<tr>
<th></th>
<th>Immediate post-op mean PAI and standard deviation</th>
<th>12 month evaluation mean PAI and standard deviation</th>
<th>Change in PAI score with 95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1 (n=33)</strong></td>
<td>3.61 ± 0.93</td>
<td>2.27 ± 0.76</td>
<td>1.34 (1.02 to 1.64)</td>
</tr>
<tr>
<td><strong>Group 2 (n=30)</strong></td>
<td>3.53 ± 0.97</td>
<td>2.30 ± 0.70</td>
<td>1.23 (0.88 to 1.58)</td>
</tr>
</tbody>
</table>

**Figure 5.** PAI score at immediate postoperative and 12-month evaluation for group 1 (one-visit randomized controlled trial) and group 2 (two-visit root canal therapy).

<table>
<thead>
<tr>
<th></th>
<th>Healed (PAI ≤ 2)</th>
<th>Not healed (PAI ≥ 3)</th>
<th>Improved (decreased PAI)</th>
<th>Unchanged (same PAI)</th>
<th>Worse (increased PAI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1 (n=33)</strong></td>
<td>67% (n=22)</td>
<td>33% (n=11)</td>
<td>85% (n=28)</td>
<td>12% (n=4)</td>
<td>3% (n=1)</td>
</tr>
<tr>
<td><strong>Group 2 (n=30)</strong></td>
<td>70% (n=21)</td>
<td>30% (n=9)</td>
<td>80% (n=24)</td>
<td>17% (n=5)</td>
<td>3% (n=1)</td>
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</table>

**Figure 6.** Proportion of teeth healed, improved, unchanged, or worse in each group at 12-month evaluation.
might not be truly representative of either specialty practice or general dental practice settings.

After root canal therapy, the probability of periapical healing increases over time, and some authors have suggested that 4 or 5 years might be necessary to adequately evaluate healing (17, 18). From a practical standpoint, considering the resource intensive nature of clinical studies and difficulty controlling patient dropouts over time, many studies have used 12 months as an end point (15, 36–38). Although longer observation periods might be ideal, evidence of periapical changes in bone density associated with healing should be apparent at 12 months when using the PAI, and longer observation times might not be necessary (39). We intend to perform follow-up radiographic and clinical evaluation on patients in this study at 24 months, although the sample size is likely to fall below the number necessary to assure adequate power.

Although the PAI is most appropriately considered an ordinal scale (7, 38, 39), there is more than one way to analyze data generated by the PAI. This is confirmed by the variable use by other authors. Some investigators have converted data extracted from the PAI into a nominal scale with a healed/not healed dichotomous outcome (15, 40), and others have treated the PAI as interval data and analyzed findings with a parametric test (analysis of variance or t-test) (36, 37). However, an important consideration in sample size calculation is identifying the type of data and statistical tests a priori. In this study, we were most interested in differences in healing between groups as measured by changes in the mean PAI score. On the basis of a previous study at our institution with the PAI (37), we expected the data to exhibit a reasonably normal distribution, and therefore we selected the method described by Walters (32) for sample size calculation for ordinal data when comparing 2 means. In fact, the data set did display an approximately normal distribution. The minimum significant difference between groups was set at 0.5 units on the PAI scale. Using the scale in this way results in a very different sample size calculation compared with, for example, the minimum clinically significant difference proposed by Trope et al. (15) (10% difference between groups), when outcome is viewed as a dichotomous variable (PAI score: healed ≥2, not healed ≤0).

Agreement between and within examiners was determined with the ICC. A score of 1.0 signifies perfect agreement, and a score of 0 represents no agreement beyond the level of agreement expected by random chance. The inter-rater reliability score of 0.95 in this study represents a very high level of agreement between examiners (0.81–1.0, almost perfect), even before meeting to establish a consensus score for each image. This finding provides further support for the reliability of the PAI method for measuring radiographic changes in apical bone density.

In conclusion, 12 months after initial nonsurgical root canal therapy on necrotic teeth with apical periodontitis, there was no significant difference in radiographic evidence of periapical healing between one-visit therapy and two-visit therapy with an interim calcium hydroxide/chlorhexidine paste dressing.

Acknowledgments

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