Clinical and Radiographic Evaluation of One- and Two-visit Endodontic Treatment of Asymptomatic Necrotic Teeth with Apical Periodontitis: A Randomized Clinical Trial

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Abstract

The present investigation recorded the 2-year clinical and radiographic outcome of one- and two visit endodontic treatment and studied the significance of the bacteriologic sampling results on the outcome. A randomization procedure allocated 53 teeth to one-visit treatment and 48 teeth to two-visit treatment. At the end of the study period, 32 teeth (65%) in the one-visit group and 30 teeth (75%) in the two-visit group were classified as healed. The statistical analysis of the healing results did not show any significant difference between the groups ($p=0.75$). Forty-nine (80%) of the 61 teeth that were obturated after a negative micobiologic sample were classified as healed. Teeth sealed after positive samples healed in 44%. The present study gave evidence that similar healing results might be obtained through one- and two-visit antimicrobial treatment. *(J Endod 2007;33:1145–1148)*

Key Words

Apical periodontitis, one-visit endodontics, randomized clinical trial

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Traditionally, endodontic treatment of teeth with apical periodontitis aims at the complete elimination of microbial invaders of the root canal system. Studies have shown that instrumentation and irrigation of the root canal system substantially reduce the number of cultivable microorganisms but rarely lead to a total eradication (1, 2). Therefore, antibacterial dressings like calcium hydroxide (CH) have been recommended to combat the persisting microbiota (3–5). Although widely accepted and used, the inclusion of CH in a treatment strategy has obvious disadvantages including the following: (1) it does not repeatedly kill the intracanal rest flora (6–10) and (2) it needs at least two visits to be optimally potent (4). The effectiveness of a clinical strategy must not be evaluated only from a biological point of view but other factors such as costs, patient comfort, and effort put into the treatment should be included in a final assessment (11). Hence, it is important to search for one-visit treatment regimens that would be as biologically effective as a CH-based two-visit procedure.

The quest for an effective scientifically supported one-visit procedure has been approached from principally two angles: (1) the exclusion of an antibacterial intra canal dressing and (2) the inclusion of a short-time dressing. In a systematic review of the literature, Sathorn et al (12) excluded all studies but three in their final meta-analysis (13–15). These investigations all used the former approach for the one-visit treatment, and the meta-analysis could not show any statistically significant difference in the healing rate to the two-visit alternative. However, conclusions must be made with care because the studies are few and the sample size is small (only 146 cases all together).

Kvist et al (10) designed a study to compare the microbiological outcome of a one-visit treatment regimen, including a 10-minute intra-appointment dressing with 5% iodine-potassium-iodide (IPI), with a standard CH including two-visit procedure. In the postmedication samples, residual microorganisms were recovered in 29% of the one-visit teeth and in 36% of the two-visit treated teeth. No statistically significant difference between the groups was found. The aims of the present investigation were (1) to record the 2-year clinical and radiographic outcome of the material earlier described by Kvist et al (10) and (2) to study the significance of the microbiologic sampling results on the outcome.

Materials and Methods

Approval for the project was obtained from the Göteborg University committee for research on human subjects, and informed consent was acquired from all participants. The patients were recruited from referrals made to the Clinic of endodontics, Göteborg Public Dental Health Service. Patients with asymptomatic teeth with necrotic pulps and apical periodontitis, as verified radiographically, were consecutively enrolled in the study and were randomly assigned to one- or two-visit treatment. Randomization was performed before the clinical examination using the "minimization method" as described by Pocock (16). Two randomization factors were considered: tooth group and size of periapical lesion (Table 1). Ninety-four patients (47 women and 47 men) (mean age, 55 years) with 101 eligible teeth consented to participate in the study. Seven patients contributed more than one tooth. The study layout is shown in Figure 1.

TABLE 1. Distribution of Teeth by Randomization Factors

Tooth group	One-visit pre treatment (n = 53) (%)	One-visit follow-up (n = 49) (%)	Two-visit pre treatment (n = 48) (%)	Two-visit follow-up (n = 40) (%)
Incisors and canines	26 (49)	25 (51)	27 (56)	22 (55)
Bicuspids	17 (32)	15 (30)	12 (25)	10 (25)
Molars	10 (19)	9 (19)	9 (19)	8 (20)
Size of lesion				
<2 mm	5 (9)	5 (10)	5 (10)	5 (13)
2-5 mm	29 (55)	26 (53)	24 (50)	22 (55)
>5 mm	19 (36)	18 (37)	19 (40)	13 (32)

Intracanal Procedures

Each tooth was isolated with a rubber dam and disinfected with 30% hydrogen peroxide and 10% iodine tincture according to the protocol proposed by Möller (17). After access preparation, the working length was established radiographically.

To expose the apical part of the root canals to microbiological sampling, the canals were sequentially enlarged with nickel-titanium instruments for rotary (GT/ Profile; Dentsply-Maillefer, Ballaigues, Switzerland) and/or hand use (Nitiflex, Dentsply-Maillefer), reaching size ISO #20 at the working length. Before further instrumentation of the canals, initial microbiological samples were taken (10). The canals were then enlarged, and apical boxes were prepared between size ISO #40 and #60, depending on the size of the root. During instrumentation, the canals were irrigated with 0.5% NaOCl (Dakins solution). Immediately after the completion of the chemomechanical preparation, postinstrumentation microbiological samples were obtained (10). Up to this point, treatment procedures were identical for both groups.

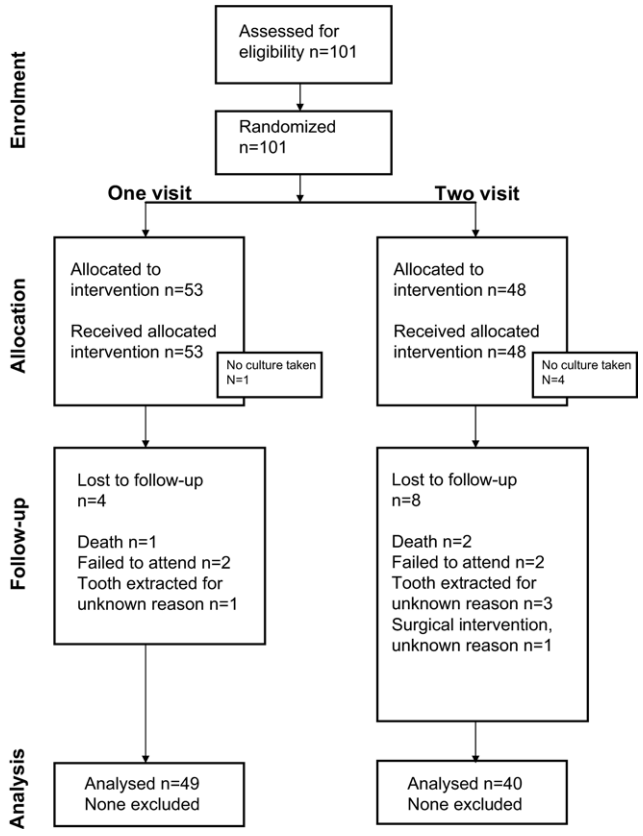

Figure 1. Flow diagram of the progress of the phases of the trial.

For the one-visit group, to remove the smear layer, the canals were filled with Tubulicid Plus (Dental Therapeutics AB, Nacka, Sweden) for 20 seconds, dried with paper points, and refilled for an additional 20 seconds. Subsequently, the canals were filled with 5% IPI solution for 10 minutes. Before root filling, a postmedication microbiological sample was taken (10). Finally, root canals were filled with gutta percha cones using cold lateral condensation technique including rosin chloroform as sealer. The root-filling quality was radiographically checked.

For the two-visit group, CH was placed meticulously by means of a Lentulo spiral, and the access cavity sealed with Coltosol (Coltène Whaledent, Cuyahoga Falls, OH). After a week, CH was removed by hand instruments and irrigation with VMGA I (17). A postmedication microbiological sample was obtained (10), and canals obturated with gutta percha as described earlier. The treatments were performed by four endodontic specialists.

Follow-up

The healing results were clinically and radiographically evaluated 2 years postoperatively.

Radiographic Assessments

All radiographic films obtained preoperatively and at follow-up were coded blind and organised in random order. Two examiners independently evaluated all radiographs. Films were examined under moderate illumination at a light table using a magnifying viewer equipped with a masking frame with the size of a dental film. To minimize the false-positive diagnoses, observers used a strict definition of periapical disease and reported a positive finding only when absolutely certain (18). In case of disagreement, joint re-evaluation was performed until a consensus was reached. The size of periapical radiolucency was assessed by measuring with a ruler (to the nearest millimeter) its largest horizontal and vertical width.

Outcome Classification

Outcome of treatment was classified by using a modification of the Strindberg (19) criteria. Teeth with symptoms of persisting periapical inflammation were scored as not healed as were cases with unchanged or increased size of the periapical radiolucency. Teeth with a reduced

TABLE 2. Distribution of Teeth According to Outcome Classification in the Two Experimental Groups*

	One visit	Two visit	Total
Healed	32	30	62
Uncertain healing	13	5	18
Not healed	4	5	9
Total	49	40	89

$p = 0.7532$.

*Mantel-Haenszels χ^2 test was used to test trends in the contingency table.

TABLE 3. Distribution of Teeth According to Outcome Classification and Postmedication Sample Results (PMS)*

	Positive R-sample	Negative R-sample	Total
Healed	12	49	61
Uncertain healing	14	4	18
Not healed	1	8	9
Total	27	61	88

$p = 0.1202$.

*Mantel-Haenszels χ^2 test was used to test trends in the contingency table.

size of the periapical rarefaction (sum of horizontal and vertical reduction ≥2 mm) were judged as uncertain. Teeth with complete restitution of the periodontal contours were judged as healed. In teeth with more than one root, the least favorable outcome was registered.

Microbiological Examination

Details of laboratory procedures and microbiologic analyses can be found in Kvist et al (10).

Statistical Methods

A Mantel-Haenszels chi-square test was used to test trends in contingency tables. All hypothesis tests were conducted at the 0.05 level of significance.

Results

The randomization procedure allocated 53 teeth to one-visit treatment and 48 teeth to two-visit treatment. Twelve teeth, eight in the two-visit and four in the one-visit group, respectively, were lost to follow-up. Reasons for drop out are given in Figure 1. At the end of the study period, 32 teeth (65%) in the one-visit group and 30 teeth (75%) in the two-visit group were classified as healed (Table 2). The number of cases classified as uncertain was higher in the one-visit group, 13 (27%) as compared with 5 (13%). Four teeth in the two-visit group showed clinical symptoms before the 2-year follow-up and were classified as not healed. The statistical analysis of the healing results did not show any significant difference between the groups ($p=0.75$). Forty-nine (80%) of the 61 teeth that were obturated after a negative micobiologic sample were classified as healed (Table 3). Teeth sealed after positive samples healed in 44%. Notably, teeth with positive samples were classified as uncertain more often (52%) than teeth with no sign of cultivable microorganisms (7%). However, the presence or absence of detectable microbes just before obturation did not influence the healing results at a statistically significant level ($p=0.12$).

Discussion

The present investigation was designed as a randomized study of the effect of one-visit and two-visit treatment procedures on periapical healing. Because the material was small and important prognostic factors might be unevenly distributed among the groups, Pocock's (16) so-called minimization method was used. Twelve teeth (12%) were lost to the 2-year follow-up. However, the loss did not alter the situation to an extent that would render statistical comparisons and conclusions invalid (Table 1).

Clinical symptoms were rare during the follow-up period (only 4 cases). Thus, the outcome was classified mainly on the radiographic evaluation. The radiographic image of periapical bone lesions develops from being impossible or difficult to see to being easily distinguished from the background (20). Radiographic diagnosis of apical periodontitis, therefore, may be regarded as a signal-detection task (18). The actual prevalence of apical periodontitis in a cohort is difficult to reveal by radiographic means (21). But, if false-positive diagnoses can be minimized, chances will increase to disclose the true relation between investigated factors or populations. Therefore, in the present study, a periapical radiolucency was reported by the observers only when absolutely certain. This implies that stated healing frequencies should not be given an absolute meaning but only a relative one.

No statistically significant difference in terms of healing was observed between the one- and two-visit groups. This finding corroborates the results of four previous studies (9, 13, 14, 22) (Table 4). It should be pointed out that beside the study by Friedman et al (22) all cited investigations report on small clinical materials. On the other hand, Friedman et al did not analyze a randomized sample. Thus, published studies including the present one have failed to show any statistically significant difference in the outcome between one-visit and two-visit root canal therapy.

Clinical outcome studies take a long time to monitor, demand substantial economic resources, and run the risk of losing patients at follow-ups. Therefore, it is desirable to find simpler but accurate surrogate endpoints for such investigations. When assessing the present material, the identical overall conclusion was drawn after both the microbiological (10) and the clinical/radiographic evaluation; no statistically significant difference was found between the one- and two-visit treatment regimens. Hence, at this level, support was given to the notion that postmicrobiologic sampling could replace radiographically based long-time studies and be used as a surrogate endpoint. However, at a more case-specific level, the relation between the results of microbiologic analysis and outcome was not as clear.

There was a tendency toward a more favorable outcome in teeth yielding a negative culture immediately before root filling ($p=0.1202$). This finding is in concordance with Bender et al (23), Heling and Shapira (24), and Peters et al (9). Others have indeed reported that presence of microbes at the time of root filling will adversely affect the outcome (25–29). The idea that absence of cultivable microbes at the time of obturation will favor healing is consistent with the idea that microorganisms are the prime reason for persistent apical periodontitis. Recently, Fabricius et al (30) reported results from an extensive experiment conducted on 175 root canals in monkey teeth in support of such an assumption. However, in this context, it must be understood that the methodology of microbiological root canal sampling is complex

TABLE 4. Data Summary of Included Studies

Citation	Randomization	All types of teeth	No. of cases	Observation Time (y)	Healing rate (%)* single versus multiple visit
Friedman et al (1995)	No	Yes	378	1.5	86 vs 75
Trope et al (1999)	Yes	No	76	1	64 vs 74
Weiger et al (2000)	Yes	Yes	67	0.5-5	83 vs 71
Peters and Wesselink (2002)	Yes	No	38	4.5	81 vs 71
Molander et al (2007)	Yes	Yes	89	2	65 vs 75

*Teeth with complete healing.

and that the diagnostic accuracy is poorly known (7, 31–33). For example, microorganisms hiding in biofilms or in untreated parts of the canal system may be hard to sample, and remnants of the medication might depress laboratory growth.

In conclusion, the present study gave evidence that, given a meticulously instrumented root canal, a one-visit antimicrobial treatment including 10 minutes of dressing with 5% IPI is as effective as a two-visit procedure using CH. Hence, at this level, support was given to the notion that postmicrobiologic sampling could replace radiographically based long-time studies and be used as a surrogate endpoint.

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