Influence of calcium hydroxide intracanal dressings on the prognosis of teeth with endodontically induced periapical lesions

R. Weiger, R. Rosendahl & C. Löst

Department of Conservative Dentistry, School of Dental Medicine, University of Tübingen, Tübingen, Germany

Abstract

Weiger R, Rosendahl R, Löst C. Influence of calcium hydroxide intracanal dressings on the prognosis of teeth with endodontically induced periapical lesions. *International Endodontic Journal,* **33,** 219–226, 2000.

Aim This prospective clinical study explored the influence of calcium hydroxide as an interappointment dressing on the healing of periapical lesions associated with pulpless teeth that had not been endodontically treated previously. This was achieved by comparing the prognosis after a two-visit root canal treatment with that following a one-visit treatment.

Methodology Seventy-three patients were recruited having one tooth with an endodontically induced lesion. Of these patients, 67 could be re-examined. Calcium hydroxide was placed in the instrumented root canals of 31 teeth for at least one week and the treatment finished at the second visit. Thirty-six teeth were root canal treated at one visit. The criteria for success were the absence of signs and symptoms indicating an acute phase of periapical periodontitis and radiographically a periodontal ligament space ofnormal width. Methods for event time analysis were used to evaluate and compare the prognosis of both treatment approaches.

Results The probability that complete periapical healing will take place increased continuously with the length of the observation period. In both treatment groups the likelihood that the root canal treatment yields a success within an observation time of five years exceeded 90%. A statistically significant difference between the two treatment groups could not be detected.

Conclusions From a microbiological perspective, one-visit root canal treatment created favourable environmental conditions for periapical repair similar to the two-visit therapy when calcium hydroxide was used as antimicrobial dressing. One-visit root canal treatment is an acceptable alternative to two-visit treatment for pulpless teeth associated with an endodontically induced lesion.

Keywords: calcium hydroxide, one-visit endodontic treatment, periapical lesion, prognosis, root canal treatment.

Received 7 January 1999; accepted 14 June 1999

Introduction

The development and progression of an endodontically induced apical periodontitis are clearly associated with the presence of microorganisms in the root canal system (Kakehashi *et al.* 1965, Sundqvist 1976, Möller *et al.* 1981). Thus, conventional root canal treatment aims primarily at eliminating these bacteria as completely as possible. The root canal is cleaned and shaped, ideally to the apical constriction (Ricucci 1998, Ricucci & Langeland 1998), under sufficient irrigation with a potent solution, e.g. sodium hypochlorite. In addition, an interappointment antimicrobial dressing is generally advocated to prevent recovery and multiplication of microorganisms remaining even after careful instrumentation and debridement of the root canal space (Byström *et al.* 1985, European

Correspondence: Dr Roland Weiger, Abt. Poliklinik für Zahnerhaltung, Zentrum für ZMK, Osianderstr. 28, W-72076 Tübingen, Germany (fax: +49 7071 295656).

Society of Endodontology 1994, Sjögren *et al.* 1997); a popular medicament is calcium hydroxide. Clinically, microbiological samples from initially infected root canals substantiated the potential of calcium hydroxide to eliminate or reduce the total number of cultivable bacteria in the root canal system when the medicament was placed in the root canal for at least one week (Byström *et al.* 1985, Sjögren *et al.* 1991).

Due to the inaccuracy of the sampling method itself, however, there is a risk of obtaining false negative bacterial samples. Thus, it can be speculated that in some teeth periapical healing occurred even when bacteria were left in inaccessible areas of the root canal system, e.g. in the dentinal tubules, following complete instrumentation and placement of an antimicrobial medicament. This may be one reason for the recent controversy about the necessity of an antimicrobial intracanal dressing (Byström *et al.* 1987, Peters *et al.* 1995, Sjögren *et al.* 1997, Weiger *et al.* 1998). It has been reported that calcium hydroxide has the potential to kill bacteria left in inaccessible areas of the root canal system and therefore favours the healing process of periapical lesions (Byström *et al.* 1985, 1987). Others have recommended for practical reasons that endodontic treatment should be completed in a single visit (one-visit treatment) without any intracanal dressing (Peters *et al.* 1995). It is argued that bacteria surviving in the root canal system after root canal preparation are entombed by obturating the root canal and perish as a result of lack of substrate (Peters *et al.* 1995). These microorganisms may no longer interfere with the periapical healing process. Likewise, some root canal sealers and gutta-percha cones elicit *in vitro* an antibacterial activity that may contribute to the elimination of intracanal microorganisms (Moorer & Genet 1982, Weiger *et al.* 1993).

The present prospective clinical study was initiated to explore the influence of calcium hydroxide applied as an interappointment intracanal dressing on the healing process of periapical lesions associated with pulpless teeth. For this purpose the prognosis after a two-visit root canal treatment was compared with that following a one-visit treatment.

Materials and methods

Clinical material

Seventy-three patients that had not taken antibiotics four weeks prior to endodontic therapy were recruited for this trial that began in September 1992. In each patient one tooth was selected that radiographically demonstrated a lesion associated with a root and did not respond to the sensitivity test. The probing depth of this tooth was recorded at up to 10 sites to exclude the possibility that a pocket communicated with the lesion.

Radiographs were taken using the paralleling technique, a beam guide, standardized bite blocks and standardized exposure times; films were processed conventionally.

The teeth had not been endodontically treated previously. The lesions detected were located predominantly periapically and in rare cases laterally or interradicularly; regardless of their location they were all called 'periapical lesions'.

Of the 73 recruited patients, 67 could be re-examined (37 females and 30 males). The mean age was 38 years (range: 11–84 years). Five patients did not respond to our repeated request to attend the recall appointments or refused further examination. One patient deceased prior to the first scheduled recall date. The recall rate related to the number of treated teeth was 92%.

Root canal treatment

Root canal treatment was carried out by two experienced endodontists (RW and RR) according to criteria defined at the outset. If present, caries lesions and leaking restorations were removed. After initially accessing the floor of the coronal pulp chamber the tooth was isolated with rubber dam and disinfected with 1% sodium hypochlorite. Subsequently, the access cavity was completed using a separate set of sterile instruments. If present, the coronal pulp tissue was removed by irrigation with a 1% sodium hypochlorite solution and the most cervical portion of the root canals flared with Gates-Glidden drills from size one through either size three or four for large root canals. The working length was determined radiographically from a coronal reference to a distance 1 mm short of the radiographic apex. The root canals were instrumented with conventional K-type files or flexible files in case of curved root canal configurations under thorough irrigation of 1% sodium hypochlorite. The apical portion of straight root canals was prepared with the standardized technique ('apical box preparation') (Tronstad 1991) to an apical size 40 or larger and curved root canals with the step-back technique to an apical size 30 or larger. The root canal walls in the middle portion of the root were filed circumferentially.

When the instrumented root canals were not obturated at the same visit, calcium hydroxide mixed

with sterile physiological saline to a creamy consistency was repeatedly placed in the root canal with sterile paper points. The calcium hydroxide paste in the root canal was step-by-step condensed with additional dry paper points. No radiograph was taken to control the proper placement of the dressing. The access cavity was sealed with a temporary dressing with a minimum thickness of 3 mm. Calcium hydroxide remained in the root canal system for 7–47 days (mean value: 22 days). At the second appointment calcium hydroxide was removed by irrigating the root canals with 1% sodium hypochlorite and filing the root canal walls with the master apical file. The root canal was obturated with a master gutta-percha point, laterally condensed gutta-percha points and a calcium hydroxide sealer (Sealapex®, Kerr Corp., Romulus, MI, USA). The pulp chamber was sealed with either a glass ionomer cement or a composite filling which served as a base for the definitive restoration. The thickness of the base varied from 1 mm to 3 mm. A final radiograph was taken to evaluate the quality of the obturation.

Pre- and postoperative findings

At the initial examination and at the recall appointments the following clinical findings were recorded: history of pain indicating symptomatic periapical periodontitis, presence of a swelling, presence of a fistula, tenderness to axial percussion, periodontal probing depths, mobility.

Radiographically, signs of periapical pathosis were recorded. The preoperative size of the periapical lesion was evaluated by averageing its largest diameter and its smallest one which were measured to the nearest 0.5 mm. After obturation of the root canal system the apical extension of the root canal filling related to the radiographic apex associated with the periapical lesion was assessed.

The clinical findings recorded at the last follow-up and the comparison of the preoperative diagnostic radiograph with that of the last follow-up were the basis for evaluating the outcome of the endodontic therapy. The radiographs were judged by both dentists involved in the study (RW and RR) by using a magnifying glass and a light box. The operators did not know whether the tooth belonged to the one-visit or the two-visit group. In case of disagreement, a joint decision was made. The criteria for success or failure were the following:

1 Complete healing (= success):
- no clinical signs and symptoms and;
- radiographically a periodontal ligament space of normal width.

2 Incomplete healing:
- no clinical signs and symptoms and;
- radiographically a reduction of the lesion in size or an unchanged lesion within a observation time of 4 years.

3 No healing (= failure):
- clinical signs and symptoms indicating an acute phase of apical periodontitis and/or;
- radiographically a persisting lesion after a follow-up time of 4–5 years and/or;
- a new lesion formed at an initially uninvolved root of a multi-rooted tooth.

Multi-rooted teeth associated with at least two periapical lesions were categorized according to the most unfavourable findings.

The time intervals planned for follow-up were 6 months and 1, 2, 3, 4 and 5 years. If the treatment was judged successful within a certain time period, no further controls were envisaged. The last patient entered into the trial 12 months before the study was finished in October 1998.

Statistical analysis

The allocation of the tooth to a treatment modality (one-visit treatment or two-visit treatment) followed the method of 'minimization' (Altman 1991) to balance the two groups of teeth with regard to the criterion 'tooth type'.

In this clinical trial the individual time to complete healing of a periapical lesion following root canal treatment (= favourable event) was of interest. An analysis of event times that also accounts for the observation periods of teeth associated with 'no healing' was applied. This approach also considers the individual time span within which the tooth under observation ('incomplete healing') is 'at hope' although this time is cut off before the event of interest possibly occurs.

The empirical distribution of the event times for both treatment groups were separately calculated on the basis of the Kaplan–Meier method (Kaplan & Meier 1958) and presented as step functions. These give the probabilities that a specific treatment resulted in a success within a certain period of time. The logrank test was applied for the comparison of the two treatment groups.

Table 1 Number of tooth types treated

	Anterior teeth	Premolar	Molar	Total
Two-visit root canal treatment	11	7	13	31
One-visit root canal treatment	15	11	10	36
Total	26	18	23	67

Table 2 Number of instrumented root canals per tooth

	1	2	3	4	Total
Two-visit root canal treatment	12	6	11	2	31
One-visit root canal treatment	24	3	5	4	36
Total	36	9	16	6	67

Table 3 Presence or absence of signs and symptoms

	Yes	No	Total
Two-visit root canal treatment	19	12	31
One-visit root canal treatment	9	27	36
Total	28	39	67

Table 4 Apical extension of the root canal filling in relation to the radiographic apex

	0–2 mm	>2 mm	Overextended	Total
Two-visit root canal treatment	23	7	1	31
One-visit root canal treatment	32	4	0	36
Total	55	11	1	67

Table 5 Type of coronal restoration prior to root canal treatment

	Filling	Crown	Inlay	None	Total
Two-visit root canal treatment	10	16	3	2	31
One-visit root canal treatment	10	12	2	12	36
Total	20	28	5	14	67

In addition, the Cox's proportional hazards model (Cox 1972) served to analyse the simultaneous effect of potential risk factors (= covariates) on the event times. The covariates included were 'tooth type' (incisor/canine, premolar or molar), 'presence of a symptomatic periapical periodontitis' (yes or no), 'apical level of the root canal filling' [0–2 mm short of the radiographic apex, > 2 mm short of the radiographic apex or overextended], 'type of root canal treatment' (one-visit or two-visit root canal treatment) and 'preoperative size of the periapical lesion' ['size' $\leqslant$ 2 mm, 2 mm < 'size' $\leqslant$ 5 mm or 'size' > 5 mm]. This approach provides relative risk ratios with the corresponding 95% confidence intervals (CI) for each covariate. *P*-values lower or equal to 0.05 indicate that the selected covariate exerts a statistically significant effect on the response variable (= event time).

The statistical unit was the patient. The level of statistical significance was set at $\alpha = 0.05$.

Results

Thirty-six of the 67 re-examined teeth (RW: 46 teeth, RR: 21 teeth) were subjected to the one-visit root canal treatment, whilst the other 31 teeth were obturated at the second visit after calcium hydroxide was placed in the root canal at the first visit. Fifty-two teeth could be categorized as 'complete healing', 11 teeth as 'incomplete healing' and four teeth as 'failure'. The estimated times to complete periapical healing used as basis for calculation ranged from 4 to 58 months. The individual observation times varied between 6 and 37 months for those teeth associated with 'incomplete healing'.

The number of tooth types and instrumented root canals, the presence of preoperative signs and symptoms, the apical level of the root canal filling and the kind of coronal restoration are given for both treatment groups in Tables 1–5. Figure 1 documents the preoperative sizes of the lesions in the two groups. The teeth lost to follow-up were not considered.

The probability (*P*) that complete healing occurred within a certain time span increased continuously with the length of the observation period (Fig. 2, Table 6). The logrank test did not reveal any statistically significant difference in both treatment groups ($P > 0.05$). In both treatment groups the probability that the root canal treatment yielded a success within

Table 6 Probability of complete periapical repair including the 95% confidence interval within a certain period of time

	1 year	2 years	3 years	4 years	5 years
Two-visit root canal treatment	0.33 [0.18–0.49]	0.62 [0.46–0.78]	0.79 [0.63–0.95]	0.87 [0.74–0.99]	0.93 [0.82–1.00]
One-visit root canal treatment	0.26 [0.11–0.42]	0.60 [0.42–0.48]	0.70 [0.52–0.88]	0.84 [0.67–1.00]	0.92 [0.78–1.00]

Table 7 Results of the Cox's regression analysis

Covariable	*P*-value	Hazard rate ratio	95% CI
Tooth type	0.60	NS	NS
Signs and symptoms	0.07	NS	NS
Type of root canal treatment	0.89	NS	NS
Size of the apical lesion	0.02	2.45*	[1.21–4.58]
Apical extension of the root canal treatment	0.66	NS	NS

*'size' > 5 mm vs. 'size' $\leqslant$ 2 mm.

P-values lower than 0.05 indicate that the covariable exerts a significant influence on the probability of complete periapical healing (CI, confidence interval; NS, not stated).

an observation time of 5 years exceeded 0.9 (Table 6).

In order to substantiate the results of the logrank test the type of endodontic treatment (one-visit versus two-visit endodontic treatment) was introduced in the Cox's regression model as a binary covariable along with four additional covariables ('tooth type', 'presence of signs and symptoms', 'apical level of the root canal filling', 'size of the lesion') known as potential risk factors. This analysis confirmed that the kind of endodontic treatment did not have any statistical impact on the likelihood that a complete periapical repair would occur ($P > 0.05$) (Table 7). By contrast, the covariable 'size of the apical lesion' exerted a significant effect on the healing process ($P < 0.05$). The hazard rate ratio of 2.45 (95% CI: 1.21–4.58) indicates an elevated risk of a failure when a large apical lesion ('size' > 5 mm) was present prior to treatment.

Discussion

Generally, the significance of the results of a prospective clinical trial dealing with the prognosis, for example, of two treatment approaches, depends

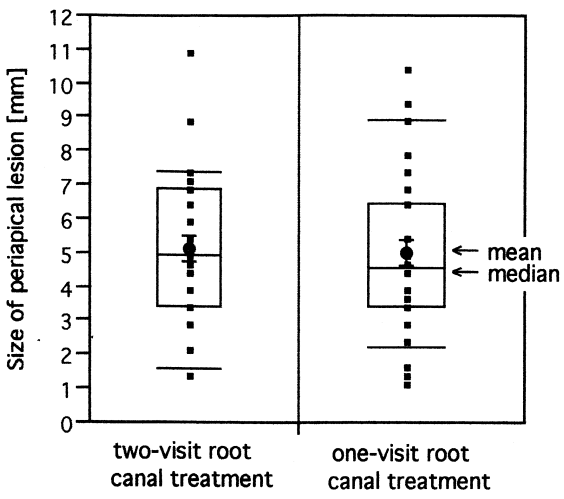

Figure 1 Individual values for the preoperative size of the periapical lesion. The mean values with the standard error and the median values with the 10th, 25th, 75th and the 90th percentile are depicted.

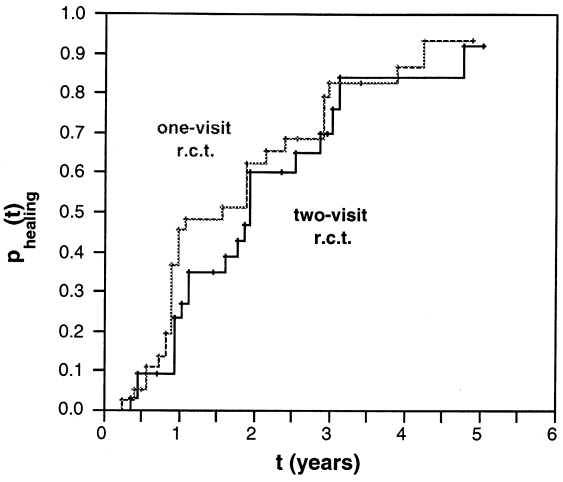

Figure 2 Estimation of the fractions of those teeth [p(t)] that demonstrate complete periapical healing following one-visit root canal treatment (r.c.t.) and two-visit r.c.t. within a certain period of time. The probability $1 - p(t)$ was calculated according to Kaplan & Meier (1958).

decisively on the recall rate of the patients treated. In the present study this rate was 92%, higher than in most other comparable studies (for review see Weiger *et al.* 1998). From a statistical point of view, therefore, the so-called bias that might be caused by those patients lost to follow-up was likely to be negligible. In contrast to two prospective studies (Byström *et al.* 1987, Sjögren *et al.* 1997) closely related to the present trial, the clinical material was not limited *a priori* to single-rooted teeth.

The root canal treatment was performed to a standard recommended by the official guidelines of the European Society of Endodontology (1994). Consequently, the elimination of bacteria from the root canal system was accomplished by mechanical instrumentation supported by sodium hypochlorite as the irrigating solution. When the biomechanical preparation was combined with calcium hydroxide as antimicrobial medicament, it was placed in the root canal for at least 7 days. Sjögren *et al.* (1991) demonstrated that after this time calcium hydroxide achieved an optimal antibacterial effect under clinical conditions.

The applied criteria for a successful root canal treatment was based closely on those established by Strindberg (1956). Accordingly, in the present investigation 30 out of 36 teeth could be judged as a success after the one-visit treatment and 22 out of 31 teeth following the two-visit treatment. Four cases failed (one-visit treatment: three; two-visit treatment: one). In multi-rooted teeth no new lesions formed on roots that were originally free of periapical disease. Radiographically, seven periapical lesions (one-visit treatment: three; two-visit treatment: four) out of the 11 cases categorized as 'incomplete healing' clearly decreased in size within the given observation time, indicating that healing was expected to occur at a later time. The probability that a treatment success will show up within a 4-year observation period was 87% (95% CI: 74–99%) for the one-visit treatment and 84% (95% CI: 67–100%) for the two-visit treatment. Although the comparison with other studies on the prognosis of root canal treatment is generally limited due to differences in methodology and statistical analysis (for review see Weiger *et al.* 1998), the numbers corroborated well with the outcomes of two closely related studies of Byström *et al.* (1987) and Sjögren *et al.* (1997) that dealt with the regeneration of periapical periodontitis after initial root canal treatment. Byström *et al.* (1987) reported a success rate (that was unadjusted for time) of 85% (95% CI: 77–93%) after the use of calcium hydroxide as final intracanal dressing. In a recent paper (Weiger *et al.* 1998) an attempt was made to extract and to analyse the event times from the data presented by Byström *et al.* (1987). The estimated probability that a periapical lesion will completely resolve within 4 years was stated to be 94% (95% CI: 87–100%). Recently, the role of microbial infection at the time of root canal filling was related to the prognosis of the one-visit endodontic treatment (Sjögren *et al.* 1997). This clinical and microbiological investigation substantiated the potential of this treatment approach. A success rate of 83% (95% CI: 73–93%) after an observation period of 5 years could be calculated on the basis of the published data. This was in line with the calculated probability of complete healing of 93% (95% CI: 82–100%) within the 5-year observation period.

The logrank-test and the Cox's regression analysis revealed that the use of calcium hydroxide as intracanal dressing did not lead to more favourable results than the one-visit treatment. The Cox's analysis ascertained that the true influence of calcium hydroxide on periapical repair was not obscured by the other identified variables that might have an impact on the healing process. Therefore, an adequate consideration of these factors is mandatory. In this study population, the size of the periapical lesion was proven to be a risk factor. That means that a larger periapical lesion was associated with a lower probability to resolve within a given period of time than a smaller lesion. However, it must be considered that the diameter of a lesion measured by means of the radiograph only approximates its true dimensions. The covariable 'apical extension of the root canal filling' did not exert a significant effect on the probability of periapical healing although some studies have demonstrated that root canal fillings, being either too short or overextended, interfere with the periapical healing process (Strindberg 1956, Sjögren *et al.* 1990, Friedman *et al.* 1995, Pelka *et al.* 1996). It is most probable that in the present investigation the number of inadequate root canal fillings was too small to reveal a true difference.

As results from a single sample are generally subject to statistical uncertainty, this imprecision should be adequately considered. In this respect, the corresponding 95% confidence intervals of the estimated parameters are an important measure of this uncertainty. Also, the simulation of a worst- case situation and a real-case situation are helpful in order to gain insight into the true treatment effects of calcium hydroxide as intracanal medicament. This

Table 8 Results of the statistical analysis after simulating a real-case situation and a worst-case situation

	Kaplan–Meier		Cox's regression analysis	
	$P_{5\,years}$	95% CI	*P*-values	
Real-case situation			Tooth type:	$P = 0.51$
One-visit root canal treatment	0.94	[0.83–1.00]	Signs & symptoms:	$P = 0.10$
			Type of root canal treatment:	$P = 0.55$
			Size of apical lesion	$P = 0.03$
Two-visit root canal treatment	0.89	[0.71–1.00]	Apical extension	$P = 0.72$
Worst-case situation			Tooth type:	$P = 0.49$
One-visit root canal treatment	0.90	[0.76–1.00]	Signs & symptoms:	$P = 0.17$
			Type of root canal treatment	$P = 0.52$
			Size of apical lesion	$P = 0.03$
Two-visit root canal treatment	0.84	[0.60–1.00]	Apical extension:	$P = 0.45$

[a]CI, confidence interval.

concerns those teeth associated with 'incomplete' healing whose observation times did not reach 4 years, making a definite decision on success or failure impossible. The worst-case situation would assume that all teeth categorized as 'incomplete healing' would result in a failure after 4 years. A real case situation would assume that the majority of the lesions that decreased in size radiographically will completely resolve within 4 years, say two out of the three in the group 'one-visit treatment' and three out of the four in the group 'calcium hydroxide'. Under these premises, the Kaplan–Meier statistic and the Cox's regression analysis were recalculated. The results of these simulations summarized in Table 8 underline that the difference between both treatment modalities remained negligible and proved not to be statistically significant; this confirmed the results of a comparative study on periapical healing in dogs (Allard *et al.* 1987). As expected, the estimated values for the probability that a periapical periodontitis will completely heal within a certain period of time decreased when taking the worst case situation as given.

An attempt to interpret the present results requires the knowledge and the analysis of potential causes for refractory periapical periodontitis. Generally, it can not be excluded that a persistent intraradicular infection may sustain the periapical inflammatory process despite careful chemomechanical instrumentation of the root canal system and even the use of calcium hydroxide (Byström *et al.* 1985, Nair *et al.* 1990). Recently, it was reported that calcium hydroxide with an appropriate vehicle like paramonochlorophenol/glycerin may be more effective on intracanal bacteria than pure calcium hydroxide (Siqueira & Uzeda 1996, Siqueira & Uzeda (1998). Nevertheless, intracanal microorganisms surviving in the obturated root canal system may interfere with the periapical healing process. In this respect, an important question addresses the immunological role of bacterial cell wall remnants (from dead bacteria) still present in the root canal system and their impact on periapical healing. To our knowledge clinical data that supports their significance are lacking. Furthermore, persistent extraradicular infection, foreign body reaction or the presence of a true cyst (Nair 1998) can impede the regeneration of periapical lesions. Undoubtedly, reinfection via leaking restorations or vertical root fractures may also be a cause for failures (Friedman *et al.* 1997). Although no additional microbiological and histological data existed in our cases that did not respond to the conservative treatment approaches, it can only be speculated about the causes for the therapy-resistant periapical lesions in both treatment groups.

In conclusion, the promising prognosis of both treatment approaches substantiated the hypothesis that from a microbiological view one-visit root canal treatment with gutta-percha cones and a calcium hydroxide-containing sealer created favourable environmental conditions for periapical healing. Thus, one-visit root canal treatment is an alternative to two-visit treatment with calcium hydroxide as an interappointment dressing for pulpless teeth associated with endodontically induced lesions.

Acknowledgements

The authors thank Professor Dr P. Wesselink, Amsterdam, for his helpful comments and contributions to the manuscript. We especially thank Mrs. Carmen Buckley-Görbing for her assistance in preparing the manuscript.

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