Outcome of root canal treatment using Thermafil and cold lateral condensation filling techniques

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Abstract

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Aim To evaluate the outcome of root canal treatment (RCT) using either Thermafil (TF) or lateral condensation (LC) as filling technique, and to compare the time required for the treatment when either filling technique was used.

Methodology This study involved all patients attending the dental clinic of a university in Hong Kong who required primary, nonsurgical RCT. It was a prospective clinical trial involving 85 teeth in 79 patients aged 15–69 years (mean 48 ± 12 years), which required root treatment and finally filling with either TF or LC by one of four dentists following a standard treatment protocol. The time used for the entire course of treatment was recorded. The treated teeth were examined both clinically and radiographically 3 years after the treatment by a single examiner who did not know their group assignment.

Results A total of 85 teeth from 79 patients were included in this study and 71 teeth from 64 patients were examined after 3 years. Thirty-four teeth were root filled with LC and 37 with TF. The overall attrition rate was 16% (14/85). There were 22 incisors and canines, 21 premolars and 28 molars for evaluation. Post-treatment disease with clinical symptoms and/or radiographic radiolucency was observed in seven teeth (21%) of the LC group and in seven teeth (19%) in the TF group. There was no statistically significant difference ($P > 0.05$) for the presence of disease between the two groups. It was found that irrespective of the filling method used, teeth later restored with extracoronal restorations had a lower association with disease than those receiving intracoronal restorations (7% vs. 30%; $P = 0.037$). RCT took, on average, 20 min less when TF was used for filling compared with LC (98 min vs. 78 min, $P = 0.003$).

Conclusions Using TF or LC in the filling of root canals did not result in significant difference in the clinical treatment outcome. TF consumed significantly less time than LC. The type of postendodontic restoration had a significant association with the presence of post-treatment disease.

Keywords: endodontics, lateral condensation, root filling, Thermafil.

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Introduction

The objective of canal filling in root canal treatment (RCT) is to prevent any communication between the oral cavity and the periapical tissues. The ingress of oral or tissue fluids via such communication may maintain the viability of any residual bacteria that survive the treatment (Sundqvist & Figdor 1998). A number of techniques have been advocated to achieve complete filling of the root canal system. In a review of root canal filling techniques, Haddix & Oguntebi (1989) commented that more research was needed to establish a standard technique with which all techniques could be compared for filling root canals.

Cold lateral condensation (LC) of gutta-percha (GP) is a commonly taught method of filling and has been widely and frequently practiced by dental practitioners (Dummer 1991, Peak *et al.* 2001, Levitan *et al.* 2003). It has been used frequently as a basis of comparison for

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new filling techniques (Dummer 1991). In brief, a master GP cone is selected, which usually corresponds to the size of the master apical file and should fit the apical terminus so that on removal a small degree of resistance or 'tug-back' is felt. Then the wall of the prepared canal is coated with sealer and the master GP cone is seated. The GP is compressed laterally with spreaders to provide space into which an accessory point can be inserted and packed in place. The process is repeated until the canal is fully filled.

LC has some advantages including low cost and the ability to control the length of the fill (Levitan *et al.* 2003). However, if there is poor preparation of the canal, inadequate pressure being applied, or a mismatch of tapers of spreader, GP cone and canal, there will be spaces between the GP cones, which is probably filled with sealer. On the contrary, overzealous application of pressure can result in vertical root fractures (Nguyen 1994).

The prototype of Thermafil (TF) obturators was first described in 1978 (Johnson 1978). The latest product consists of a plastic core, or carrier, coated with α-phase GP (Gulabivala & Leung 1994). The prepared canal is first checked with a 'Verifier' prior to final rinsing, drying and then application of sealer. A corresponding, preheated TF obturator (Tulsa Dental Products, Tulsa, OK, USA) is inserted with firm apical pressure until the working length is reached. There have been a number of laboratory studies comparing the apical sealing ability of LC and TF, majority of which reported either similar or significantly better seal with TF (Bhambhani & Sprechman 1994, Dummer *et al.* 1994, Gulabivala *et al.* 1998, De Moor & De Boever 2000, Gencoglu *et al.* 2002). TF is also seemed to be more effective than LC in filling lateral canals (Reader *et al.* 1993, DuLac *et al.* 1999, Clinton & Van Himel 2001, Goldberg *et al.* 2001). A study comparing the core-to-sealer ratios of different GP filling techniques reported that TF was better than LC because TF produced higher GP content (Gencoglu *et al.* 1994, Goldberg *et al.* 2001). Tested in a coronal-to-apical direction, studies reported that TF showed less leakage (Gilbert *et al.* 2001, Gencoglu *et al.* 2002) or a degree of leakage not significantly different from that of LC (Saunders & Saunders 1994a). However, the canal length of fill is difficult to control and is affected by the rate of insertion. A fast insertion rate may produce overextension of the GP whereas a slow insertion rate may result in underfill (Levitan *et al.* 2003).

Many factors can affect a clinician's choice of treatment material or technique. These may include the method that they learnt in dental school, the experience they have with the material or technique, chair-side time required for a particular technique, the ease of manipulation of a material and, perhaps more importantly, the treatment outcome. Outcome of RCT is influenced by many factors. Presence of periapical radiolucency, iatrogenic (technical) complications, observation period and apical extension of root filling are considered factors that affect the success rate of RCT (Cheung 1996). Studies also reported that quality of filling and postendodontic restoration could influence the prognosis of RCT (Sjögren *et al.* 1990, Rappaport 1999).

Reviews (Gulabivala & Leung 1994, Becker & Donnelly 1997) suggested that TF could provide a seal at least as good as that of LC; and be fast and simple to use. Subjective evaluation by a group of clinicians indicated that TF was rapid, predictable, easy to use, effective and useful in small or curved canals (Christensen 1991). Thus, TF may be a good method to obturate the canal if it has a high rate of successful treatment outcome. However, the clinical outcome of RCT with TF filling has not been reported in the literature. A successful clinical outcome is commonly regarded as absence of signs and symptoms and no radiological evidence of periapical pathology (Peak *et al.* 2001). The aim of this study was to evaluate the clinical treatment outcome of RCT using either TF or LC as filling technique, and to compare the time required for treatment when either filling technique was used in a general practice clinic.

Materials and methods

The University of Hong Kong runs an in-house Dental Health Service (DHS) for its staff members and dependents. The University heavily subsidizes the cost of dental treatment. Patients pay for the chair-side time consumed irrespective of the type of treatment.

This study involved all patients attending the DHS from September 1996 to August 1997 who required primary, nonsurgical RCT. They were invited to participate in the study if they satisfied the following criteria:-

1. The patient had no history of periodontitis and the tooth which required RCT was periodontally healthy.
2. The patient had a good preoperative periapical radiograph of the tooth requiring RCT that demonstrated the presence or absence of apical periodontitis (AP).

Patients who agreed to participate in this study were graded sequentially for RCT by one of the four dentists involved in the study. These dentists attended a continuous education programme in endodontics and followed the same clinical procedures in root canal preparation as described below. They all practised rubber dam isolation for RCT. In cases where the remaining coronal structure was inadequate for rubber dam placement, a reinforced glass–ionomer cement (Ketac-Molar; Espe Dental-Medizin GmbH & Co., Seefeld, Germany) was used for temporary core build-up before treatment. Barbed broaches were used, if necessary, for pulp extirpation and K-files for instrumentation. Teeth were prepared using the Stepdown Technique (Goerig *et al.* 1982). Sodium hypochlorite (5%) was used for irrigation. An EDTA-containing paste (RC-Prep; Premier Dental Products, Philadelphia, PA, USA) was used to aid the negotiation of sclerotic or blocked canals where necessary.

Insurmountably difficult cases were referred to an endodontic specialist and were excluded. Single-visit RCT was not practised and the treatment took at least two visits for completion. A nonsetting calcium hydroxide paste (Reogan-Rapid; Vivadent, Schaan, Liechtenstein) or an antibiotic-corticosteroid paste (Ledermix; Lederle Pharmaceuticals, Cyanamid GmbH, Wolfratshausen, Germany) was used for the inter-appointment dressing. Root canal filling was carried out in the final visit, in which two dentists used LC and another two used TF. AH-26 (Dentsply DeTrey GmbH, Konstanz, Germany) was used in both groups as the sealer. To reduce the chance of inadequate extension of the root canal filling, the filling procedure was preceded by a check radiograph with master cone(s) for LC and with size verifiers for TF *in situ*. The treated teeth then received either an intracoronal restoration (amalgam or resin composite) or a porcelain-fused-gold crown. As patients were charged by the number of 20-min units spent, data in the payment system allowed the appointment time to be calculated. The total time used in the RCT, from start to finish, was recorded to the nearest 20 min.

All study patients were invited to attend a review in August 2000, that is, a period of 36–48 months after the RCT in the same clinic. Charges for this recall were waived to encourage attendance. One examiner, who was blind to the type of root filling material used, carried out all the clinical examinations. The root filled tooth was regarded as 'clinically sound' if there was no clinical sign or symptom such as pain, tenderness to percussion, mobility and soft tissue pathosis like abscess or sinus tract.

Periapical radiographs were taken using a paralleling technique with a film holder. Blind to the treatment record, the same examiner assessed the pretreatment and post-treatment radiographs of the study patients in a dark room using a magnifier. The radiographs were evaluated for the periapical status of the tooth. The periapical status was categorized into three groups (Petersson *et al.* 1991).

1. Normal – normal appearance of the surrounding osseous structure.
2. Apical periodontitis – periapical radiolucency observed.
3. Periapical status not classified – the quality of the radiograph was insufficient for examination of the periapical structure.

Multi-rooted teeth with differing periapical status at different roots were graded according to the most severely affected root. It was considered as unclassified if the quality of the radiograph was insufficient for examination of the periapical structure.

A treatment failure was recorded if the tooth had been extracted, demonstrated any clinical symptoms or was associated with AP at the evaluation. Ten preoperative and 10 postoperative radiographs (14% of all films) were randomly selected and re-examined to assess the intra-examiner reliability in reading radiographs. The treatment outcome was categorized as success only when a treated tooth was both clinically sound and rated as normal in the radiographic examination.

Data collected were entered into a computer and analysed using the software, SPSS 11.5 for Windows (SPSS Inc., Chicago, IL, USA). Intra-examiner reproducibility of the radiographic examination was measured by the κ statistic (Hunt 1986). In the bivariate analysis, chi-square test and *t*-test were used to assess the statistical significance of the effects of filling technique (LC or TF), patient age, tooth type, number of roots, presence of preoperative AP and type of postendodontic restoration on the endodontic treatment outcome. Logistic regression analysis was used to assess the effects of the above independent variables in a multivariate model with treatment outcome (1 = success; 0 = failure) as the dependent variable. Independent Student's *t*-test was performed to compare the time used for the course of RCT for the two groups. The level of significance used in all the tests was set at 0.05.

Results

At the baseline, a total of 85 teeth in 79 patients were included in this study. The patients were 15–69 years of age (mean = 48 ± 12 years). A total of 71 teeth from 64 patients were reviewed at the 3-year evaluation. Among them 34 teeth received LC and 37 teeth received TF as root canal fillings (Table 1). The mean observation period was 40 months. In this study, four teeth of the LC group and three teeth of the TF group, that is a total of seven teeth were extracted due to fracture of tooth structure before the recall examination. They were included for evaluation and the preextraction radiographs were used for radiographic examination. Clinically they were classified as failure. The intra-examiner reproducibility of radiographic examination measured by κ was 0.75 and the percentage of agreement was 90% (Table 2).

Among the 37 study teeth filling using TF, 30 were clinically sound and did not have signs and symptoms suggesting failure at the evaluation. The success rate was thus 81% (Table 3). Among the seven teeth (19%) classified as failures, four were classified based on clinical criteria alone, two were due to the presence of periapical radiolucency in the evaluation radiographs and one was classified so by both the clinical and radiograph criteria. Among the 34 study teeth filling with LC, 27 (79%) were classified as success. Four teeth were classified as failure based on both clinical and radiographic criteria, two on clinical criteria only, and one on radiographic criteria.

Results of the bivariate analysis show that there was no significant difference in the treatment failure rates

Table 1 Distribution of the teeth evaluated according to some selected independent variables in the two filling groups

	Thermafil (n = 37)	Lateral condensation (n = 34)	Significance
Patient age (year)	46 ± 11	50 ± 13	NS
Review period (month)	40 ± 10	39 ± 11	NS
Tooth type			NS
Incisors and canines	6	16	
Premolars	14	7	
Molars	17	11	
Preoperative apical periodontitis			NS
No	6	7	
Yes	31	27	
Postendodontic restoration			NS
Intracoronal	23	20	
Extracoronal	14	14	

NS, not statistically significant.

Table 2 Agreement on the presence of apical periodontitis in the first and the second radiographic examination

	First observation		
Second observation	No	Yes	Unclassified
No	1	0	0
Yes	1	14	1
Unclassified	0	0	3

P-observe = 0.9; *P*-expect = 0.6; κ = 0.75.

Table 3 Clinical and radiographic status of the endodontically treated teeth at the 3-year evaluation

Treatment group	Thermafil n = 37 (%)	Lateral condensation n = 34 (%)
Successful		
No clinical or radiographic failure	30 (81)	27 (79)
Failure		
(a) both clinical and radiograph failure	1 (3)	4 (12)
(b) clinical failure (radiograph not classified)	4 (11)	2 (6)
(c) Radiolucent area present, no clinical signs	2 (5)	1 (3)
Total (a) + (b) + (c)	7 (19)	7 (21)

Table 4 The effects of filling technique, tooth type, presence of preoperative apical periodontitis, type of postendodontic restoration, patient age and treatment time used on the endodontic treatment outcome

	Treatment outcome		Significance
	Success	Failure	
Filling technique			NS
Thermafil	30	7	
Lateral condensation	27	7	
Tooth type			NS
Incisor	18	4	
Premolar	19	2	
Molar	20	8	
Number of root			NS
Single	30	4	
Multiple	27	10	
Presence of apical periodontitis			NS
Yes	46	12	
No	11	2	
Postendodontic restoration			P = 0.037
Intracoronal	31	12	
Extracoronal	26	2	
Patient age	49 ± 12	45 ± 13	NS
Treatment time used (min)	85 ± 26	99 ± 39	NS

NS, not statistically significant.

Table 5 Final model of the logistic regression analysis on the success of the root canal treatment

Factors	β (SE)	Odds ratio (95% CI)	*P*-value
Postendodontic restoration			
Extracoronal	1.68 (0.81)	0.20 (0.04–0.97)	0.046
Intracoronal[a]			
Constant	4.18 (1.51)		0.006

$\chi^2 = 5.17$; d.f. = 1; $P = 0.023$.
[a]Reference category.

between the TF and LC groups (Table 4). Patient age, the review period, tooth type, presence of preoperative AP at baseline were also found to have no statistically significant influence on the treatment outcome. Only the type of postendodontic restoration had a significant effect ($P = 0.037$) on the success rate, with teeth restored with an extracoronal restoration being more likely to be successful. The above finding was confirmed in the logistic regression analysis. Only the variable postendodontic restoration remained in the final regression model and the other independent variables were removed because they did not have a statistically significant effect on the success of RCT (Table 5).

The number of 20-min units required to complete the whole course of RCT was 4.91 ± 1.52 for the LC and 3.92 ± 1.19 for the TF group, giving a total time of 98 ± 30 and 78 ± 24 min, respectively. This difference was statistically significant ($P = 0.003$). On average, RCT using TF for filling was about 20 min faster than that using conventional LC technique for filling.

Discussion

Many laboratory studies have been performed on various attributes of TF filling including apical or coronal leakage, the quality of filling or material adaptation (Reader *et al.* 1993, Bhambhani & Sprechman 1994, Dummer *et al.* 1994, Saunders & Saunders 1994a, Gulabivala *et al.* 1998, DuLac *et al.* 1999). Most reports concluded that TF is an acceptable alternative to the LC technique. However, clinical trials are scarce. A literature search of the MEDLINE electronic database from 1990 to January 2004 written in English language with TF as the keyword revealed a total of 87 published articles. Among these publications, one was an *in vivo* evaluation in dogs (Golden & Hennet 1992) and the others were all laboratory investigations. The present study on the clinical and radiological outcome of teeth filling with TF is probably the first clinical study to provide information on the clinical outcome of using TF for root canal filling. In the present study, no difference in the clinical and radiographic status was observed in teeth filled using TF compared with those using LC after some 36 months of observation. This lack of difference suggests that TF is an acceptable alternative to the conventional cold LC technique.

A good success rate of RCT of about 85% were reported in several studies (Barbakow *et al.* 1980, Peak *et al.* 2001, Dammaschke *et al.* 2003) The purpose of this study was to determine if TF is an acceptable alternative to LC (equivalence in treatment outcome). A sample of 35 teeth in each group can detect a 15% difference in success rate with a power of 80% using a two-tailed chi-square test. Peak *et al.* (2001) reported teeth without AP had a higher success rate than those with AP (87% vs. 80%). This study did not stratify teeth with and without AP at baseline prior to their allocation to the two treatment group. However, the effect of this factor has been studied in the bivariate analysis with chi-square test and again in the multivariate analysis with logistic regression analysis.

Treatment outcome is an important part of evidence-based practice. It is the basis of treatment planning and prognostic considerations (Peak *et al.* 2001). A successful outcome for RCT relies on adequate removal of microorganisms from the root canal system and prevention of recolonization or reinfection through the placement of a root canal filling that obliterates the canal space and a restoration with good coronal seal (Briggs & Scott 1997). The result of the present study indicates that the type of postendodontic restoration is a significant factor affecting the treatment outcome, which corroborates with the literature (Saunders & Saunders 1994b, Cheung 1996).

The present study is not without problems. One of these is the nonrandom nature of the treatment assignment. In the study, the choice of dentists for carrying out the different filling techniques was based on operator preference, primarily because the DHS is a service clinic and not a research centre in the university. No attempt was made to randomize the two techniques for each operator. Thus, there might be an operator effect on the treatment outcome in the study. For the same reason, the distribution of types of teeth depended on the teeth requiring endodontic treatment from the participating patients. There was no attempt to evenly distribute the types of teeth in the study.

A number of treated teeth in this study failed because of fracture of the tooth structure. In this study, a total of seven teeth were extracted due to fracture before the

recall examination. The fracture was reported or detected largely within the first two years following treatment. From the patients' records, the fractured teeth were either a maxillary premolar or a molar and none of them had received cuspal coverage restorations after RCT. High incidences of tooth fracture, up to 30% and 11%, have been reported for root filled posterior teeth restored only with amalgam (Hansen *et al.* 1990) and light-cured composite resin (Hansen & Asmussen 1990), respectively. In the absence of occlusal coverage, the prognosis of root filled premolars and molars is significantly lower compared with those with such restoration (Sorensen & Martinoff 1984). Thus, failures due to fracture of tooth structures might be related to the lack of proper restoration and not necessarily 'true' endodontic failures, although this could not be verified from the information available. If these fractured cases were excluded from the analysis in this study, the failure rates for TF and LC over a mean period of 40 months would be 11 and 12%, respectively. This result is similar to that of Barbakow *et al.* (1980) who found an overall success rate of 87% of RCT on 566 teeth performed by general dental practitioners.

Filling root canals with TF is more rapid than LC. Dummer *et al.* (1994) reported spending 37 ± 11 and 218 ± 61 s to fill an extracted single-rooted tooth using TF and LC, respectively. Gulabivala *et al.* (1998) reported that TF took 32 ± 5 s and LC took 354 ± 34 s to fill one canal of a single- or multi-rooted tooth. These data, however, may not have much clinical value as they were conducted in the laboratory and do not represent the actual clinical setting. Moreover, many laboratory studies were performed on single-rooted teeth, the canals of which were usually wide and straight and did not pose any treatment difficulty.

Conclusions

Root filling with TF obturators did not result in a significantly different treatment outcome compared with cold LC of GP after 3–4 years. The study also found that using TF for root canal filling required significantly less time than LC. Furthermore, root filled teeth restored with extracoronal restorations had a lower association with post-treatment disease than those with simple intracoronal restorations.

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