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

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Abstract

Aim: *This study aimed to evaluate the outcome of root canal therapy using either Thermafil (TF) or Lateral Condensation (LC) as obturation technique, and to compare the time required for the treatment when either obturation technique was used.*

Methodology*: This was a prospective clinical trial involving 85 teeth in 79 patients aged 15-69 years (mean 48±12 yr), which were root canal treated and finally obturated 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 71 teeth from 64 patients were examined at the evaluation, of which 34 teeth were obturated with LC and 37 with TF. The overall attrition rate was 16% (14/85). Failure was observed in 7 teeth (21%) of the LC group and also in 7 teeth (19%) in the TF group. There was no statistically significant difference ($p>0.05$) in the failure rates between the two groups. It was found that irrespective of the obturation method used, treated teeth later restored with extracoronal restorations had a lower failure rate than those receiving intracoronal restorations (7% vs. 30%; $p=0.037$). The root canal treatment took, on average, 20 minutes less when TF was used for obturation compared with LC (98 minutes vs. 78 minutes, $p=0.003$).*

Conclusions: *Using TF or LC in the obturation of root canal did not result in significant difference in the clinical treatment outcome and that TF consumed significantly less time than LC. Furthermore, the type of post-endodontic restoration had a significant effect on the success rate.*

Introduction

The objective of obturation in root canal therapy (RCT) is to provide a three-dimensional seal of the root canal system 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 obturation techniques, Haddix and Oguntebi (1989) commented that more research is needed to establish a standard technique with which all techniques could be compared for obturating root canals.

Cold lateral condensation (LC) of gutta-percha (GP) is a commonly taught method of obturation 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 new obturation 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 the low cost and the ability to control the length of the fill (Levitan *et al*. 2003). However, if there is a 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 probably is filled up with sealer material. On the other hand, overzealous application of pressure can result in vertical root fractures (Nguyen 1994).

The prototype of Thermafil obturators (TF) was first described in 1978 (Johnson 1978). The latest product consists of a plastic core, or carrier, coated with alpha-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, pre-heated Thermafil 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 gutta percha obturation techniques reported that TF was better than LC because TF produced higher gutta percha 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 root canal treatment 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 obturation and post-endodontic restoration could influence the prognosis of root canal therapy (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 it can be fast and simple to use. Subjective evaluation by a group of clinicians indicated that TF is fast, 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 root canal treatment with Thermafil obturation 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 root canal therapy using either Thermafil (TF) or Lateral Condensation (LC) as obturation technique, and to compare the time required for treatment when either obturation 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 dependants. 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 first time, non-surgical 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 pre-operative 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 arranged sequentially for RCT by one of the four dentists involved in the study. These dentists attended continue education program in endodontics and followed the same clinical procedures in root canal preparation as described below. They all practiced rubber dam isolation for RCT. In case 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 the endodontic treatment. Barbed broaches were used, if necessary, for pulp extirpation and K-files for instrumentation. Teeth were prepared using the Step-down 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 in this study. Single visit RCT was not practiced and the treatment took at least 2 visits for completion. A non-setting 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 obturation 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 obturation procedure was preceded by a check radiograph with master cone(s) for LC and with size verifiers for TF in site. The treated teeth then received either an intracoronal restoration (amalgam or resin composite) or a porcelain-fused-gold crown. Since patients were charged by the number of 20-minute 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 minutes.

All study patients were invited to attend a review in August 2000, that is, a period of 36 to 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 canal treated tooth was regarded as 'clinically sound' if there was no clinical sign or symptom such as pain, tender to percussion, mobility and soft tissue pathology like abscess or sinus tract.

Periapical radiograph was taken using paralleling technique with a film holder. Blind to the treatment record, the same examiner assessed the pre-treatment and post-treatment radiographs of the study patients in a dark room using a magnifier. The radiographs were evaluated for the presence of AP (Petersson *et al.* 1991). 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 ten 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 analyzed using the software, SPSS 11.5 for Windows (SPSS Inc., Chicago, IL, USA). Intra-examiner reproducibility of the radiographic examination was measured by the Kappa statistic (Hunt 1986). In the bivariate

analysis, Chi-square test and t-test were used to assess the statistical significance of the effects of obturation technique (LC or TF), patient age, tooth type, number of roots, presence of preoperative AP and type of post-endodontic 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 to 69 years of age (mean = 48 ± 12 yr). 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, 4 teeth of the LC group and 3 teeth of the TF group, that is a total of 7 teeth, were extracted due to fracture of tooth structure before the recall examination. They were included for evaluation and the pre-extraction radiographs were used for radiographic examination. Clinically they were classified as failure. The intra-examiner reproducibility of radiographic examination measured by Kappa was 0.75 and the percentage of agreement was 90% (Table 2).

Among the 37 study teeth obturated 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 7 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 obturated 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 between the TF and LC groups (Table 4). Patient age, the review period, tooth type, presence of pre-operative apical periodontitis at baseline were also found to have no statistically significant influence on the treatment outcome. Only the type of post-

endodontic 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 post-endodontic 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-minute units required to complete the whole course of root canal treatment 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 minutes, respectively. This difference was statistically significant (p=0.003). On average, RCT using TF for obturation was about 20 minutes faster than that using conventional LC technique for obturation.

Discussion

Many laboratory studies have been performed on various attributes of Thermafil obturation 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 Thermafil is an acceptable alternative to the lateral condensation technique. However, clinical trials are scarce. A literature search of the MEDLINE electronic database from 1990 to January 2004 written in English language with "Thermafil" 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 obturated with TF is probably the first clinical study to provide information on the clinical outcome of using Thermafil for root canal obturation. In the present study, no difference in the clinical and radiographic status was observed in teeth obturated 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 lateral condensation 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 study 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 2-

tail Chi-square test. Peak et al (2002) reported teeth without apical periodontitis had a higher success rate than those with apical periodontitis (87% vs. 80%). This study did not stratify teeth with and without apical periodontitis at baseline prior to their allocation to the two treatment group. However, 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 post-endodontic 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 non-random nature of the treatment assignment. In the study, the choice of dentists for carrying out the different obturation techniques was based on operator preference, primarily because the DHS is a service clinic and not a research center 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 therapy 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 7 teeth were extracted due to fracture before the recall examination. The fracture was reported or detected mostly within the first two years following treatment. From the patients' records, the fractured teeth were either a maxillary premolar or a molar (upper or lower) and none of them had received a cuspal coverage restoration after the endodontic treatment. Quite 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.

Obturating root canals with TF is quicker than LC. Dummer *et al.* (1994) reported spending 37±11 and 218±61 seconds to obturate an extracted single-rooted tooth using TF and LC, respectively. Gulabivala *et al.* (1998) reported that TF took 32±5 seconds and LC took 354±34 seconds to obturate one canal of a single- or multi-rooted tooth. These data, however, may not have much value to clinicians because obturation of extracted teeth in the bench top did not relate well to the actual clinical setting. Moreover, many laboratory studies were performed on single-rooted teeth, the canal of which were usually wide and straight and did not pose much difficulty to the practitioners clinically. What a clinician concerns is the amount of chairside time that he/she may save by adopting, say, a new method of obturation in his daily endodontic practice. The result in this study indicates that an average of 20 minutes per tooth can be saved by using TF, instead of LC for obturation. As the same technique for root canal preparation was used in both treatment groups in this study, the time was saved mostly during the obturation phase. Although the material cost of the master cone in using TF is higher than that for LC, less clinical time is consumed. Moreover, TF requires one cone for obturation while LC requires a master cone plus accessories points. The cost difference is reduced when a large number of accessory points are used in the LC obturation. Since cost-effectiveness is a function of the relative costs of the chairside time and of the materials, TF may be a more cost-effective technique than LC especially in a busy practice. Subjectively, the two dentists using TF in obturation in this study commented that both the patient and the operator experienced less stress and fatigue throughout the treatment because the appointment time was shorter.

Conclusions

In this study, root canal obturation with Thermafil obturators did not result in a significantly different in the endodontic treatment outcome compared with cold lateral condensation of gutta percha after 3 to 4 years. The study also found that using TF for root

canal obturation required significantly less time than LC. Furthermore, root canal treated teeth restored with extracoronal restorations in this study had a higher success rate than those with simple intracoronal restorations.

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

	Thermafil (n = 37)	Lateral Condensation (n=34)	Significance
Patient age (year)	46±11	50±13	N S
Review period (month)	40±10	39±11	N S
Tooth type			N S
Incisors and canines	6	16	
Premolars	14	7	
Molars	17	11	
Pre-operative apical periodontitis			N S
No	6	7	
Yes	31	27	
Post-endodontic restoration			N S
Intracoronal	23	20	
Extracoronal	14	14	

N S – Not statistically significant

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

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

P-observe=0.9; P-expect = 0.6; Kappa = 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 obturation technique, tooth type, presence of preoperative apical periodontitis, type of post-endodontic restoration, patient age and treatment time used on the endodontic treatment outcome

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

N S – Not statistically significant

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

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

$\chi^2 = 5.17$; df = 1; p=0.023

[a] Reference category