A Prospective Randomized Comparative Study of Cold Lateral Condensation Versus Core/Gutta-percha in Teeth with Periapical Lesions

Gözde Kandemir Demirci, DDS, PhD, and Mehmet Kemal Çalışkan, DDS, PhD

Abstract

Introduction: The aim of this study was to compare the outcome of root canal treatment using either Thermafil (TF; Dentsply Maillefer, Ballaigues, Switzerland) or the cold lateral condensation (CLC) obturation technique in teeth with periapical lesions and to investigate the influence on postoperative pain and treatment outcomes. **Methods:** After standardized root canal preparation technique, 112 teeth were obturated with either the TF or the CLC technique during 2 sessions by single operator. Postoperative pain, obturation length, and treatment outcomes were recorded. The teeth were reviewed clinically and radiographically for 2 years. **Results:** Although there were no significant differences between the techniques in the incidence of postoperative pain at 24 hours ($P > .05$), the incidence of pain was significantly higher in the TF group than in the CLC group at 48 hours ($P < .05$). During the 2-year follow-up period, there was no statistically significant difference in the success rate of the teeth treated with TF (96.4%) in comparison with those treated with CLC (98.2%) ($P > .05$). **Conclusions:** In this study, the outcome of the root canal treatment of teeth using the TF and CLC techniques revealed that these techniques are useful for root canal obturation. *(J Endod 2016;42:206–210)*

Key Words

Clinical outcome, lateral compaction, postoperative pain, Thermafil

From the Departmentof Endodontology, Ege University, School of Dentistry, Izmir, Turkey.

Address requests for reprints to Dr Gözde Kandemir Demirci, Department of Endodontology, School of Dentistry, Ege University, Izmir, 35100, Turkey. E-mail address: dt.gozdekandemir@hotmail.com

0099-2399/$ - see front matter

http://dx.doi.org/10.1016/j.joen.2015.10.022

Three-dimensional obturation of the root canal and the creation of a hermetic apical seal are the goals of endodontic treatment. Approximately 60% of endodontic failures have been attributed to inadequate obturation of the root canal system (1).

Cold lateral condensation (CLC) is the most commonly practiced technique in endodontic clinics. The advantages of CLC include its relative ease of use, low cost, predictability, and controlled placement (2). However, poor preparation of the root canal reportedly led to voids and sealer pools and less adaptation to canal walls (3). This technique was also reported to result in excessive amounts of sealer and apical voids (4). Previous research also found that using too much pressure when applying the spreader in CLC may lead to vertical root fractures (5).

The prototype of the Thermafil (TF) obturator was described by Johnson in 1978 (6). It is an endodontic obturator consisting of a flexible special plastic core carrier that is homogenously coated with a layer of refined "alpha-phase" gutta-percha. It is stated that when heat activated this gutta-percha gains flow characteristics and it obturates the main and accessory canals (7).

A literature search of an electronic database, MEDLINE, from 1990 to August 2015 for English-language articles with the key words TF and lateral compaction (LC) revealed 111 published articles. Many of these articles were *in vitro* studies of various properties of TF, including apical or coronal microleakage, the quality of the root canal filling, and biocompatibility (8–10). Most of those articles concluded that TF was an acceptable alternative to the LC technique. Two clinical studies have examined the clinical treatment outcomes in root canal treatment (RCT) using TF and LC (11, 12). These studies investigated the influences of significant outcome predictors, such as the patient's sex/age, treatment time, postoperative pain, and obturation length (11–14). However, both were retrospective in nature. Furthermore, they were performed by supervised undergraduate students or different operators. A prospective clinical study is needed to reach a consensus on the treatment efficacy of TF.

The aim of this prospective study was to evaluate the outcome of RCT using either TF or CLC as the obturation technique in asymptomatic teeth with periapical lesions and to investigate the impact of potential prognostic factors on postoperative pain and treatment outcomes during a 2-year follow-up.

Materials and Methods

We included 120 anterior teeth of 100 patients (56 women and 44 men) in this study. The patients were fully informed about the treatment, postoperative care, follow-up examinations, possible complications, and alternative treatment options before their participation in the study. The study protocol was approved by the Human Ethical Committee of Ege University, Izmir, Turkey. The selection and inclusion criteria were patients with a noncontributory medical history who had mature maxillary anterior teeth with periapical lesions (<5 mm). The exclusion criteria included no previous endodontic therapy, more than 5-mm periodontal attachment, and bone loss. Patients with asymptomatic apical periodontitis were diagnosed using clinical and radiographic examination. The patient's age and sex, obturation time, postoperative pain, and obturation length were recorded.

The treatment groups were randomly allocated to the TF or CLC technique, with each participant choosing an envelope after they had been shuffled. Each participant

chose 1 of the sealed envelopes to allocate the obturation materials to be used. Preoperative radiographs were obtained under standard exposure conditions using standard dental X-ray film (Ektaspeed Plus; Eastman Kodak, Rochester NY) and a positioning device (Rinn XCP; Rinn Corp, Elgin, IL). One endodontist performed all the endodontic treatment procedures, which were completed in 2 visits. Under local anesthesia and rubber dam isolation, the working lengths for the root canals were determined using an electronic apex locator (Propex II; Dentsply Maillefer, Ballaigues, Switzerland), and working lengths were confirmed with periapical radiographs. Gates-Glidden drills (Dentsply Maillefer) were used for middle coronal preflaring. The root canals were prepared using the step-back technique with hand instrumentation, and they were irrigated with 2.5% sodium hypochlorite using a 30-G endodontic irrigating needle (SybronEndo Corp, Orange, CA). After the application of calcium hydroxide paste as an intracanal medicament (Merck, Whitehouse Station, NJ) for 1 week in both groups, glass-ionomer cement (Ketac-Molar; 3M ESPE, St Paul, MN) was used as a temporary restoration.

In the TF obturation, a verifier (Dentsply Maillefer) was placed into the canal, and a radiograph was taken to control the adaptability at the second visit. Final irrigation was performed with 5 mL 5% EDTA, 2.5% sodium hypochlorite, and 2% chlorhexidine (Klorhex; Drogsan, Ankara, Turkey) (15). The root canal was dried and coated with AH Plus sealer (Dentsply Maillefer) using a suitable paper point up to the middle third of the canal. The second paper point was used to distribute the sealer, and the third was used to remove excess sealer as described by Castelo et al (16). After the canal walls have been lightly coated with sealer, a heated TF obturator was inserted with a slow, firm, and continuous movement in the apical direction to the previously determined working length. The coronal gutta-percha around the carrier was then vertically condensed with a plugger, and excess gutta-percha in the root canal was removed.

After using the same final irrigation method for the CLC group, an appropriate master cone (Dia Dent Group International Inc, Burnaby, BC, Canada) was fitted to within 0.5 mm of the working length and then coated with sealer and placed into the canal. Accessory gutta-percha cones were used until the spreader could no longer penetrate beyond the coronal third. After completing the obturation, excessive gutta-percha was removed with a hot instrument. In both groups, the coronary restoration was completed using composite resin.

The quality of the root canal fillings and the status of the periapical tissues were evaluated according to the periapical index (PAI) (17). The obturation length was classified into groups of "short" (>2 mm from the radiographic apex), "acceptable" (0–2 mm from the radiographic apex), or "overfilled" (beyond the radiographic apex).

Postoperative pain was measured with a scale that was based on the visual analog scale, which was initially modified by Bodian et al (18) and later was further scored by El Mubarek et al (19). The postoperative pain was scored as 1 (no pain), 2 (mild pain), 3 (moderate pain/pain relieved by analgesics), or 4 (severe pain or flare-up pain and/or swelling not relieved by analgesics and requiring an unscheduled visit). The patients were instructed in the use of the visual analog scale forms and told to complete them 24 hours and 48 hours after the completion of the procedure.

The patients were followed up periodically to assess the clinical and radiographic signs of healing. Previously informed patients were contacted by telephone for their follow-up every 3 months for 1 year and then at 6-month intervals for 2 years. Based on the clinical and radiographic features, the teeth, which were scored PAI 1 and PAI 2 and displayed no symptoms and clinical signs, were classified as healed (20). Outcome was classified as "disease" when any clinical signs and symptoms and/or PAI score 3 were present.

Statistical Analysis

To assess the treatment outcome, a power analysis was performed at the beginning of the present study according to Chu et al (11). The power analysis results showed that a minimum sample size of 48 teeth per group is required. However, our study samples included 60 teeth per group, and this yielded a power of 80%.

Before the case analyses, 2 independent and experienced endodontists who were blinded to the treatment groups standardized the radiographic evaluation criteria according to the PAI scoring system. After *a priori* education regarding radiographic evaluation criteria, these observers evaluated the periapical lesions. Any disagreement in the assessment of the periapical status resulted in discussion until an agreement was reached. To assess the reliability, they repeated the evaluation after 2 months, and the Cohen kappa was used to measure inter- and intraobserver agreement. Student's t test, Mann-Whitney U test, and Pearson's chi-square test (or Fisher's exact) were used for 2 independent samples, and the Wilcoxon test was used for 2 dependent samples. The odds ratios and 95% confidence intervals were also calculated. A significance level of $P = .05$ was accepted. Data analysis was performed with IBM SPSS version 20.0 software (IBM SPSS Inc, Chicago, IL).

Results

One hundred twenty teeth were initially included in the study; however, 8 patients were not available for recall. Ultimately, 112 teeth from 92 patients were followed up for at least 2 years postoperatively (recall rate = 93%). The Cohen kappa value ranged from 0.909–1.00, revealing very good intra- and interexaminer reliability in the evaluation of the pre- and postoperative apical rarefaction and length of root filling.

The patient's age varied from 18–65 years. The mean age of the patients was quite low (29.55 years in the TF group and 30.36 years in the LC group). The majority of the patients were between 18 and 45 years. The time required for the obturation of the root canal with the LC technique averaged 7.582 ± 1.274 minutes, whereas it averaged 0.673 ± 0.112 minutes with the TF technique. This difference was statistically significant ($P < .001$). In both groups in which $Ca(OH)_2$ was used as an interappointment dressing, none of the patients reported postoperative pain and/or flare-ups during the 2-visit RCT. The occurrence of postoperative pain in 24- and 48-hour periods after obturation with TF and CLC in relation to the length of the obturation is presented in Table 1. Although an attempt was made to confine the instrumentation procedures and the subsequent root filling within the canal space, 19 (34%) teeth filled with TF and 7 (12%) filled with CLC were overfilled. In the present study, overfilling was defined as filling that reached to the radiographic apex and extruded into periapical lesions. It was impossible to differentiate the gutta-percha and the sealer in cases in which the root canal filling reached up to the radiographic apex. In both groups, 4 root canal fillings reached the radiographic apex. Fifteen root canals in the TF group and 3 root canals in the CLC group showed slight extrusion of the root canal filling into the periapical lesions. The extruded root canal material in the periapical lesion was AH Plus Sealer because the radiographic density of the extruded material was low, and some of this material was resorbed. There was a statistically significant difference between the obturation length in the TF and CLC groups ($P < .05$). There were no significant differences between both techniques in the incidence of postoperative pain at 24 hours ($P > .05$), but the incidence of pain at 48 hours in the TF treatment group was significantly higher than in the CLC treatment group ($P < .05$) (Table 2). Voids in whole root canal filling were not observed radiographically in either treatment group.

Figure 1 shows the PAI scores of both groups after the root canal treatment during the 2-year follow-up period. In both groups, there