ABSTRACT

Objectives: The aim of this study was to evaluate the apical sealability of Fillapex®, Endo-CPM-Sealer® and Sealapex®. Material and Methods: Ninety-four freshly extracted single-rooted teeth were selected and decoronated. All teeth were radiographed to confirm the existence of a single and straight root canal, which was prepared using Protaper Universal and 2.5% sodium hypochlorite. The teeth were randomly divided in groups of 10 specimens each according to the sealer, and the canals were filled using the single cone technique and one of the sealers. Four additional teeth were used as controls. The teeth were submitted to dye leakage with Rhodamine B for 24 h but using vacuum on the initial 15 min. Thereafter, they were cut longitudinally and the leakage was measured in a linear fashion from apex to crown. Data were analyzed by ANOVA and Tukey’s tests at 5% significance level. Results: Fillapex® and Sealapex® showed significantly less dye leakage than Endo-CPM-Sealer® (p<0.05). Conclusions: It was concluded that Fillapex® and Sealapex® were able to prevent apical dye leakage differently from Endo-CPM-Sealer®.

Key words: Root canal filling material. Leakage. Fillapex.

INTRODUCTION

One of the of root canal obturation goals is to obtain hermetic sealing of the root canal system favoring the process of apical and periapical repair after endodontic therapy17. Inadequate filling can result in fluid movements into the filling defects favoring a periapical chronic inflammatory reaction and compromising the treatment success29.

Root canal ramifications, such as lateral, secondary and accessory canals can establish connection between the main root canal and periodontal ligament, as well as the apical foramen3,9. Several authors described that localized periodontal problems might be associated with necrotic and infected root canal ramifications highlighting the importance of the capacity of the endodontic sealer to flow into these irregularities3,4. Despite the significance of this physical property, the relationship between flow and its ability to penetrate narrow root canal ramifications has not been investigated3,30.

Root canal sealers used clinically have several bases including zinc oxide-eugenol, epoxy resin, glass ionomer, and calcium hydroxide. Sealapex® (Sybron Endo Glendora, CA, USA) is an endodontic sealer that contains calcium oxide, which, in contact with water, forms calcium hydroxide and it was used in the present article as a reference.

A new formulation of MTA-labeled endo-CPM-Sealer® (Egeo S.R.L., Buenos Aires, Buenos Aires, Argentina) was created to be used as root canal sealer. The composition of CPM Sealer is MTA with the addition of calcium carbonate to reduce the pH from 12.5 to 10.0 after set. This way, the surface necrosis in contact with the material is restricted, which allows the action of the alkaline phosphatase14.

Besides CPM Sealer, Fillapex® (Angelus Indústria...
Tooth selection and preparation

Ninety-four single-rooted teeth recently extracted for several reasons were selected and stored in neutral formaldehyde for at least 72 h from the tooth bank of the Araçatuba School of Dentistry, UNESP - Univ. Estadual Paulista, Brazil. The teeth were radiographed to confirm the existence of a single and straight canal and were decoronated at a mean distance of 11 mm from the apex.

Root canal instrumentation and obturation

Instrumentation was held by a single operator. A #10 K file (Dentsply Maillefer, Ballaigues, Switzerland) was introduced into the root canal until it was visible at the apical foramen. The working length was determined by subtracting 1 mm from this length. Root canal instrumentation was performed using the ProTaper Universal rotary instruments (S1, S2, F1, F2 and F3) (Dentsply Maillefer) activated by an electric motor with controlled speed of 300 rpm (Endo-Plus, Driller, Jaguarié, SP, Brazil). Originally a #10 or #15 K file was first introduced to the middle third of the canal. Instruments S1 and S2 were advanced until resistance was encountered, but not more than two thirds of the depth of the canal. It was carried out to introduce a #15 K file up to the working length followed by reinsertion of the instrument S1 to this length. The other instruments were then inserted into full-length work in sequence S2, F1, F2 and F3. The canals were irrigated with 3 mL of 2.5% sodium hypochlorite (Apothicário Compounding Pharmacy, Araçatuba, SP, Brazil) after each file. The fluid content was aspirated and the canals were dried with sterile absorbent paper points.

All root canals were filled by the single cone technique with the use of master gutta-percha F3 cone (Dentsply Maillefer). The teeth were divided into experimental groups of 30 specimens each according to the sealer as follows: Group 1: Fillapex®, Group 2: Endo-CPM-Sealer®, Group 3: Sealapex®. The remaining 4 teeth were used as control, two as positive control and two as negative control. Master gutta-percha point was calibrated with a calibration rule (Dentsply Maillefer) using the #30 hole. The materials were handled according to the manufacturer’s instructions and inserted into the root canals with a lentulo (Dentsply Maillefer). The calibrated master gutta-percha point was involved by sealer and inserted into the root canal until reaching the working length. The excess of filling material was cut with the use of a heated condenser followed by vertical condensation. No sealer was used in the positive control group and the negative control teeth were filled in the same way as in Group 1.

Dye leakage assay

After instrumentation, the teeth were sealed with nail polish leaving only the apex free for penetration of 0.2% Rhodamine B during 7 days, using vacuum in the first 15 min. The teeth in the negative control group were sealed, including apex. For analysis of the sealing ability of the tested materials, leakage of the dye was linearly measured on the photographs that were taken under stereomicroscopy using the SigmaScan® Pro Image Analysis Software (Systat Software, San Jose, CA, USA). Leakage measurement considered the line with longer length of dye, on the material/dentin wall interface, from the most apical to the most cervical portion. If the leakage length were not similar on both sides of the root canal, only the longer length was considered. Leakage was independently measured by three calibrated examiners. The results (mean of leakage values obtained by each examiner) obtained in millimeters were tabulated and analyzed by ANOVA to investigate possible differences between materials, and Tukey’s test to confirm the significance of difference between groups, using Pacotico statistical software. The significance level was set at 5%.

RESULTS

Kappa statistics showed that agreement between the three examiners was higher than 90%. The positive control showed total leakage in all specimens and the negative control did not show leakage (Figure 1). Analysis of the data for the 3 experimental groups revealed that Endo-CPM-Sealer® allowed more leakage than the other materials (p=0.001258). Fillapex® was similar (p>0.05) to Sealapex® and both materials showed significantly less (p<0.05) leakage when compared to Endo-CPM-Sealer® (Table 1).
DISCUSSION

The goal of this study was to evaluate the degree of apical leakage of Fillapex® compared with Sealapex® and endo-CPM-Sealer® after filling of root canals prepared with the Protaper Universal system using the single-cone filling technique.

All procedures were performed by the same operator to avoid intra-operator discrepancies. Only teeth with single straight root canals were used because they can offer a more standardized method for evaluation of apical leakage. In addition, assessing the difficulties of managing curved canals was not within the study’s scope.

The Protaper Universal system is the new version of the Protaper™ NiTi rotary system, which includes shaping, finishing and retreatment instruments1,2. Protaper Universal system was used in this study for reducing the time required for biomechanical preparation and improving the standardization of instrumentation1,2. Moreover, using the single cone technique for root canal filling allowed observing the sealability of the sealers in a more critical situation than that offered by the lateral condensation technique, as it is possible to speculate that the single master cone needs a greater interaction with the sealer to promote the sealing.

There is a lot of skepticism about the value of in vitro leakage studies with regard to clinical significance and limitations of the results13,31. Even so, they are widely used to evaluate and compare the sealing efficiency of materials, which must be assessed prior to their use in patients. Although in the present study the intensity of the coloration produced after the leakage was not evaluated, Rhodamine B was used because it does not suffer discoloration by calcium hydroxide-based materials, as occurs with methylene blue12,30. Vacuum was used according to studies that showed higher levels of leakage when it was employed compared with groups without its utilization, probably because the presence of air bubbles in the filling mass makes it difficult the penetration of dye, though they do not prevent the penetration of bacteria11,13.

The results of this study showed lower leakage of dye in the groups filled with Sealapex® and Fillapex®, and higher leakage with endo-CPM-Sealer®.

Sealapex® is a material specifically developed to be used as a sealer. It contains calcium hydroxide that will only be biologically active if calcium and hydroxyl ions are released over time10,12,26. An increase of pH has been shown to be bactericidal, interfering with the osteoclastic activity and promoting an alkalinization in the adjacent tissues. Calcium ions are also important in the activation of calcium-dependant adenosine triphosphatase, cell migration and differentiation, and reaction with carbonic gas to form calcium carbonate crystals (birefringent to polarized light), which serve as a nucleus for calcification and make possible the observation of mineralization with Von Kossa technique12,24. These biologic activities can explain the good clinical results observed with the use of

![Leakage pattern according to the groups. a) Negative Control, observe absence of leakage (reddish staining); b) Positive Control, observe leakage along the walls from apical to the cervical root third; c) Endo CPM-Sealer®, observe leakage along the walls from the apical to the middle root third; d) MTA Fillapex®, observe absence of staining; e) Sealapex®, observe leakage only on the apical portion of the master cone](image)

Table 1- Comparison of mean dye leakage values (mm) and standard deviations (SD) of the endodontic sealers

| Materials          | n  | Mean±SD (mm) |
|--------------------|----|--------------|
| Fillapex®         | 30 | 0.80±0.61α   |
| Endo-CPM-Sealer®  | 30 | 2.44±1.00β  |
| Sealapex®         | 30 | 1.22±0.53α  |

*Same letters indicate no statistical difference among the groups (P>0.05).

**Figure 1** - Leakage pattern according to the groups. a) Negative Control, observe absence of leakage (reddish staining); b) Positive Control, observe leakage along the walls from apical to the cervical root third; c) Endo CPM-Sealer®, observe leakage along the walls from the apical to the middle root third; d) MTA Fillapex®, observe absence of staining; e) Sealapex®, observe leakage only on the apical portion of the master cone.
some sealers containing calcium hydroxide, which stimulates apical foramen closure by mineralized tissue deposition, thus determining the biological sealing. Besides the biological characteristics, the use of the calcium hydroxide-containing root canal sealer Sealapex has been questioned regarding its predisposition to solubility and subsequent effect on the root canal seal and periapical healing. In this study, Sealapex showed an adequate sealability, demonstrating that a calcium-hydroxide sealer can have not only adequate biological but also physical and chemical properties, such as sealability. The results obtained with Fillapex were similar to those obtained with Sealapex. Fillapex is based on MTA with additional substances to obtain a consistency suitable to be used in root canal treatment. MTA can form calcium ions and hydroxyl ions important for stimulation of hard tissue deposition. The presence of MTA also suggests a possibility of setting expansion, which might have favored the sealability. Most dental materials have a tendency to shrink away from their interfacial margins, exposing a gap through which contaminating elements can penetrate. MTA setting results in the hydration of anhydrous mineral oxide compounds to produce calcium silicate hydrate and calcium hydroxide phases, which produces expansion against its confining margins, enhancing the seal and minimizing leakage.

According to its manufacturer, Endo-CPM-Sealer has similar or better physical, chemical and biological characteristics compared with MTA, and have the same clinical indications. Endo-CPM-Sealer has similar composition to that of MTA, but with the addition of calcium carbonate to reduce the pH after setting to 10, thus limiting the surface necrosis of the adjacent tissue and allowing the alkaline phosphatase action. Endo-CPM-Sealer has been shown to have adequate radiopacity, hydroxyl and calcium ion release, antimicrobial activity, biocompatibility (including stimulation of mineralization), and no cytotoxicity to fibroblast culture. However, in the present study, this material allowed the highest leakage level, demonstrating that it was not able to prevent dye apical leakage, which can hazard the success of the endodontic treatment. Maybe the physical properties of the material can explain this finding.

CONCLUSIONS

Based on the results of the present study, it may be concluded that Sealapex and Fillapex were able to significantly prevent apical leakage differently from Endo-CPM-Sealer, which showed the highest levels of leakage.

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