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The Properties of Endocal 10 and Its Potential Impact on the Structural Integrity of the Root
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Abstract

The purpose of this research was to determine if the use of Endocal 10 (previously called Biocalex 6.9) is associated with root fracture and to assess its sealability. Thirty-six freshly extracted, single canal human mandibular incisors were instrumented and randomly divided into two equal groups ($n = 15$). Canals in group A were obturated with vertically compacted gutta-percha and Sealapex, and those in group B were filled with Endocal 10 placed with a #25 Lentulo spiral per manufacturer's instructions. Two blinded investigators evaluated the teeth for fractures using transillumination and an operating microscope at 12x magnification. Three of the fifteen samples filled with Endocal 10 had vertically fractured in half, whereas none of the teeth filled with gutta-percha had any evident fracture lines. The remaining teeth were tested for leakage via a fluid filtration model at 1 wk and 30 days postobturation. No leakage was found among any of the samples whether filled with gutta-percha or with Endocal 10 at either time interval. Statistical analyses were completed using Fisher's exact test ($p = 0.023$), which showed that there was a significant increase in chance of fracture when using Endocal 10 versus gutta-percha. The results indicate that, although Endocal 10 is able to seal the tooth as well as gutta-percha and sealer, there is a significant potential risk of root fracture.

Endodontics has been a cornerstone of conservative dentistry for over 50 years. Endodontic materials used for the obturation of root canals consist of core and sealer combinations, plasticized gutta-percha, setting pastes, or non-setting pastes (1). Many materials have been used successfully within the tooth, ranging from calcium hydroxide to metal files (2, 3). However, each one has its own inherent weakness that prevents its widespread use. Gutta-percha, on the other hand, is a biologically inert material that has historically demonstrated high success rates when used to obturate root canals (4-7). There are members of the dental and medical community that consider gutta-percha to be potentially dangerous because its chemical composition is similar to that of natural rubber latex. It has been postulated that a person with a latex allergy may react to gutta-percha (8, 9), though recent studies dispute this (10, 11). Due to this potential problem, there has been a search for a hypoallergenic material that will be biologically inert, antimicrobial, and have the ability to seal the apical portion of the root canal space (12). Biocalex 6.9 (currently known as Endocal 10) is a calcium oxide material that has been used mainly in European

countries for more than 30 yr, but its popularity is minimal in the United States; this may be changing with the recent FDA approval of Endocal 10. "Holistic dentists" have adopted this material as the replacement for gutta-percha, and they cite that it is a safe and useful substitute. Studies have shown that Biocalex 6.9 possesses specific properties, including the promotion of significant intratubular calcium diffusion (13, 14), biocompatibility (15, 16), and expansion to reduce the dentin/material interface to a minimum allowing stable micromechanical intratubular attachment (13-15). However, the American Association of Endodontists "cautions practitioners who choose to use this product[horizontal ellipsis]" (17). Biocalex 6.9 expands upon setting, a property the manufacturer refers to as material "migration," which is responsible for its enhanced sealing ability (12).

Meryon and Brook (16) have shown that this migration of material can cause root fracture as it sets to calcium carbonate, a hard cement. While testing the cytotoxicity of Biocalex 6.9, they observed that the material expanded and fractured their artificial samples. The purpose of this study is (a) to determine if Endocal 10 is associated with root fracture, and (b) to determine the sealing ability of the material

MATERIALS AND METHODS

Sample Preparation and Fracture Study

Thirty-six freshly extracted mandibular incisors with a single canal were selected and randomly divided into two groups ($n = 15$). The coronal portion of each tooth was removed with an Isometric saw with water coolant (Buehler Ltd, Evanston, IL), leaving the roots 12 mm in length. The working length was set at 11 mm, and patency of the canal was confirmed by inserting a size-15 file through the apical foramen before and after completion of the root canal instrumentation.

Preparation of the root canals was started with a crown down technique using Profile GTs: 30./10, 30./08, and 30.06 (Tulsa Dentsply, Tulsa, OK). When the apical constriction was reached using a 15./04 Profile, the apical 1/3 was shaped with a 20./04 Profile and then to a final ISO size of 25./04 at a constant speed of 300 rpm in a Quantec-E electric handpiece (SybronEndo, Orange, CA). Rotary instruments were replaced after instrumentation of five teeth or at the first visible sign of deformation. Each canal was irrigated between each instrument with 2 ml of 5.25% sodium hypochlorite administered with a syringe and a 27-gauge needle. After completion of instrumentation, 5 ml of 17% EDTA was applied to the root canal for 3 to 4 min to remove the smear layer. The EDTA was flushed from the canal using a 10 ml rinse with 5.25% sodium hypochlorite. All instrumentation and obturation was completed by the primary investigator. The canals were dried with paper points (Dentsply Maillefer, Ballaigues, Switzerland) and examined for fractures using a surgical operating microscope (Global Surgical Corp. St. Louis, MO) at 12x magnification and fiberoptic transillumination by the other two investigators. After confirming that no fractures were present post instrumentation, the two groups were obturated in the following manner:

* Roots in group A were filled by warm vertical condensation with gutta-percha and Sealapex sealer (Kerr Mfg. Co., Romulus, MI) mixed according to manufacturer's instructions.

* Roots in group B were filled with Endocal 10 (Biodent, Montreal, Quebec) according to manufacturer's instructions. The Endocal 10 was mixed and inserted into the canal with a #25 Lentulo paste carrier at 500 rpm 1.5 mm short of the apex.

All roots were temporized with Cavit (Espe, Seefeld, Germany), placed into individual containers containing cotton saturated with isotonic saline (0.9% NaCl) to ensure 100% humidity, and stored at 37[degrees]C for the length of the study.

The roots were evaluated for fractures at 24 hours, 7 days, and 30 days using a surgical operating microscope with fiberoptic transillumination.

Fluid Filtration Study

All of the filled root sections were kept at 37[degrees]C and 100% humidity for 1 wk. Before the leakage test, the lateral surface of the 30 experimental roots and 3 positive controls and the whole surface of each negative control were coated with two layers of nail varnish.

The method to test fluid transport was described previously by Wu et al. (20) (Fig. 1). One end of each root was connected to a rubber tube (Cole-Parmer, Vernon Hills, IL) filled with distilled water. These connections were closed tightly by twisting pieces of stainless steel wires (0.2 mm round). A standard 25- μ l glass capillary (VWR International, South Plainfield, NJ) was connected at the outlet side of the specimen. Water was sucked back with a 2-ml Gilmont syringe (Cole-Parmer, Vernon Hills, IL) for approximately 3 mm in the open end of the glass capillary, creating an air bubble within the capillary. The entire set up was then placed in a water bath, and the air bubble was adjusted to a suitable position using the syringe. A headspace pressure of 100 kPa (1 atm) from the coronal side was applied, forcing the water through any voids along the root canal filling and causing the displacement of the bubble within the capillary tube. The volume of fluid transport through the obturated root was then determined by observing the movement of the air bubble in the glass capillary over a 30 min time period and expressed as μ l/min.

Fig 1 Modified fluid filtration assembly.

The specimens were evaluated for leakage at 7 days and 30 days postobturation.

RESULTS

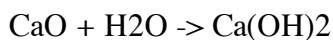
None of the gutta-percha samples developed any fractures during the evaluation period of this study. However, two of the fifteen Endocal 10 samples fractured vertically after 24 hours; a third vertically fractured root was observed at the 7-day evaluation. In the three positive controls, the air bubble moved too fast

to be measured, whereas the negative controls showed no fluid transport. The results of the fluid filtration study showed that none of the gutta-percha samples nor the 12 remaining Endocal 10 samples demonstrated any leakage at either time interval. Data was analyzed for difference between the two groups using Fisher's exact test. For a two-tailed test, the p-value was 0.023. Significant differences did exist between the two groups. Statistical analyses using Fisher's exact test ($p = 0.023$) showed that there was a significant increase in chance of fracture when using Endocal 10 versus gutta-percha.

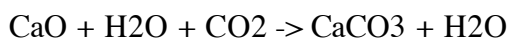
DISCUSSION

Previous studies have shown that Biocalex 6.9 expands on setting (12, 16). However, the effects of this reported expansion have never been demonstrated in human teeth. In the present study, Endocal 10 (previously known as Biocalex 6.9) was shown to cause vertical fracture of the roots of mandibular incisors, whereas the gutta-percha samples did not. The results of the fluid filtration study showed, in the remaining samples, that Endocal 10 sealed as well as gutta-percha and sealer, demonstrating that Endocal 10 has the ability to provide a hermetic seal. However, this study only used a 30-min evaluation period, and none of the experimental samples demonstrated any leakage. A longer time period may have given different results.

Endocal 10 consists of heavy calcium oxide mixed with zinc oxide and a solution of ethylene glycol in distilled water. Calcium oxide has been reported to maximize hermetic sealing properties during canal obturation by penetrating dentinal tubules and reducing the dentin-material interface to a minimum (15). The chemical combination of one molecule of calcium oxide with one molecule of water to form calcium hydroxide gives rise to an expansion in volume during the chemical reaction.



This chemical expansion allows the calcium hydroxide to penetrate into accessory and lateral canals, apical deltas, and dentinal tubules while simultaneously obturating the canal (14, 19). However, the chemical reaction that occurs when the calcium oxide (CaO) combines with water and residual CO₂ results in the formation of CaCO₃ (limestone).



CaCO₃ is a hard set cement that is insoluble in water. Endocal 10 expands and hardens simultaneously, building up internal stresses from within the root canal that could eventually lead to fracture. Previous studies have shown that the material possesses specific properties, including the promotion of significant intratubular calcium diffusion (13, 14), biocompatibility (16, 18), and expansion to reduce the dentin/material interface to a minimum allowing stable micromechanical intratubular attachment (15, 18, 19). While all of the aforementioned benefits sound appealing, the use of this material can ultimately lead to fracture and loss of the tooth. This study demonstrated that 20% of the specimens filled with Endocal 10 resulted in fracture, whereas none of the samples obturated with gutta-percha fractured. (Figs. 2 and 3). The authors agree with the previous recommendations of the AAE (17) and stress caution to those practitioners who choose to use this material.

Fig 3 Transillumination of tooth obturated with Endocal 10 demonstrating fracture of the root in (A) cross section and (B) longitudinal section.

Fig 2 Transillumination of tooth obturated with gutta-percha. No fracture evident.

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