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Eighteen-month clinical and radiographic evaluation of two root canal-filling materials in primary teeth with pulp necrosis secondary to trauma

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Abstract – *Aim*: This study compared clinically and radiographically the use of zinc oxide and eugenol cement (ZOE) and a commercial calcium hydroxide and polyethylene glycol-based paste (Calen®) thickened with zinc oxide as root canal-filling materials for primary teeth with pulp necrosis secondary to trauma within 18 months of follow up. *Material and methods*: Eligible patients of both genders aged 2 years and 6 months to 5 years and 10 months who had been referred for dental treatment at a pediatric dental trauma service and presented at least one anterior primary tooth (central and/or lateral incisor) with pulp necrosis secondary to traumatic injury were selected. Twenty-six children ($n = 31$ teeth) with mean age of 3.4 years met the inclusion criteria and were enrolled after parental written consent. The root canals were instrumented and filled with either ZOE (group I; $n = 15$ teeth) or Calen® paste [composition: 2.5 g calcium hydroxide, 0.5 g zinc oxide, 0.05 g colophony, and 1.75 ml polyethylene glycol 400 (vehicle)] thickened with zinc oxide (Calen®/ZO; group II; $n = 16$ teeth). ZO was added to the Calen® paste for slowing paste resorption, which should ideally occur simultaneously with the physiologic resorption of primary tooth roots. Clinical success after 18 months of follow up was considered as absence of pain, tooth mobility or fistula, and radiographic success as the partial or total remission of apical periodontitis, absence of pathological root resorption or presence of new bone formation. *Results*: Eighteen months after treatment, the teeth obturated with ZOE and Calen®/ZO presented statistically similar (Fisher's exact test; $P > 0.05$) success rates of 93.3% and 87.5%, respectively. *Conclusion*: Our results showed the clinical and radiographic outcomes for Calen®/ZO to be equal to those for ZOE after 18 months, suggesting that both materials can be indicated for obturating primary teeth with pulp necrosis after trauma.

Traumatic injuries to the primary dentition has become a more frequent occurrence in dental practice over the years (1), and the incidence of pulp necrosis in traumatized primary teeth has also increased, requiring endodontic treatment to preserve the teeth until their physiologic resorption. Injuries to primary dentition are important because of the potential for periapical sequelae, which can adversely affect the development of the permanent teeth and the developing occlusion. However, from published works, it is clear that more attention has been given to injuries to permanent than to primary teeth (1, 2), and trauma to the primary dentition are frequently overlooked by parents/caregivers. The sequelae of trauma to primary teeth in the development and eruption of permanent teeth are unpredictable (2), and there are very few published studies evaluating endodontic treatment in primary teeth after trauma (3, 4).

Different protocols have been proposed for the endodontic treatment of primary teeth with pulp necrosis regarding biomechanical preparation with hand or rotary instruments, use of intracanal dressings, and type of root canal-filling materials (5–8). Although different materials have been used for root canal filling in primary teeth, including zinc oxide and eugenol cement (ZOE), iodoform-containing materials, and calcium hydroxide-based materials, no single material fulfills all requirements. An ideal root canal-filling material for primary teeth should provide a hermetic seal, be resorbed in synchrony with the physiologic root resorption, be biocompatible, radiopaque, hydrophilic and bactericidal, be easily taken to and removed from the canals (if necessary), have good adhesion to the root canal walls, and not stain the teeth.

Calen® (S.S. White, Artigos Dentários, Rio de Janeiro, RJ, Brazil) is the proprietary brand of a paste

developed by Leonardo and Leal (9) with the following formulation: calcium hydroxide (2.5 g), zinc oxide (0.5 g), hydrogenized colophony (0.05 g) and polyethyleneglycol 400 (1.75 ml; vehicle). Calen® paste has been used in apexification procedures, treatment of large periapical lesions originated from infected root canals, interappointment dressing in pulpectomy, acute apical periodontitis, and endodontic retreatment after failures of non-surgical and surgical endodontic interventions (9). In primary teeth, the Calen® paste has been indicated as a root canal-filling material because of its recognizably good tissue tolerance, hydrosoluble nature (viscous), and low solubility (8).

In vivo (10) and *in vitro* (11) studies have indicated the addition of ZO to the Calen® paste to reduce the velocity of paste phagocytosis, which should accompany the physiologic resorption of the roots of the primary teeth. The antibacterial activity and the biocompatibility of calcium hydroxide-based materials are well demonstrated (9, 11).

Although ZOE is one of the most widely used materials after pulpectomy in primary teeth, some untoward reactions can be elicited by this material. These adverse effects include being irritating for the tissues and triggering inflammatory and foreign-body reactions if extruded into the periapical space. In addition, it has a questionable bactericidal activity and low resorption capacity, leaving ZO and eugenol particles within the periapical tissues as the physiologic root resorption occurs.

Because the reports in the literature show divergent outcomes and taking into account that a consensus on which should be the best root canal sealer for primary teeth has not yet been reached, the aim of this study was to compare clinically and radiographically the use of ZOE and Calen® thickened with zinc oxide (Calen®/ZOE) as root canal-filling materials for primary teeth with pulp necrosis secondary to trauma within 18 months of follow up.

Material and methods

This study was a longitudinal, single-blinded investigation with randomized distribution of groups.

Eligible participants were selected from patients of both genders who had been referred for dental treatment at the Pediatric Dentistry Clinic of the School of Pharmacy, Dentistry and Nursing, Federal University of Ceará, Brazil, between July 2007 and October 2008 and presented at least one anterior primary tooth (central and/or lateral incisor) with clinical and radiographic signs of pulp necrosis secondary to traumatic injury. Fulfillment of the following inclusion criteria was required: tooth crown discoloration associated with evidence of endodontic infection (pain, abscess, mobility, fistula, periapical lesion, and/or external root resorption); no systemic alterations or use of antibiotics or antimicrobials within the previous 3 months; tooth (teeth) with less than 2/3 of root resorption, and no previous root canal treatment. Twenty-six patients aged 2 years and 6 months to 5 years and 10 months (45% boys and 54% girls) who met all of these inclusion criteria were enrolled, providing a total of 31 teeth. There was no predilection for gender or ethnical group. The study purposes were fully explained to the parents/guardians, who signed an informed consent form authorizing children's enrollment in the study. The research protocol was reviewed and approved by the institutional Research Ethics Committee (Process # 104/07).

All clinical procedures were performed by two trained, experienced operators. If a patient had two teeth to be treated, one of them was randomized to be filled with ZOE and the other with Calen®/ZO. The treatment was completed in two sessions.

After infiltrative local anesthetic, a rubber dam was placed and the tooth surfaces were cleaned with 2.0% chlorhexidine digluconate. Coronal access to root canals was prepared with air/water-cooled high-speed spherical diamond burs (KG Sorensen Indústria e Comércio, São Paulo, SP, Brazil) followed by tapered safe-ended steel burs (Batt burs; Maillefer Instruments, Ballaigues, Switzerland). Chemomechanical instrumentation of the canals was performed according to the progressive neutralization technique using a sequence of three K-files (Maillefer Instruments) compatible with the canal size and irrigation with 2 ml of 0.5% sodium of hypochlorite at each change of file followed by suction of the solution. The working length was established 1 mm short of the radiographic apex. The canals were dried with sterile absorbent paper points, filled with 17% ethylenediaminetetraacetic acid (EDTA; Odahcan-Herpo Produtos Dentários Ltda., Rio de Janeiro, RJ, Brazil) for 3 min, followed by a final flush with 2 ml of sterile saline, suction, and drying with sterile absorbent paper points.

The root canals were then filled with Calen® paste using a special syringe (ML; S.S. White Artigos Dentários Ltda) followed by lentulo spirals. Complete filling of the canals was confirmed radiographically. The pulp chambers were cleaned, and the access cavities were sealed with conventional glass ionomer cement (Vidrion R; S.S. White Artigos Dentários Ltda.).

After 30 days, the teeth were examined clinically and radiographically for the presence of signs and symptoms that would contraindicate obturation, such as tooth mobility, fistula, pathological root resorptions, apical periodontitis, and pain. If any of these conditions persisted, the teeth were reinstrumented and the Calen® paste was renewed for more 30 days. If not, the intracanal medication was removed with a K-file and the canals were gently flushed off the canals with sterile saline, dried with sterile paper points, and filled with either ZOE or Calen®/ZO in a randomized manner. For preparation of Calen®/ZO in an adequate clinical consistency for obturation, an amount of Calen® paste equivalent to 12 mm diameter was dispensed onto a glass plate and mixed with 3/4 of one measuring spoon of ZO. The resulting material was taken to the canals with a size 20 or 25 K-file and a cotton pellet, followed by a lentulo spiral. Complete filling of the canals was confirmed radiographically. Pulp chambers were cleaned, and access cavities were restored with light-cured composite resin.

Clinical and radiographic evaluation of the patients was carried out 1, 3, 6, 12, and 18 months after treatment by a single-blinded examiner. The treated cases were considered clinically successful if there was absence of spontaneous pain, tenderness to percussion, abnormal mobility, or signs of pathology like intraoral and/or extraoral abscess. Treated cases were considered successful radiographically when the size of periapical radiolucent images decreased or remained the same compared to the preoperative condition, and the inflammatory root resorption ceased. Increase in the size of periapical radiolucencies and/or persistence of inflammatory root resorption at the follow-up visits was considered as radiographic failure (5).

Data were analyzed by Fisher's exact test using GraphPad Prism® version 5.00 for Windows® statistical software (GraphPad Software Inc., San Diego, CA, USA) to verify the association between each type of filling material used in the post-trauma endodontic treatment and their clinical and radiographic success. A significance level of 5% was set for all analyses.

Results

The most frequently affected teeth were the primary maxillary left central incisor (51.6%), maxillary right central incisor (41.9%), and the maxillary right and left lateral incisors (3.2% each). ZOE and Calen®/ZO were used in 48.3% and 51.6% of the cases, respectively. During the course of treatment, three patients were removed from the study: one patient was lost to follow up and in two patients the composite resin restoration was lost.

In the ZOE group, after 18 months of follow up, success rates of 93.3% was obtained for ZOE. Failure of ZOE treatment was observed in one patient, and it was because of the increase in the inflammatory resorption root at the earlier post-treatment visits (Fig. 1). In the Calen®/ZO group, the success rate was 87.5%. Two cases of Calen®/ZO failure showed presence of intraoral abscess after 1-month follow up. Canal reinstrumentation and renewing of the intracanal dressing were carried out, but the abscess persisted. Eighteen months after treatment, there was no statistically significant difference ($P > 0.05$) between the materials (Fig. 2).

Discussion

To the best of our knowledge, this is the first study to compare the use of ZOE and Calen®/ZO as root canal-filling materials for primary teeth with pulp necrosis after trauma. The Calen® paste was thickened with ZO at the moment of obturation because there is no ready-to-use commercial product in the market. The consistency of the resulting mixture should be such as to allow for taking the material to the root canal and improve the physical properties (hydrosolubility and low viscosity) of the Calen® paste. There is no consensus in the literature about which should be the best root canal sealer for pulpectomized primary teeth. The endodontic treatment of primary teeth should aim at maintaining the integrity of the apical and periapical tissues and the germ of the permanent successor. Preserving the primary dentition is of paramount importance for the developing occlusion.

Mani et al. (12) evaluated the efficacy of calcium hydroxide associated with a methylcellulose-based material and ZOE as root canal-filling material for human primary teeth and found higher success rates after 6 months of follow up. Considering the high success rate of the calcium hydroxide-based sealer, those authors

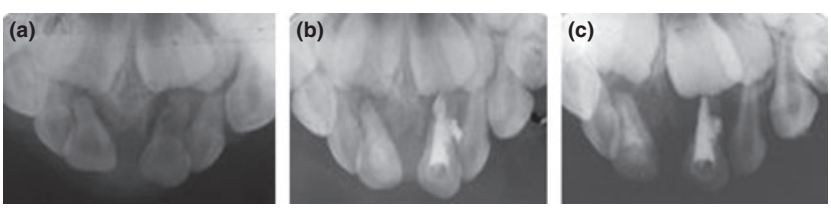

Fig. 1. Radiographic images illustrating cases of success of Calen®/ZOE and failure of zinc oxide and eugenol cement (ZOE) at 6-month follow up. (a) Initial radiograph: teeth 51 and 61 with periapical radiolucent images and inflammatory root resorption. (b) Radiograph taken immediately after complete filling of canal with Calen®/ZOE (tooth 51) and ZOE (tooth 61). (c) Six-month follow up: in tooth 51, the size of the periapical radiolucent image decreased and the inflammatory root resorption ceased; in tooth 61, increase in the size of the periapical radiolucency and persistence of inflammatory root resorption were observed.

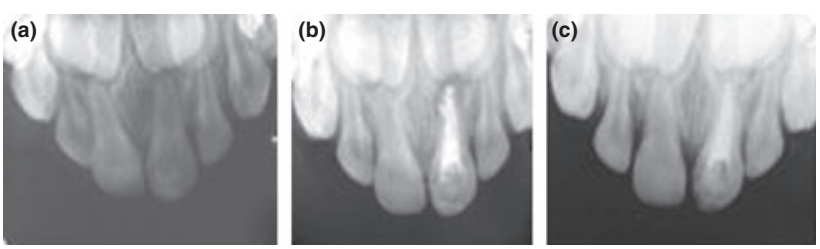

Fig. 2. Radiographic success of zinc oxide and eugenol cement (ZOE) treatment at 18-month follow up. (a) Initial radiograph: tooth 61 with periapical radiolucent image. (b) Complete filling of the canal with ZOE. (c) After 18 months: absence of periapical radiolucent image.

recommend their use for root filling in primary teeth. In this study, the cases of failure associated with ZOE were attributed to the persistence of inflammatory resorption which is in agreement with the findings of Mani et al. (12).

Although ZOE is the most widely used filling material in pulpectomized primary teeth, previous studies (7, 12) have found chronic inflammatory responses to the zinc ions (13) and eugenol (14) contained in the material. The failure of pulpectomies with ZOE in primary teeth has been attributed to the irritating effects of the material (7) and foreign-body reaction developed in the periapical region attributed to eugenol (14). The findings of this study showed a slow resorption of ZOE in the first 6 months of follow up in the cases of extravasation of filling material to the apical region.

The high success rate achieved in the teeth filled with Calen®/ZO (87.5%) confirm the capacity of this material of preventing/arresting pathological root resorptions and inducing new bone formation. This is in agreement with the findings of Hendry et al. (15), who indicate calcium hydroxide-based sealers as definitive root-filling materials for primary teeth. In this study, there was no radiographic evidence of extravasation of Calen®/ZO after 3 months of follow up, suggesting complete resorption of this material, as observed by Mani et al. (12). Rapid resorption is considered as an advantage of Calen®/ZO over ZOE for minimizing damage to the germ of the permanent successors (16).

In spite of the excellent biologic properties of calcium hydroxide, some of its physicomechanical properties are not adequate. Calcium hydroxide is hydrosoluble, radiolucent, does not have good viscosity and flow, and is permeable to tissue fluids. The vehicle of Calen® paste, polyethylene glycol 400, is a viscous material and permits slower ion dissociation, reducing paste solubility. According to Silva et al. (10), the addition of ZO to Calen® paste provides a better consistency for the filling of root canals without affecting its resorption.

In this study, although ZO was added to the Calen® paste to improve the clinical consistency for root canal filling and slow the resorption rate of the paste, complete resorption of the material inside the canal occurred after 18 months of follow up in 1 case, but the patient did not present clinical signs or symptoms that indicated the need of a new obturation. This case was accompanied at 3-month intervals for a more strict surveillance. The cases of failure with Calen®/ZO were attributed to the persistence of active fistula.

ZOE and Calen®/ZO showed good success rates after 18 months of clinical and radiographic follow up and both can be indicated as root canal-filling materials for primary teeth with necrotic pulp because of trauma.

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