Root fillings with Endoflas in primary teeth: a retrospective study

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The aim of this retrospective study is to report the success rate of root canal treatments (RCT) using Endoflas as a filling material in primary teeth. Fifty-five (55 teeth, 27 maxillary incisors and 28 molars) of 47 children fulfilled the criteria to be included in the study. The immediate post-operative radiograph was evaluated and the root filling was rated overfilled, flush or underfilled. Thirty-one (31) teeth were overfilled; of these 9 (29%) were normal pre-operatively and the remaining 22 (71%) presented with bone pathology. Twenty-four (24) teeth were flush or underfilled; of these, 50% had pre-operative bone pathology. The children were examined clinically and radiographically at follow-up visits ranging from 6 to 52 months. Approximately 70% of the cases were successful at the last follow-up examination. The remaining 30% presented with pathology (Po); however, only one tooth had to be extracted (Pi). Overfilling led to a success rate of 58%, while in the combined flush and underfilled the success rate was 83%.

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INTRODUCTION

The primary objective of pulpal treatment is to preserve the integrity and health of the oral tissues.[1] Pulpectomy is indicated in teeth that show evidence of chronic inflammation or necrosis in the radicular pulp, with or without periapical or furcation pathology. The goal of this treatment is to maintain primary teeth that would otherwise be lost.

Developmental anatomical and physiological differences between primary and permanent teeth call for differences in the criteria for root canal filling materials. The ideal root filling material for primary teeth should resorb at a similar rate as the primary root, be harmless to the periapical tissues and to the permanent tooth germ, resorb readily if pressed beyond the apex, be antiseptic, fill the root canals easily, adhere to the walls, not shrink, be easily removed if necessary, be radiopaque and not discolor the tooth.[1-3] None of the materials currently available meet all the above mentioned criteria.

Presently, the most commonly used materials are: zinc-oxide eugenol, iodoform based pastes, and calcium hydroxide.[1]

Zinc-oxide eugenol paste is probably the most commonly used filling material for primary teeth in the United States.[1] It has been reported that this material is irritating to the periapical tissues, does not resorb at the same pace as the roots, can cause necrosis of bone and cementum[4,5] and may alter the path of eruption of the succedaneous tooth.[6] Iodoform based pastes such as KRI[7,8] and Maisto's[9] are based on the original Walkhoff paste[10] and contain iodoform, camphor, parachlorophenol and menthol. The difference between them is that the Maisto's paste also contains zinc-oxide, thymol and lanolin. Good clinical results have been reported with these two materials and, when inadvertently extruded from the canals, these pastes are resorbed within two weeks, without damaging the succedaneous teeth.[7-9]

Calcium hydroxide has also been employed as a root filling material for primary teeth alone,[11-13] or associated with iodoform.[14] A commercial product named Vitapex, containing a viscous mix of calcium hydroxide and iodoform has been used initially in Japan,[15-20] and more recently inthe U.S.A.[21] and South America,[22] with good clinical and radiographic results.

Endoflas (Sanlor & Cia. S. en C.S., Cali, Colombia), a resorbable paste produced in South America, contains similar components as Vitapex, with the addition

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of zinc-oxide and eugenol. This paste is obtained by mixing a powder containing tri-iodmethane, zinc-oxide, calcium hydroxide, barium sulfate and iodine dibutilorthocresol with a liquid consisting of eugenol and paramonochlorophenol. The main difference between Endoflas and the other pastes is that the latter resorbs when extruded extra-radicularly, but does not wash out intra-radicularly. Despite being utilized clinically for several years and the availability of some publications in the South American literature,[23] there are no reports on the success rates of Endoflas root fillings in primary teeth.

The purpose of the present retrospective study is to report the success rate of root canal treatments using Endoflas as a filling material in primary teeth.

MATERIALS AND METHODS

Records of patients treated at the Pediatric Dentistry Undergraduate and Postgraduate Clinics were examined, and those that had received a root canal filling were selected. After an explanatory telephone conversation with the parents, the children were invited for a follow-up examination. A very low response was attained, as only 56 children with 66 root fillings presented for examination. Of these, 11 had to be excluded, as they did not meet the study criteria that called for at least 6 months follow-up, and the availability of good quality pre-operative and immediately post-operative radiographs. Thus, the study material consisted of 55 teeth (27 maxillary incisors and 28 molars) of 47 children that had Endoflas root fillings 6 to 52 months previously.

Pulpectomy technique

The teeth were treated under local anesthesia and rubber dam following a conventional technique, as taught at the Department of Pediatric Dentistry, as follows: mechanical preparation of the canal with files, rinsing with sodium hypochlorite and saline, filling with Endoflas using a spiral lentulo mounted on a slow speed engine, and sealing with IRM. The primary molars were restored with stainless steel crowns, and the incisors had the palatal access cavity filled with a bonded composite resin, either in the same day or at a subsequent appointment.

The presence of pre-operative periapical or interradicular pathological areas at baseline were noted from the diagnostic radiograph. A periapical radiograph was exposed immediately after completion of the root canal treatment, and the root filling was rated as *overfilled*, when the filling material was expressed beyond the apex, *flush*, when it filled the canal till the radiographic apex, and *underfilled,* when it was short from it.

The success rate was based on the tooth satisfying clinical and radiographic criteria at the last examination.

Clinical criteria

- A-no abnormal mobility (other than from normal exfoliation).
- B-no sensitivity to percussion.
- C-healthy appearance of the soft tissue (no swelling, redness or sinus tract).

Radiographic Criteria — (modified from Payne *et al.*[24])

- A-no evidence of bone or root resorption, except for that associated with the exfoliation process (N).
- B-pathological resorption associated with bone rarefaction; follow-up in six months (Po).
- C-pathological resorption associated with bone rarefaction; extract immediately (Px).

Periapical radiolucencies that remained unchanged were not regarded as failure (Po).

The pulpectomized teeth were evaluated simultaneously by the junior (NP) and one of the senior investigators (ABF or EE), which were trained in the radiographic criteria to establish an inter-rater agreement. A sample of 5 cases were randomly selected and rated again and independently by the senior investigators, to assess the inter-rater and intra-rater reliability. The Kappa Statistics used to test the reproducibility of the scoring by examiners indicated a highly significant reproducibility between the two examiners, with a measurement of agreement of 0.81 ($p < 0.001$).

RESULTS

Radiographs of the root treated teeth at the last follow-up examination were compared to those taken immediately after completion of the root canal treatment (baseline) to assess effectiveness. The tooth condition and the length of the root filling at baseline are summarized in Table 1. Thirty one teeth were overfilled (18 incisors, 58% and 13 molars, 42%); of these, 9 (29%) were normal pre-operatively, and the remaining 22 (71%) presented with bone pathology. Twenty four teeth (9 incisors, 37.5% and 15 molars, 62.5%) were flush or underfilled; of these 50% had preoperative bone pathology.

The success rate of root treatments according to root filling length and preoperative tooth condition is presented in Tables 2 and 3. Approximately 70% of the cases were successful at the last follow-up examination (N). The remaining 30% of the teeth presented with pathology (Po); however, only one tooth had to be extracted (Px). In 42% (13/31) of the overfilled teeth the pathologic lesions remained unchanged or increased, leading to a success rate of 58%. Conversely, the combined flush and underfilled led to a success rate of 83%, and pathology remained in 4 of 24 teeth treated (Table 3). Borderline significance ($p > 0.09$) was found between the overfilled and the combined flush

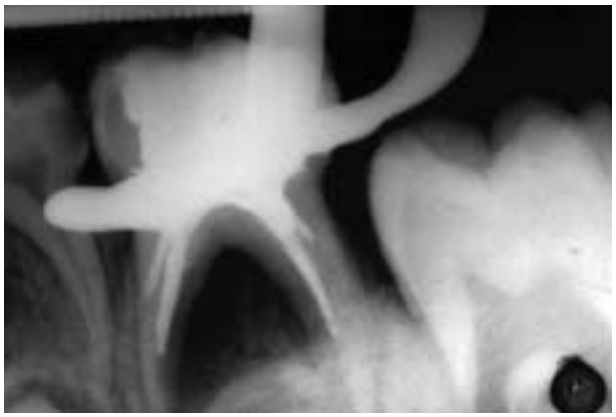

Figure 1A. Post-operative control radiograph of a mandibular second primary molar immediately after root treatment with Endoflas. Notice the short root filling and the extensive inter-radicular bone lesion.

Figure 1B. The same tooth two and a half years later. The bone lesion has healed and a normal lamina dura is evident.

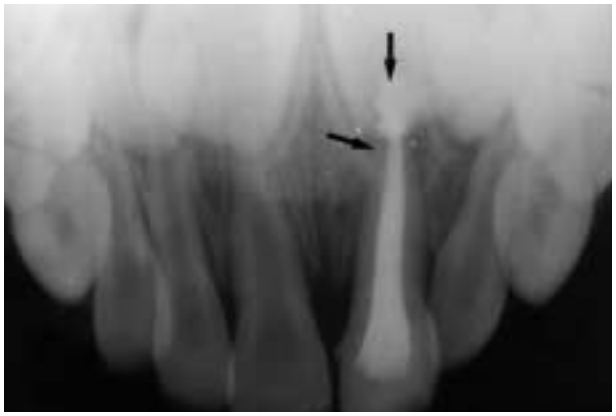

Figure 2A. Maxillary central incisor immediately after root filling with Endoflas. A periapical lesion (arrow) and the presence of paste extruded through the apex (overfilling arrow) can be observed.

Figure 2B. A year and a half later the excess paste is partially resorbed, but the lesion persisted. The degree of root resorption in the root treated tooth is more advanced when compared to the untreated contra-lateral, but the location of the permanent buds is even.

and underfilled group. Representative radiographs of root treated teeth can be seen in Figures 1 and 2.

DISCUSSION

Root canal treatment of primary teeth has been a controversial issue, particularly after the publication of a classical study by Hibbard and Ireland, in 1957.[25] These authors described the variable and often unpredictable root canal anatomy of primary teeth, as a result of deposition of secondary dentin. This article was widely quoted as evidence that debridement and obturation of the root canal systems of primary teeth was next to impossible, and became the principal deterrent to the development of pulpectomy procedures in the primary dentition.[24]

Some clinicians hesitated to perform pulpectomy procedures because they felt it would lead to uneven or abnormal root resorption. Prove *et al.*[26] demonstrated that uneven root resorption is a normal occurrence in normal untreated teeth. Thus, proper diagnosis and controlled management of pre-existing pathosis is the basis of all primary root canal treatment techniques.[27,28] Presently, this treatment modality is an accepted procedure and is recommended by the American Academy of Pediatric Dentistry (AAPD.)[29] According to the AAPD guidelines, pulpectomy is indicated for primary teeth with carious pulp exposures in which, following coronal pulpal amputation, the radicular pulp exhibits clinical signs of hyperemia, or in cases where there is evidence of radicular pulpal necrosis, with or without caries involvement. This rationale has been questioned by Yacobi *et a1*.[30] that proposed pulpectomies for vital primary teeth, to eliminate the need for aldehyde containing compounds currently utilized in pulpotomy. The AAPD guidelines for pulpectomy include: debriding, enlarging. disinfecting and filling the canals with a resorbable paste, without specifying its chemical composition or brand.[29]

Zinc oxide-eugenol (ZOE) is still widely utilized for obturation of root canals, and the success rates reported range from 65% to 88.5%[6,8,13,31,33] This variability might be due to differences in the evaluation criteria or in the pre-operative status of the root treated tooth. Thus, while Gould[31] and Holan and Fuks[8] describe success rates of 68.6% and 65% respectively for necrotic teeth, with or without periapical involvement, Yacobi *et a1*.[30] reported a success rate of 84% one year post-treatment for vital teeth. One would expect a much better result in Yacobi's study,[30] particularly for the posterior teeth, that were all restored with stainless steel crowns. This type of restoration ruled out the possibility of microleakage, a definite risk for the short-post and composite restorations utilized for the anterior teeth.

The difficulty in obturating primary root canals with thick mixes of zinc oxide-eugenol pastes might have contributed to the search for operator friendlier root filling resorbable pastes.

The use of a resorbable iodoform paste instead of zinc oxide-eugenol has been suggested initially by Rifkin,[3,7] based on excellent clinical and radiographic findings. This author reported that the excess of iodoform paste extruded from the apex was resorbed within one to two weeks. The iodoform paste he used was KRI 1 paste, basically the original

Walkhoff's paste.[10] Good clinical results utilizing this paste have also been reported in other clinical studies.[8,9,34] Another option for root fillings in primary teeth was suggested by Dominguez *et a1*.[14] They obtained excellent results by combining pure iodoform with calcium hydroxide powder.

Vitapex, a commercial paste containing calcium hydroxide and iodoform is presently available in premixed syringes and disposable tips. High clinical and radiographic success have been reported in several studies.[15-22] Nurko *et a1*.[35] reported a case where Vitapex resorbed not only where extruded extra-radicularly, but also intraradicularly, without any apparent ill effect. However, the authors show concern of what will be the effect of the intra-radicular resorption in the long term. Similar findings were observed with KRI 1.[1] In the Endodontics lexicon there is the well known "hollow-tube" effect,[36] where it is thought that an unfilled root canal can be permeated with tissue fluid that becomes stagnant, and eventually a nidus for infection; whether this actually occurs still has to be determined.

Endoflas, the resorbable paste utilized in the present study has the advantage of having the resorption limited to the excess extruded extraradicularly, without washing out intra-radicularly.

The percentage of teeth in which the pathological area remained unchanged (31%) might suggest that the success rate with Endoflas is lower when compared to other studies. However, it should be emphasized that in the present study more than half of the teeth (62%) presented with periapical lesions at baseline, a finding not described in other studies. The presence of these lesions might have contributed to overfilling, as the pathologic resorption of the bone and root apex might have facilitated the penetration of the paste.

When observing the results of the combined flash and underfilling in the present study (83%), one may realize that the success rate is similar to the ones described in other studies utilizing KRI or Maisto.[7,9,34]

Another point to consider is the criteria for radiographic assessment. Traditionally, root treatments were considered successful when no pathologic resorption associated with bone rarefaction is present.[8,34] Payne *et al.*[24] claim that most clinicians are prepared to accept pulp-treated primary teeth that have a limited degree of radiolucency or pathological root resorption (Po), in the absence of clinical signs and symptoms. This is contingent on the assurance that the parent will contact the dentist if there is an acute problem and the patient will return for recall in 6 months. According to Payne *et a1*.[24] most of the pulp therapy studies in the existing literature have considered such teeth to be "successfully treated". Although the overall success rate of this study was 69%, as it did not include teeth in which the pathology was not completely healed (Po), only one tooth had to be extracted (Px). The remaining (Po) teeth were left for follow-up.

One may conclude that Endoflas may be successfully used for root canal treatments in primary teeth, particularly if care is taken not to overfill. The fact that this material does not wash out from the canals might be an advantage, although it is still not clear what is the importance of the "hollow tube effect" on the development of a nidus for infection.

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