

## **Bioceramic Materials in Pediatric Dentistry**

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## **1 Introduction**

The American Dental Association (ADA) defines pediatric dentistry as "an age-defined specialty that provides both primary and comprehensive preventive and therapeutic oral health care for infants and children through adolescence, including those with special health care needs" and Endodontics as "the branch of dentistry which is concerned with the morphology, physiology and pathology of the human dental pulp and periradicular tissues. Its study and practice encompass the basic and clinical sciences including biology of the normal pulp, the etiology, diagnosis, prevention and treatment of diseases and injuries of the pulp and associated periradicular conditions." By a combination of these definitions, this chapter will cover all endodontic treatment procedures within the agedefined pediatric population.

For decades, the management of the dental pulp in the primary dentition was performed worldwide with semi-toxic products such as Buckley's formocresol and in some countries with iodoform pastes. The latter was especially advocated because of their antibacterial activity and their ability to resorb [\[1](#page-12-0)]. With the introduc-

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tion of mineral trioxide aggregate (MTA) and, more recently, several new hydraulic tricalcium silicate–based cements, the management of pulpotomy of primary molars has been undertaken using these materials. Furthermore, a more biological treatment approach in deep carious lesions of immature permanent molars became accepted. This change involved a shift of the traditional paradigm regarding excavating all carious dentin with the risk of pulp exposure into the more conservative (i.e., biological) way leaving a thin layer of infected dentin in the cavity and covering this layer with a hydraulic tricalcium silicate– based material. A comparable paradigm shift also exits for the management of traumatized immature permanent incisors with pulpal involvement. After decades of using calcium hydroxide for indirect and direct cappings, pulpotomy, and apexification/apexogenesis procedures, hydraulic tricalcium silicate–based cements have replaced it and are now the materials of choice for all the aforementioned indications owing to its increased desirable interaction with biological tissues.

For the both abovementioned clinical situations—deep carious lesions in the primary molars or the permanent immature molars and in addition after traumatic injuries, calcium silicate– based materials gained enormous attention and use. These cements are hydraulic and a number of them are self-setting materials whose physicochemical properties are suitable for pulp therapy.

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## **2 Endodontic Management of the Primary Molars**

The dental pulp in the primary dentition is histologically similar to that of permanent dentition. Endodontics in the primary dentition is part of the overall treatment plan in young children, especially in the high caries/trauma-risk group. This therapy depends on an accurate diagnosis of the pulp status, and whether the pulp is vital, inflamed or necrotic. It is well known that in 80% of primary teeth with carious exposures, the clinical and radiographic pathology show inflammation that is only limited to the coronal part of the pulp. This is mainly known as *chronic coronal pulpitis*. The different pulpal conditions in the primary teeth are summarized in Table [1](#page-1-0) [[2\]](#page-12-1):

Knowledge on pulp response to caries and being able to interpret symptoms correctly is of utmost importance whether performing a rather conservative treatment (stepwise excavation, indirect pulp capping), an intermediate invasive treatment (direct pulp capping), or a radical intervention (partial and full pulpotomy) (Table [2](#page-1-1) and Fig. [1](#page-2-0)).

The following factors should be considered during the decision-making for an endodontic intervention.

<span id="page-1-0"></span>



Therapy	Procedures	Indications
Stepwise excavation	Removal of most carious dentin. Demineralized dentin covered with glass- ionomer lining and cement and left temporarily under an intermediate restoration	Deep carious lesion, carious softened tissue close to pulp but no exposure. No clinical signs of pulpitis
Indirect pulp capping	Removal of almost all the carious dentin. Affected dentin covered with glass-ionomer lining	Deep carious lesion, carious softened tissue close to pulp but no exposure. No clinical or some radiographic signs of pulpitis
Direct pulp capping	No surgical removal of exposed pulp tissue. Pulp covered with a bioceramic material	Accidental minimal exposure of healthy pulp during preparation or via trauma. Little or no contamination of the exposed area
Partial pulpotomy	Excision of a superficial part of the pulp. A bioceramic material should be applied in tissue contact with the wound without an extra pulpal blood clot	Accidental exposure of healthy pulp; carious exposure-partial chronic pulpitis
Pulpotomy	Removal of the coronal pulp. Wound surfaces placed in the orifices of the root canals	Carious exposure—pulpitis, partial or coronal chronic pulpitis, marginal ridge breakdown

<span id="page-1-1"></span>Table 2 Endodontic techniques<sup>a</sup> for primary teeth (after Duggal and Nazzal [\[2\]](#page-12-1))

a Pulpectomy was not included in the table because this technique should have a very limited use. From a clinical point of view, it can be considered if there is an irreversible pulpitis including the entire pulp system or in the presence of necrotic pulp or acute infection. However, there are a lot of considerations necessary for making this decision (see below). In a case where the second premolar is missing, while the retention of the primary molar is required for orthodontic reasons, pulpectomy can maybe be considered [\[2\]](#page-12-1)

<span id="page-2-0"></span>**Fig. 1** Schematic representation of endodontic therapies in primary molars. (Drawings used with permission of Wiley-Blackwell)



- Pulpal diagnosis
- Occlusal considerations
- The patient's ability to cooperate. Can the treatment be performed conventionally or is sedation/general anesthesia needed?
- Patient's general and oral health
- Patient's and parent's motivation and consent
- Patient's caries risk
- The risk of injury/infection of the underlying permanent tooth germ
- The effect of the proposed endodontic intervention on the patient's health, for example, infective endocarditis in children who have congenital heart defects or have had heart surgery
- The effect of the proposed endodontic intervention on the underlying permanent tooth germ

All these factors should help the clinician in his decision whether to keep or extract the tooth [[2](#page-12-1)].

## **2.1 Stepwise Excavation and Indirect Pulp Capping**

During stepwise excavation, the soft part of carious dentine is removed and dentine floor is covered with a glass-ionomer liner and the tooth is completely filled with a semi-permanent filling material. Secondary dentin formation during at least 3–6 months will lead to less risk of exposing the pulp during further excavation of carious dentin [[3,](#page-12-2) [4\]](#page-12-3). This technique, however, is not recommended as a favored approach for deep carious

lesions in primary molars for children because another appointment with the administration of local anesthesia should be avoided. In cases where reversible pulpitis is diagnosed, a single-visit indirect capping must be considered. During this procedure, removal of almost all carious dentin is performed and affected dentin will be covered with hydraulic tricalcium silicate–based cements, and the tooth will be permanently restored.

#### **2.2 Direct Pulp Capping**

Direct pulp capping is well known as a technique whereby the exposed vital pulp is capped with a medicament. For many years, this was preferably performed using calcium hydroxide. It has been shown that inflammation of the pulp precedes the exposure of the pulp [[5,](#page-12-4) [6](#page-12-5)]. Dentinal tubules are wide in primary molars, and bacteria penetrate the pulp, causing inflammation before clinically being exposed. For that reason, direct capping should not be considered if the exposure resulted from caries excavation. The only situation where direct pulp capping could be considered in primary teeth is where pulp exposure is traumatic and not due to the caries [\[7](#page-12-6)]. Nowadays, hydraulic tricalcium silicate–based cements are recommended for these purposes [[8,](#page-12-7) [9\]](#page-12-8).

#### **2.3 Partial Pulpotomy**

In cases of healthy pulp exposure or partial chronic pulpitis, a partial pulpotomy is the treatment of choice. However, the clinician should be

sure that pupal inflammation is very localized at the point of exposure. Any history of continuous pain after cold or heat or continuous pain indicating signs of pulpitis should be excluded, and only normal bleeding after pulpotomy procedure should be seen. This bleeding must be controlled after gentle pressure with a wet cotton pellet. If more hemostasis is needed, the clinician should proceed to the full pulpotomy. Nowadays, hydraulic tricalcium silicate based–cements are recommended for these purposes [[10,](#page-12-9) [11\]](#page-12-10).

## **2.4 Pulpotomy, Wound Dressing, Tissue Reaction, and Outcome**

The most widely used vital pulp therapy technique for the treatment of deciduous teeth with carious pulp exposure is pulpotomy. According to the American Academy of Pediatric Dentistry, a pulpotomy is defined as the ablation of infected or affected pulp tissues leaving the residual vital pulp tissues intact, thus preserving vitality and function (totally or partially) of the radicular pulp, while the remaining pulp stump is covered with a medicament [\[12](#page-12-11)]. The rationale for pulpotomy is based on the assumption that inflammation and impaired vascularity caused by the bacterial invasion is confined to the superficial part of the coronal pulp, while the radicular pulp tissue remains functional. The primary objective in the treatment of the tooth with pulpal involvement is to retain it in a functional state (mastication, phonation, swallowing, and esthetics), so that it may fulfil its role as a useful component of the primary and young permanent dentition [\[13](#page-12-12)].

Pulpectomy should be avoided because of the risk of infecting the underlying permanent tooth germ, the number of accessory canals which can be assessed, and the difficulty to find a resorbable material [\[14](#page-12-13)]. As stated above, there is limited indication and if so, the use of hydraulic tricalcium silicate based–cements will not be an option as they are not resorbable [[15\]](#page-12-14).

An ideal pulpotomy agent must be bactericidal, promote healing of the radicular pulp, be biocompatible, offer the dentine–pulp complex a relatively stable environment, support the regeneration of dentine–pulp complex, and not interfere with the physiological process of root resorption [[13,](#page-12-12) [16\]](#page-12-15). Covering the floor of the pulp chamber is crucial, in order to ensure that the auxiliary canals traversing to the furcation are sealed and the pulp can thus benefit from the effect of applied materials.

For decades, calcium hydroxide was used as a biological wound dressing on the dental pulp. In primary teeth, however, clinical outcomes were poor with the most cited failure reported as internal resorption [[17\]](#page-12-16). This can be explained by the fact that in most cases where pulp therapy is required, the pulp is chronically inflamed, and calcium hydroxide has no healing effect inflamed pulp. It thus should no longer be used on primary pulp tissue.

Although not biologic, leakage of drug and leaving the pulp in a metastable condition having no healing effect, formocresol (well known as Buckley's formocresol) was worldwide used for many years. The success rate can be estimated between 50% and 95%. Since the International Agency for Research on Cancer classified formaldehyde as a carcinogenic to humans [[18\]](#page-12-17), efforts have been made to ban formocresol in endodontic therapy.

Iodoform-based pastes were developed as an alternative to formocresol and have a long-term bactericidal effect. Compared to formocresol, there was no diffusion into the inter- and periradicular area and so less or no toxicity. Success rates were 87–95% [[19\]](#page-12-18). A combination of a fastsetting calcium hydroxide–iodoform-silicone paste showed 100% clinical success and 97% radiographical success [\[20](#page-12-19)].

In the last decade, regeneration approaches include pulpotomy agents that have the cellinductive capacity to either replace lost cells or induce existing cells to differentiate into hard tissue–forming elements. However, iodoform-based pastes did not induce tissue regeneration and were not bioinductive. As a consequence, the trend nowadays is towards the use of bioactive materials to promote the healing of the pulp and keeping the teeth in the dentition. Since the availability of hydraulic tricalcium silicate–based

cements and the great clinical success in endodontic therapy, formocresol has been replaced by hydraulic tricalcium silicate–based cements.

From a comparison of MTA (ProRoot Dentsply) and formocresol in 60 pulpotomies randomly selected in 46, 7-year olds, MTA was shown to be a valuable and safe alternative. After 24 months, there was no difference in clinical and radiographic success [\[21](#page-12-20)]. The same was shown for a comparison of formocresol with MTA (Angelus) in 45 pulpotomies in 23 children (5–9 years). In the MTA group, dentin bridges were seen in 29% of cases [[22\]](#page-12-21). From a limited systematic review [[23\]](#page-13-0), it was suggested that the use of MTA is the best clinical practice. Regardless of the limited evidence [[24\]](#page-13-1), the use of MTA became generally accepted for vital pulpotomy in primary molars. Figure [2](#page-4-0) illustrates a number of studies with the clinical outcome for formocresol versus MTA [\[22](#page-12-21), [25–](#page-13-2)[33\]](#page-13-3). From this figure, it can be concluded that on average the clinical outcome of MTA at least equals or is slightly better compared to formocresol.

Besides MTA, other hydraulic tricalcium silicate based–cements can be considered for

pulpotomy in the primary dentition. Although, several cements are referred to as hydraulic tricalcium silicate–based cements, they can be classified based on their origin of tricalcium silicate as either Portland cement derivatives (MTA and its formulations) or laboratory synthesized (Biodentine™, BioAggregate, EndoSequence, and iRoot BP). The laboratory-synthesized hydraulic tricalcium silicate–based materials have different characteristics to the original formulation of MTA; this includes elimination of aluminum, addition of alternative radiopacifiers, minimizing particle size, and additives to enhance physical properties. Biodentine™ incorporates all of these changes in the cement composition and its clinical efficiency in pulp therapy has been compared with MTA in the following sections.

Biodentine™ is a hydraulic tricalcium silicate–based inorganic nonmetallic restorative cement commercialized and advertised as a "bioactive dentine substitute" [[34\]](#page-13-4). The material is claimed to possess far better physical and biological properties such as material handling [[35\]](#page-13-5), faster setting time [\[36](#page-13-6)], increased compressive strength [\[37](#page-13-7)], increased density [\[38](#page-13-8)], decreased

<span id="page-4-0"></span>

MTA clincial outcome ■FC clinical outcome ※MTA radiographic outcome ※FC radiographic outcome

**Fig. 2** An overview of clinical and radiographic success rate comparison between formocresol and MTA in primary molar pulpotomies. The asterisk indicates significant difference between the outcomes

porosity [\[39](#page-13-9)], and induction of reparative dentine synthesis [\[40](#page-13-10)] when compared to similar material types [[41,](#page-13-11) [42\]](#page-13-12).

The very first randomized clinical trial (RCT) on Biodentine™ in primary molar pulpotomy was a parallel-design RCT comparing it to ProRoot White MTA [\[43](#page-13-13)]. Patients above 3 years of age with carious primary teeth with vital pulps without spontaneous pain or history of swelling were included. Fifty-eight patients (82 teeth) with a mean age of  $4.79 \pm 1.23$  years were included. The teeth were randomized, blinded, and allocated to one of the three groups (Biodentine™, ProRoot® White MTA (WMTA) or Tempophore™) for pulpotomy treatment. All teeth were followed up clinically and radiographically (after 6, 12, and 18 months) by two-blinded calibrated investigators. Forty-six patients and 69 teeth were available for follow-up after 18 months. Clinical success (radiographic success in parenthesis) was 95.24% (94.4%), 100% (90.9%), and 95.65% (82.4%) in the Biodentine™, ProRoot<sup>®</sup> WMTA, and Tempophore™ groups, respectively, but the difference was not significant. Pulp canal obliteration was significantly different amongst the experimental groups as the Biodentine™ group exhibited significantly more pulp canal obliteration when compared to the WMTA group at 6 months  $(P = 0.008)$  and the 18 months ( $P = 0.003$ ). One of the cases is illustrated in Fig. [3](#page-5-0). From this RCT, it could be concluded that after 18-month follow-up, there was no significant difference between Biodentine™ in comparison with White ProRoot MTA or Tempophore™.

In the meantime, several other studies became published comparing MTA with Biodentine™ [\[43](#page-13-13)[–52](#page-14-0)]. The clinical success rates vary between 60% and 100% (Fig. [4\)](#page-6-0). However, except for one study [[50\]](#page-14-1), the overall clinical success rate of both hydraulic tricalcium silicate–based cements is higher than 90%.

<span id="page-5-0"></span>

**Fig. 3** The Biodentine case series with 18 months follow-up. Arrows indicate the region of interest (**a**) preoperative radiograph (**b**) immediate postoperative (**c**) dentine bridge formation and pulp canal obliteration (**d**)

<span id="page-6-0"></span>

**Fig. 4** The clinical and radiographic success rates of various studies comparing MTA and Biodentine™ in primary molar pulpotomy. No significant differences between the two materials were observed

#### <span id="page-6-1"></span>**2.5 Clinical Procedure**

The following steps should be followed:

- Administration of local anesthesia.
- Application of rubber dam.
- Caries removal and coronal access using a high-speed cylindrical diamond bur with ample water spray.
- Removal of the coronal pulp or with a sterile bur or with a sterile spoon excavator.
- Checking root canal orifices.
- Normal hemostasis by application of light pressure with a wet cotton pellet. Additional tools can be calcium hydroxide powder or cellulose pellets. If hemostasis was not obtained within 5 min [[17\]](#page-12-16), pulp tissue in the canal was assumed to be infected, and then extraction should be considered (see above).
- Application of minimum of 2 mm layer of the pulpotomy agent according to the manufacturer's instructions.
- Coverage with appropriate cement is needed in case of ProRoot MTA applications. For Biodentine™, the wound dressing can also fill up the entire pulp chamber and even be used as a temporary filling. The latter is a major

advantage compared to other hydraulic tricalcium silicate–based cements. However, several other hydraulic tricalcium silicate–based cements could also be used for this purpose and the restoration protocol depends on the type of cement used.

The final restoration can be obtained with adhesive restorations or stainless steel crowns.

In this respect, the clinician should be aware of the fact that healing of the dental pulp is not exclusively dependent on the supposed stimulatory effect of a particular type of agent but is also directly related to the capacity of both the dressing and permanent restorative material to provide a biological seal against immediate and longterm microleakage along the entire restoration interface [\[53](#page-14-2)]. Stainless steel crowns protect the underlying pulp against leakage and are a necessity for the long-term success of vital pulp therapy in cariously exposed teeth [\[54](#page-14-3), [55\]](#page-14-4). The use of stainless steel crowns increases the success rate of pulpotomy. In case there is a choice for MTA and an esthetic filling on top, one should be aware of potential discoloration. Especially, MTAs with bismuth oxide will cause grayish discoloration. MTAs with other radiopacifiers or other hydraulic tricalcium silicate based–cements with alternative radiopacifiers will have no or significantly less discoloration [[56\]](#page-14-5).

## **3 Deep Carious Lesions in Immature First Permanent Molars**

In time, deep caries management was performed to "extension for prevention" principles which were destructive with complete removal of all carious dentine. Thanks to the "adhesive" dental materials, minimal invasive dentistry (i.e., prevention of extension) with selective caries removal became accepted worldwide. In the last two decades, with the evolution into hydraulic tricalcium silicate–based cements, biological treatment strategies have been advocated.

From a recent consensus document, deep caries was defined as radiographic evidence of caries reaching the inner third or inner quarter of dentine with a risk of pulp exposure [[57\]](#page-14-6). Clinically, the depth of caries and residual dentine thickness are difficult to assess [\[58](#page-14-7)]. Recent research on deep carious tissue management supports less invasive strategies. Most recently, leaving a thin layer of infected dentine covered by these new materials is recommended [\[57](#page-14-6)]. With these approaches, reduced risk of pulp exposure and pulp healing are obtained. Management strategies for the treatment of cariously exposed pulp are also shifting with avoidance of pulpectomy and the reemergence of vital pulp treatment techniques such as partial and complete pulpotomy. Especially, the development of MTA and other hydraulic calcium silicates has resulted in more predictable treatments from both a histological and a clinical perspective [[59\]](#page-14-8).

This approach is of particular interest in deep carious immature first permanent molars. In these young children, an invasive endodontic treatment can be avoided. Figure [5a–d](#page-8-0) illustrates a full pulpotomy on a first permanent molar in the third quadrant and an indirect capping on the contralateral molar in a 10-year-old boy. The procedures performed were exactly the same as described earlier for the primary teeth. In both cases, Biodentine™ was used. Although it is perfectly possible to keep this hydraulic calcium silicate–based cement for at least 6 months in the mouth as a provisionary filling [[60\]](#page-14-9) having a second visit for permanent restoration, a one-visit treatment is also allowed and recommended. The setting time of Biodentine™ (i.e., up to 12 min according to manufacturer's instructions) is a bit crucial, but a recent report showed that after 3 min one could put permanent adhesive materials on top  $[61]$  $[61]$ .

## **4 Pulpotomy in Traumatized Immature Teeth**

Crown fractures with pulp exposure represent 18–20% of traumatic injuries involving the teeth, the majority being in young permanent central incisors [[62\]](#page-14-11). These injuries produce changes in the exposed pulp tissues, and a biological and functional restoration of immature young permanent teeth represents an important clinical challenge [\[63](#page-14-12)]. The treatment plan in such cases is to maintain pulp vitality via apexogenesis, which allows continued root development along the entire root length [\[64](#page-14-13)]. Apexogenesis after traumatic exposure in vital young permanent teeth can be accomplished by implementing the appropriate vital pulp therapy such as pulp capping (direct or indirect) or pulpotomy (partial or complete) depending on the time between the trauma and treatment of the patient, degree of root development, and size of the pulp exposure [[65\]](#page-14-14). Histologic examination of traumatized pulp shows that the depth of inflammatory reaction does not exceed 2 mm from the exposed surface within 48 h [[66\]](#page-14-15). Therefore, if treated within 48 h, 2 mm of the injured pulp can be successfully removed, leaving the non-inflamed healthy radicular pulp to reorganize.

In this era of regenerative endodontics, it is of utmost importance to define the real meaning of regenerative endodontics. As long as the vital pulp is present where we use hydraulic tricalcium silicate–based cements, we are performing a therapy which repairs the dentin–pulp complex. When we are revitalizing teeth using the fresh

immature incisors is to perform a therapy to repair the dentin–pulp complex. Figure [6](#page-10-0) illustrates MTA pulpotomies in two immature maxillary incisors. The procedure is the same as explained in Sect. [2.5.](#page-6-1)

<span id="page-8-0"></span>

**Fig. 5** (**a**) Clinical (b) and radiographical (a, c) illustrations of deep caries in the 4.6 (a) and extremely deep carious in the 3.6 (c) in a 10-year-old boy. (**b**) Clinical and radiographical illustrations of extremely deep carious in the 36 (a, b). A Biodentine™ pulpotomy was performed (c) followed by an imm0ediate adhesive restoration (d). (**c**) Deep carious lesion (a, e); cavity preparation (b); indirect capping with Biodentine™ (c, f) followed by an immediate adhesive restoration (d). (**d**) Radiographical follow-up from baseline up to 18 months (a–f) showing the formation of dentin bridges (c) or extensively hard tissue formation (f) and further apexogenesis (c, f)





**Fig. 5** (continued)



<span id="page-10-0"></span>

**b**



**Fig. 6** (**a**) MTA pulpotomies in two central incisors. Teeth were further opened after injury and pulp was removed from the chamber (a), after hemostasis pulp was covered with MTA (b). X-ray control was performed (c). Courtesy to R. Cauwels, Dept Paed Dent, UGent. (**b**)

24 months radiographical follow-up after MTA pulpotomy (a–d) with early signs of dentin bridge formation (b), extending (c) combined with full apexogenesis (c, d). Courtesy to R. Cauwels, Dept Paed Dent, UGent

In another 7-year-old Caucasian female who visited the emergency service after she had an accident in the playground, an enamel dentine fracture with pulp exposure with respect to tooth 11 was diagnosed (Fig. [7a\)](#page-11-0). Due to severe anxiety, treatment under local analgesia was impossible. The treatment was performed the following day under general anesthesia. The pulp exposure was further opened with a sterile high-speed diamond bur with sufficient water

cooling. The pulp tissue until the cement– enamel junction was removed (complete pulpotomy). Pulp capping or partial pulpotomy was not a viable option in this instance as the duration of between trauma and treatment was more than 24 h. Hemostasis was achieved with a moist cotton pellet, and the pulp exposure was capped with Biodentine™ and used as a temporary filling. A radiograph at this appointment showed an immature open apex, and the

<span id="page-11-0"></span>



# **Baseline**

24 Months

# **48 Months**

**Fig. 7** (**a**) A 7-year-old girl presented with a complex crown fracture with pulp exposure (a, c). After further opening (d) a Biodentine™ pulpotomy was performed (b,

Biodentine™ pulpotomy could be noted at the cingulum level. Three weeks later, a permanent composite restoration was made. Clinical tooth vitality and digital radiographical evaluation were performed after 6, 12, 18, 24, and 48 months (Fig. [7b\)](#page-11-0). No subjective discomfort e). This bioceramic was also holded as a provisionary filling. (**b**) Radiographical follow-up after Biodentine™ pulpotomy up to 48 months with full apexogenesis

was reported during the entire follow-up period. Clinically, the tooth remained vital, and no discoloration was observed. Radiographically, starting from 18 months, complete apexogenesis was evident, and this was further confirmed at the 24- and 48-month follow-up.

#### **5 Conclusions**

With the better understanding of the dentin– pulp complex and its molecular biology in conjunction with the development of newer materials especially based on hydraulic tricalcium silicate cements, a total paradigm shift has become possible for the management of deep carious lesions in the primary dentition and in immature permanent molars as well as in traumatic injuries. The use of hydraulic tricalcium silicate–based materials in pediatric endodontics is the best clinical practice with a most favorable outcome.

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