R.T.R.
β-TCP FOR BONE REGENERATION
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PAOLO BRUNAMONTI BINELLO
MASSIMO GALLI
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R.T.R.
ALLOPLASTIC GRAFTS - β-TCP
MARIO ERNESTO GARCÍA-BRIGEÑO

BIODENTINE™
PULPOTOMY ON PRIMARY MOLARS
LUIC MARTENS & RITA CAUVELS

BIODENTINE™
PULP CAPPING
LUIC MARTENS & RITA CAUVELS
Since its foundation Septodont has developed, manufactured and distributed a wide range of high quality products for dental professionals.

Septodont recently innovated in the field of gingival preparation, composites and dentine care with the introduction of Racegel, the N’Durance® line and Biodentine™, which are appreciated by clinicians around the globe.

Septodont created the “Septodont Case Studies Collection” to share their experience and the benefits of using these innovations in your daily practice. This Collection consists in a series of case reports and is published on a regular basis.

This 9th issue is dedicated to two of Septodont’s innovative products:

- **R.T.R.**, an easy-to-use synthetic bone grafting material. In addition to its ability to provide an optimal osteoconductive environment to promote the growth of new dense bone, R.T.R. comes in 3 different presentations to suit all the clinical situations.

- **Biodentine™**, the first biocompatible and bioactive dentin replacement material. Biodentine™ uniqueness not only lies in its innovative bioactive and “pulp-protective” chemistry, but also in its universal application, both in the crown and in the root.
Use of ß-tricalcium phosphate for bone regeneration in oral surgery  
Giuseppe Galvagna, Paolo Brunamonti Binello, Massimo Galli and Mauro Labanca

Alloplastic Grafts - Beta-tricalcium phosphate  
Mario Ernesto García-Briseño

Biodentine™ - Pulpotomy on primary molars  
Luc Martens and Rita Cauwels

Biodentine™ - Pulp capping  
Luc Martens and Rita Cauwels
Use of β-tricalcium phosphate for bone regeneration in oral surgery

A multicenter study to evaluate the clinical applications of R.T.R. (Resorbable Tissue Replacement)

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In prosthetic implant rehabilitation, loss of bone volume in atrophic maxillae is one of the major problems faced by surgeons in their clinical practice. In the presence of horizontal and vertical bone defects, atrophic ridges need to be restored to make them suitable for implant placement and for restoration of masticatory and aesthetical functions. For this reason, in recent years the term “GBR” has been closely associated with the concept of prosthetically guided implantology. The purpose of this study is to demonstrate the osteoconductive properties of synthetic biomaterials, particularly β-tricalcium phosphate or R.T.R., and its benefit for a suitable GBR.

Introduction

In order to obtain effective bone regeneration using natural or synthetic fillers, a series of favourable conditions must occur that allow the body to perform the bone growth (15) as follows:
- presence of a blood clot with a high concentration of mesenchymal stem cells (MSC) capable of evolving in the osteoblast line and of endothelial cells forming a rich vascular network
- presence of vital bone tissue, from which osteogenic and angiogenic cells originate

through adequately prepared surrounding bone (cortical perforation)
- stabilization and maintenance of volume underneath the membrane
- protection of blood clot with a membrane, with the function of the stabilization of the clot, protecting growing vascular structures and blocking the migration of epithelial cells, which proliferate faster than bone cells.

In 1980 Nyman and Karring first introduced the concept of guided tissue regeneration (GTR) of
periodontal tissues, showing that the cells of soft tissue can grow faster than bone tissue (10). Thus, based on the results obtained, the migration of soft tissue cells above the implanted material must be stopped, thereby blocking migration within the porosity of the same material, thus promoting osseointegration rather than fibrointegration. The main characteristic of a membrane should be semi-permeability, i.e. the presence of porosity approximately 22 microns in diameter. Initially, a thin vascular network and a primary fibrous osteoid tissue -also called primary spongiosa- will begin to form within the clot. The latter is later mineralized thanks to osteoblasts that cover its surface, forming a new poorly calcified cortical bone. The process stops when intertrabecular spaces narrow due to the formation of new bone tissue, until they reach the characteristic dimensions of Havers channel which, along with concentric lamellae, originate primary osteomas. All this occurs during the first 3-4 months, though actual bone remodelling requires more time, as it creates secondary spongiosa. Research conducted by Hämmerle in 1996 (11) on human subjects confirmed what had previously been observed in animals, i.e. in the presence of large bone defects, regeneration can be limited to the more peripheral areas of the defect, while less activity is observed in the central area, where granules of biomaterial remain over time, though less frequently when tricalcium phosphate is used. The process of ossification always starts from the walls of the defect toward the center of the clot, along the newly formed vessels. A number of studies clearly describe the regenerative ability of autologous bone compared with synthetic biomaterials, but unfortunately not without negative aspects. Indeed, collection from the donor site is very often painful for the patient; additionally, this results in longer surgical procedures and postoperative pain; finally, the implanted material has a high degree of resorption (not a negligible factor). The materials used for bone regeneration are grouped into: Autogenous bone, allogenic bone, xenogenic bone, alloplastic bone.

Graft biomaterials

The alloplastic biomaterials available on the market represent an excellent alternative to autologous bone graft and are classified into two large groups: bioinert and bioactive, according to their interaction when they come into contact with the receiving site. The main requirement of a synthetic biomaterial is to have a surface porosity that must promote colonization and development within its structure. These porosities must measure between 200/400 microns in diameter (Lynch et al., 2000; Bauer and Muschler, 2000). Synthetic biomaterials have been the subject of many studies, though their long term results have not always been considered. (1-2-3) Today, osteoblastic cells or bone morphogenetic proteins (BMP obtained with in vitro cultures) can be added to a graft material (4-5) to enhance its osteoinductive and osteoconductive abilities and therefore reduce the time required for cells colonization. (6-7-8) Among alloplastic biomaterials, β-tricalcium phosphate is the one that mostly displays a stable bond with bone neoformation; indeed, its characteristics have made it suitable for use in orthopedics since the early 1900s. In the presence of H2O it becomes instable, turning into hydroxyapatite, and this characteristic makes it suitable as an osteoconductive material (Coetree, 1980, De Leonardis and Pecora, 1999; 2000). β-TCP is characterized by a lower Ca/P ratio, which makes it more soluble than natural apatite. The Beta form is commonly obtained by mixing calcitis (CC) and dibasic calcium phosphate anhydrous (DCPA). The product obtained is rapidly cooled, and Alfa-TCP is obtained. Conversely, extended repeat baking at 800/950°C results in the beta form (9-12-13). Multiple studies conducted on the TC and bone interaction have shown that histological examination at four months shows an initial bone neoformation in the intergranular spaces and in the surface porosity that helps guided bone formation. Indeed, the granules are reabsorbed by phagocytosis, releasing Ca/Mg and phos-
phosphates in the surrounding bone tissue, thereby activating alkaline phosphatase, a key ossification process. Between 6 and 18 months, fibroblasts begin invading the biomaterial, activating the extracellular dissolution process which ends with the calcification phase. If this should occur sooner, graft integration, rather than biodegradation, would happen. (5-6-7-8).

**R.T.R.**

Synthetic, biocompatible and totally resorbable 99% pure tricalcium phosphate bone replacement, available in granules and in a cone shape, for regeneration in periodontal defects, implant, post-extraction bone defects and bone lesions following endodontic surgery.

The micro and macro-porous R.T.R. structure, with macropores measuring between 100 and 400 µm and micropores measuring less than 10 µm. These morphological characteristics allow excellent osteogenic cell in-depth colonization and easy compacting.

Unlike hydroxyapatite, R.T.R. is progressively and totally reabsorbed, thereby releasing calcium and phosphate ions that participate actively in the formation of new bone tissue. Over a period of time between 6 and 9 months, which may vary according to the patient’s physiological response, while stimulating bone regeneration, R.T.R. is progressively reabsorbed, leaving space for bone neoformation.

**Indications:**
- Post-extraction sites
- Filling post-extraction sites to maintain the dimensions of alveolar bone
- Implant defects
- Sinus lift procedure
- Reconstruction of peri-implant defects
- Filling periodontal pockets with two or more walls
- Residual cavities after oral surgery (like cyst)
- Filling defects after apicectomy
- Alveolar filling following extraction of impacted teeth.

**Materials and methods**

We conducted a multicenter study to evaluate the clinical application of R.T.R. (β-tricalcium phosphate).

This study examines the regeneration of bone defects with R.T.R. (β-tricalcium phosphate) in patients eligible for prosthetic implant rehabilitation. Patients were randomly selected, according to the following key criteria:
- aged between 20 and 60 years
- either male or female
- non-smokers
- in good general health
- having at least one crestal bone defect (no morphology and etiopathogenesis restrictions).

The cases treated were identified in the following clinical situations:
- Post-extraction sites
- Bone regeneration around implants placed in areas with bone loss or post-extraction.
- GBR (sinus lift or major bone defects).

In all cases, patients received antibiotic therapy with 1 gr every 8 h of Amoxicilline plus Clavulanic Acid (starting 24 hours before surgery up to day 5 post-surgery), repeated daily rinses with chlorhexidine and therapy with FANS (ibuprofen 800 mg/day in single dose), as necessary.
Case Report no.1

Patient: Female
Age: 30
History: odontogenic cyst in maxillary bone at 2.1.
Cyst was removed in October 2013. Vertical guided regeneration with resorbable membrane and R.T.R. was performed. Implant placement: bone peak follow-up intraoral X-ray in consecutive months. 2nd surgery ISQ value: 61.

Fig. 1-4: Different projections of radiographic C.T images show the large bone defect in site 2.1.

Fig. 5: Temporary prosthesis to cover the cosmetic defect.

Fig. 6: X-ray image before grafting.

Fig. 7: X-ray image after 5 months.

Fig. 8: X-ray after insertion of the implant.

Fig. 9: The local objective examination and routine radiographic examination showed a good short-term healing.

Fig. 10: The ISQ test confirms a good stability of the implant.

Fig. 11: To obtain a good aesthetics of the final prosthesis is important to condition the soft tissue with the healing screws that favors the emergence profile.
Case Report no.2

Patient: female
Age: 60
History: large cyst in upper maxillary bone extending from 2.2 to 1.1.
The cyst was removed and the cavity was filled with R.T.R. enhanced with PRGF (platelet-enriched plasma) and simultaneous placement of five implants was also performed.

Fig. 12-13: Presence of large cysts of 2.1. The oral cavity examination shows a poor oral hygiene.

Fig. 14-15: Removal of the cyst; it is very important to remove all residual epithelial.

Fig. 16-17-18: Filling the bone cavity with granular R.T.R.

Fig. 19-20: During the same surgery were included five implants.

Fig. 21: X-ray control after five months.
Case Report no.3

Patient: female  
Age: 50  
History: severe atrophy of the alveolar ridge, upper right jaw, affecting the area of 1.3, 1.4, 1.5, 1.6. These teeth were extracted and the alveolar ridge was reconstructed with R.T.R., covering biomaterial with Tabotamp (oxidized cellulose).

Fig. 22-23: Resorption of the alveolar process caused by periodontal disease. The local examination shows the class III mobility of the teeth.

Fig. 24-25-26: Resorption of the alveolar process caused by periodontal disease. The local examination shows the class III mobility of the teeth.

Fig. 27-28: Use of Tabotamp to cover the graft.

Fig. 29-30: The local examination after 10 days.

Fig. 31-32: The radiographic image after 4 months showed an increase in the vertical dimensions.
Case Report no.4

**Patient:** female  
**Age:** 30  
**History:** root fracture of 1.6, previously treated with root canal treatment and large crown composite reconstruction. The roots were carefully extracted, and an implant was placed, using the interradicular septum bone and by performing an elevation of the maxillary sinus with osteotomes. The alveoli were filled with R.T.R. and covered with a collagen membrane.

Fig. 33-34: Fracture of the first molar with the insertion of implant with post-extraction procedure.

Fig. 35-36-37: Extraction was performed with piezosurgery technique to preserve the alveolar bone.

Fig. 38-39-40: The gap was filled using R.T.R.-size cone.

Fig. 41-42: The intraoral examination and radiographic examination after 4 months showed good integration of the implant.
Case Report no.5

**Patient:** female  
**Age:** 64  
**History:** loss of 2.2 and 2.3 due to trauma.  
CT revealed a significant resorption of buccal vestibular alveolar process.  
Two implants were placed (measuring 3.3 mm in diameter and 13 mm long) and the gap was filled with R.T.R.  
Re-opening was done after 5 months and evaluation of osteointegration with Osstel.  
2.2 showed a value of 22-ISQ, and 2.3 –ISQ 64.

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**Fig. 43-44-45:** Severe post-traumatic atrophy of the alveolar process in place 2.2-2.3.

**Fig. 46-47:** Insertion of two implants with “split-crest” surgical technique.

**Fig. 48-49:** The gap between the two margin bone was filled with phosphate-tricalcium R.T.R.

**Fig. 50:** X-ray control after 4 months showed a good bone density.

**Fig. 51-52:** The intraoral examination does appreciate a good recovery and an increase in bone volume.

**Fig. 53-54:** The ISQ value confirms a good osseointegration.
Case Report no.6

**Patient**: female  
**Age**: 55  
**History**: residual cyst at 3.6. To proceed to prosthetic molar rehabilitation with an implant, the cyst was extracted and the cavity was filled with R.T.R.; after a 4-month period for bone regeneration, the implant was placed.

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**Conclusion**

Based on the results obtained in the short term, the authors confirm the excellent properties of R.T.R., both in the first weeks of healing and in the following months, and they consider it an excellent alternative to autologous bone grafts. No inflammatory reactions or loss of bone volume evaluated clinically and radiographically occurred in any of the cases examined. The most encouraging data came from the observation of the compactness and density of the bone neo-formation, which easily allowed the placement of implants with high ISQ values both during and after the placement of R.T.R. graft.
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### Alloplastic Grafts - Beta-tricalcium phosphate

#### Presentation of clinical cases

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This case report presents a brief review of bone loss due to periodontal infection and tooth extraction, and evaluates the biological characteristics, description and indications of an alloplastic graft material, beta-tricalcium phosphate, as an alternative treatment in two clinical cases.

#### Introduction

The effects of periodontal infection and its consequences, attachment and bone losses, result in the formation of periodontal bone defects (1,2). Tooth extraction involves two processes, the healing of the alveolus (3) and any change that may appear during post-extraction healing (4). The clinical consequences of tooth extraction are the resorption of the alveolar ridge (5) and the pneumatization of the maxillary sinus (6). If the effects of periodontal disease and tooth extraction are combined, the consequences will be even more severe and will complicate tooth restoration (7). The use of bone grafting materials prevents and/or repairs the insufficient bone conditions due to the previously mentioned situations (8). We will first evaluate the biological characteristics (9) of the alloplastic graft material, beta-tricalcium phosphate, before presenting Clinical Cases using a commercial presentation of beta-tricalcium phosphate. The objective of this presentation is to demonstrate the clinical applications of beta-tricalcium phosphate alloplastic graft in periodontal bone defects and extraction sites.

#### Modifications in the Alveolar Process

The most common modifications involving the bone tissue of the oral cavity are: Horizontal bone loss due to periodontal infection, bone defects caused by periodontal disease, tooth extraction resulting in vertical and horizontal...
resorption, pneumatization of the maxillary sinus and a combination of these. The clinical consequence of these conditions are inappropriate bone dimensions for prosthetics on natural abutment teeth and the placement of its substitutes, dental implants (10).

**Periodontal bone defects**

As a result of inflammatory and immune reactions to the presence of bacterial plaque and the way in which it progresses apically over the cement surface in one of the periodontal attachment components, the alveolar bone, specific patterns of destruction can be observed. These patterns depend mainly on the type of subgingival bacterial plaque and the anatomical characteristics of the alveolar process (11). Basically there are two bone loss patterns, horizontal or vertical forms. The vertical form of bone loss has been described as intrabony loss and the resulting defects have been historically classified according to the number of bone walls lost: one, two or three-wall intrabony defects. Other bone loss patterns have been described as osseous craters and circumferential defects. The special anatomy of molars and premolars involves furcations as a special condition in periodontal defect (12).

**Tooth extraction**

The consequences of tooth extraction represent specific conditions and a special challenge in conventional restorative dentistry and oral rehabilitation, especially with the use of dental implants (13). Whether in case of single or multiple implants - as abutments for fixed bridges and/or removable prosthesis – or in complete oral rehabilitation, the bone loss that follows tooth extraction in alveolar area or in edentulous arch represents a clinical challenge (14). The consequences of this biological process are both functional -which complicates the prosthesis design - and aesthetic, especially in the anterior zone. After tooth extraction, the alveolus has a very high and predictable chance of healing in a natural and healthy way without any intervention. The biological principle of the alveolus repair is based on the formation of a blood clot that covers it completely. Post-extraction healing process has been accurately described. The stages of this natural process may be summarised in the following manner: At 30 minutes: clot; at 24 hours: formation of blood clot and haemolysis; at 2-3 days: formation of granulation tissue. At 4 days: increase in fibroblast density and epithelial proliferation over the edge of the wound and presence of osteoclasts indicating the alveolus remodelling. At 1 week: defined vascular network and maturing connective tissue; osteoid formation in the bottom of the alveolus. At 3 weeks: dense connective tissue; full epithelial cover. At 2 months: full bone formation is complete but without reaching the original height (15,16).

**Graft Material Characteristics**

Autogenous bone is the only graft material that meets the requirement of being osteogenic activating new bone formation via viable osteogenic cells (Periostium osteoblasts, endostium, bone marrow cells, perivascular cells and undifferentiated and/or stem cells) which are transplanted with the material and is considered as the “Gold Standard” as it also has osteoinductive and osteoconductive properties (17,18). The term “Osteoinduction” implies the biological effect of inducing differentiation of pluripotent undifferentiated cells and/or potentially inducible cells to express the osteoblast phenotype leading to new bone growth both within bone tissue and in ectopic sites. i.e. sites in which there is no natural bone formation. Even though there are several molecules able of inducing “de novo" bone tissue formation, the Bone Morphogenetic Protein (BMP) is the main protein involved (19). The term “Osteoconduction” refers to the characteristic of the graft material to act as a scaffold or mesh on which existing bone cells can proliferate and form new bone. In the absence of this supporting structure
provided by the material, the defect or bone surface would be filled or covered by fibrous soft tissue. The porosity, pore size, shape, particle size and physical/chemical characteristics influence the biological effects of cell adhesion, migration, differentiation and vascularisation at the receptor site (20,21).

**Classification of graft materials by origin**

Autogenous materials or Autografts are tissues from the same individual transplanted from one site to another. Viable cortical or spongy/medullar bone is commonly used in periodontology and maxillofacial surgery. Allogenic materials or Allografts are tissue from one individual of the same species; usually via a freeze-drying process; bone and skin are the most common ones. Xenografts are tissue from different species; mainly mineral bone component or collagen. Alloplastic graft materials are synthetic materials, i.e. they are manufactured by industrial processes and the most representative in medical dental use are Hydroxyapatite, β-Tricalcium Phosphate and Bioactive glasses or polymers (22).

**Beta-tricalcium phosphate**

Beta-tricalcium phosphate (β-TCP) is a synthetic ceramic bone graft material which has been used in orthopaedic and dentistry -periodontology and maxillo-facial surgery - for more than 30 years (23). β-TCP can be treated during the manufacturing process so that it has a structure similar to the bone mineral component, either in a block or in particles similar to spongy or trabecular bone (24). This structure has randomly interconnected pores. Porosity may range from 20% to 90%. The variation in pore size ranges from 5µm to 500µm depending on the particle size. The particle size in dental use is generally inferior to 1000µm. The mechanism of action of β-TCP as a graft material is via osteoconduction with the subsequent resorption and replacement by host bone. (25) Osteoconduction is facilitated by the interconnection between pores. In the biological process the material is resorbed and replaced by bone from the receptor individual. When the graft is placed in the receptor site, serum proteins are adsorbed on the surface of the particles, which later favours cell migration to initiate neovascularisation in the porous structure. Over time, the particles inferior to 1 micron start to dissolve and are then resorbed in a process mediated by phagocytic cells, thus allowing bone deposit over the material. The level of porosity and the particle size will define the resorption rate and the bone replacement process which occurs in 9 to 12 months in average (26).

**Case Report no.1**

48-years-old male patient in general good health conditions with two localized areas presenting some discomfort since a couple of months mainly in tooth 15 where the patient refers recurrent swelling but without need to take analgesics. A full periodontal examination reveals a localized distal periodontal probing of 10 mm with bleeding and suppuration and a mild redness (Fig. 1).

![Fig. 1: Bleeding and suppuration in 10 mm pocket in tooth 15](image)
On X-ray examination a wide distal intrabony-two walls defect is present (Fig. 2). The previous root canal treatment seems without complications in the periapical area. The localized periodontal attachment loss and the overall periodontal health could support the etiology of pulpar complication i.e. a lateral canal since the patient report at least 8 years of root canal treatment after a painful episode in the tooth.

A flap debridement procedure is indicated and it is confirmed the bone defect and irregular bone loss in the vestibular cortical plate. (Fig. 3).

With the pulpar involvement as main etiology an effort is done to find clinical evidence i.e. localized area of resorption and/or lateral foramen without confirmation. It is decided to use β-tricalcium phosphate “R.T.R.” (Septodont) as a graft material. (Fig. 4).
Case Report no. 2

A second problem is identified at the periodontal examination in tooth 46 and confirmed with the X-ray. An extensive root resorption on the distal root is present (Fig. 7) with any symptom reported by the patient except some discomfort and “bad taste” occasionally. The root canal treatment was done at the same time than tooth 15 (eight years before). The clinical condition makes difficult to try endodontic retreatment or other treatment options like hemisection, the extraction is indicated. In order to avoid the collapse of the residual alveolar bone and the socket, particles of β-tricalcium phosphate “R.T.R.” (Septodont) is used as graft material. (Fig. 8, 9).

Conclusion

In concepts of Osteogenesis, remains today still open the debate as to which type of currently available bone grafting material is the best.

Fig. 7: X-ray showing extensive root resorption on the distal root of tooth 46.

Fig. 8: Clinical view showing the extensive bone loss in the residual ridge after the tooth extraction. Notice the minimal width at the crestal area in the buccal and lingual plates and the attachment loss at the mesial root of tooth 47.

Fig. 9: Composite blood clot and β-tricalcium phosphate “R.T.R.” (Septodont) used as graft material prior the suture. In the area of resorption a cone shaped β-tricalcium phosphate “R.T.R.” (Septodont) is used and in the mesial root alveolus particles of β-tricalcium phosphate “R.T.R.” (Septodont) are used.

Fig. 10: X-ray taken immediately after the surgical procedure showing β-tricalcium phosphate “R.T.R.” (Septodont) in the bone defect and mesial root alveolus.

Fig. 11: 6 months of clinical healing.

Fig. 12: X-ray 6 months post-surgery where the particles of β-tricalcium phosphate “R.T.R.” (Septodont) have been replaced by recently formed trabecular bone in the bone defect and mesial root alveolar.
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Biodentine™
Pulpotomy on vital carious primary molars

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In pediatric dental care, we try to keep primary teeth free of caries until they are replaced naturally. However, extensive caries in contact with the pulp still occurs. In such cases, a timely endodontic procedure can enable us to avoid early extraction of primary teeth, thereby preserving the primary objective of dental caries treatment, which is to maintain the function of chewing, speaking, swallowing and esthetic appearance.

Introduction

Diagnosis in children presenting with pain is not always easy. Pulpal diagnosis in primary teeth is imprecise as clinical symptoms do not reflect the histologic condition of the pulp. Age and behavior may jeopardize the reliability of pain as an indicator of the degree of pulpal inflammation. Also, asymptomatic chronic pulpitis is seen in primary molars. Therefore, adequate radiographic diagnosis is necessary in cases of multiple caries.

Why pulpotomy?

In primary teeth, pulpotomy is the most widely accepted pulpal treatment throughout the world. Above all, it is the complex root canal anatomy of the primary teeth, the proximity of permanent teeth and the absence of filling materials compatible with physiologic root resorption that determine this choice. A pulpotomy is based on the hypothesis that the inflammation and reduced vascularization, caused by bacterial invasion, are confined to the coronal pulp, while the root pulp remains vital (Fig. 1)³.

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Fig. 1: Pulpotomy: Overview of preparation, control of bleeding and product application
An ideal pulpotomy material should be bactericidal, promote root pulp healing, provide a relatively stable environment for the dentin-pulp complex, stimulate dentin-pulp complex regeneration and not disturb the physiologic process of root resorption.

An ideal material for pulpotomy

- Remove any caries and the pulp from the pulp chamber
- Control bleeding at the canal entrances
- Mix the material following the manufacturer’s instructions
- The material can be applied deep within the cavity with a spatula or amalgam carrier.
- The material can be compacted using dry pluggers or cotton pellets.

How to perform pulpotomy with Biodentine™

- On no account should the cotton pellets be moistened with water (!); any residual liquid from Biodentine™ (calcium chloride) may be used for moistening later, after which the cotton pellet should be squeezed out thoroughly using a towel.

What the literature tells us

Despite its limited bactericidal action and potential toxicity, formocresol is regarded as the reference standard worldwide. Iodoform pastes which have a greater bactericidal action and are histologically better tolerated are less widespread and are used more on a regional level. At the same time, scientific evidence has emerged showing that pulpotomy performed with Mineral Trioxide Aggregate (MTA) produces better clinical and radiographic results than formocresol.

Meanwhile, Biodentine™, a non-metallic, inorganic, tricalcium-silicate (Ca₃SiO₅)-based restorative cement, marketed and recommended as a “bioactive dentin substitute”, has been shown to have much better physical and biologic properties, such as material handling, faster setting time, better resistance to pressure, greater leak resistance and faster dentin bridge formation compared with MTA. Although clinical studies (long-term studies) are still rare, Biodentine™ appears to be an effective substitute for MTA in pulpotomy.

Fig. 2: Comparison of percentage success of formocresol and MTA
Choice of filling material after pulpotomy

Biodentine™ can be used as a temporary filling material that can be exposed to saliva for 6 months. This can be an advantage for lengthy treatments or in uncooperative children. If the dentist wishes to make a permanent filling, he or she is then advised to wait 6 minutes until the material has completely hardened, after which bonding restoration can be performed. Studies have shown that etching the Biodentine™ surface with a \( \text{H}_3\text{PO}_4 \) gel for 15 seconds and applying a bonding layer achieves greater adhesive strength and less micro-infiltration\(^5\). It is also possible to opt for a steel crown.

Case studies

All the cases described below took place under general anesthesia as part of a randomized clinical trial (RCT).

Case no.1

In a 6-year-old girl, pulpotomy with Biodentine™ was performed on tooth 75. The radiograph at one-year follow-up showed no complications whatsoever (Fig. 3).

Case no.2

In a 5-year-old boy in whom tooth 84 had been treated by pulpotomy with Biodentine™, the radiograph at 1-year follow-up shows complete obliteration (Figs. 4-5-6).

In the RCT in progress at the Pedodontics Department, obliteration is the most common observation when Biodentine™ is used for pulpotomy of primary molars. It is considered a positive sign as obliterated canal pulp usually does not cause any clinical complications.
Case no.3

A 3-year-old girl had been treated 1 year previously for multiple caries. Pulpotomy was then performed with Biodentine™ on tooth 75 (Fig. 7). After 6 months of follow-up, there were no complaints such as spontaneous pain, tenderness on percussion, tenderness on palpation, increased mobility or swelling. A sign of internal resorption on the mesial root was visible on the radiograph (Fig. 8). It was decided to follow up the tooth every 3 months. After 9 months of follow-up, the patient had no pain and the tooth was in order clinically. After 12 months of follow-up, the tooth was still not causing any problems. Early obliteration was visible on the radiograph in the place of the internal resorption (Fig. 9). The appearance of internal resorption after pulp treatment is attributed to inflammation of the residual pulp whereas obliteration results from increased activity of odontoblast-like cells. The formation of tertiary dentin leads to obliteration and should be considered an attempt by vital pulp tissue to heal. Consequently, in the case presented above, the incipient inflammation may have been halted, leading to a healing process.

Remarks

- Owing to limited radio-opacity, it can sometimes be difficult to see dentin bridge formation and it can be confused with natural dentin. In a 6-year-old girl, 3 pulpotomies were performed with three different materials. The radio-opacity of the 3 materials can be compared on the radiographs (Figs. 10, 11 and 12).
- A major advantage of Biodentine™ over MTA is the absence of grayish-black discoloration. Figure 13 shows a clinical view of a primary tooth treated by MTA pulpotomy a year earlier. Figure 14 shows a clinical view of a primary tooth treated with Biodentine™, also at 1-year follow-up. There is absolutely no discoloration.
Clinical Success

As a pulpotomy material, MTA has been shown to produce better clinical and radiographic results than formocresol. In the authors’ clinical study, no clinical or radiographic differences were found between Biodentine™ and MTA when used as a pulpotomy agent in carious primary molars.

Conclusion

The era of formocresol and other mummification products for the treatment of deep caries of vital primary molars appears to be past. In regard to MTA, a modified Portland cement, there is already a fair amount of evidence in the literature. Biodentine™, with its superior properties in comparison with MTA, also appears to show this in clinical practice. Moreover, the absence of coronal discoloration is a major additional benefit.

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References

Introduction

It is a well-known fact that calcium hydroxide has a major antibacterial action and thereby minimizes or eliminates bacterial penetration. While this has been recognized for decades, the healing mechanism has only recently been described. “Bone morphogenetic protein” and “bone transforming growth factor beta 1” play a very important role here, in both pulp healing and new dentin formation. However, the disadvantages of calcium hydroxide are that it does not have good adhesion on its own, resulting in poor sealing, and that it is highly soluble. MTA, well known as an aggregate of tricalcium silicate, dicalcium silicate and tricalcium aluminate, has, with water, calcium hydroxide as its principal reaction product. It is to this that MTA owes its biocompatibility. Moreover, a single seal with dental tissue is found, following a bioactive reaction. Another disadvantage is its high solubility and long setting time. Three studies were published between 2003 and 2008 in which no clinical differences were found between calcium hydroxide and MTA, while 4 other studies considered MTA to be more effective. However, histologic studies revealed that there was less pulpal inflammation with MTA and that a tissue barrier with superior hardness was formed. A very recent (2013)
practice-based randomized clinical trial has established the superiority of MTA as a direct capping material.

As regards Biodentine™, various in vitro animal experiments have established its biocompatibility, bioactivity and ability to induce pulp healing. In a study on direct capping in piglets, Biodentine™ showed much faster hard tissue induction than calcium hydroxide in the short term (1 week). However, beyond 3 months, no further difference

in barrier formation was observed. It was shown, via a “human dental culture model”, that Biodentine™ and ProRoot™ MTA both initiated reparatory dentin synthesis. The possibility of inducing cell proliferation as well as biomineralization was clearly demonstrated on immortalized murine pulp cells.

In a study of human pulp in which capping was performed on premolars due for extraction for orthodontic reasons, no difference between MTA and Biodentine™ was apparent. In both cases, complete dentin bridges were observed in the presence of inflammatory cells. Moreover, layers of odontoblasts and pseudo-odontoblastic cells forming tubular dentin were observed.

Besides the good histologic reactions established since then, Biodentine™ has the added advantage that discoloration never occurs (unlike MTA) and that the material can act as a temporary filling material and be exposed to saliva for a certain number of months. This is comforting for both patient and practitioner.

Case report

Patient A (7 years) presented for treatment of caries on tooth 46. He had not previously complained of pain. During curettage (see Fig. 1a), the pulp was almost exposed. After eccentric removal of all the caries, indirect capping was performed with Biodentine™, after which the entire cavity was filled with it. Figures 1b and 1c show the radiographic image before and after. During follow-up, no subjective complaint was reported. After only a year, the continued formation of radicular apices was apparent on radiographs. The formation of hard tissue in the pulp chamber is also probable (Fig. 2b).

In patient B (14 years) very deep caries was found on tooth 47 during treatment (Fig. 3a). There had been no previous symptoms. Biodentine™ was placed inside the entire cavity (Fig. 3b). Figures 3c and 3d illustrate Biodentine™ in place immediately after treatment and a few weeks later, respectively. Due to its special properties, Biodentine™ can be used as a temporary

![Fig. 1: Indirect capping of tooth 46 with Biodentine™](image1)

![Fig. 2: Radiograph after treatment (2a) and at 12-month follow-up (2b)](image2)

![Fig. 3: Deep caries on tooth 47 (a) and radiograph after treatment with Biodentine™ (b) clinical view after immediate treatment with Biodentine™ (c) and after 4 weeks (d)](image3)
filling material, unlike MTA. Here also, there were no complaints of pain during the follow-up period. In patient C (12 years) who had absolutely no complaints previously, an occlusal lesion was treated and the pulp was almost exposed unexpectedly (Fig. 4a). Biodentine™ was placed here as a cap and cavity lining (Fig. 4b) and immediate restoration with composite was performed (Fig. 4c, d). The patient had no complaints of pain during the follow-up period.

In patient D (11 years) deep caries on tooth 46 was detected radiographically, on which pulp exposure appeared inevitable (Fig. 5a). Direct capping with Biodentine™ was performed (Fig. 5b). There were no further complaints at follow-up. The control radiographs suggest the formation of hard tissue after 4 and 8 months (Fig. 5c, d).

### Conclusion

Biodentine™ calcium silicate cement is suitable for use as a capping material for deep carious lesions and pulp exposure. The material can be used as a temporary filler and can be exposed to saliva for a certain number of months and act as a cavity liner, on which an immediate composite restoration can be placed. Clinical follow-ups reveal no complaints from patients at 2-3 years. Radiographs show continued maturation of immature molars and hard tissue formation can be seen in pulp chambers.

### References

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