The use of premixed bioceramic materials in endodontics

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Abstract With both antimicrobial and sealing properties, premixed bioceramic materials are unique materials available in endodontics that contribute to the success of both the microbial control phase (instrumentation, irrigation, intra-canal medication) and the filling phase (root and top filling) of root canal treatment. Bioceramic material may be an essential element in the indirect and direct pulp capping and pulpotomy procedures that are an integral part of endodontic therapy’s goal of maintaining the vital pulp to ensure a healthy periapical periodontium. For all these reasons, premixed bioceramic materials are now the material of choice for pulp capping, pulpotomy, perforation repair, root-end filling, and obturation of immature teeth with open apices, as well as for sealing root canal fillings of mature teeth with closed apices. © 2016 Società Italiana di Endodonzia. Production and hosting by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Riassunto Scopo: Avendo sia proprietà antimicrobiche che sigillanti, i materiali bioceramici premiscelati sono materiali unici disponibili in endodonzia che possono contribuire al successo sia nella fase di

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Introduction

Microbes within the root canal system are the cause of apical and periradicular periodontitis (endodontic disease). The absence of microbes ensures that apical periodontitis of endodontic origin does not occur. Therefore, the aim of endodontic treatment is to prevent microbial contamination of the root canal system and/or to remove enough microbes to ensure clinical and radiographic success. A common misconception is that endodontics encompasses only root canal treatment, retreatment, or surgical treatment of post-endodontic disease. Nothing could be further from the truth. A major part of endodontics is maintaining the vital pulp to ensure a healthy periradicular periodontium. Thus, in addition to root canal treatment, indirect and direct pulp capping and pulpotomy procedures are integral parts of endodontic therapy. Root canal treatment is divided into the microbial control phase (instrumentation, irrigation, intra-canal medication) followed by the filling phase (root and top filling). With both antimicrobial and sealing properties, premixed bioceramic materials are one of the few materials available in endodontics that contribute to both critical phases for endodontic treatment success.

Bioceramics

Bioceramics are ceramic materials specifically designed for medical and dental use. During the 1960s and 1970s, these materials were developed for use in the human body such as joint replacement, bone plates, bone cement, artificial ligaments and tendons, blood vessel prostheses, heart valves, skin repair devices (artificial tissue), cochlear replacements, and contact lenses. Bioceramics are inorganic, non-metallic, biocompatible materials that include alumina and zirconia, bioactive glass, coatings and composites, hydroxyapatite and resorbable calcium phosphates, and radiotherapy glasses. They are chemically stable, non-corrosive, and interact well with organic tissue. Bioceramics are classified as:

- bioinert—non-interactive with biologic systems;
- bioactive—durable in tissues that can undergo interfacial interactions with surrounding tissue;
- biodegradable, soluble, or resorbable—eventually replace or are incorporated into tissues.

There are numerous bioceramics currently in use in dentistry and medicine. Alumina and zirconia are bioinert ceramics used in prosthetics. Bioactive glass and glass ceramics are available for use in dentistry under various trade names. In addition, porous ceramics such as calcium phosphate-based materials have been used for filling bone defects. Some calcium silicates (mineral trioxide aggregate [MTA], ProRoot®, MTA Root Repair, DENTSPLY Tulsa Dental Specialties) and bioaggregates (DiaRoot®, BioAggregate, DiaDent) have also been used in dentistry as materials for root repair and for apical root filling.

Bioceramics in endodontics

Bioceramic materials used in endodontics can be categorized by composition, setting mechanism, and consistency. There are sealers and pastes, developed for use with gutta-percha, and putties, designed for use as the sole material, comparable to MTA. Some are powder/liquid systems that require manual mixing. The mixing and handling characteristics of the powder/liquid systems are very technique sensitive and produce a considerably waste. Premixed bioceramics require moisture from the surrounding tissues to set. The premixed sealer, paste, and putty have the advantage of uniform consistency and lack of waste. These premixed bioceramics are all hydrophilic.

Endodontic bioceramics are not sensitive to moisture and blood contamination and therefore are not technique sensitive. They are dimensionally stable and expand slightly. When set, they are hard, allowing full compaction of a final restoration, and they are insoluble over time, ensuring a superior long-term seal. When setting, the pH is above 12 due to the hydration reaction, which first forms calcium hydroxide and then dissociates into calcium and hydroxyl ions. Therefore, when unset, the material has antibacterial properties. When fully set, it is biocompatible and even bioactive. When bioceramic materials come in contact with tissue fluids, they release calcium hydroxide, which can interact with phosphates in the tissue fluids to form hydroxyapatite. This property may explain some of the tissue-inductive properties of the material. For the reasons above, these materials are recommended for pulp capping, pulpotomy, perforation repair, root-end filling, and obturation of immature teeth with open apices,
as well as for sealing root canal fillings of mature teeth with closed apices.

Available bioceramic materials in endodontics

Mineral trioxide aggregate (MTA)

Few clinicians realize that original MTA is a classic bioceramic material with the addition of some heavy metals. MTA is one of the most extensively researched materials in the dental field.\(^{12,13}\) It has the properties of all bioceramics—i.e., has a high pH when unset, is biocompatible and bioactive when set, and provides an excellent seal over time. It has some disadvantages, however. It requires mixing, resulting in considerable waste, is not easy to manipulate, and is difficult to remove from the root canal when set. Clinically, both gray and white MTA stain dentin, presumably due to the heavy metal content of the material or the inclusion of blood pigment while setting.\(^{14,15}\) Finally, MTA is hard to apply in narrow canals, making the material poorly suited for use as a sealer together with gutta-percha. Efforts have been made to overcome these shortcomings with new compositions of MTA or with additives. However, these formulations affect MTA’s physical and mechanical characteristics.

Biodentine

Biodentine\(^{14}\) (Septodont) is considered a second-generation bioceramic material. It has properties similar to MTA and thus can be used for all the applications described above for MTA.\(^{1,16}\) Its advantages over MTA are that it sets in a shorter period of time (approximately 10–12 min) and it has a compressive strength similar to dentin. A major disadvantage is that it is triturated for 30 s in a preset quantity (capsule), making waste inevitable, since in the vast majority of endodontic cases, only a small amount is required.

Endodontic premixed bioceramics

In 2007, a Canadian research and product development company (Innovative BioCeramix, Inc., Vancouver, Canada), developed a premixed, ready-to-use calcium silicate based material, iRoot\(^{14}\) SP injectable root canal sealer (iRoot\(^{14}\) SP).\(^{1}\)

Since 2008 these endodontic pre-mixed bioceramic products are available in North America from Brasseler USA as EndoSequence\(^{13}\) BC Sealer\(^{TM}\), EndoSequence\(^{13}\) BC RRM\(^{TM}\) (Root Repair Material\(^{TM}\), a syringable paste), and EndoSequence\(^{16}\) BC RRM-Fast Set Putty\(^{TM}\) (Fig. 2). Recently, these materials have also been marketed as TotalFill\(^{13}\) BC Sealer\(^{TM}\), TotalFill\(^{13}\) BC RRM Paste\(^{TM}\), and TotalFill\(^{13}\) BC RRM Putty\(^{TM}\) / Fast Putty\(^{TM}\) (Fig. 3) by FKG Dentaire, Switzerland.\(^{16}\)

All three forms of bioceramic are similar in chemical composition (calcium silicates, zirconium oxide, tantalum oxide, calcium phosphate monobasic, and fillers), and they have excellent mechanical and biological properties and good handling properties. They are hydrophilic, insoluble, radiopaque, and aluminum free with a high pH, and require moisture to set and harden. The working time of the BC Sealer and BC RRM is more than 30 min, and the setting time is 4 h in normal conditions, depending on the amount of moisture available. The recently introduced EndoSequence BC RRM Fast-Set Putty has all the properties of the original putty but with a faster setting time (approximately 20 min). RRM putties and paste are recommended for perforation repair, apical surgery, apical plugging, and vital pulp therapy. Pre-mixed BC Sealer is the only pure medical-grade bioceramic product available as a sealer for endodontic obturation. It has the same basic chemical composition as the other pre-mixed bioceramic products, but it is less viscous, which makes its consistency ideal for sealing root canals. It is used with a gutta-percha point, which is impregnated on the surface with a nano particle layer of bioceramic. The gutta-percha is used primarily as the delivery device (plugger) (Fig. 4) to allow hydraulic movement of the sealer into the irregularities of the root canal and accessory canals (Fig. 5).

Interestingly when the taper is not excessive and the gutta-percha point is used primarily as a plugger to move the sealer into the canal irregularities and accessory canals, a radiographic picture similar to the classical vertical condensation technique is often seen (Fig. 6). In addition, its surface bonding to the sealer eliminates a critical pathway for coronal leakage of microbes if the coronal restoration has a defective seal. The gutta-percha also is used as a pathway for post preparation or for retreatment if necessary.

Properties of the bioceramic sealer and potential changes in root filling technique:

1. The bioceramic sealer is highly hydrophilic and thus the natural moisture in the canal and tubules is an advantage, unlike most other sealers where moisture is detrimental to their performance.

Figure 1  Hydration reaction of bioceramic material in contact with water (A and B). Precipitation reaction of the bioceramic (C).
When unset, the bioceramic sealer has a pH of above 12. Thus its antibacterial properties are similar to calcium hydroxide. Setting is dependent on physiologic moisture in the canal, therefore it will set at different rates in different environments, but since it has a high pH any delay in setting can be argued as a benefit.

The sealer does not shrink, but expands slightly and it is insoluble in tissue fluids. If used with a gutta-percha point that is impregnated and coated with nano particles of bioceramic, as suggested, it will bond to the core point thus eliminating the gap between the core and sealer.

The properties listed above, particularly in the presence of a sealer that does not shrink and is insoluble in tissue fluids, should change the longheld rule that in root fillings the core material should take up as much space as possible in order to mask the shortcomings of the sealer and by keeping the sealer as thin as possible. In fact, if it were possible to fill the canal in a
homogeneous way, the need for a core material at all is questionable.

Studies on endodontic premixed bioceramic materials

To date, more than 70 studies have been performed on premixed endodontic bioceramic materials. The vast majority of these studies have shown that the properties conform to those expected of a bioceramic material and are similar to MTA.

Biocompatibility and cytotoxicity

Several in vitro studies report that BC materials display biocompatibility and cytotoxicity that is similar to MTA.\textsuperscript{22–32} Cells required for wound healing attach to the BC materials and produce replacement tissue.\textsuperscript{23} In comparison to AH Plus\textsuperscript{16} (Dentsply) and Tubli-Seal\textsuperscript{TM} (SybronEndo), BC Sealer showed a lower cytotoxicity.\textsuperscript{22,23} On the other hand, one study concluded that BC Sealer remained moderately cytotoxic over the 6-week period\textsuperscript{32} and osteoblast like cells had reduced

Figure 4  A representative radiograph of a root filled tooth with BC Sealer hydraulically moved with the gutta-percha point. Note that the cold hydraulic technique results in lateral canal “puffs” similar to the warm vertical technique.

Figure 5  Molar roots filled with BC Sealer cut at different distances from the apex (0.5 mm, 1.5 mm and 3 mm). One gutta-percha point is used as a plugger to move the sealer using hydraulic pressure. Note the irregularities are very well filled with the sealer.
bioactivity and alkaline phosphatase activity compared to MTA and Geristore\textsuperscript{33} (DenMat).

A recent study comparing the results of apicoectomies done with MTA or bioceramic putty on dogs showed the bioceramic putty to be slightly better than the MTA, presumably due to its superior handling properties.\textsuperscript{34}

### pH and antibacterial properties

BC materials have a pH of 12.7 while setting, similar to calcium hydroxide, resulting in antibacterial effects.\textsuperscript{8} BC Sealer was shown to exhibit a significantly higher pH than AH Plus\textsuperscript{35} for a longer duration.\textsuperscript{36} Alkaline pH promotes elimination of bacteria such as *Enterococcus faecalis*. In vitro studies reported EndoSequence Paste produced a lower pH than white MTA in simulated root resorption defects\textsuperscript{37} and EndoSequence Paste, Putty, and MTA had similar antibacterial efficacy against clinical strains of *E. faecalis*.\textsuperscript{38}

### Bioactivity

Several studies evaluated bioactivity. Exposure of MTA and EndoSequence Putty to phosphate-buffered saline (PBS)
resulted in precipitation of apatite crystalline structures that increased over time, suggesting that the materials are bioactive.\textsuperscript{39} iRoot SP exhibited significantly lower cytotoxicity and a higher level of cell attachment than MTA Fillapex, a salicylate resin-based, MTA particles containing root canal sealer.\textsuperscript{40} EndoSequence Sealer had higher pH and greater Ca\textsuperscript{2+} release than AH Plus\textsuperscript{15} and was shown to release fewer calcium ions than BioDentine\textsuperscript{R} (Septodont) and White MTA.\textsuperscript{41}

**Bond strength**

A number of studies evaluated bond strength. One study reported that iRoot SP and AH Plus performed similarly, and better than EndoREZ\textsuperscript{R} (Ultradent) and Sealapex\textsuperscript{TM} (SybronEndo).\textsuperscript{42} Another study found that iRoot SP displayed the highest bond strength to root dentin compared to AH Plus, Epiphany\textsuperscript{R}, and MTA Fillapex, irrespective of moisture conditions.\textsuperscript{43} In a push-out test, was similar to AH Plus and greater than MTA Fillapex.\textsuperscript{44} When iRoot SP was used with a self-adhesive resin cement, the bond strength of fiber posts were not adversely affected.\textsuperscript{45} Smear layer removal had no effect on bond strengths of EndoSequence Sealer and AH Plus, which had similar values.\textsuperscript{46} The presence of phosphate-buffered saline (PBS) within the root canals increased the bond strength of EndoSequence Sealer/gutta percha at 1 week, but no difference was found at 2 months.\textsuperscript{47} Because of the low bond values in these studies, it is doubtful that any of these findings are clinically significant.

![Figure 8](image1.png)

Figure 8  (A) Preoperative radiograph of a case demonstrating apical periodontitis. (B) Postoperative radiograph at 4 weeks. (C) 1-year follow-up with complete healing. Courtesy of Dr. Gilberto Debelian.

![Figure 9](image2.png)

Figure 9  (A) Preoperative radiograph of carious exposure on tooth 36. (B) Direct pulp coverage with BC Sealer. (C) Immediate postoperative radiograph. (D) Radiograph taken at 6-month follow-up visit. Courtesy of Dr. Mohammed A. Alharbi.
Resistance to fracture

iRoot SP was shown in vitro to increase resistance to the fracture of endodontically treated roots, particularly when accompanied with bioceramic impregnated and coated gutta-percha cones. Fracture resistance was increased in simulated immature roots in teeth with iRoot SP, and in mature roots with AH Plus, EndoSequence Sealer, and MTA Fillapex. Similar results were reported for EndoSequence Sealer and AH Plus Jet sealer in root-filled single-rooted premolar teeth.

Microleakage

Microleakage was reported to be equivalent in canals obturated with iRoot SP with a single cone technique or continuous wave condensation, and in canals filled with AH Plus sealer with continuous wave condensation. A recent study show a superior sealability of EndoSequence Putty compared with grey MTA.

Solubility

High levels of Ca\(^{2+}\) release were reported from in a solubility from iRoot SP, MTA Fillapex, Sealapex, and MTA-Angelus, but not AH Plus. Release of Ca\(^{2+}\) ions is thought to result in higher solubility and surface changes. However, the study tested the materials following ANSI/ADA spec. No. 57, which is not designed for premixed materials that require only the presence of moisture to set. This could be the reason for the difference in findings in this study and in vivo observations.

Retreatment

Removal of EndoSequence Sealer and AH Plus were comparable in a study comparing hand instruments and ProTaper Universal retreatment instruments. None of the filling materials could be removed completely from the root canals, however. Micro-computed tomography showed that none of the retreatment techniques completely removed the gutta-percha/iRootSP sealer from oval canals.

Figure 10  (A) Preoperative radiograph tooth 36. (B) Postoperative radiography after full pulpotomy with BC putty was performed. (C) Tooth was asymptomatic at 18-month follow-up. (D) Signs of root development after 24-month follow-up. (E) Contralateral tooth at 18-month follow-up. Courtesy of Dr. Guillaume Jouanny.
Clinical studies

A randomized clinical trial evaluated iRoot BP and white ProRoot MTA as direct pulp-capping materials. The study evaluated clinical signs/symptoms and histological pulp reactions, such as inflammation and mineralized bridge formation. No significant differences were found in pulpal inflammation, or in the formation or appearance of a hard tissue bridge. However, clinical sensitivity to cold was significantly less for teeth treated with MTA ($p < 0.05$). All teeth formed a hard tissue bridge, and none of the specimens in either group had pulpal necrosis.

Indications and case examples

Indirect and direct pulp capping and pulpotomy of carious exposures

Historically, endodontists have not recommended vital pulp therapy of cariously formed in the 1970s showed poor results for this procedure. However, these studies used calcium hydroxide as the pulp-capping agent and amalgam as the coronal restoration; therefore, if/when the amalgam leaked, the calcium hydroxide base would wash out. This resulted in calcified canals—if the pulp survived—or necrotic pulps with infection and apical periodontitis. New studies and case series observations have shown that if the base used is antibacterial (such as calcium hydroxide), sets hard, and—most critically—seals well, both indirect and direct pulp-capping and pulpotomy procedures have a very good chance of a successful outcome. In relatively young patients, these should be the treatment of choice.

Case 1: direct pulp cap

Fig. 8 shows the preoperative radiograph of an apparent carious exposure on tooth 46 of a 20-year-old male patient. A diagnosis of reversible pulpitis was made based on the history and clinical exam. After anesthesia and caries removal, the exposure was seen and covered with BC RRM-Fast Set. After the BC base had fully set, a bonded resin was placed and a postoperative radiograph taken. At the 6-month follow-up visit, the tooth was asymptomatic and tested vital. Radiographically, no signs of pathology were noted.

Case 2: pulpotomy

In this case (Fig. 9), the tooth tested vital but showed clinical signs of irreversible pulpitis. Treatment with a full pulpotomy was chosen to improve the chances the remaining pulp would
survive and remain healthy. The preoperative radiograph shows extensive caries in the tooth and a slightly widened apical periodontal ligament. A full pulpotomy was performed using the BC putty. After the putty set, a coronal restoration was placed, and an immediate postoperative radiograph was taken and viewed. At the 1-year follow-up, the tooth was asymptomatic, and the radiograph showed continued root development, a healthy apical periodontium, and, importantly, no calcifications in the remaining pulp (as is often seen with a calcium hydroxide therapy). A radiograph taken of the contra-lateral tooth showed similar root development.

Case 3: primary endodontic treatment of a non-vital pulp

Lower first molar with signs and symptoms of periapical lesion (Fig. 10). The tooth was treated over 2 visits with an intra canal medication (Ca(OH)₂). Three weeks after the obturation was carried on with BC Sealer and gutta-percha using a single point technique. One year Follow-up radiograph showing signs of periapical healing.

Case 4: apicoectomy and retrofill

A patient presented with clinical symptoms and radiographic signs of post-endodontic disease (Fig. 11a). It was determined that the crown and the post was well adapted and an apicoectomy was to be performed. After apicoectomy the canal was instrumented with an ultrasonic tip to its length and until the tip of the post (b). The canal was filled with BC Sealer first and a 2 mm plug BC RM-Putty was condensed inside the retrograde cavity (c). (d). Final placement and verification of BC Putty retrofill. (e) Immediate radiograph after the surgery, note the presence of the BC Sealer along the extension of the post. A 1 year follow-up shows radiograph signs of advanced periapical healing (f).

Conclusions

The premixed bioceramic materials are hydrophilic, they do not shrink and are insoluble in tissue fluids. With both antimicrobial and sealing properties, premixed bioceramics are unique materials available in endodontics that have changed the way we perform both vital pulp therapy and root canal treatment. For root canal treatment they contribute to the success of both the microbial control phase (instrumentation, irrigation, intra-canal medication) and the filling phase (root and top filling) of root canal treatment. This allows the practitioner to perform the microbial control without removing dentin unnecessarily and leaving a stronger root for restorative reconstruction. They are also an essential element in the indirect and direct pulp capping and pulpotomy procedures due to their sealing ability and also the fact that they do not discolor the surrounding dentin. Because of these properties more vital healthy pulps can be maintained ensuring a healthy surrounding periodontium. For these reasons, premixed bioceramic materials are now the material of choice for pulp capping, pulpotomy, perforation repair, root-end filling, and obturation of immature teeth with open apices, as well as for sealing root canal fillings of mature teeth with closed apices.

Conflict of interest

The authors are consultants from FKG Dentaire, Switzerland and Brasseler, USA.

References


