

The use of a biocompatible cement in endodontic surgery. A randomized clinical trial¹

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ABSTRACT

PURPOSE: To evaluate the clinical applicability of Pozzolana Biologic Silva cement (PBS[®]) in endodontic surgery.

METHODS: Persistent apical periodontitis was diagnosed in 30 teeth of 12 patients by cone-beam computed tomography (CT). All patients had 2 or 4 affected teeth and underwent endodontic surgery with root-end filling. Patients with 2 affected teeth had one tooth (control) treated with mineral trioxide aggregate (MTA-Angelus[®]) as a root-end filling material, and the other tooth treated with PBS (experiment). When the patient had four affected teeth, two of them were treated with MTA and two with PBS. Six months after surgery, all patients were assessed by CT scan. Between-group comparisons of measurements were performed using the Wilcoxon test.

RESULTS: Periradicular tissue regeneration was observed in all cases. Significant within-group differences in long axes of the lesion were found in the bucco-palatal direction (PBS group, $p=0.0012$; MTA group, $p=0.024$) and coronal-apical direction (PBS group, $p=0.0007$; MTA group, $p=0.0015$) between pre- and postoperative measurements.

CONCLUSIONS: Pozzolana Biologic Silva cement can be used in the treatment of persistent periradicular lesions. The clinical use of PBS as a root-end filling material may be an alternative to MTA. PBS has additives, which provide enhanced strength.

Key words: Apicoectomy. Biocompatible Materials. Dental Cements.

Introduction

Endodontic surgery is a therapeutic resource indicated when conventional endodontic treatments fail^{1,2}. The development of biocompatible cements made this surgical treatment a viable alternative for the preservation of the tooth as a functional unit³⁻⁶. Root-end filling materials are required to provide hermetic sealing and to be biocompatible and a precursor for carbonate-apatite formation, which promotes biomineralization, resulting in periodontal ligament at the bone-cement-dentin interface⁷⁻⁹.

Mineral trioxide aggregate (MTA) is currently the cement of choice, meeting standard requirements for use as a root-end filling material¹⁰⁻¹². However, MTA has no additives. The absence of additives may affect the mechanical strength of the material¹³. Also, bismuth oxide is added to MTA for radiopacity, but it can result in increased porosity and decreased resistance in the long term^{14,15}.

Portland cement is the most common type cement used in civil engineering applications. The major components of Portland cement are comparable to those of MTA, except for the radiopaque agent bismuth oxide¹³⁻¹⁵. Other similarities between the two materials include antimicrobial activity and biocompatibility^{3,13,16-20}. Previous studies indicate the potential viability of using Portland cement in the same applications as MTA. Silva Neto and colleagues^{13,16} compared experimentally Portland cement containing natural additives (pozzolana and calcium carbonate) with MTA-Angelus and found that both materials are biocompatible and induce biomineralization. These authors also found that the presence of natural additives in Portland cement had no effect on these properties and may provide superior resistance to masticatory forces^{13,16}. Studies on surface electromyography (EMG) of masticatory muscles, orofacial motion, temporomandibular disorders (TMD), and orofacial myofunctional status according to gender, age, tooth status, and facial morphology have shown that both healthy and treated teeth require resistance to occlusal forces. Thus, root-end filling materials should provide resistance to masticatory load^{13,16,21,22}.

Pozzolana Biologic Silva cement (PBS®) is a biocompatible medical Portland cement that contains pozzolana and calcium carbonate as additives, which confer compressive strength to the material²³. PBS was developed as part of a doctoral dissertation (J.D.S.N.) and master's thesis (S.R.S.), based on the white structural Portland cement with additives (WSPCA), which was adapted for clinical use. WSPCA has shown good physical properties and to be a biocompatible material^{13,16}. A patent was filed for the use of WSPCA as a dental filling material at the Brazilian patent office (INPI, Instituto Nacional de Propriedade Industrial, in Portuguese) in June 2013 and published in November 2015 (patent

no. BR10 2013 031603-2 A2). The trademark application for the PBS cement was filed at INPI (case no. 909673667) in July 2015 and the medical cement is currently in the industrialization phase. A pilot clinical study²³ was conducted comparing the WSPCA (later called PBS cement) with MTA-Angelus® as a root-end filling materials in endodontic surgery; serving as basis for this study with a larger sample. Because it is essential that root-filling materials resist masticatory forces^{24,25}, PBS may be an alternative to MTA in endodontic surgery.

Thus, the aim of this study was to compare the regeneration of periradicular tissues after endodontic surgery using PBS and MTA-Angelus as root-end filling materials.

Methods

This prospective clinical study was approved by the Research Ethics Committee of the Universidade do Vale do Sapucaí (UNIVÁS) (approval n° 280009) and Brazil Platform System (approval n° CAAE 15093613.5.0000.5102), and performed in full accordance with the ethical principles of the Declaration of Helsinki of 1975 as revised in 2008. For all patients, written informed consent was obtained prior to their inclusion in the study, and anonymity was assured.

Eligibility criteria included patients 18 to 60 years of age, who had two or four teeth with persistent periradicular lesions.

Exclusion criteria were diabetes, heart diseases, being pregnant, renal diseases, and chronic debilitating diseases. Patients lost to the 6-month follow-up were also excluded from the study.

In order to calculate the sample size, the following criteria were used for comparisons of measurements of the long axes of lesions in the bucco-palatal direction and coronal-apical direction. Mean ± standard deviation (SD) values of 4.1 ± 3.0 mm and 0.84 ± 1.3 mm were estimated for the axes on the bucco-palatal and coronal-apical directions, respectively. The sample size was calculated using the formulas:

$$n_1 = \frac{(\sigma_1^2 + \sigma_2^2 / \kappa)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

$$n_2 = \frac{(\kappa * \sigma_1^2 + \sigma_2^2)(z_{1-\alpha/2} + z_{1-\beta})^2}{\Delta^2}$$

where, n_1 and n_2 = sample size for the PBS and MTA groups, respectively; σ_1 and σ_2 = standard deviation for the PBS and MTA groups, respectively; Δ = difference between mean values; $Z_{1-\alpha/2}$ = two-tailed Z-value = 1.96; $Z_{1-\beta}$ = power of 80%. Setting the significance level α at 5%, the confidence interval at 95%, and the power of the sample at 80%, the sample size of 8 teeth in each group would be required to detect this difference. Anticipating some dropouts and to prevent errors, 15 teeth were

allocated to each group, increasing the statistical power to 97.14%, which was estimated using the method of approximation to normal distribution.

Thus, a total of 30 teeth showing no degree of mobility, with persistent periradicular lesions of 12 patients were selected for the study. The lesions were diagnosed using cone-beam computed tomography (cone-beam CT; Model i-CAT 17–19, Imaging Sciences International LLC, Hatfield, PA, USA)^{23,26,27}. The dimensions of the long axes of the lesions in the bucco-palatal and coronal-apical directions were measured using CT images analyzed with the Dental Slice virtual navigation software (Bioparts Prototipagem Biomédica, Brasília, DF, Brazil).

All patients had 2 or 4 affected teeth and underwent endodontic surgery with root-end filling. Patients with 2 affected teeth had one tooth (control) treated with MTA-Angelus as a root-end filling material, and the other tooth treated with PBS (experiment). When the patient had four affected teeth, two of them were treated with MTA and two with PBS. The teeth were randomly allocated to the control (MTA) or study (PBS) groups using the Random software (Excel 4.0, Microsoft, Redmond, WA, USA).

Before the surgical procedure, the patients rinsed their mouth with 5 ml of 0.12% chlorhexidine digluconate for one minute and then received 2% lidocaine with noradrenaline 1:100,000 as supraperiosteal infiltration, according to conventional techniques. A relaxing incision was made in the gingival sulcus with a scalpel blade (no. 15). Blunt dissection was carried out with a Molt elevator; the apical lesion was located using a no. 5 dental explorer; and osteotomy was made using an Ostby chisel and a carbide bur no. 4. Next, curettage of the lesion was done with a periodontal curette (no. 13/14). A low-speed bur (no. 700) was used for apicoectomy. A step-back instrumentation technique performed with an ultrasonic tip (SD90, Dabi Atlante, Ribeirão Preto, SP, Brazil) was used for root-end cavity preparation. The cavity was dried with absorbent paper points and root-end filling was carried out with either PBS or MTA. The root-end filling material was packed and the root was planed to the apical end using appropriate instruments. Periapical radiographs were obtained with a periapical film. The bone cavity was cleaned with sterile saline solution and filled with calcium carbonate powder. The flap was repositioned and secured with 4-0 silk suture. All patients were prescribed 875-mg amoxicillin-clavulanate potassium tablet twice daily for seven days, 4-mg dexamethasone tablet twice daily for three days, and 750-mg paracetamol tablet every six hours in the first postoperative day. The suture was removed seven days after surgery.

The teeth and surrounding tissues were assessed clinically and by CT scan at the 6-month follow-up²⁸. The dimensions of the long axes of the lesions in the bucco-palatal and coronal-

apical directions were measured preoperatively and 6-month postoperatively using CT images.

Statistical analysis

The Wilcoxon test was used to compare delta percent ($\Delta\%$) changes in linear measurements (long axes of the lesions) and measurements related to root-end filling materials between groups and over time.

Statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS) 18.0 (SPSS Inc., Chicago, IL, USA). All statistical tests were performed at a significance level α of 0.05 ($p < 0.05$).

Results

Periradicular tissue regeneration was observed in all cases. Significant within-group differences in the long axes of the lesions were found in the bucco-palatal direction (PBS group, $p = 0.0012$; MTA group, $p = 0.024$) and coronal-apical direction (PBS group, $p = 0.0007$; MTA group, $p = 0.0015$) between pre- and postoperative measurements. Pre- and postoperative cone-beam CT images are shown as examples (Figures 1 and 2).

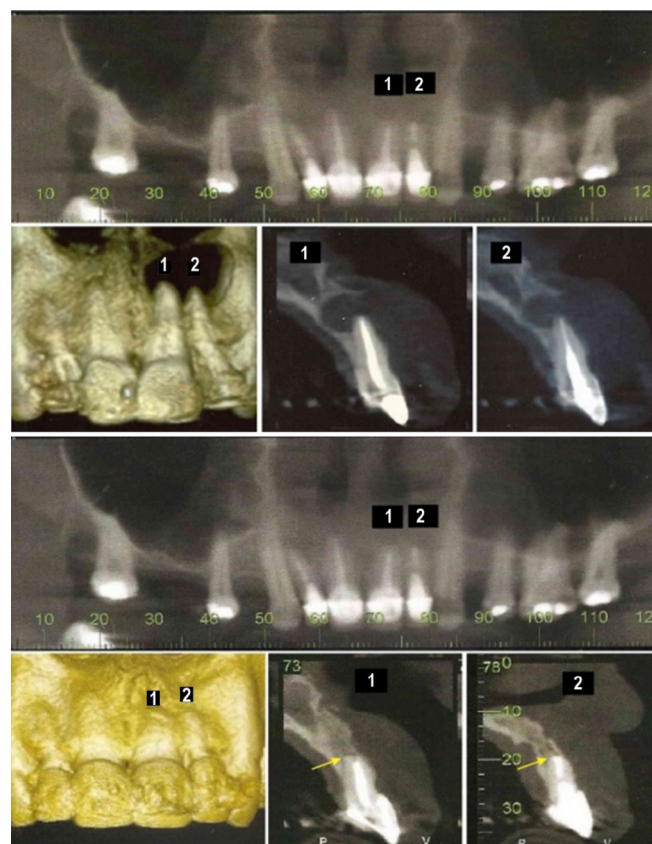


FIGURE 1 – Preoperative (top) and 6-month postoperative (bottom) cone-beam CT images showing affected teeth treated with either MTA (tooth 1) or PBS (tooth 2) as root-end filling materials.

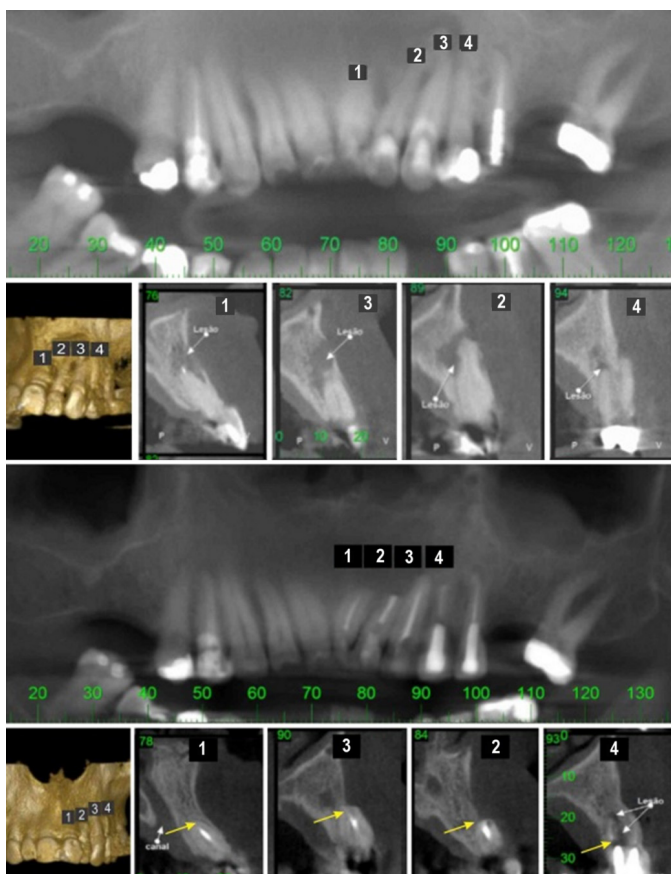


FIGURE 2 – Preoperative (top) and 6-month postoperative (bottom) cone-beam CT images showing affected teeth treated with either MTA (teeth 1 and 3) or PBS (teeth 2 and 4) as root-end filling materials.

Discussion

When conventional endodontic treatments fail, endodontic surgery is an alternative to save the tooth. For the success of this surgical procedure, the cement used as root-end filling material must meet necessary requirements, including biocompatibility, resistance to masticatory forces and ability to induce biomineralization^{8,9}.

MTA is considered the gold standard for root-end filling^{7,17,21}, induces biomineralization, and is associated with favorable prognosis in endodontic surgeries. However, MTA contains bismuth oxide, which is a factor that must be taken into consideration when using this cement as a root-end filling material. Bismuth oxide is added to MTA for radiopacity, but in the long term it can cause changes in the cement, resulting in increased porosity and decreased mechanical resistance^{14,15,24,25}. Comparisons of Portland cement used in civil construction with MTA have indicated that both materials have similar composition and physical and biological properties^{3,18,19,29,30}. These studies

suggest further investigation of the feasibility of using Portland cement as an endodontic material.

The development of PBS began with experimental studies comparing Portland cement containing natural additives (pozzolana and calcium carbonate) with MTA when used in the repair of root perforations in dogs. Periradicular tissue regeneration was observed for both materials and the presence of cement additives had no effect on biocompatibility^{13,16}. The literature provides solid foundation for the development of clinical studies with Portland cement^{10,22}. Petrou *et al.*²⁰ conducted a clinical study using Portland cement and MTA and defined Portland cement as medical cement.

A pilot clinical study was designed to compare the outcomes of endodontic surgery using either MTA or PBS as a root-end filling material and it was found that PBS led to tissue regeneration²⁹. The present study was conducted with a sample larger than that of the previous pilot study and the use of both cements as root-end filling materials resulted in significant periradicular tissue regeneration, consistent with other studies^{13,16,20,23}.

The PBS cement is a biocompatible and bioactive material with resistance to compression due to the presence of natural additives (pozzolana and calcium carbonate) in its composition. The human masticatory system is complex. The anterior (incisors and canines) and intermediate (premolars) teeth treated by endodontic surgery in the present study had different masticatory and mechanical demands. Studies on surface EMG have shown that masticatory muscles and teeth are subject to fatigue effects during the mastication process that are influenced by different factors, such as gender, age, tooth status, and facial morphology, resulting in different occlusal relationships during static and dynamic occlusion. Both healthy and treated anterior and intermediate teeth need to show mechanical resistance to masticatory forces²¹. The presence of PBS can be detected in radiographs without the addition of radiopaque agents. Thus, PBS is an alternative to MTA-Angelus in endodontic surgery. Further clinical studies are necessary to assess the effectiveness of PBS in the different applications in which MTA is utilized.

Conclusions

The use of Pozzolana Biologic Silva and mineral trioxide aggregate as root-end filling materials led to regeneration of periradicular tissues and repair of periradicular lesions. Thus, the clinical use of PBS is an alternative to the treatment of endodontic surgery.

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