UNIVERSITAT DE BARCELONA

The new bioactive hydraulic sealers in endodontics

Giulia Bardini

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THE NEW BIOACTIVE HYDRAULIC SEALERS IN ENDODONTICS

Doctoral thesis report submitted by Giulia Bardini to obtain a doctoral degree from the University of Barcelona

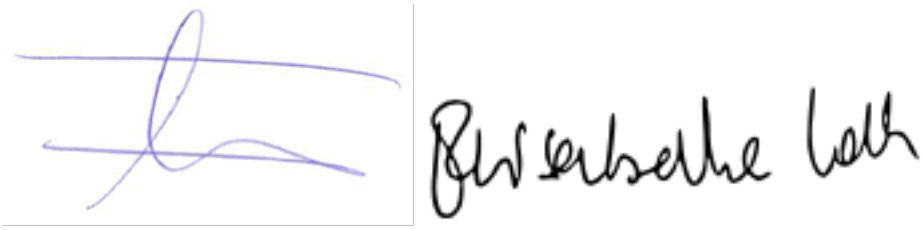
Supervised by Dr. Montserrat Mercade Bellido, University of Barcelona, Department of Dentistry, Barcelona, Spain (Director and Tutor), and Dr. Elisabetta Cotti, University of Cagliari, Department of Dentistry, Cagliari, Italy (Director)

A doctoral program in Medicine and Translational Research Faculty of Medicine and Health Sciences, University of Barcelona

July 2022

La present tesis doctoral ha estat realitzada per compendi de publicacions de la doctoranda Giulia Bardini. El primer article ha estat publicat a una revista de Q2 i el segon a Q1. El primer article es basa en el primer objectiu de la tesi que va ser comprovar la possibilitat que el ciment basat en silicat de calci es podia eliminar de l'interior del sistema de conductes radiculars, després d'haver estat dins el mateix durant un periode de 12 mesos; la qual cosa no s'havia demostrat fins el moment. El segon article es basa en el segon objectiu de la tesi, que era avaluar l'èxit clínic i radiogràfic del tractament de conductes radiculars realitzat amb ciment basat en silicat de calci. Jo, Dra Monserrat Mercade Bellido, autoritzo a que aquest manuscrit de la tesi sigui dipositat a la Universitat de Barcelona.

This doctoral thesis comprises two papers published by Giulia Bardini based on research for her doctorate. The first paper was published in a Q2 journal and the second in Q1. The first article is based on the primary objective of the research, which is to verify the possibility that a calcium silicate-based sealer can be removed from the root canal space, after having a storage period of 12 months; this has not been demonstrated before. The second article is based on the second objective of the research, which is to assess the clinical and radiographical success of a root canal treatment carried out with a calcium silicate based-sealer. I, Dr. Elisabetta Cotti, authorize this thesis manuscript to be deposited at the University of Barcelona.



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I, Dr. Giulia Bardini, declare that my doctoral thesis does not include any content that may constitute plagiarism. I agree to submit my thesis to verify its originality.

I, Dr. Montse Mercade, the thesis supervisor, declare that codes of ethics and good practice have been followed and that I am not aware of any plagiarism.

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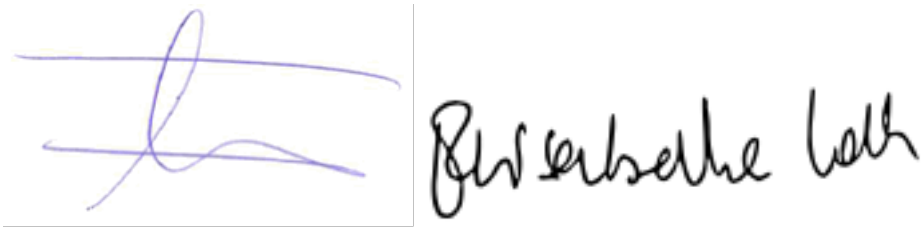

A Cristiano,

il mio mare più blu.

"Venivano dai più lontani estremi della vita, questo è stupefacente, da pensare che mai si sarebbero sfiorati se non attraversando da capo a piedi l'universo, e invece neanche si erano dovuti cercare, questo è incredibile, e tutto il difficile era stato riconoscersi, riconoscersi, una cosa di un attimo, il primo sguardo e già lo sapevano, questo è il meraviglioso."

Alessandro Baricco, Oceano Mare

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I thank my family for accepting my every decision, even those that have removed me from “home”. I am grateful to them for allowing me to daydream.

Finally, I thank every person that life has placed in my way: everyone has left a trace within me that I will keep with care.

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I would like to thank Septodont for kindly providing the sealer Bioroot™ RCS.

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GLOSSARY

AH Group: AH Plus Group, retreated after one month of storage

AP: apical periodontitis

Bio Group: BioRoot™ RCS Group, the general sample of all teeth obturated with the SC technique and CSBS

BIOAP: BioRoot RCS Group, the sample of all teeth obturated with the SC technique and the CSBS, which presented pre-operative periapical lesion

BR group: BioRoot™ RCS Group, retreated after one month of storage

BR* group: BioRoot™ RCS Group, retreated after one year of storage

CSBS: calcium silicate-based sealer

EDS: energy dispersive spectroscopy

GIC: glass ionomer cement

GP: gutta-percha

MTA: mineral trioxide aggregate

PAI: Periapical Index Score

PCS Group: Pulp Canal Sealer Group, the general sample of all teeth obturated with the WVC technique and the ZOE sealer

PCSAP: Pulp Canal Sealer Group, the sample of all teeth obturated with the WVC technique and the ZOE sealer, which presented pre-operative periapical lesion

PDL cells: periodontal ligament cells

RBS: resin-based sealer

RCT: root canal treatment

SC technique: single-cone technique

SEM: scanning electron microscope

SM: stereomicroscope

WL: working-length

WVC technique: warm vertical compaction technique

ZOE: zinc-oxide eugenol

LIST OF ARTICLES THAT COMPRISE THE THESIS

The thesis is presented in the form of a collection of published articles.

This thesis comprises two published articles, each of which represents a primary research objective. This thesis also comprises nine sub-objectives.

The articles were published as follows:

Bardini G, Casula L, Ambu E, Musu D, Mercadè M, Cotti E. "A 12-month follow-up of primary and secondary root canal treatment in teeth obturated with a hydraulic sealer." Clin Oral Investig. May 2021; 25(5):2757-2764. doi: 10.1007/s00784-020-03590-0. Epub 2020 Sep 28. Erratum in: Clin Oral Investig. 2021 Aug; 25(8):5121. PMID: 32989597; PMCID: PMC8208934.

Clinical Oral Investigation: H-Index: 82; Quartile: Q1; Subject area and category: Dentistry, dentistry (miscellaneous)

Bardini G, Cotti E, Congiu T, Caria C, Aru D, Mercadè M. "Medium- and long-term re-treatment of root canals filled with a calcium silicate-based sealer: an experimental *ex vivo* study." *Materials.* May 2022; 13;15(10):3501. doi: 10.3390/ma15103501. PMID: 35629528; PMCID: PMC9145273.

Materials: H-Index: 111; Quartile: Q2; Subject area and category: Materials Science (miscellaneous), Physics and Astronomy (Condensed Matter Physics)

SUMMARY/RESUMEN

Título: Los nuevos cementos selladores hidráulicos en endodoncia

Introducción: En los últimos veinte años los cementos selladores basados en cementos de silicato tricálcico han sido introducidos en el mercado para la obturación ortógrada del sistema de conductos radiculares. Estos cementos selladores basados en silicatos (CSBS) han demostrado excelentes resultados en ambientes húmedos, ya que tienen una gran biocompatibilidad al inducir la formación de tejido duro cuando entran en contacto con los fluidos tisulares. La presente tesis doctoral tiene por objetivo investigar las ventajas potenciales de estos nuevos materiales a través de un estudio *ex vivo* y de uno *in vivo*.

Hipótesis: ¿Pueden los CSBS afectar al pronóstico de los retratamientos endodónticos? ¿Pueden los CSBS afectar al pronóstico de los tratamientos de conductos radiculares (RCT) primarios o secundarios?

Objetivos: Evaluar el retratamiento de dientes obturados con un CSBS (estudio *ex vivo*) y evaluar el pronóstico del RCT realizado con un CSBS (estudio *in vivo*).

Metodología:

1. En el estudio *ex vivo* se instrumentaron 36 premolares mandibulares y se distribuyeron de forma aleatorizada de la siguiente manera: grupo BR y BR* = obturados con CSBS y retratados después de un mes y de un año de almacenaje, respectivamente; y grupo AH = obturado con un cemento sellador resinoso (RBS) y retratado después de un mes de almacenaje.

Los especímenes retratados se seccionaron longitudinalmente y se examinaron bajo el estereomicroscopio (SM). Las microfotografías obtenidas se procesaron mediante el software Image J para evaluar la cantidad de material de obturación remanente en el conducto radicular y en especial en el tercio apical. También se analizó la capacidad para llegar a la longitud de trabajo (WL), si se consiguió permeabilidad o no y el tiempo que se tardó en completar el retratamiento. Se aplicó el test de ANOVA y el post hoc de Bonferroni ($p < 0.05$).

2. En el estudio *in vivo* 69 pacientes se dividieron de forma aleatorizada en dos grupos, según la técnica utilizada: técnica de cono único (SC) en el grupo BIO group y técnica de condensación vertical de la gutapercha (WVC) en el grupo PSC group. Asimismo, dos subgrupos (BIOAP y PCSAP) contenían los casos de periodontitis apical (AP).

   Cuatro residentes en endodoncia realizaron los casos bajo un protocolo de instrumentación y desinfección estandarizado. Se analizaron los resultados mediante el índice periapical (PAI) y se evaluaron los resultados clínicos y radiográficos en los meses uno, tres, seis y doce. El éxito del tratamiento fue evaluado de acuerdo con la curación periapical y la supervivencia dental. Se aplicaron, según el caso, el test de igualdad de proporciones, el t-test para la igualdad de medias y el test no paramétrico K-sample para la igualdad de medianas.

<u>Resultados principales:</u>

1. En el estudio *ex vivo* se consiguió permeabilidad y llegar a la longitud de trabajo de todos los dientes. El porcentaje medio de material residual fue estadísticamente significativo entre los grupos BR y BR* (p-valor = 0,048). Además, el tiempo medio para completar el retratamiento fue significativamente menor para el grupo AH, seguido del grupo BR (p = 0,0001) y el BR* (p = 0,0078).

2. En el estudio *in vivo* el índice de supervivencia fue similar para los grupos BIO y PCS (p = 0,4074) y para los BIOAP y PCSAP (p = 0,9114). Asimismo, el índice de éxito fue superior para los grupos *BIO*, aunque sin diferencias estadísticamente significativas (p = 0,0735). Una disminución progresiva en el índice PAI fue observada en los dos grupos (*BIOAP* y *PCSAP*).

Conclusiones:

1. El cemento sellador CSBS evaluado pudo ser removido con éxito de todos los conductos radiculares con anatomía sencilla.
2. Las dos técnicas demostraron éxito clínico a los doce meses de evaluación y obtuvieron un porcentaje de éxito clínico y radiográfico similar.

INTRODUCTION

Obturation is the last step of root canal treatment. Once the disinfection and instrumentation phases are completed, the prepared space is filled and sealed. It has been shown that is not possible to sterilize the root canal space or to completely remove the bacteria biofilm from it; for this reason, the purpose of a root canal filling is to enhance the disinfecting procedure by sealing the space, thus ensuring that residual microorganisms cannot proliferate and reach the periradicular space (1). The final part of the treatment procedure is the coronal restoration, which should be done as soon as possible, following the obturation of the root canal/s, to obtain a hermetic seal of the tooth as a whole.

Over time, different products and techniques have been developed to maximize the properties of the materials used for endodontic obturation (2). The original idea behind the modern standard for root canal filling was to use a core material in association with a sealer. The main core material that has been used over the years is gutta-percha (GP) (3). A traditional root canal filling thus comprises a standard GP cone combined with a sealer, which has the role of filling the spaces left between the GP and the dentinal walls, sealing the anatomical space.

Over the past 50 years, a range of endodontic sealers have been introduced to the market and used. These include sealers based on a mix of chloroform and GP, zinc oxide–eugenol, calcium hydroxide, silicon, glass ionomer cements (GIC), and epoxy or methacrylate resins (2–4). Since they fill the empty spaces left between the wall of the endodontic space and the gutta-percha, sealers are supposed to help prevent microbial leakage. However, traditional sealers do not bond to the core material, leaving gaps, when the sealer shrinks on setting, that can be infiltrated by bacteria (3,5–12). In addition, they tend to wash out in the presence of tissue fluids (3,5–12). Therefore, in order to achieve a hermetic seal over time, sealers need to be applied in the form of as thin a film as possible.

In the 1960s, Schilder tried to improve the obturation techniques used at the time (13), because he recognized that one of the problems of obtaining a three-dimensional filling of the endodontic space was the discrepancy between the rounded shape of the core material used (GP) and the oval shape more commonly found in the canals. This discrepancy made it hard to use a thin layer of sealer, which was often vulnerable to shrinkage and wash-out. Following these considerations, and based on a deep study of the thermal properties of gutta-percha, Schilder introduced a method for heating GP so that it was pliable and able to flow into the irregular areas of the canals, keeping the amount of sealer as thin as possible (14,15). Although widely employed, this technique has not been proved to overcome completely the weaknesses of the original single-cone (SC) or lateral condensation techniques. The rationale is that, once the heated GP cools, it may shrink even more than the sealer does on setting (16,17). In addition, the combined shrinkage of the GP and sealer (rather than the sealer alone) may result in a gap between the two materials, increasing the consequences of the absence of a bond. Indeed, over the years, numerous studies have shown no particular benefit in sealing the root canal with this warm vertical compaction method (WVC) compared with the traditional lateral compaction or the single cone techniques (18,19).

Furthermore, considering that the warm vertical compaction system advocates a continuous flared preparation of the root canal space, it has recently been shown that large tapered instruments can produce micro-fractures in the root (20–24). This happens mainly when associated with a thinning of the root dentin, which has already weakened the tooth by exposing it to potential fractures (21,23,24). Finally, traditional sealers suffer from the humid conditions present in the endodontic space, which can influence their setting properties.

To overcome this last drawback, Torabinejad et al., in the 1990s introduced to the market the “mineral trioxide aggregate” (MTA), a Portland-based cement, with the purpose of obtaining an adequate seal of the root canal spaces over time, even when the environment is wet (25). MTA was initially proposed for

root-end fillings, for sealing endo-perio communications, and for vital pulp therapy. MTA performs in unfavourable conditions thanks to the following properties:

- ✓ hydrophilicity
- ✓ bioactivity
- ✓ biocompatibility

However, despite the innovative role represented by MTA in the endodontic field, together with its main advantages, a few drawbacks, including tooth discoloration and a long setting time have created some concerns, and products with similar characteristics have been investigated to improve its properties.

Biodentine™ is a similar compound, first introduced to overcome these limitations, followed by other so-called bioceramic cements (26,27). Bioceramics are ceramic materials specifically designed for use in medicine and dentistry. They can be classified as:

- ✓ Bioinert, as they do not interact with biological systems.
- ✓ Bioactive, as they can undergo interfacial interactions with the surrounding tissue.
- ✓ Biodegradable, soluble, or resorbable, because they can be replaced or incorporated into tissues.

Endodontic bioceramics are not sensitive to moisture and blood contamination (27–32); they are dimensionally stable and expand slightly on setting (28,30–35). When set, they are hard and insoluble, and therefore ensure a superior long-term seal. Thanks to the hydration reaction that forms calcium hydroxide, and the subsequent dissociation into calcium and hydroxyl ions (28,31,36), bioceramics develop a pH above 12 upon setting. During the setting phase, the materials develop antibacterial properties while, when fully set, they are biocompatible and bioactive. Bioactivity develops when these cements, upon coming into contact with tissue fluids, release calcium hydroxide, which interacts with phosphates to form hydroxyapatite (36). This latter property may justify the

numerous uses of these cements, because it translates into tissue-inductive effects. Endodontic bioceramics have then become the material of choice for pulp capping, pulpotomy, perforation repair, and root-end fillings. Last they are widely used for the treatment of immature teeth with open apices, and mature teeth with mature, but large apices (37).

Based on the clinical success of the Portland-based and bioceramic cements, in the past 15 years, endodontic sealers based on tricalcium silicates and other calcium silicate formulations have been introduced to the dental market (38) for orthograde root canal obturation. These materials have a range of characteristics that make them suitable as sealers to be used with the single cone (SC) obturation technique. Due to hydration and contact with phosphate from tissue fluids, di- and tricalcium silicate cements release calcium hydroxide, leading to the precipitation of calcium phosphate or calcium carbonate on the material's surface (39–42). In addition, the formation of hydroxyapatite on the surface of a calcium silicate sealer after contact with phosphate has been reported (39). This explains the bioactive potential of tricalcium and dicalcium silicate sealers. Furthermore, calcium silicates form an interfacial layer at the dentin wall denoted as the "mineral infiltration zone" (43). Another important characteristic of these materials is their excellent performance in a humid environment, hence the definition of "hydraulic sealers", an essential requirement in dentistry, particularly in endodontics. A further appreciable feature of these calcium silicate-based sealers (CSBS) is their good biocompatibility (40–42).

Due to the major component of all types of CSBS being calcium silicate, their setting reactions are comparable. Several days are required for the hydration and hardening phases of the reaction to be throughout the material to be completed (44). While all products vary in terms of composition, one major difference exists in the type of delivery, between premixed products with an external water supply (body fluid), on the one hand, and two-component products that use an internal water supply (Table 1), on the other. Their biological properties depend on their chemical composition and their setting reaction (45).

TABLE 1: DIFFERENT CSBS AVAILABLE ON THE INTERNATIONAL MARKET (44)

SEALER	MANUFACTURER	IDENTICAL PRODUCTS	DELIVERY	COMPOSITION
iRoot SP	Innovative Bioceramix, Vancouver, Canada	Endosequence BC Sealer Brasseler USA, Savannah, USA	1 component materials	Zirconium oxide, dicalcium silicate, tricalcium silicate, calcium phosphate monobasic, calcium hydroxide, filler, thickening agents
Endoseal MTA	Maruchi, Wonju, Korea		1 component materials	Calcium silicates, calcium aluminates, calcium aluminoferrite, calcium sulfates, radiopacifier, thickening agents
Well-Root ST	Vericom, Gangwon-Do, Korea		1 component materials	Calcium aluminosilicate, zirconium oxide, filler, thickening agents
Nano-Ceramic Sealer	B&L Biotech, Fairfax, USA		1 component materials	Calcium silicates, zirconium oxide, filler, thickening agents
EndoSequence BC Sealer Hi-Flow	Brasseler USA, Savannah, USA		1 component materials	Until now no information about composition available; the manufacturer states it is a variation of Endosequence BC Sealer
CeraSeal	Meta Biomed Europe GMBH, Germany		1 component materials	Tricalcium silicate, dicalcium silicate, tricalcium aluminate, zirconium dioxide
NeoSelaer Flo	Avalon Biomed, Houston, TX		1 component materials	Inorganic powder of Tricalcium/dicalcium silicate in an oranic medium
AH Plus Bioceramic	Dentsply Sirona		1 component materials	Zirconium dioxide, tricalcium silicate, dimethyl sulfoxide, lithium carbonate, thickening agents
TotalFill BC sealers™	FKG, La Chaux de-Fonds, Switzerland		1 component materials	Tricalcium silicate, Zirconium oxide, tantalum pertoxide, dicalcium silicate, calcium sulfate (anhydrous)
BioRoot™ RCS	Septodont, Saint-Maur-des-Fossés, France		2 component materials	Powder: tricalcium silicate, zirconium oxide, povidone Liquid: aqueous solution of calcium chloride and polycarboxylate
Endo CPM	EGEO SRL, Buenos Aires, Argentina		2 component materials	Powder: mineral trioxide aggregate, bismuth oxide, barium sulfate, silica dioxide Liquid: aqueous solution of calcium chloride, sodium citrate, propylenglycolalginate, propylenglycol
Tech BioSealer Endo	Isasan SRL, Revello Porro, Italy		2 component materials	Powder: White Portland cement, bismuth oxide, anhydride, sodium fluoride Liquid: Alfacaine SP solution (4% articaine + 1/100.000 epinephrine)
ProRoot ES	Dentsply, York, Usa		2 component materials	Powder: tricalclium silicate, dicalcium silicate, calcium sulfate, bismuth oxide, tricalcium aluminate Liquid: water, viscous water-soluble polymer

TABLE 2: COMPOSITION, INFORMATION ON INGREDIENTS OF DIFFERENT CSBS ACCORDING FROM THE MANUFACTURER'S INSTRUCTIONS

	BioRoot	EndoSequence BC	NeoSealer Flo	CeraSeal	AH Plus Bioceramic	TotalFill BC Sealers
Hazardous Components	Concentration (WT%)	Concentration (WT%)	Concentration (WT%)	Concentration (WT%)	Concentration (WT%)	Concentration (WT%)
Tricalcium Silicate		20.0-35.0%	<25%	20-30%	5-15%	20-35%
Dicalcium Silicate		7.0-15.0%	<10%	1-10%		7-15%
Calcium Hydroxide		1.0-4.0%				1-4%
Calcium Aluminate			<25%			
Tricalcium Aluminate			<5%	1-10%		
Calcium Sulfate			<1%			
Calcium Carbonate	25-50%					
Zirconium Oxide		35.0-45.0%				35-45%
Zirconium Dioxide	25-50%			45-50%	50-70%	
Dimethyl Sulfoxide					10-30%	
Lithium Carbonate					<0.5%	
Tantalite			<50%			
Thickening agents					<6%	

Following the introduction of the bioactive-hydraulic endodontic sealers there has necessarily been a conceptual shift from an obturation where the most important role was played by the core material, to a filling concept mostly based on the sealer. There are several potential changes expected in terms of the root filling technique. First of all, as the bioactive sealer is highly hydrophilic, it takes advantage of the natural moisture of the dentinal tubules, unlike most other

sealers whose performance is impaired by moisture. This property gives bioactive sealers a significant advantage over traditional sealers. Bioactive sealers do not shrink but expand slightly, and are insoluble in tissue fluids (26–28,30,32–36) (Fig. 7). This prevents any gaps between sealer and dentinal walls and between sealer and GP core material.

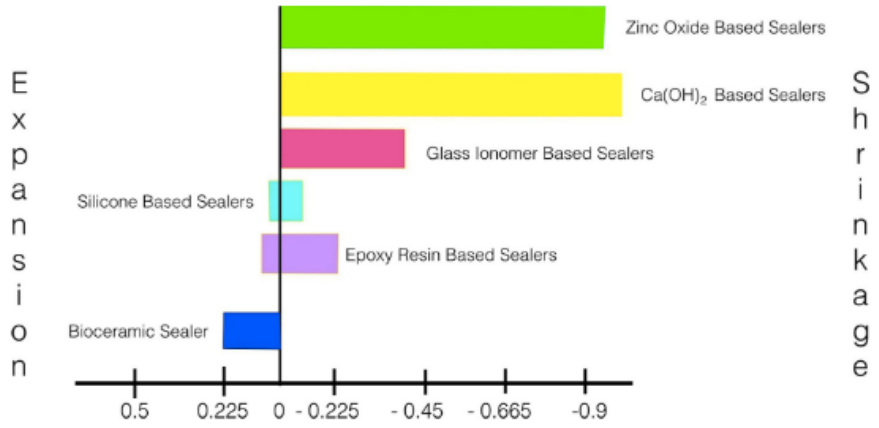

FIGURE 1: EXPANSION/SHRINKAGE OF POPULAR SEALERS, WITH THE ADDITION OF BIOACTIVE SEALER. CSBS EXPANDS SLIGHTLY ON SETTING BUT DOES NOT SHRINK; ACCORDING TO TROPE ET AL. 2015 (46)

Before setting, bioactive sealers have a pH above 12 and feature antibacterial properties similar to calcium hydroxide (31,32,34,35,47). The setting is dependent on physiologic moisture within the canal. As a result, different sealers will set at different rates in different environments, but since they have a high pH, any delay in setting can be argued as a benefit.

Other properties listed above, in particular their dimensional stability and insolubility in tissue fluids, could change the long-held rule of using the minimum amount of sealer in conjunction with a major core material, described earlier about fillings. The space allocated to the GP core material could be reduced in favour of the bioactive sealer. In the single-cone technique, GP points are used primarily to deliver the CSBS and to allow hydraulic movement of the sealer into

the irregularities of the root canal and accessory canals. In such cases, operators could perform a more conservative antimicrobial protocol without removing unnecessary dentin and leaving a stronger root.

BioRoot™ RCS (Septodont, Saint-Maur-des Fosses, France) is a powder/liquid hydraulic tricalcium silicate-based cement, marketed since 2015, and recommended for the single-cone technique or cold lateral condensation root filling. The powder contains tricalcium silicate, povidone, and zirconium oxide; the liquid is an aqueous solution of calcium chloride and polycarboxylate (Figure 1). This specific formulation imparts definitive characteristics to the hydraulic material. It is water-based and the switch from cement to sealer depends on the inclusion of a water-soluble polymer that allows the material to flow. The addition of this polymer to MTA has not altered the hydration characteristics of the material, however, and has resulted in an endodontic sealer with improved properties (48). Furthermore, the novel sealer demonstrates adequate setting time and dimensional stability. Thus, BioRoot™ RCS shows potential to be used as a root canal sealer in clinical practice (49).

BioRoot™ RCS has shown the following properties in studies:

1. Its final setting time is 324 (+/- 1) minutes (39).
2. Contact with a wet environment lengthens the setting time considerably (50).
3. It is less soluble than AH Plus immediately after immersion in water, but its solubility becomes higher over time when compared with a resin-based sealer (RBS). (39)
4. It exhibits a lower flow and higher film thickness (51) than the limits specified by ISO 6976;2021 recommendations (52).
5. Its radiopacity is greater (39) than the lower limit specified by ISO 6976;2021 recommendations (52).
6. BioRoot™ RCS releases high levels of calcium in the solution (50).

7. It exhibits biomineralization and deposition of phosphates when in contact with the dentin (50).
8. BioRoot™ RCS induces, *in vitro,* the production of angiogenic and osteogenic growth factors by human periodontal ligament cells (53); moreover, it has low cytotoxicity, may induce hard tissue deposition (39), and has antimicrobial properties (54).

FIGURE 2: BIOROOT RCS (SEPTODONT, SAINT-MAUR-DES FOSSES, FRANCE): A POWDER/LIQUID HYDRAULIC TRICALCIUM SILICATE-BASED SEALER.

Although the use of CSBS in endodontics is increasing (55,56), the information on how to effectively remove these sealers is inconsistent, because most studies have used a short storage time of one to four weeks (39,57–60). In a few reports, the samples were stored for a longer time before evaluation, which never exceeded six months (61–64). Furthermore, in the scientific literature, while several preclinical studies have analysed the biochemical and

physical properties of the new hydraulic sealers (34,65–71), the number of studies conducted *in vivo* is limited.

This doctoral thesis aims to investigate some aspects related to these new materials through an *ex vivo* study and an *in vivo* study to provide conclusions that can guide clinicians to understand and use these new materials. First, we evaluate whether a storage time of 12 months affects the results of retreatment procedures; secondly, we evaluate the outcome of secondary and primary root canal treatments in human teeth obturated with the SC technique and a CSBS.

HYPOTHESES

Considering the tissue-inductive properties of bioactive hydraulic calcium silicate-based sealers, the hypothesis of this thesis is to investigate whether:

- Long-term storage (i.e., 12 months) of teeth obturated with the SC technique and a CSBS affects retreatment procedures, in an *in-vitro* setting
- The SC technique in association with a CSBS affects the outcome of primary and secondary endodontic treatments

OBJECTIVES

The overall purpose of this project is to assess whether the data reported so far from the *in vitro* studies are also reflected in the *in vivo* study and the clinical counterpart.

Based on the hypotheses previously reported, the specific objectives and sub-objectives of this research project are:

1. To evaluate the retreatment of teeth obturated with a *bioactive-hydraulic sealer*
   1.1. To assess the re-establishment of working length (WL) and patency
   1.2. To assess the time required for retreatment procedures
   1.3. To assess the percentage of residual filling materials (RFM) in the whole root canal space (%RFM)
   1.4. To assess the percentage of residual filling materials in the apical third of the canal (apical 3rd RFM (%))
   1.5. To assess the data obtained with SEM and EDS microanalysis

2. To evaluate the outcome of primary and secondary endodontic treatment performed with a *bioactive-hydraulic sealer*
   2.1. To assess the overall survival rate in BIO and PCS groups
   2.2. To assess the success rate in BIOAP and PCSAP groups
   2.3. To assess the overall survival rate in BIO and PCS groups
   2.4. To assess the survival rate in BIOAP and PCSAP groups

Main objective 1.

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Title: Medium- and long-term re-treatment of root canals filled with a calcium silicate-based sealer: an experimental *ex-vivo* study

materials

MDPI

Article

Medium- and Long-Term Re-Treatment of Root Canals Filled with a Calcium Silicate-Based Sealer: An Experimental Ex Vivo Study

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Abstract: This study investigated the possibility of re-treating a calcium silicate-based sealer (CSBS), compared to an epoxy-resin sealer (RBS), using rotary instrumentation at different times from obturation (1 month/1 year). Thirty-six human mandibular premolars, extracted as a result of orthodontic or periodontal problems, were instrumented and randomly divided into three groups of 12: BR and BR*, which were filled with CSBS and re-treated after one month and one year of storage, respectively, and AH, which was filled with RBS and re-treated after one month. The same re-treatment protocol was used for all teeth, and the times required for the procedure was recorded. The re-treated specimens were longitudinally sectioned and examined at the stereomicroscope (SM) at 20× magnification. Image J Software was used to process the microphotographs. The percentage of residual filling materials in the root canal and the apical third, the ability to reach working length WL and patency, and the time taken to complete the re-treatment were recorded and analyzed by ANOVA and post hoc Bonferroni test ($p = 0.05$). Scanning electron microscopy (SEM) and coupled energy-dispersive spectroscopy (EDS) were applied to representative samples to evaluate canal cleanliness and chemical elements. Patency and WL were re-established in all of the teeth. Residual filling materials were retained in all specimens of the three groups. The mean percentage of residual materials was significantly different between BR and BR* (p-value = 0.048), with BR* showing the highest values. The mean time to complete re-treatment was significantly lower for AH, followed by BR ($p = 0.0001$) and BR* ($p = 0.0078$). Conclusions: After both medium and long storage periods, the CSBS can be concluded to have been successfully removed from canals with simple anatomy.

Keywords: bioroot RCS; AH Plus; calcium silicate-based-sealer; epoxy resin-based-sealer; re-treatability

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1. Introduction

Re-treatments have assumed greater importance in clinical practice since several scientific studies indicated secondary orthograde endodontic therapy to be the treatment of choice for apical periodontitis (AP) as a first-step alternative to retrograde treatment [1,2].

Failure of primary endodontic treatment is most frequently due to the persistence of bacteria and viruses within un-instrumented volumes of the root canal system [3]; thus, accessing every area of the latter becomes an essential requirement for the success of secondary treatments [4].

State-of-the-art endodontic obturation, obtained using gutta-percha (GP) cones in conjunction with a sealer adapted to the canal walls, should prevent microorganisms and fluids from leaking to the periapical tissues by sealing the entire system [5]. Sealers are designed to improve the seal provided by the core obturation material. Currently, many different sealers are being used in endodontics. They can be categorized according to their

chemical composition into zinc oxide and eugenol-, calcium hydroxide-, non-eugenol-, glass ionomer-, resin-, silicone-, and calcium silicate-based sealers (CSBS) [6]. Resin-based sealers (RBS) have a long history of use, provide adhesion, and do not contain eugenol. There are two major categories: epoxy resin-based and methacrylate resin-based sealers. Ah Plus (Dentsply International Inc., York, PA, USA) is an epoxy resin-amine-based system in two tubes. The epoxide paste tube contains a diepoxide and fillers as the primary ingredients; the amine paste tube contains a primary monoamine, a secondary diamine, a disecondary diamine, silicone oil, and fillers as the major ingredients. Ah Plus was formulated to avoid the formation of formaldehyde [7]. Hydraulic calcium silicate-based materials were first introduced as root repair cement [8,9] and later as root canal sealer [10]. Calcium silicate materials may include alumina and zirconia, calcium silicates, hydroxyapatite, and calcium phosphates in their formulation [11]. A new CSBS is BioRoot^{TM} RCS, [BR] (Septodont, Saint-Maur-des-Fossés, France), consisting of powder and liquid. According to the manufacturer, the powder mainly consists of tricalcium silicate, povidone, and zirconium dioxide. The liquid is an aqueous calcium chloride solution with polycarboxylate. Alkalizing activity associated with releasing calcium ions, bioactivity with the apatite-forming ability, hard tissue formation, and dentinal tubule penetration was reported for BioRoot RCS [11–13].

The interaction of CSBS with the dentinal surface of the canal walls, which produces the formation of a *mineral infiltration zone* [14,15], has led many clinicians to assume that these materials were not easily removable from the canals. Currently, information regarding the re-treatability of CSBS is unclear.

The purpose of this ex vivo study was to assess the removal of the filling material from root canals obturated with either a bioactive hydraulic sealer or an epoxy-resin sealer by evaluating the feasibility to achieve apical patency and the time necessary to complete the procedure and to assess the amount residual sealer within the root canals. The null hypotheses were that there would be no differences in the amount of residual filling materials or the times required for the re-treatment procedure among the groups.

2. Materials and Methods

2.1. Materials

The experimental study was performed ex vivo and compared two obturation techniques performed by two calibrated, expert operators.

The root canals were obturated either with a novel CSBS (BioRoot^{TM} RCS, [BR]) and the single cone GP technique or with an RBS (AH Plus, [AH]) performed with the warm vertical compaction of the gutta-percha [16].

BioRoot^{TM} RCS is a tricalcium silicate-based bioactive sealer developed to be used in conjunction with GP points and the single cone technique, or with cold lateral condensation of GP, for permanent root canal obturation [17,18].

AH Plus is an epoxy resin-amine-based system traditionally used with a GP master cone, which may be further adapted to the canal using a compaction technique with multiple accessory cones or with heat and a continuous wave of condensation technique [16].

2.2. Sample Size Calculation

Sample size calculation was performed using the G*Power v. 3.1.9.4 software (Heinrich Heine, Universität Dusseldorf, Germany). The power analysis indicated that 36 specimens (n = 12) were required. This gave at least 80% power to detect a maximum difference between group means. The advisable specimen size was determined based on a previous study that used a similar methodology [19].

2.3. Sample Selection

Thirty-six single-rooted mature, human mandibular premolars extracted for orthodontic or periodontal reasons, with a single straight and regular canal and a completely formed root, were selected. Exclusion criteria were root caries, internal calcifications, and exter-

nal and internal resorption. Internal resorption was verified with periapical radiographs (Figure 1A).

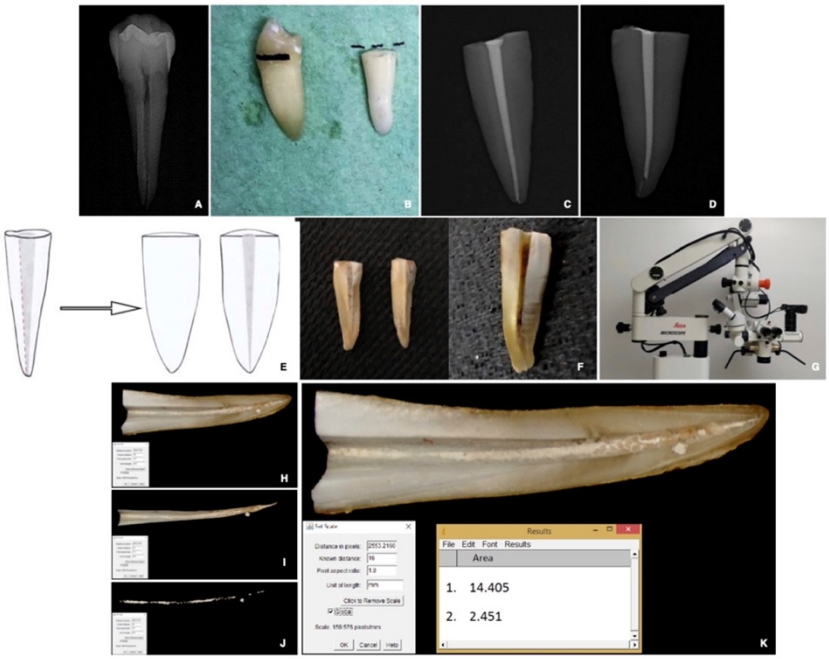

Figure 1. (**A**) A representative specimen of the experimental group. (**B**) The crowns of selected teeth were removed to obtain standardized samples with 16 mm root length. (**C**,**D**) A representative radiograph of two roots obturated at WL (groups) and WL-1 (subgroups), respectively. (**E**,**F**) Teeth were sectioned longitudinally along the main axis, and photographs of each half-root were taken under 20× magnification using a stereomicroscope and a digital camera (Alpha NEX-5; Sony, Tokyo, Japan). (**G**) Leica M655 (Leica Microsystems, Wetzlar, Germany). (**H**–**K**) Image J software (version 1.41, National Institute of Health, Bethesda, MD, USA). An examiner highlighted, for each tooth, the following: root canal surface (**I**), apical third surface, amount of residual root filling materials in the canals, and (**J**) in the apical third. Image J software was used to express the highlighted areas in pixels (**K**).

2.4. Study Procedure

2.4.1. Specimen and Root Canal Preparation

The crowns of the selected teeth were removed with a diamond bur to standardize the specimens at 16 mm root length (Figure 1B).

A #10 K-file (Dentsply Maillefer, Ballaigues, Switzerland) was used to determine the working length (WL) until visible at the apical foramen. Instrumentation of teeth was performed with ProTaper Next Rotary System (Dentsply Maillefer, Ballaigues, Switzerland) to size 30/0.07 taper. A #10 K-file was used to reconfirm patency; each canal was irrigated

with 2 mL of 5.25% sodium hypochlorite (NaOCl) solution, followed by 2 mL of sterile saline, and then dried with paper points.

2.4.2. Root Canal Obturation

The specimens were numbered and randomly divided into three groups (n = 12) depending on the material used for root canal filling and the time of re-treatment:

- BR: single-cone GP and BioRoot™ RCS, re-treated after 1 month;
- AH: warm vertical condensation of GP and AH Plus re-treated after one month;
- BR*: single-cone GP and BioRoot™ RCS, re-treated after 12 months.

Two subgroups (n = 6) were further created for each group based on the working length chosen for the filling:

In six specimens, the GP cone (master cone) was seated with a tug back at the working length (WL), and in six samples, the cone (pilot cone), not exhibiting a tug back, was placed 1 mm coronal to WL (WL-1), to permit the CSBS to seal the apex.

All canals were filled with a matched-taper single-cone technique to maintain consistency. Each canal was trial fitted with a size 30.06 taper gutta-percha.

According to the manufacturer's instructions, both sealers were mixed and placed into the root canals using a coated paper point.

The GP cones were seared at the orifices with a heat carrier (System B, KerrHawe SA, Bioggio, Switzerland), and the accesses were sealed with bonded composite resin.

The specimens were then radiographed to confirm a homogenous root canal filling (Figure 1C,D), and each element was preserved in saline solution at 37 °C.

2.4.3. Re-Treatment Procedure

Following the manufacturer's instructions, the root filling materials were removed from the canals using ProTaper Universal D1, D2, and D3 files (Dentsply Maillefer, Ballaigues, Switzerland).

A ProTaper Universal D1 file was used in the coronal third of the canal, the canals were then irrigated with 2 mL of 5.25% NaOCl, ProTaper D2, and D3 files were then used, respectively, to remove the obturation material from the middle and apical third of the canal. Each rotary instrument was used with slight apical pressure and inspected upon each removal. The re-treatment procedures were completed with a #30 k-file and a solvent (Endosolv, Septodont, Saint-Maur-des-Fossés, France) left in the canal for one minute, mostly to remove residual from gutta-percha, and followed by a final rinse with 5.25%. NaOCl.

Throughout the procedure, canal patency was confirmed by manual K-file # 10.

Re-treatment was considered completed when no residual was observed on canal instruments, using a magnifying system (Zeiss 4.5 × 350), and when the canal appeared clear on the intraoral periapical radiograph.

A digital chronometer recorded the times required for the re-treatment procedure in minutes (ADANAC 3000, Marathon, La Chaux-de-Fonds, Switzerland).

The timer was started when an instrument was introduced in the canal and turned off when it was removed. The irrigation time and the time required for changing rotary instruments were not recorded.

2.4.4. Preparation and Evaluation of the Re-Treated Samples

After re-treatment, the roots were split longitudinally and subsequently photographed (Figure 1E). Grooves were made in a mesiodistal direction along the main axis of each tooth, under constant water cooling, to proceed with a cut in the para-median position of each specimen. The samples were divided into two halves, and the portion containing the complete half-canal was then polished with an Arkansas stone under water cooling (Figure 1F).

A photograph of each half-root was taken under 20× magnification using a stereomicroscope (SM) (Leica M655, Leica Microsystems, Wetzlar, Germany) and a digital camera (Alpha NEX-5; Sony, Tokyo, Japan) (Figure 1G).

The images were imported into imaging software (Image J version 1.41; NIH, Bethesda, MD, USA) (Figure 1H–K) and randomly evaluated by a third independent trained examiner. Considering the standardized length of the roots, the scale set associated the image pixels with the corresponding millimeters of the canal. Each canal was isolated from the rest of the tooth to calculate the area of the entire wall (Figure 1H) and its apical 3rd. The *Versatile Wand Tool* plug-in highlighted the area of the whole root canal wall (Figure 1H) and its apical 3rd, and the residual filling materials (RFM) (Figure 1J). RFM was extrapolated and measured (Figure 1K).

Subsequently, the amount of residual filling material (RFM), concerning the area of the canal and of the apical 3rd, was calculated in percentage values by using a proportion [19] as follows:

$$\text{RFM } (\%) = \frac{\textit{residual filling materials throughout the area of the entire canal } (\text{mm2})}{\textit{extension of the entire root canal surface } (\textit{mm2})} \times 100$$

$$\text{apical 3rd RFM } (\%) = \frac{\textit{residual filling materials throughout the area of the apical 3rd of the canal } (\text{mm2})}{\textit{residual filling materials throughout the area of the entire canal } (\text{mm2})} \times 100$$

Finally, two representative samples for each group were chosen, subjected to air drying, and examined at SEM (FEI Quanta 200 ESEM, CeSAR, University of Cagliari) at 10–20 kV and under low-vacuum conditions (n = 2 for each group) (Figure 2A,B). The analysis was performed using the Back-Scattered Electron (BSE) method and the X-ray microanalysis for energy dispersion (EDS). The magnification used varied from 30× to 1600× (Figure 3A–F). SEM observation showed the interfaces between sealer and dentin, and EDS analysis was used to identify the chemical composition of dentin, CSBS, and their interfaces (Figure 3D–F).

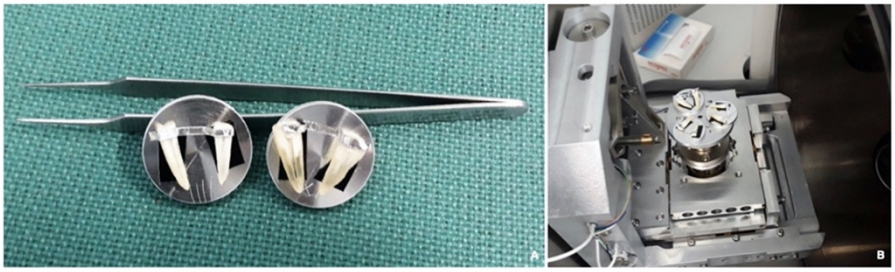

Figure 2. (**A**,**B**) The samples were examined with a scanning electron microscope (SEM), FEI Quanta 200 ESEM, at 10–20 kV, under low-vacuum conditions. The analysis of the root surface was conducted according to the Back-Scattered Electron (BSE) method and in X-ray microanalysis for energy dispersion (EDS).

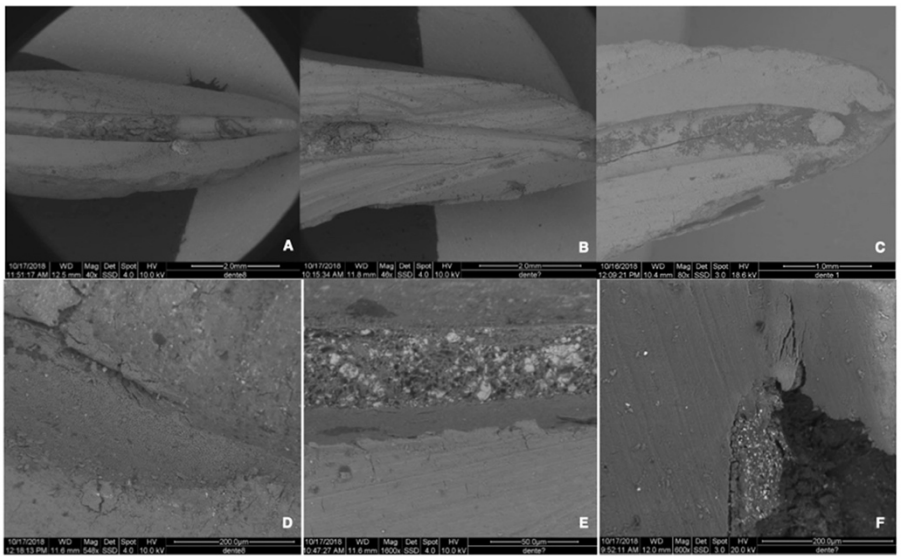

Figure 3. SEM images of the samples. (**A**–**C**) 50× magnification of BR, BR*, and AH group samples, respectively. (**D**–**F**) High-magnification images showing bonding at the interface between sealer and dentin, respectively, in BR, BR*, and AH groups. (**D**,**E**) Micrographs highlighting the *mineral infiltration zone* between CSBS and dentin.

2.4.5. Data Presentation and Statistical Analysis

STATA/SE, version 14, software (StataCorp LP, College Station, TX, USA) was used for the statistical analysis.

Of all data extrapolated from the evaluation of the samples (Table 1), the variables analyzed were: 1. percentage of residual filling materials in the whole surface of the canal (in %); 2. percentage of residual filling materials in the apical 3rd of the canal (in %); 3. times required for re-treatment procedure (in minutes); 4. re-establishing working length and patency (Table 2).

Table 1. Data of the entire study sample (n = 36).

Variables	Mean	Median	Standard Deviation	Min	Max	Range	IQR
RFM (%) *	29,104	28,900	9192	13,460	48,920	35,460	14,060
Apical 3rd RFM (%) **	18,025	14,355	13,759	0.540	68,230	67,690	20,730
Times required for re-treatment procedure (min)	2124	2075	0.865	1000	4520	3520	1000

* Percentage of residual filling materials in the whole surface of the canal. ** Percentage of residual filling materials in the apical 3rd of the canal.

Kolmogorov–Smirnov test was used to check whether the variables had a normal distribution.

The variables showed a normal distribution. The experimental groups were compared using the ANOVA test and Student's t-test with post hoc Bonferroni correction, where appropriate.

The significance level was set at $p = 0.05$.

Table 2. Summary values of the variables considered.

Variables	Mean	Standard Deviation
RFM (%) *	29,104	9192
Apical 3rd RFM (%) **	18,025	13,759
Times required for re-treatment procedure (min)	2124	0.865

* Percentage of residual filling materials concerning the area of the canal. ** Percentage of residual filling materials concerning the area of the apical 3rd of the canal.

3. Results

Overall, the sample (36 teeth) presented the characteristics summarized in Table 1.

The variables were as follows: 1. percentage of residual filling materials in the whole surface of the canal (in %); 2. percentage of residual filling materials in the apical 3rd of the canal (in %); 3. time required for re-treatment procedure (in minutes) showing a normal distribution (Kolmogorov–Smirnov test p-value > 0.05). Consequently, these data were summarized as mean (SD) (Table 2). ANOVA analyses showed statistical relevance for RFM (%) (p-value = 0.038) and times required for the re-treatment procedure (min) (p-value = 0.003). Student's t-tests with post hoc Bonferroni's correction were applied to the variables where ANOVA was significant (Table 3).

Table 3. Student's t-test with post hoc Bonferroni correction (variables where ANOVA was significant).

Dependent Variables	(I) Groups	(J) Groups	Mean Difference (I–J)	Sig.	Confidence Interval 95%	
					Inferior	Superior
RFM (%) *	AH, AH-1	BR, BR-1	7126	0.149	−1701	15,952
		BR*, BR*-1	−1775	1000	−10,601	7051
	BR, BR-1	AH, AH-1	−7126	0.149	−15,952	1701
		BR*, BR*-1	−8901	0.048	−17,727	−0.074
	BR*, BR*-1	AH, AH-1	1775	1000	−7051	10,601
		BR, BR-1	8901	0.048	0.074	17,727
Times required for re-treatment procedure (min)	AH, AH-1	BR, BR-1	−0.981	0.0001	−1397	−0.565
		BR*, BR*-1	−0.988	0.0078	−1687	−0.288
	BR, BR-1	AH, AH-1	0.981	0.0001	0,565	1397
		BR*, BR*-1	−0.007	0.9852	−0.741	0.728
	BR*, BR*-1	AH, AH-1	0.988	0.0078	0.288	1687
		BR, BR-1	0.007	0.9852	−0.728	0.741

* Percentage of residual filling materials in the whole surface of the canal.

3.1. Percentage of Residual Filling Materials in the Whole Surface of the Canal [RFM (%)]

All specimens of the three groups exhibited RFM (Figures 1 and 3 and Tables 1 and 4).

Table 4. Mean and standard deviation of the percentage of remaining filling materials in the experimental groups and subgroups.

Variables	Overall	Subgroups (WL)	Subgroups (WL-1)
BR	23.76 (9.41)	22.37 (5.46)	33.09 (7.14)
*BR**	32.66 (8.05)	32.24 (9.55)	25.15 (12.66)
AH	30.89 (8.19)	27.98 (10.04)	33.79 (5.13)

The lowest mean percentage of RFM was observed in BR (Table 4).

The most significant mean percentage of RFM was observed in BR* (Table 4).

The mean percentage of RFM was significantly different between BR and BR* (p-value = 0.048); the experimental group of teeth that were re-treated after one year showed higher values than those that re-treated after one month (Table 3).

3.2. Percentage of Residual Filling Materials in the Apical 3rd of the Canal (Apical 3rd RFM (%))

The mean percentages of RFM in the apical third are shown in Table 1.

No statistical difference was detected for this variable in the three groups.

3.3. Time Required for Re-Treatment Procedure

The mean time to complete the re-treatment procedures was significantly different between the groups (Table 3). AH showed the lowest values compared to BR and BR* ($p = 0.0001$ and $p = 0.0078$). When BR and BR* were compared, there was no significant difference.

3.4. Re-Establishing Working Length and Patency

Patency and WL were re-established in all the teeth (100%) in the AH, BR, and BR* groups.

High-resolution SEM images showed RFM in the re-treated samples, confirmed the data obtained from the photomicrographs at SM, and revealed what could be considered an *infiltration zone* between CSBS and dentin (Figure 3A–F).

EDS microanalysis highlighted the presence of calcium phosphate in the *infiltration zone*, both in the re-treated samples previously filled with a CSBS and in the CSBS itself (Figure 4B,C).

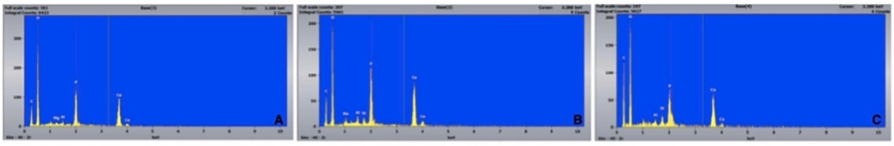

Figure 4. EDS microanalysis highlighted the presence of calcium phosphate ions within the dentin (**A**), *mineral infiltration zone* (**B**), and BioRoot RCS (**C**). More calcium phosphate ions were found in the *mineral infiltration zone* (**A**).

Finally, EDS revealed a more significant amount of calcium and phosphorus ions in the *infiltration zone* than in dentin and CSBS (Figure 4A–C).

4. Discussion

Failure after primary endodontic treatment can occur if infection persists in the root canal system. The root canal space should therefore be adequately cleaned and disinfected when performing a secondary treatment, by removing the previous filling, and re-establishing the WL. Furthermore, re-achieving patency in these cases significantly improves periapical healing rates [2].

Recently, there has been an increasing use of CSBS in endodontics [20,21]; however, the information available on the possibility of effectively removing these root-filling materials is not consistent. Hence, this study evaluated the potential of re-treating a relatively new bioactive sealer (BioRoot^{TM} RCS) compared to a more commonly used resin-based-sealer (AH Plus).

Most of the research performed on the removal of root canal sealers has used a storage time of 1 to 4 weeks [22–26], and the samples have been stored for a longer time before evaluation in only a few reports, which has never exceeded six months [27–30]. However, patients may require re-treatment several months or years after primary root canal treatment in a clinical setting. For this reason, part of the specimens filled with CSBS was stored for 1 month and part for 12 months before re-treatment in this experiment. To our knowledge, this is the first work that evaluates the removal of a CSBS following long-term storage. Interestingly, this study shows that the bioactive hydraulic sealer tested does not seem to exhibit washout 12 months following obturation, which may have particular clinical relevance.

To minimize the sampling bias, single-rooted mature human teeth with a completely formed root and a single straight and regular canal were selected (Figure 1), with strict instrumentation and irrigation protocol. This standardization allowed us to focus on the differences between the groups related to the characteristics of the sealers (BioRoot^{TM} RCS vs AH Plus), the time required to re-treat the CSBS (BR* vs. BR), and the possibility of regaining the working length (WL vs. WL-1).

To assess the percentage of RFM, various re-treatment and imaging methods have successfully been employed over time [19,31,32]. NiTi rotary instruments have been recommended to remove GP, and multiple studies have reported their efficacy, cleaning ability, and safety [31,33]. In this experiment, the removal of GP was performed first by means of Protaper Universal Re-Treatment, followed by leaving the samples in contact with a solvent for one minute. Re-treatment procedures were considered complete when no residual material could be seen on instruments at 4.5× magnification and further confirmed by intraoral periapical radiograph. Nevertheless, the observation of all samples revealed that the complete removal of filling materials was not achieved in any of the groups (Figure 3 and Table 3). This finding confirmed that the enlargement of the canal preparation, the achievement of the WL, and the lack of debris in the files could not guarantee the complete removal of the sealer from the canal walls. This observation is consistent with other reports [19,34,35] and should be considered during clinical re-treatment procedures [31].

Once the roots were split into two halves, root filling removal was photographed at the SM and evaluated through Image J software (Figure 2), a simple and efficient method to analyze a three-dimensional structure through a two-dimensional image. Further, to avoid biases, the third examiner randomly evaluated each image without knowing which treatment group it belonged to. Several studies assessed the amount of RFM following re-treatment by optical microscope inspection and digital evaluation of samples with ImageJ software [36–38]; hence, the method used in the present study is well established. In other reports, the removal of RFM was evaluated using high-resolution micro-computed tomography [19,31,34,39], an approach that allows the development of accurate three-dimensional models with a non-destructive imaging process [39], and enables the assessment of previous canal filling materials [40].

Our results show that obturation with the new bioactive hydraulic sealers does not permanently block the apical area, a finding that is in agreement with a previous report [41]. Using standardized straight canals made it possible to disclose the differences between the obturation techniques without the influence of the complexity of the tooth [19,34]. This can explain why previous studies evaluating more complex anatomies demonstrated a discrepancy with these results [42]. Furthermore, this study used the matched-taper, single-cone filling technique, which enalbes the easier penetration of rotary re-treatment instruments into the obturation [31]. While CSBS is hard upon setting, our study showed that apical patency and WL were achieved in 100% of the samples, indistinctively, whether the pilot or master cone was used. This finding confirms what was reported recently by Alsubait et al. [43].

Among the teeth obturated with BioRoot^{TM} RCS, the group re-treated after one year (BR*) showed a mean percentage of RFM significantly higher than BR (Table 3). The null hypothesis was thus rejected. This difference may be attributed to the increased mineral infiltration interface with time. It has been discussed that the precipitation of calcium phosphate ions within the dentinal tubules should explain the more effective sealing ability of the CSBS material over time [35,44–46].

According to the present results, the re-treatment time was affected by the type of sealer. This is in agreement with other studies [36,43]. Since there were differences in the time required for re-treating the samples, whether CSBS or RBS were used in our research, the null hypothesis was rejected. In our study, the AH group showed the lowest values. This finding is inconsistent with an earlier study [36]. However, a direct comparison cannot be made, due to the rotary instruments used for re-treatment. Finally, in our study, a long time was needed to complete the re-treatment procedures when the CSBS had been in

the canal for a longer time, a condition justified by the observations mentioned above conducted via SEM. This difference was statistically significant; however, it may not have clinical significance.

High-resolution SEM photomicrographs were also obtained to better observe the debris in the re-treated canals and to evaluate the cleanliness of the dentinal interfaces (Figure 3C,D). Two roots, representative of each group, were subjected to air-drying only, avoiding dehydration and potentially altering the samples. Thus, the images obtained were directly related to the scattering characteristics of the different materials analyzed (dentin, sealers, and gutta-percha, when present).

As previously reported [35], CSBS seem to induce mineralization at the interface with biological tissues, thus establishing a chemical bond between sealer and dentine, and SEM was used to observe this interface in our study. RBS exhibited continuity with the dentinal walls. In contrast, the interface CSBS/dentin appeared to be mediated by the formation of an *infiltration zone* (Figure 3D–F), which, on the basis of EDS microanalysis, was defined as a *mineral infiltration zone* for the presence of calcium phosphate ions (Figure 4A–C), which were also found in the CSBS.

Regarding clinical safety, no instrument separation and procedural preparation errors occurred during the re-treatment procedure. This was probably related to the choice of working on easy samples. This aspect represents a limitation of our study, because it does not allow us to extend the results to curved canals. Another potential limitation is the solvent used to remove the root filling materials, even if its use was mostly chosen to help in cleaning every residual from gutta-percha, as there is no evidence that currently available solvents are effective on CSBS. We believe it may be necessary to develop a solvent that improves the re-treatment of CSBS.

5. Conclusions

The re-treatability of the novel BioRoot™ RCS, based on this ex vivo model, can be considered manageable in teeth with simple anatomy. However, conventional re-treatment techniques are not always able to entirely remove it, especially when primary root canal treatment has been performed over a long time and a solid cementum-dentin sealing interface has been established. This may represent critical information for clinics, especially when re-treating long-term filled teeth with a CSBS. Still, these results need to be confirmed by studies performed in vivo.

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Main objective 2.

2. To evaluate the outcome of primary and secondary endodontic treatment performed with a *bioactive-hydraulic sealer*
   2.1. To assess the overall survival rate in BIO and PCS groups
   2.2. To assess the success rate in BIOAP and PCSAP groups
   2.3. To assess the overall survival rate in BIO and PCS groups
   2.4. To assess the survival rate in BIOAP and PCSAP groups

Title: A 12-month follow-up of primary and secondary root canal treatment in teeth obturated with a hydraulic sealer.

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ORIGINAL ARTICLE

A 12-month follow-up of primary and secondary root canal treatment in teeth obturated with a hydraulic sealer

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Abstract
Objectives This randomized, controlled, pilot study assessed the outcome of non-surgical primary/secondary root canal treatments either with a novel bioactive sealer and the single-cone technique or with gutta-percha, zinc oxide-eugenol sealer (ZOE), and warm vertical compaction.
Materials and methods Sixty-nine patients were randomly divided into two groups that were treated using the single-cone technique with BioRoot^{TM} RCS (Septodont) (BIO group) or warm vertical compaction with gutta-percha and ZOE sealer (PCS group). Two subsamples (BIOAP and PCSAP) comprised the cases with apical periodontitis. Treatment was undertaken by four residents using a standardized instrumentation and disinfection protocol. The periapical index (PAI) was recorded, and clinical and radiographic follow-up performed at 1, 3, 6, and 12 months. Treatment success was assessed according to "periapical healing" and "tooth survival". The test for the equality of proportions, *t* tests for the equality of means, and non-parametric K-sample tests for the equality of medians were applied when appropriate.
Results The survival rate was similar in the BIO and PCS ($p = 0.4074$) and the BIOAP and PCSAP groups ($p = 0.9114$). The success rate was higher in the BIO groups, but not statistically significant ($p = 0.0735$). In both BIOAP and PCSAP groups, a progressive decrease in the PAI was observed.
Conclusion At 12 months, both techniques showed reliable results. Further studies and longer follow-ups are needed.
Clinical relevance This study documents the feasibility of using a bioactive sealer in conjunction with the single-cone technique to obturate the root canal and obtaining a predictable outcome.
Trial registration ClinicalTrials.gov Identifie: NCT04249206

Keywords Root canal obturation · Bioactive sealers · Single cone · Endodontic outcome

Introduction

Apical periodontitis (AP) is a chronic inflammatory disease caused by an endodontic infection and is characterized by hard tissue resorption and destruction of periapical tissues [1, 2]. Apical periodontitis can be prevented or treated by an appropriate root canal treatment (RCT) [3]. According to the recent literature, the estimated weighted success rates of primary and secondary RCTs range between 68–85% and 70–86%, respectively, when strict criteria are used [3–7]. The quality of the root canal filling is a very important potential prognostic factor influencing the success of RCTs [6]. A state-of-the-art endodontic obturation obtained using gutta-percha (GP) cones together with a sealer adapted to the canal walls should prevent microorganisms and fluids from passing through the canal to the apical tissues by sealing the entire system [8, 9].

In recent years, bioactive endodontic cements (*Portland's bioceramics*) have been introduced to the market; they have been used as pulp capping agents, as filling materials to seal endodontic/periodontal joins or, more recently, as sealers to be used in conjunction with GP [10]. The precursor of these cements, mineral trioxide aggregate (MTA), which is a Portland-derived cement, exhibited excellent hydraulic properties (since it sets and seals well in the presence of moisture

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because its properties are enhanced by the interaction with tissue fluids), biocompatibility, and induction of hard tissue formation [11, 12]. Subsequently, developed products have different compositions, most of which contain calcium and silicate [10, 13–17], and show similar performances [18–20]. A common property of these cements is their "bioactivity"; when they are in contact with tissue fluids, they release calcium ions and produce calcium hydroxide and apatite on their surfaces with the potential to create an interfacial layer between the sealer and the dentin walls [11, 12, 21]. Researchers have also reported a decreased inflammatory response in bone in the presence of these products [22–25]. BioRoot™ RCS (Septodont, Saint-Maur-de-Fossés, France) is a tricalcium silicate–based bioactive cement developed to be used as a sealer together with GP points and the single-cone technique or with cold lateral condensation for permanent root canal obturation [26, 27]. There is a paucity of information in the specialized literature on the outcomes achieved with the new bioactive sealers used with the single-cone obturation technique in vivo; the latter (sealers and technique) are often advertised.

The purpose of this *pilot* study was to evaluate the outcome of endodontic primary and secondary treatment of teeth prepared with a similar protocol and obturated using either the single-cone technique with gutta-percha and a bioactive sealer or warm vertical compaction with gutta-percha and a ZOE sealer at a 1-year follow-up. This is intended to be the first part of a modular project that will provide data on the behaviour of the two groups over time (at 1 year, 2 years, and 4 years).

Materials and methods

The pilot study was approved by the Ethics Committee (PROT. PG/2017/16759, Ca, November 2017) and was conducted in the Department of Conservative Dentistry and Endodontics of the University Hospital in accordance with the Declaration of Helsinki of 1975 (as revised in 2000) between 1 May 2016 and 31 December 2017.

Inception cohort

Fifty-five Caucasian subjects aged between 18 and 80 years who were referred for endodontic treatment at the university clinic were included in the study. The selected subjects had at least one permanent single or multi-rooted mature tooth with signs and/or symptoms indicating the need for endodontic treatment (primary or secondary) according to ESE guidelines [9], and teeth requiring retreatment with a poor prognosis (root canal morphology altered) were excluded. Clinical and medical data were recorded before treatment. During the visit, each tooth was clinically examined to determine whether it needed endodontic treatment; the history of pain was assessed, and responses to sensitivity tests, palpation, and percussion were performed [28]. One or more periapical radiographs of the involved teeth were obtained at baseline and evaluated to assess the crown, root, and periapical status.

Patients with any medical condition, immune-compromised status, or with an overall poor prognosis for their treatment were not included.

Informed consent to undergo the treatment and follow-up and a second consent to participate in the study were obtained from all patients before treatment commenced.

The 55 selected patients required root canal treatment of 84 single or multi-rooted teeth.

Endodontic therapy was performed using a standardized protocol that varied only in terms of the technique and sealer used for the obturation of the root canal. Four endodontic residents performed the primary and secondary RCTs, who were divided into two groups of two (depending on the day of the week they worked in the hospital). The clinical supervisor of the day assigned each resident either Bioactive cement or ZOE sealer respectively. This was randomly done by a flip of the coin. Every day, each patient was randomly assigned to one technique or another: the first patient who arrived on the same day of treatment was randomly assigned (by a flip of the coin) to one of the two obturation groups, while the second was assigned to the other group; the third patient was assigned to the initial group, and so on until the end of the day.

Dental treatment and follow-up

Local anaesthesia was administered, the teeth were isolated under a rubber dam, and the root canals were subjected to preflaring using K-files 08/10/15 (Kerr© Corporation, Orange, California) and NiTi Protaper Next™ X1, X2, and X3 rotary files (Dentsply Sirona, Ballaigues, Switzerland) when necessary. For the secondary RCTs, the GP and sealer were removed by hand and with rotary instrumentation by using Gates-Glidden drills #4, #3, and #2 (in this sequence) and 0.1 mL of solvent (Endosolv® E, Septodont, Saint-Maur-des-Fossés, France); the canals were then renegotiated by hand with K-files. In all cases, the working length was assessed with the apex locator (DentalPort ZX, J. Morita MFG. CORP©, Kyoto, Japan) and confirmed with one or more periapical radiographs Kodak ultra-speed dental film, size 31 × 41 mm (Carestream Health©, Stuttgart, Germany) and X-safe 70 70 KV/8 mA (Cefla Medical Equipment, Imola, Italy). The root canals were continuously irrigated with 5% sodium hypochlorite (Niclor 5-Dentale, Ogna lab, Muggiò, Italy) throughout the instrumentation.

Following instrumentation, the canals were dried with sterile paper points and obturated as follows:

Table 1 Descriptive data for the groups: general samples and subsamples

		All teeth ($N = 69$)			Teeth with AP ($N = 52$)		
		BIO group ($n = 39$)	PCS group ($n = 30$)	Test	BIOAP group ($n = 28$)	PCSAP group ($n = 24$)	Test
Sex	Female Male	27 (69.23%) 12 (30.77%)	12 (40.00%) 18 (60.00%)	0.0152*	20 (71.43%) 8 (28.57%)	11 (45.8%) 13 (54.2%)	0.0608*
Age	Mean ± st.dev	55.44 ± 15.04	56.37 ± 20.21	0.8270**	56.79 ± 16.02	52.67 ± 19.97	0.4132**
Type of treatment	Primary Secondary	13 (33.33%) 26 (66.67%)	20 (66.67 %) 10 (33.33%)	0.0060*	8 (28.57%) 20 (71.43%)	17 (70.83%) 7 (29.17%)	0.0024*
Initial PAI	Mean	2.54 ± 1.43	2.70 ± 1.29	0.6292**	3.14 ± 1.24	3.13 ± 1.08	0.9563**
	Median	2	2.5	0.4760***	3	3	0.8780***
	1	11 (28.21%)	6 (20.00%)		-	-	
	2	13 (33.33%)	9 (30.00%)		13 (46.43%)	9 (37.5%)	
	3	4 (10.26%)	6 (20.00%)		4 (14.29%)	6 (25.00%)	
	4	5 (12.82%)	6 (20.00%)		5 (17.86%)	6 (25.00%)	
	5	6 (15.38%)	3 (10.00%)		6 (21.43%)	3(12.50%)	

*Test for the equality of proportions

**t tests for the equality of means

***Non-parametric K-sample test for the equality of medians

The overall survival rate of treated teeth at 12 months was 97.44% in the BIO group and 93.33% in the PCS group ($p = 0.4074$). The success rate at 12 months was higher in the BIO group than in the PCS group (76.92% versus 56.67%), although the difference was not significant ($p = 0.0735$). Similarly, the survival rates in the BIOAP and PCSAP groups were comparable at 12 months, and the healing rate was higher in the BIOAP group than in the PCSAP group (67.86% versus 50.00%), but the difference was not statistically significant ($p = 0.1908$) (Table 2). A successful treatment was found at the 12-month follow-up for all teeth without a preoperative periapical lesion. The PAIs for each treatment group and subgroup are shown in Figs. 1 and 2, respectively. Globally, all PAIs decreased over time. For all teeth with a PAI of 5 or 4 at baseline, the score was decreased at the 12-month follow-up in the BIOAP groups, while teeth with a PAI of 4 did not show a change at 12 months in the PCSAP groups (Figs. 1a and 2a).

Discussion

The aim of endodontic filling is to finalize the treatment by sealing, as hermetically as possible, the root canal space and prevent microleakage, which may cause treatment failure [8, 9]. Endodontic obturation is traditionally performed with a GP master cone combined with a sealer, which may be further adapted to the prepared canal using a compaction technique with heat [29] or multiple accessory cones [28]. The use of a well-fitting cone in conjunction with a bioactive sealer that should enhance the sealing properties when in contact with fluids and lead to successful single-cone obturation has been recently advocated [21]. The technique is easy and fast and aims to create a biological seal [10–16, 18–20, 22, 23, 26, 27]. We designed this randomized pilot study to obtain the first insights into this technique because there was, and still is, a paucity of clinical information in the specialized literature on the use of the new bioactive cements as sealers with single-cone obturation. This article reports the 12-month follow-up of a modular project in which the outcomes of primary and secondary root canal treatments were assessed in teeth obturated with either the single-cone technique and a bioactive sealer or with continuous compaction with GP and ZOE sealer, which is considered a classic reference treatment [34].

To minimize bias, four endodontic residents performed all the treatments in the same clinical setting using a standardized instrumentation and disinfection protocol. In addition, each tooth was restored with direct composite upon the completion of RCT. The sample size was small, but the follow-up rate was good (Table 1). We have combined primary and secondary endodontic therapies to empower the statistical analysis. This choice was also supported by the literature, as the documented success rates of initial treatment and retreatment were similar as long as the teeth to be retreated did not exhibit visibly altered root canal morphology [3, 35–37].

The follow-ups were conducted at short intervals (1 month, 3 months, and then every 3 months) to obtain detailed information on the healing course of the teeth during the first year of treatment to evaluate a new material with supposedly better sealing ability (Figs. 1 and 2) [21]. This information may be useful in clinical practice, especially for teeth with extensive lesions requiring prosthetic rehabilitation. This is also the reason we intend to report the treatment outcomes progressively (at 1, 2, and 4 years).

(a) BIO group: A standardized GP master cone that fit snugly at the working length was selected; BioRoot™ RCS (Septodont) was prepared according to the manufacturer's instructions. A coating of the sealer was applied onto the canal walls using the GP point. Obturation was completed by inserting the GP master cone that had been previously coated with the sealer into the canal; a hot instrument was used to remove the excess GP.
(b) PCS group: Warm vertical compaction with GP and Pulp Canal Sealer™ EWT (Kerr© Corporation, Orange, CA) was performed [29].

A periapical radiograph was obtained to assess the quality of the root canal fillings, and subsequently, all teeth were restored with direct composite.

Clinical and radiographic follow-up were performed at 1, 3, 6, and 12 months for each tooth, and data were recorded in a dedicated chart and updated at every follow-up.

All radiographs were digitally scanned, saved in JPEG format and imported into ImageJ software version 1.41 (National Institute of Health, Bethesda, MD). The application Turbo Reg (Biomedical Imaging Group, Lausanne, Switzerland) was used to reduce the distortion factors of the radiographs [30].

Two trained and calibrated examiners (weighted kappa values, $k = 0.8$ for inter-examiner agreement and $k = 0.9$ for intra-examiner agreement) [31] assigned a PAI score to each radiograph [32]; in the case of a disagreement, the highest of the two scores was retained. In multi-rooted teeth, the root with the highest score was used as the reference. Following the assignment of a PAI score, the radiographs of each tooth were divided into two groups: absence of AP (score 1) or presence of AP (score 2–5).

The same examiners then assessed the quality of the coronal restorations according to the criteria described by Ng et al [3, 6].

Outcome assessment

Treatment success was assessed using two outcome measures.

The primary outcome measure was "periapical healing", including clinical and radiographic evidence of the healing of each tooth or the absence of apical periodontitis [3]. Treatment success was defined according to strict criteria as the absence of pain or clinical evidence of inflammation or swelling and by conventional radiographic measures of complete healing/continuous presence of a normal periodontal ligament space (PAI score < 2).

The secondary outcome measure was "tooth survival". Success was achieved if the tooth was asymptomatic and considered to be functional regardless of its PAI score [33].

If a tooth had been extracted because of endodontic problems (persistent pain, swelling, or sinus or periapical radiolucent lesion), treatment was considered to have failed. Tooth extraction without any exit data regarding the postoperative periapical status excluded the tooth from further analysis for "periapical healing". The whole tooth was considered the assessment unit.

Statistical analysis

Continuous variables were reported as the mean ± SD, while dichotomous variables were reported as the number of cases and the percentage; qualitative ordinal variables were reported as the number of cases and the median value. Different tests were used to verify the presence of a statistically significant difference between the BIO and PCS groups; the test for the equality of proportions, t tests for the equality of means, and non-parametric k-sample tests for the equality of medians were applied when appropriate. The level of significance was set at 5% ($p < 0.05$); STATA version 14 (STATA Corp., TX, USA) was used to perform all statistical analyses.

Results

The follow-up rate of this study was 82%. Of the 55 patients originally enrolled, who had 84 treated teeth, 13 patients with 15 treated teeth (2 of which were extracted without further information collection) failed to attend the follow-up appointments and were excluded from the analysis. The patients who were excluded from the statistical analysis exhibited characteristics similar to those of the patients included.

Sixty-nine teeth from 42 patients were then included in the outcome assessment (Table 1), and they were therefore distributed as follows:

BIO group = 39 teeth in 23 patients (26.09% males and 73.91% females, average age = 53.17 years) obturated using the single-cone technique and BioRoot™ RCS (Septodont).

PCS group = 30 teeth in 19 patients (47.37% males and 52.63% females, average age = 51.26 years) obturated with the warm vertical compaction technique using gutta-percha and Pulp Canal Sealer™ EWT (Kerr©).

The teeth with AP from both groups were then further divided into two subsamples: BIOAP = 28 teeth in 18 patients from the BIO group, and PCSAP = 24 teeth in 16 patients from the PCS group (Table 1).

The BIO and PCS groups were homogeneous in terms of age and initial periapical status; the majority of the BIO group comprised females, while the subsamples of patients with teeth with AP were homogeneous in terms of gender. The BIO group included more secondary RCTs than the PCS group. The test used to assess whether the type of treatment was equally distributed between groups indicated that there was no significant difference and that the two groups were comparable (Table 1).

Table 2 Between-group comparison in terms of the two outcomes (healing and survival) in the general samples and subsamples

		All teeth ($N = 69$)			Teeth with AP ($N = 52$)		
		BIO group ($n = 39$)	PCS group ($n = 30$)	Test	BIOAP group ($n = 28$)	PCSAP group ($n = 24$)	Test
Healed	No	9 (23.08%)	13 (43.33%)	0.0735*	9 (32.14%)	12 (50%)	0.1908*
	Yes	30 (76.92%)	17 (56.67%)		19 (67.86%)	12 (50%)	
Survival	No	1 (2.56%)	2 (6.67%)	0.4074*	1 (3.57%)	1 (4.17%)	0.9114*
	Yes	38 (97.44%)	28 (93.33%)		27 (96.43%)	23 (95.83%)	

*Test for the equality of proportions

The overall survival and success rates at 12 months were good and comparable in both treatment groups (Table 2).

All teeth without a preoperative periapical lesion did not develop signs and/or symptoms of AP at 12 months.

The degree of healing in the teeth with AP at the first-year follow-up was slightly but not significantly better in the BIOAP group than in the PCSAP group, confirming the validity of both the established and the relatively new technique. Interestingly, in the BIOAP group, all teeth with extensive lesions with an initial PAI of 5/4 showed a significant reduction in the PAI to 3/1 at 12 months (Fig. 2a). This result seems promising, since the odds of healing for AP decrease for larger lesions [3, 38]. Unfortunately, the roots were not matched in terms of the PAI in the two groups when the study was started. The potential benefits of the single-cone/bioactive sealer combination are that this technique is simple and can be

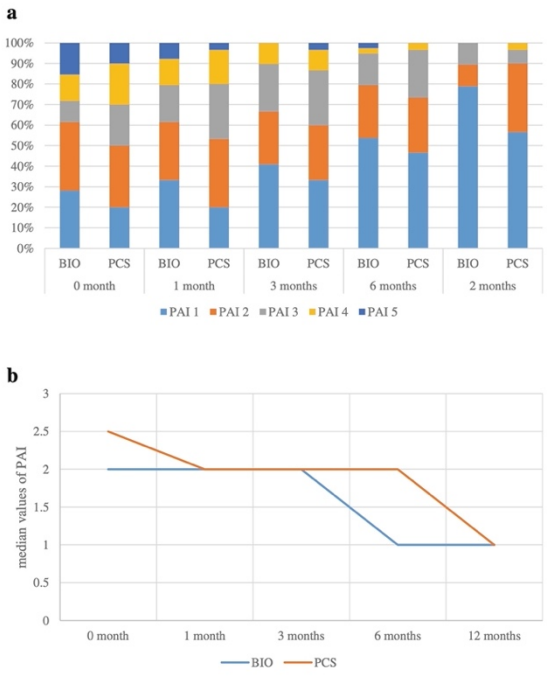

Fig. 1 **a** PAI value distribution per treatment group at every follow-up—general samples. **b** Median values of PAI over time per treatment group—general samples

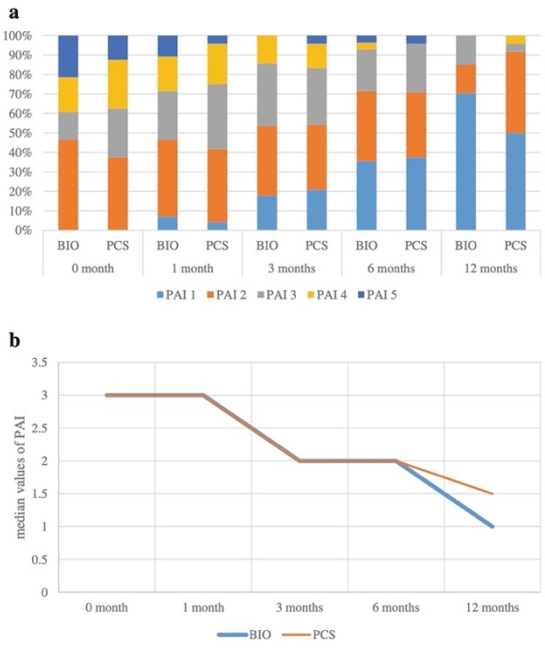

Fig. 2 **a** PAI value distribution per treatment group at every follow-up—subsamples of teeth with AP. **b** Median values of PAI over time per treatment group—subsamples of teeth with AP

implemented with a more conservative root canal preparation, and the biocompatibility of the sealer is reportedly optimal [11, 12, 39].

To the best of our knowledge, this is the first clinical trial that has compared the outcomes of the treatment of teeth obturated with a bioactive sealer and a single cone and teeth subjected to warm vertical compaction with gutta-percha and a ZOE sealer, which is a standard endodontic procedure for obturation [9]. These results are encouraging and consistent with those obtained from a recent retrospective study by Chybowski et al. [38], who reported an overall healing rate of 83.1% after an average of 30.1 months for 307 teeth that were endodontically treated or retreated with a bioactive sealer (EndoSequence Bioceramic Sealer, BC; Brasseler USA, Savannah, GA) and the single-cone technique. The better results obtained in their study are probably related to the longer follow-up time compared with that used in this initial prospective report. Unfortunately, the two investigations are not fully comparable because the tested sealers were both bioactive but different, and the authors dichotomized the outcomes as either healed or healing cases, all of which were considered "successful", while we used strict criteria [3, 4]. Furthermore, in the other study, four endodontists performed the RCTs using different protocols in private practices, while in this study, four residents performed the RCTs in

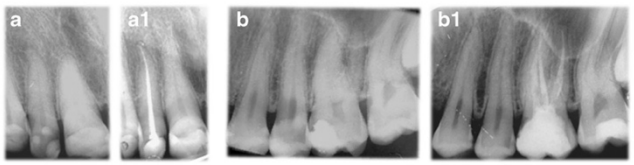

Fig. 3 Representative case from the single-cone technique and BioRoot™ RCS group, at month 0 (**a**) and 12 months follow-up (**a1**). Representative case from the warm vertical compaction of gutta-percha with zinc oxide-eugenol sealer group, at month 0 (**b**) and 12 months follow-up (**b1**)

a university setting with the same protocol. These differences make the data collected for single-cone obturation with a bioactive sealer in this study even more reliable. The most interesting difference in the results of the two clinical studies is that Chybowski et al. [38] found a negative predictive value for healing for lesions > 5 mm, while we observed a fast reduction in the sizes of larger lesions at 12 months (Fig. 2a).

Among the limitations of this study, the number of patients enrolled was not high, which reduces the statistical power of the research and produces extreme variability in the dental conditions, which may lead to obvious difficulties in the comparisons of the samples (Fig. 3).

Conclusion

Based on the findings of this pilot investigation, it is possible to advance the hypothesis that the use of a bioactive sealer together with the single-cone obturation technique may represent a good filling alternative to the use of warm vertical compaction with GP and ZOE sealer. To confirm this hypothesis, the cases included in this report will need to be followed up for a longer period of time, and further trials should be performed.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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DISCUSSION

Root canal obturation is necessary to fill the empty space left behind when the pulp is removed. Root canal treatment methodologies have not undergone significant changes over the past 20 years. Obturation is usually undertaken using a solid core material (GP cone) and a sealer.

Various types of endodontic sealers and filling techniques have been advocated to accomplish a satisfactory root filling (14). Until now, a WVC technique in conjunction with an epoxy resin-based or a zinc-oxide eugenol sealer has been recognized as the gold standard (72,73). Recently, a sealer-based obturation technique using calcium silicate-based sealers (CSBS) has become popular because it is less operator sensitive, requires less armamentarium, and is easier to perform (74). Nowadays, several types of CSBS are available on the dental market; they differ in composition, but their major component is calcium silicate.

The biological properties of CSBS depend on their chemical composition and setting reaction (45). Some authors have suggested that the filling quality of the SC technique in conjunction with a CSBS sealer is not inferior, but rather superior to the WVC techniques (74,75).

This research project was designed to investigate a new CSBS, BioRoot^{TM} RCS, to obtain precise information on the proper use of this sealer.

1. *To evaluate the retreatment of teeth obturated with a bioactive-hydraulic sealer*

We have investigated whether the new CSBS respects the Grossman principle, according to which an ideal filling material must be removable from

the canal space. Hence, an *ex-vivo* study on extracted mandibular premolar teeth evaluated the potential of retreating BioRoot™ RCS compared with the more commonly used resin-based sealer AH Plus (Dentsply International Inc., York, PA, USA).

Although recently there has been increasing use of CSBS in endodontics (55,56), the information on effectively removing these root-filling materials is inconsistent. Most of the research used a storage time of one to four weeks (39,57–60), while in just a few reports the samples were stored for a longer period before evaluation, which never exceeded six months (61–64). However, patients may require retreatment several months after primary root canal treatment in a clinical setting. Moreover, the scientific community considers it appropriate to wait for an average time of four years before deciding on endodontic failure if the patient has no symptoms (76,77). For this reason, in our study, a sample specimen filled with the CSBS was stored for one month and another for 12 months before retreatment procedures. We compared the two different storage times to evaluate whether, over time, the deposition of phosphate on the material's surface (39–42) and the formation of an interfacial layer at the dentin wall (43) had some influence on the re-treatment. To our knowledge, this is the first work that has evaluated the removal of a CSBS following long-term storage. Interestingly, this study also showed that the bioactive hydraulic sealer tested did not exhibit washout 12 months after obturation, a finding that may have particular clinical relevance.

Time required for retreatment procedures and percentage of residual filling materials RFM in the whole root canal space [RFM(%)]

Our results confirm what we supposed, and justify the decision to test long-term storage. Among the teeth obturated with BioRoot™ RCS, the group of samples that retreated after one year (BR*) showed a mean percentage of residual filling material for the whole canal (RFM %) that was significantly higher

than the group that retreated after one month (BR)(p-value=0.048). Furthermore, AH showed the least amount of time required for retreatment compared with both BR and BR* (p=0.0001 and p=0.0078, respectively). These results may be attributed to the increased mineral infiltration interface over time (43). It has been discussed that the precipitation of calcium phosphate or calcium carbonate ions within the dentinal tubules (39–42) and the formation of hydroxyapatite on the CSBS surface (39) should explain the more effective sealing ability of the CSBS material over time (78–81). As previously reported (80), a chemical bond is achieved through a mineral infiltration zone at the bioactive material to the tooth interface. This property is essential because the adhesion of the sealer to the canal walls will lead to less microleakage.

SEM and EDS microanalysis

SEM was used to observe the interface dentin/material in our study. RBS exhibited continuity with the dentinal walls. By contrast, the CSBS/dentin interface appeared to be mediated by the formation of an infiltration zone, which, using EDS microanalysis, was defined as a mineral infiltration zone for the presence of calcium phosphate ions also found in the CSBS. These data show a certain clinical relevance since, as previously mentioned, secondary endodontic treatments are generally carried out several months after primary therapies. According to our study, the material used changes the environment it comes into contact with over time (81), making it more difficult to remove, since the mineral infiltration zone and the sealer tags ensure sealer adaptation and bonding to the dentinal wall. Moreover, CSBS creates a strong bond with the GP core material. In addition, according to our results, the time taken for retreatment was affected by the type of sealer, a condition explained by the observations mentioned above (82,83). This difference is statistically significant; however, it may not have clinical significance (82,83).

Re-establishing working length (WL), patency and percentage of residual filling materials in the apical third of the canal [Apical 3rd RFM (%)]

Each retreatment was successfully completed in all samples, and therefore the Grossman principle is respected. Since endodontic failure can occur if infection persists in the root canal system, the root canal space should be adequately cleaned and disinfected when performing a secondary treatment. Once the previous materials have been removed, re-establishing the WL and re-achieving patency significantly improves periapical healing rates (77). Our results show that the obturation with the new bioactive hydraulic sealers did not permanently block the apical area. This data may be supported by the results concerning the apical third. In fact, where apical third RFM(%) was considered, no significant difference was detected for this variable between the three groups.

Our study used the matched-taper, single-cone filling technique, which allowed the easier penetration of rotary retreatment instruments into the obturation (84). While CSBS is hard upon setting, our study showed that apical patency and WL were achieved in 100% of the samples, irrespective of whether the pilot or master cone was used. However, we recommend the use of the master cone inserted at the working length, so that, in case of failure, it is possible to carry out safety retreatments, avoiding any apical transport or procedural mistakes.

2. *To evaluate the outcome of primary and secondary endodontic treatment performed with a bioactive-hydraulic sealer*

Once the removability of the CSBS and its suitable application as a filling material had been verified, we designed a randomized case-controlled pilot study to obtain insights into the use of the new bioactive cement as a sealer with single-cone obturation. In fact, despite the growing trade in and use of the new

bioactive sealers, there is a paucity of information in the specialized literature on the outcomes achieved with the new CSBS, particularly when used with the single-cone obturation technique *in vivo*. Our article reported a 12-month follow-up of a modular project in which the outcomes of primary and secondary root canal treatments were assessed in teeth obturated with either the SC and a bioactive sealer, or with WVC with GP and ZOE sealer, which is considered the classic reference treatment (85).

First, our study was based on a standardized protocol to minimize each bias that could affect the results. Four endodontic post-graduate residents performed all the treatments in a university setting. They used a standardized instrumentation and disinfection protocol, which varied only in terms of the technique and sealer used for the obturation of the root canal. The assignment of each patient to the four residents and the assignment of the type of obturation technique for each case occurred randomly with a flip of the coin. Clinical and radiographic follow-ups were performed for each tooth, and two trained and calibrated examiners (86) assigned a periapical index (PAI) score to each radiograph (87). The follow-ups were conducted at short intervals (1, 3, 6, and 12 months) to obtain detailed information on the course of healing of the teeth during the first year of treatment to evaluate the supposedly better sealing ability of the new material compared with the standard one (42).

It was advocated that using a well-fitting cone with a bioactive sealer would enhance the sealing properties of the material when in contact with fluids and lead to successful single-cone obturation (42). First of all, BioRoot^{TM} RCS allowed simple and effective root canal obturation. The method was easy to use and relatively cost-effective because no special armamentarium was required.

Overall success rate in BIO and PCS groups, success rate (periapical healing) in BIOAP and PCSAP groups, overall survival rate in BIO and PCS groups and survival rate in BIOAP and PCSAP groups

As recently advocated by Ng et al. (76,77), treatment success was assigned using two outcome measures. The primary outcome measure was periapical healing, defined according to strict criteria (PAI <2). The secondary outcome measure was tooth survival, which was defined regardless of the PAI score; success was achieved if the tooth was functional and asymptomatic. We felt it was clinically relevant to offer the results on the basis of two interpretations, using strict and loose criteria. As it is known that some periapical lesions may take several months or even years to completely heal, we wanted to show the survival rate criteria, as this outcome measure clearly describes a condition that is still potentially healing. On the other hand, we also reported the periapical healing to show if and what effect the CSBS had on the healing time.

Our study's survival rate was similar in the BIO and PCS groups (p = 0.4074) and the BIOAP and PCSAP groups (p = 0.9114). The success rate was higher in the BIO groups but not statistically significant (p=0.0735). The healing rate was higher in the BIOAP group than in the PCSAP group (67.86% versus 50.00%), but the difference was not statistically significant (p = 0.1908). The group of teeth obturated with the CSBS and SC technique showed slightly better results than those obturated with WVC with GP and a ZOE sealer. However, the analysed outcome measures did not reveal significant differences. Thus, our data reveals that the two techniques are good and comparable.

The potential benefits of the single cone/bioactive sealer combination are that this technique is easy and fast and aims to create a biological seal (32,34,91–94,38,40,41,66,71,88–90). Moreover, the technique can be implemented with a more conservative root canal preparation, and the biocompatibility of the sealer is reportedly optimal (40,41,95). This data confirms both the established and relatively new techniques. Interestingly, in the group of teeth obturated with the CSBS and SC technique, all teeth with extensive pre-operative lesions and an initial PAI of 5/4 showed a significant reduction in this periapical index score to 3/1 at 12 months. This result seems promising since the odds of healing for AP decrease for larger lesions (96,97). These results seem to confirm the advantages

and potential benefits of the new CSBS. We can assume that the inductive potential of this sealer, thanks to the precipitation of calcium phosphate or calcium carbonate and the formation of hydroxyapatite on the material's surface (39–42), may favour the healing of AP. Furthermore, given the relative simplicity of this technique that leads to a biological hermetic seal, we believe that this information may be useful in clinical practice, especially for teeth with extensive lesions requiring prosthetic rehabilitation.

To the best of our knowledge, this is the first clinical trial that has compared the outcomes of the treatment of teeth obturated with a CSBS and SC technique and teeth subjected to WVC with gutta-percha and a ZOE sealer, which is a standard endodontic procedure for obturation (98). These results are encouraging and consistent with those obtained from Chybowski et al. (97), and Zavattini et al. (55). Chybowski (97) reported an overall healing rate of 83.1% after an average of 30.1 months for 307 treated teeth, and Zavattini (55) showed an overall healing rate of 90% after an average of 12 months for 53 treated teeth. The first was a retrospective study conducted in private practices, while the second was a non-randomized case-control study conducted in a university setting.

Unfortunately, the study's design differences do not make the three articles fully comparable. Chybowski et al. and Zavattini et al. considered both healed and healing cases "successful," while we have used stricter criteria (96,99). Thus, they obtained more positive results in their study compared with ours. Furthermore, the types of CSBS used were not the same: Chybowski et al. used EndoSequence (Bioceramic Sealer, BC; Brasseler USA, Savannah, GA), while Zavattini et al. used Bioroot^{TM} RCS.

Most of the materials based on tricalcium silicate contain Portland cement. Portland cement is used in construction and manufactured from natural minerals. Most types of CSBS contain trace elements leached in solution when in clinical use (100–102), and Portland cement itself only has 68% tricalcium silicate (103). By contrast, BioRoot™ RCS is made entirely of pure tricalcium silicate

cement with no other cementitious additions. This is essential not only to avoid trace minerals but also because the active part of the material is the tricalcium silicate. Thus, all the properties attributed to the tricalcium silicate (i.e., the formation of calcium hydroxide, which is responsible for the biomineralization, bone and hard tissue formation, and antimicrobial properties) will be better expressed with the use of this sealer than the classic Portland cement.

A recent randomized case-controlled clinical trial reported similar results to those from our study (104). The authors compared the clinical efficacy and outcome of an SC technique using Endoseal TCS (SBO) with a WVC technique using AH Plus (CWC). Kim et al. obtained a recall rate lower than ours (79% versus 82%), but a higher average follow-up period (17 versus 12 months). Healing was determined as a decreased PAI score and lack of symptoms. They divided teeth into the following categories: healed, healing, and diseased. Their success rate was comparable to ours when both loose and strict criteria were considered. In fact, for the group of teeth obturated with the SC technique using the CSBS, they reported a success rate of 94.3% (loose criteria) and 71.4% (strict criteria), while the group of teeth obturated using a WVC and an RBS showed a success rate of 92.3% (loose criteria) and 60.8% (strict criteria). Unfortunately, they did not use a standardized instrumentation protocol, and they did not enroll patients before treatment but after the first treatment visit.

Limitations of the studies

In the experimental *ex-vivo* study we chose to work on easy samples. This represents a limitation of our study because it does not allow us to extend the results to curved canals. Another potential limitation is the solvent used to remove the root-filling materials, even if its use was primarily chosen to help clean every residual from gutta-percha. There is no evidence that currently available solvents are effective on CSBS. We believe it may be necessary to develop a solvent that improves the retreatment of CSBS.

Among the limitations of the pilot study, the number of patients enrolled was not high, which reduced the statistical power of the research and produced extreme variability in the dental conditions, which may lead to apparent difficulties in comparing the samples. Another limitation is that our success rate was lower than the pooled weighted success rate based on strict criteria of the systematic reviews (105,106). This is because we adopted a short follow-up period (12 months), which may include more healing cases than fully healed ones. Systematic reviews have revealed that success rates increase with longer follow-ups (106). The first bioceramic root canal sealer was only introduced in 2007, and various types of CSBS have not been evaluated for a long time (44). Therefore clinical studies of bioceramic root canal sealers are rare, and the follow-up duration of this study was short. As stated in the article, this is intended to be the first part of a modular project that will provide data on the behaviour of the two groups over time (at one year, two years, and four years).

Future perspectives

Long-term *ex vivo* studies conducted on teeth with complex anatomies may evaluate the re-treatability of CSBS. Future research conducted *in vivo* will confirm our data.

To confirm our results, the cases included in the pilot study will need to be followed up for a longer period of time; this is the reason we intend to report the treatment outcomes progressively (at two and four years of follow-up). Moreover, well-designed, randomized, case-controlled clinical trials should be performed. Within the limitations of this study, it was found that the SC technique using BioRoot^{TM} RCS can be a feasible alternative to WVC using Pulp Canal Sealer. Further follow-up and other studies with larger sample sizes are needed for better reliability.

CONCLUSIONS

1. Obturation of retreating teeth with a bioactive-hydraulic sealer was successful. In addition:
   1.1. We were able to re-establish the working length (WL) and patency in 100% of the samples.
   1.2. The time required for retreatment procedures was affected by the type of sealer used and the time of storage; AH showed the lowest value of time taken for retreatment procedures when compared both to BR and BR* ($p=0.0001$ and $p=0.0078$, respectively).
   1.3. The percentage of residual filling materials in the whole root canal space (%RFM) was significantly higher in the group of samples obturated with the CSBS and retreated after one year (BR*) (p-value=0.048).
   1.4. The percentage of residual filling materials in the apical third of the canal (apical 3rd RFM (%)) did not show any difference between the three treatment groups.
   1.5. High-resolution SEM images confirmed the data obtained from SM, and EDS microanalysis highlighted the presence of calcium phosphate in the mineral infiltration zone between CSBS and dentin.

2. The outcome of primary and secondary endodontic treatment performed with a bioactive-hydraulic sealer was similar to results from those obturated with WVC of gutta-percha and ZOE sealer. In addition:
   2.1. The overall survival rates of treated teeth at 12 months were comparable in the BIO and PCS groups (97.44% versus 93.33%).
   2.2. The survival rates in the BIOAP and PCSAP groups were similar (96.43% versus 95.83%).
   2.3. The overall success rate at 12 months was higher in the BIO than in the PCS groups, although the difference was not significant ($p= 0.0735$).

2.4. The success/healing rate was slightly higher in the BIOAP group than in the PCSAP groups (p= 0.1908).

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1. *Privacy Form*

ESPRESSIONE DEL CONSENSO AL TRATTAMENTO DEI DATI PERSONALI E SENSIBILI (PRIVACY)
ART.81 D.LGS 196/2003
"Codice in materia di protezione dei dati personali"

Consapevole che le dichiarazioni non veritiere sono punite dalla legge, sotto la mia responsabilità dichiaro:

Io sottoscritto (nome e cognome)……
Nato a …… il……
Codice fiscale……..
Residente a ……provincia…… in via……C.A.P……..

Per sé oppure in qualità di
- Tutore
- Amministratore di Sostegno
- Esercente Potestà Genitoriale
- Rappresentante legale
- Minorenne esercitante la patria potestà o rappresentante legale

Di (nome e cognome)
Nato a …… il……
Codice fiscale……..
Residente a ……provincia…… in via……C.A.P……..
Per sé oppure in qualità di

Ricevuta l'informativa di cui all'Art. 13 del D.lgs 196/2003 "Codice in materia di protezione dei dati personali" e consapevole che:

1. Il trattamento riguarda, in particolare, i dati personali e sensibili
2. Il consenso, una volta manifestato, in qualsiasi momento, potrà essere modificato e revocato, in tutto o in parte
3. Potrò decidere di oscurare, in qualsiasi momento, singoli documenti relativi ad episodi di diagnosi e cura
4. Per la modifica o l'oscuramento di cui sopra potrò rivolgermi al Reparto di Odontoiatria Conservativa ed Endodonzia dell'A.O.U. di Cagliari – presidio Policlinico Universitario di Monserrato, Responsabile Prof.ssa Elisabetta Cotti (SS 554; Bivio per Sestu, Monserrato, CA; tel. 070 51096125)

Dichiaro di aver compreso il contenuto dell'informativa e presto liberamente e consapevolmente il consenso al trattamento dei dati personali e sensibili da parte del Reparto di Odontoiatria Conservativa ed Endodonzia dell'A.O.U. di Cagliari – presidio Policlinico Universitario di Monserrato, titolare del trattamento, come di seguito espresso.

1

1. **CONSENSO AL TRATTAMENTO DEI DATI PERSONALI E SENSIBILI**

(dati prodotti ed utilizzati dal Reparto di Odontoiatria Conservativa ed Endodonzia dell'A.O.U. di Cagliari per erogare le prestazioni richieste)

ACCONSENTO AL TRATTAMENTO

- o SI
- o NO (FINE DELLA COMPILAZIONE)

2. CONSENSO ESAMI DIAGNOSTICI E STRUMENTALI

ACCONSENTO A SOTTOPORMI AI SEGUENTI ESAMI

- o VISITA SPECIALISTICA ODONTOSTOMATOLOGICA
- o RADIOGRAFIA OANORAMICA (OPT)
- o RADIOGRAFIE ENDORALI SUPPLEMENTARI
- o ESAMI STRUMENTALI ADDIZIONALI (qualora strettamente necessari a fini diagnostici)

3. CONSENSO AL TRATTAMENTO DEI DATI PER SCOPI DI RICERCA CLINICA, EPIDEMIOLOGICA E FORMAZIONE (con l'obiettivo di migliorare conoscenze, cure e prevenzione)

ACCONSENTO CHE I DATI CLINICI, COMPRESE LE IMMAGINI FOTOGRAFICHE E RADIOGRAFICHE, OGGETTO DEL TRATTAMENTO, RESI ANONIMI, POSSANO ESSERE UTILIZZATI PER SCOPI DI RICERCA CLINICA, EPIDEMIOLOGICAL FORMAZIONE E STUDIO DI PATOLOGIE.
I dati trattati mediante strumenti anche elettronici, saranno diffusi solo in forma rigorosamente anonima, ad esempio attraverso pubblicazioni scientifiche, statistiche e convegni scientifici.
Il suo consenso implica che il personale medico, il Comitato Etico e le autorità sanitarie italiane e straniere potranno conoscere i dati che La riguardano, contenuti anche nella Sua documentazione clinica originale, con modalità tali da garantire la riservatezza della Sua identità.

ACCONSENTO

- o SI
- o NO

Il presente consenso al trattamento dei dati ha validità permanente in questo ente salvo revoca e/o modifica e/o raggiungimento della maggiore età.
In caso di delega alla consegna, presentarsi con delega e documento in corso di validità proprio e del delegante (anche in copia).

Data ……. Firma ……
(firma estesa e leggibile) (1)

(1) Il modulo può essere compilato e sottoscritto dal paziente o direttamente dal medico che raccoglie la dichiarazione di consenso del paziente e che sottoscrive il modulo per relativa attestazione ai sensi dell'art. 81 del D.lgs. n. 196/2003 – Codice Privacy. Il consenso può essere rilasciato: nel caso di paziente minorenne, dal/i genitore/i (esercente/i potestà genitoriale); nei casi di emergenze sanitarie, da un familiare, un convivente o un responsabile/accompagnatore della struttura in cui dimore il paziente, previa autocertificazione ai sensi dell'art. 46 del D.P.R. n. 445/2000.

2. *Research Consent Form*

INFORMAZIONI SCRITTE
PER IL PAZIENTE
Versione 1

Titolo dello studio: Esito del Trattamento Endodontico in pazienti trattati con cementi bioattivi-ETECB

Medico referente: *Dott.ssa Giulia Bardini, Dipartimento di Odontoiatria Conservativa ed Endodonzia.*

Gentile Signora / Egregio Signore,

con la presente desidero informarla sulla possibilità di pubblicare, in forma rigorosamente anonima, il suo caso clinico su riviste scientifiche specializzate.

La prego di leggere attentamente queste informazioni scritte prima di prendere una decisione. Lei avrà a disposizione tutto il tempo necessario per decidere se acconsentire o meno.

Potrà, inoltre, porre liberamente qualsiasi domanda di chiarimento e riproporre ogni quesito che non abbia ricevuto una risposta chiara ed esauriente.

Nel caso in cui, dopo aver letto e compreso tutte le informazioni ivi fornite, decidesse di acconsentire alla pubblicazione, Le chiederò di voler firmare e personalmente datare il modulo di Consenso Informato allegato a questo documento.

Quali sono le caratteristiche della pubblicazione
Il caso per cui è stato seguito presso il nostro dipartimento dal 2017 ad oggi.

Cosa comporta la pubblicazione
Nel caso in cui Lei decidesse di acconsentire alla pubblicazione del suo caso clinico, questo non comporterà alcun cambiamento per Lei. Non è prevista alcuna indagine aggiuntiva. Le Sue cure mediche attuali e future presso l'Ospedale non saranno compromesse dalla Sua decisione ed i medici continueranno a seguirLo/a con la dovuta attenzione.
I suoi dati saranno diffusi solo in forma rigorosamente anonima.

Informazioni finali
Al termine del processo di pubblicazione, potrà esserLe fornita una copia della stessa.

INFORMAZIONI IN MERITO AL TRATTAMENTO DEI DATI PERSONALI:

Titolari del trattamento e relative finalità
Il Centro di sperimentazione del Policlinico di Monserrato in accordo alle responsabilità previste dalle norme della buona pratica, tratteranno i Suoi dati personali, in particolare quelli sulla salute e, soltanto nella misura in cui sono indispensabili in relazione alla pubblicazione.
Il trattamento dei dati personali relativi a è indispensabile alla stesura della pubblicazione.

Natura dei dati
Il medico che La segue renderà i suoi dati completamente anonimi, in questo modo sarà impossibile per chiunque abbia accesso alla pubblicazione, risalire alla sua identità.

Modalità del trattamento
I dati, saranno diffusi solo in forma rigorosamente anonima attraverso pubblicazione scientifica, statistica e convegni scientifici. La Sua adesione implica che il Comitato etico potrà conoscere i dati che La riguardano, con modalità tali da garantire la riservatezza della Sua identità.

Esercizio dei diritti
Potrà esercitare i diritti ai sensi del D. lgs 196/2003 "*Codice in materia di protezione dei dati personali*" e del Regolamento UE 2016/679, nonché della Deliberazione del Garante (Del. 52 del 24/7/08).

Dott./Prof.	Giulia Bardini
Telefono	+39 3408363517
Email	supergiu.gb@gmail.com

Giulia Bardini

_____	_____	_____
Nome per esteso del medico che ha consegnato l'informativa	Data	Firma

MODULO DI CONSENSO INFORMATO

Versione 1

Titolo dello studio: Esito del Trattamento Endodontico in pazienti trattati con cementi bioattivi-ETECB

Medico referente: *Dott.ssa Giulia Bardini, Dipartimento di Odontoiatria Conservativa ed Endodonzia.*

Io sottoscritto/a _____ nato/a il ___/___/_____
residente a_____ via/piazza _____ Tel._____
domicilio (se diverso dalla residenza) _____

DICHIARO

- di aver ricevuto dal Dottor _____ esaurienti spiegazioni in merito alla richiesta in oggetto, secondo quanto riportato nella scheda informativa, facente parte di questo consenso, della quale mi è stata consegnata una copia in data _____;
- che mi sono stati chiaramente spiegati e di aver compreso la natura, le finalità, le procedure della pubblicazione;
- di aver avuto l'opportunità di porre domande chiarificatrici e di aver avuto risposte soddisfacenti;
- di aver avuto tutto il tempo necessario prima di decidere se acconsentire o meno;
- di non aver avuto alcuna coercizione indebita nella richiesta del Consenso;

DICHIARO pertanto di

☐ **Acconsentire** ☐ **NON Acconsentire**
alla pubblicazione

☐ **volere** ☐ **NON volere**
ricevere copia della pubblicazione

_____ ___/___/_____ _____ _____
Nome per esteso del paziente (adulto, minore maturo) Data Ora Firma

Sottoscrivendo questo modulo acconsento al trattamento dei miei dati personali nei limiti e con le modalità indicate nell'informativa fornitami con il presente documento.
_____ ___/___/_____ _____ _____ Nome per esteso del paziente (adulto, minore maturo) Data Ora Firma

Io sottoscritto Prof./Dr. Giulia Bardini

Dichiaro che il Paziente ha firmato spontaneamente il suo consenso alla pubblicazione
Dichiaro inoltre di:

- aver fornito al Paziente esaurienti spiegazioni in merito a quanto in oggetto
- aver verificato che il Paziente abbia sufficientemente compreso le informazioni fornitegli
- aver lasciato al Paziente il tempo necessario e la possibilità di fare domande
- non aver esercitato alcuna coercizione od influenza indebita nella richiesta del Consenso

Giulia Bardini	20\09\2019	
Nome per esteso del medico che ha fornito le informazioni e raccolto il consenso informato	Data	Firma

NOTA BENE

una copia del presente modulo, firmato e datato, allegato alle "Informazioni scritte per il Paziente" dovrà essere consegnata al Paziente stesso

3. *Informed Consent*

DICHIARAZIONE DI RICEVUTA INFORMAZIONE E CONSENSO AD INTERVENTO DI TERAPIA ENDODONTICA

Sig. / Sig.ra .....
Via .....

Gentile Paziente,

con questo modulo si riassumono i concetti relativi al suo trattamento già oralmente espressi nel corso della visita, in presenza del personale di studio e dei suoi accompagnatori, certi anche che la rilevazione anamnestica da lei sottoscritta sia completa essendo la sua salute al centro del nostro interesse, in modo da avere, anche per iscritto, il Suo assenso alla esecuzione delle terapie preventivate come previsto dal nuovo Codice Deontologico. Pertanto autorizzato ad effettuare o a richiedere esami radiografici ai fini diagnostici del tipo OPT, Rx endo orali, Dentascan, ed effettuata la visita specialistica con questi ausili riteniamo sulla base della nostra esperienza clinica che lei sia affetto/a da
Diagnosi:…….

Descrizione dell'intervento
La terapia da noi effettuata ha lo scopo di raggiungere il risultano clinico sperato pertanto agiremo in tutta scienza e coscienza per tale finalità sperando di raggiungere la guarigione clinica attraverso la rimozione con apposito strumentario della carie ed eventualmente apertura camera pulpare, rimozione del tessuto pulpare, strumentazione manuale e/o meccanica secondo la tecnica di…,otturazione secondo la metodica di…; successiva ricostruzione del dente. Nel Suo caso poi :

.....
.....
.....

Benefici dell'intervento
Conservazione del dente ed eliminazione di infezione, infiammazione e dolore derivanti dalla patologia dentale.

Rischi dell'intervento
Sono relativi: all'impiego possibile e/o inevitabile di anestetico locale, con vasocostrittore o senza, a cui alcuni soggetti possono risultare particolarmente sensibili per allergie, patologie renali, cardiache, endocrine o stato di gravidanza; alla possibilità di traumi sulle mucose a causa degli strumenti manuali o meccanici; all'eventualità di ingestione accidentale di detti strumenti. Ad errori nella strumentazione e nella otturazione relativi a bruschi ed incontrollati movimenti per eccessivo stress del paziente con conseguenti perforazioni camerali o radicolari, come a complicanze nervose per piccole lesioni del nervo anestetizzato o per fuoriuscita del materiale dall'apice dentario con conseguenti sintomi compressivi sulle strutture nervose o per invasione di cavità preformate (seno mascellare).

Materiali impiegati
Otturazione provvisoria: .....
Otturazione definitiva: .....
Otturazione del canale radicolare: .....
Perni endocanalari costituiti da: .....

Complicazioni
Dopo l'anestesia del tipo tronculare può persistere per qualche giorno un leggero fastidio di tipo muscolo articolare nei movimenti di apertura e chiusura della bocca, dopo la strumentazione del canale relativamente alla patologia parodontitica acuta siero-purulenta possono presentarsi sintomi di dolore e/o gonfiore localizzato all'elemento dentario trattato e/o agli elementi limitrofi con possibilità di gonfiore fino a situazioni ascessuali.
Una volta effettuata l'otturazione canalare, è possibile la permanenza per tempi più o meno lunghi di sensibilità localizzata all'elemento dentario specialmente alla compressione dello stesso sia in articolazione che per stimolazione con sensazione di allungamento dell'elemento dentario trattato.
I denti devitalizzati risultano più fragili del normale, per la disidratazione relativa alla perdita della vitalità e perciò del nutrimento, per tale motivo risulta indispensabile a seconda della perdita di tessuto smalto dentinale, procedere ad una ricopertura protesica per l'alto percentuale di possibili fratture che determinerebbero sia la perdita del dente che l'inutilità del trattamento effettuato, nei tempi indicati dal professionista. Nell'attesa va ricordato che sull'elemento trattato vanno evitate sostanze alimentari o atti che per la loro intensità ne possano provocare la frattura, che purtroppo resta anche situazione occasionale. In alcuni altri casi, per raggiungere la guarigione, è possibile che sia necessario provvedere ad un lembo chirurgico diagnostico,alla resezione dell' apice dentario con otturazione retrograda della zona (apicectomia e otturazione retrograda) o anche all'estrazione dell'elemento dentario nonostante il trattamento ortogrado.

Possibili alternative proposte al trattamento con costi, benefici e controindicazioni
.....
.....

Altre informazioni richieste dal paziente (scrivere le eventuali domande o la frase "Nessuna Domanda")
.....
.....
.....
.....

Io sottoscritto .....

dichiaro di essere stato/a informato/a e di aver compreso lo scopo e la natura della terapia endodontica ed eventualmente conservativo protesica indicata nel presente modulo, e di avere altresì consapevolezza dei rischi e delle complicazioni che ne potrebbero derivare. Inoltre a completa conoscenza delle problematiche inerenti la mia situazione clinica attuale, delle possibili alternative terapeutiche e dei loro costi, delle ulteriori procedure cliniche non adottate in questo studio, do il mio assenso alle terapie che mi sono state illustrate e spiegate.

Tale documento è composto da fogli 2.

Luogo ……....., Data … / … / ……

Firma del Paziente

.....

Firma del Medico/Odontoiatra

.....