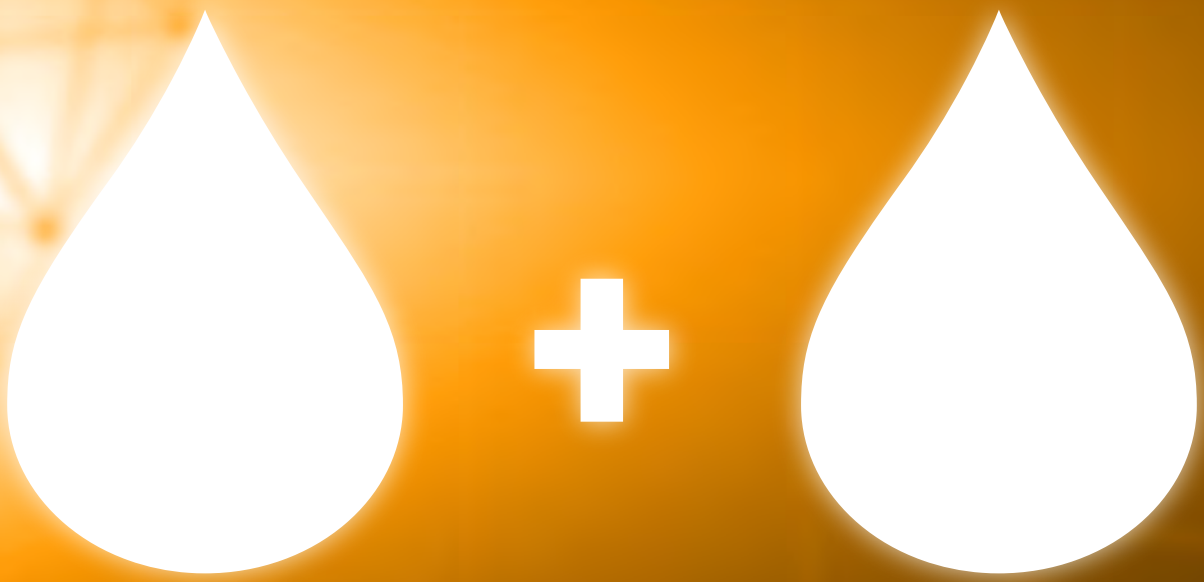
Technical Scientific Profile

ENG

MTA-Fillapex

Bioceramic root canal sealer



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Summary

1. GENERAL INFORMATION

1.1. General considering about endodontic sealers

Since ancient times there is a concern of dental professionals in relation to root canal filling. The science of Endodontics has been continuously seeking to improve the knowledge and performance of endodontic sealers, as well as other materials and instruments used in this specialty field. The aim of filling a root canal is to keep the periapical tissues healthy. McElroy in 1955 had already described many substances that were used for filling root canals. With the evolution of research, new materials became available in the market for root canal filling.

According to GROSSMAN (1974), root canal filling materials must have the following properties:

A. **It should be easily introduce inside the root canal.**

B. **It should seal the whole root canal system, including lateral and accessory canals.**

C. **Once inserted, it should not shrink.**

D. **It should be impervious to moisture.**

E. **It should be antimicrobial or, at least, unsuitable for microbial growth.**

F. **It should be radiopaque.**

G. **It should not stain the tooth structure.**

H. **It should be sterile or capable of being easily and quickly sterilized.**

I. **It should not irritate the periapical tissues.**

J. **If necessary, it should be easy to remove.**

Being established the ideal profile of a filling material, it is possible to point the ideal parameters for research and development of new products, as well as the evaluation of those already on the market.

1.2. MTA-Fillapex

MTA-Fillapex is an bioceramic endodontic sealer based on MTA, developed by Angelus (Londrina/Parana/Brazil) and launched commercially in 2010. It is a new product that combines the proven advantages of MTA with a superior canal obturation product. Its formulation in the paste/paste system allows a complete filling of the entire root canal, including accessory and lateral canals.

MTA, present in the composition of MTA-Fillapex, is more stable than calcium hydroxide, providing constant release of calcium ions for the tissues and maintaining a pH which elicits antibacterial effects. The product is eugenol free and will not interfere with adhesive procedures inside the root canal. Also, it does not cause discoloration of the tooth structure.

MAIN FEATURES AND ADVANTAGES

A. **Biocompatible:** fast tissue recovery without causing inflammatory reactions;

B. **High Radiopacity:** great radiographic visualization;

C. **Excellent Flow:** allows filling of accessory canals;

D. **Release of Ca^{2+}:** helps in the quickly recovery of bone and cementum formation;

E. **Paste-to-Paste System:** easy to manipulate;

F. **Adequate working time:** allows its use by endodontists and general practitioner;

G. **Resin-Based:** easy to remove with gutta-percha solvents;

2. COMPOSITION

COMPONENT NAME	CHEMICAL NAME	FUNCTION
PASTE A		
Salicylate resin	Methyl Salicylate Butylene Glycol Colophony	Ionic polymer formation
Calcium Tungstate	Calcium Tungstate	Radiopacity
Silicon Oxide	Silicon Oxide	Filler
PASTE B		
Silicon Oxide Titanium Dioxide	Silicon Oxide Titanium Dioxide	Filler Pigment
Mineral Trioxide Aggregate	Tricalcium silicate Dicalcium Silicate Calcium Oxide Tricalcium Aluminate	Active ingredient and responsible for ionic polymer formation
Base resin	Pentaerythritol Rosinate P - Toluenesolfonamide	Plasticity Plasticity

3. PRESENTATION

The product is presented in dual syringes with automix tips or in tubes.

Syringe with automix tip - 4g

or

Syringe with automix intracanal tip - 4g

Base paste tube - 18g
Catalyst paste tube - 12g
or
Base paste tube - 7,2g
Catalyst paste tube - 4,8g

PRESENTATIONS

826	Tubes (30g) packing with 1 tube of base paste (18g), 1 tube of catalyst paste (12g) and 1 mixing block.
827	Syringe (4g) packing with 1 syringe (4g), 15 self-mixing tips and 1 mixing block.
8288	Tubes (12g) packing with 1 tube of base paste (7,2g), 1 tube of catalyst paste (4,8g) and 1 mixing block; 158 - Pack with 10 automixing tips.
8270	Syringe (4g) packing with 1 syringe (4g), 15 intracanal self-mixing tips and 1 mixing block.

4. INDICATIONS

MTA-Fillapex is intended for permanent sealing of root canals in combination with gutta-percha cones.

Root canal filling performed with MTA-Fillapex. (Ramos, CAS et al 2011)

CONTRAINDICATION

In patients with hypersensitivity against the resins or other components of the product.

In perforations, resorption sites and apical plugs (these cases must be filled with MTA Reparative Cement (Angelus MTA)).

5. PHYSICAL, CHEMICAL AND BIOLOGICAL PROPERTIES

5.1. Manipulation and insertion

The MTA-Fillapex is paste/paste material presented in automix double syringes or tubes which provide an adequate consistency for the cement insertion in the root canal.

5.2. Sealing of root canals

MTA-Fillapex shows an optimized flow. It provides excellent filling and sealing of the canals, main and lateral, as shown below.

5.2.1. Flow ISO 6876:2012 Test

(SANTIAGO, GC, 2011)

1. A total of 5 samples were prepared for MTA-FILLAPEX. The base and catalyst pastes of MTA-FILLAPEX were dispensed in equal proportion on a glass plate, mixed for 60 seconds.
2. Approximately 0.05 ml of the mixture was dispensed between two glass plates (40x40mm). A 100 g weight was applied on the second plate.
3. Five determinations were accomplished for each sample in order to determine the extent of flow of the material.

Results:

SAMPLES	FLOW (millimeters)
1	24.74
2	24.72
3	25.18
Average	24.88
SD	0.26

Conclusion: Each disc had a diameter above the minimal required of 17 mm by ISO 6876:2012.*

5.2.2. Film Thickness ISO 6876:2012 Test

1. A total of 3 samples were prepared. The catalyst and base paste of MTA-FILLAPEX was dispensed in equal proportion in a glass plate and mixed for 60 seconds.

2. A portion of the sample was applied onto the center of a glass slab. A second glass slab was placed centrally on the sealer. Finally, a weight of 150+-3N (15 Kg) was applied on the center of the plate;

3. After one minute from the start of the mixing, a load of 15 N was carefully applied vertically on the top of the slab.

4. The thickness of the film was measured using a micrometer.

Results: MTA-FILLAPEX presented film thickness of 15.00 (± 2.65) µm, as can be seen in the Table below.

SAMPLES	FILM THICKNESS (MICROMETERS)
1	16.00
2	17.00
3	12.00
Average	15.00
SD	2.65

Average film thickness: 15 µm

Standard Deviation film thickness: 2.65 µm

Conclusion: MTA-FILLAPEX presented film thickness of 15.00 ± 2.65 µm. As expected, film thickness of MTA-FILLAPEX, determined in accordance with EN ISO 6876:2012, did not exceed 50 µm.*

*Internal Bench Test

5.3. Dimensional Change ISO 6876:2001 Test

The MTA-Fillapex, unlike resin cements, presents an important characteristic required by the sealing materials, which is the setting expansion.

1. 2g of MTA-Fillapex were prepared with 0.02 ml of water and dispensed into a mold to obtain three samples;
2. Two glass plates were pressed up on both surfaces of the mold containing the material. The glass plates were fixed with the aid of a device for stabilization;
3. After 5 minutes, the mold was taken to a relative humidity chamber of 95 % to 100% and later placed in dry heat at 37°C to reach the setting time (2h 20min);
4. Setting was confirmed by surface indentation with a Gilmore needle until the sample did not present any visible marks;
5. The samples were polished with 600 grit sandpaper;
6. The samples were measured;
7. These samples were placed in distilled water and in dry heat at 37°C;
8. Thirty days later, the samples were measured again.

Results:

Table Measurements before dimensional change testing

SPECIMEN	MEASURE (mm)
1	13.261
2	13.382
3	13.363

Table Measurements after dimensional change testing

SPECIMEN	MEASURE (mm)
1	13.280
2	13.379
3	13.363

The values obtained before and after dimensional changes testing were calculated in percentage to obtain the value of dimensional change for each sample.

Sample 1 - showed 0.1% expansion

Sample 2 - showed 0.022% shrinkage

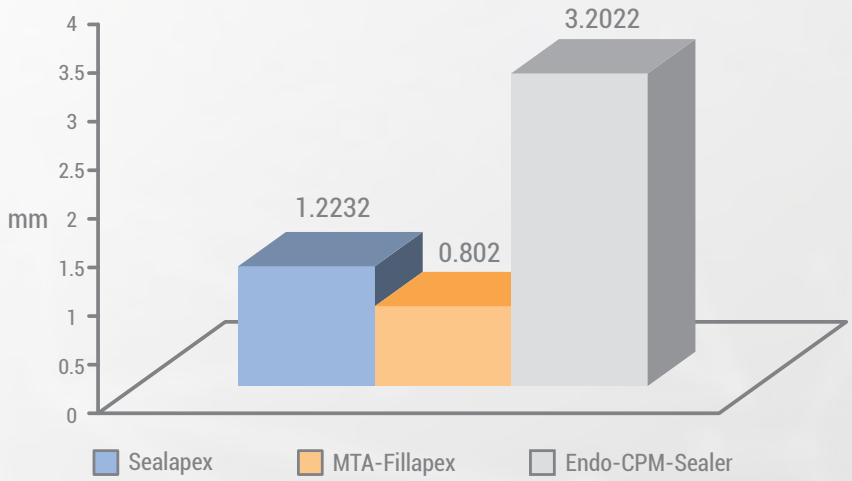
Sample 3 - showed 0.022% expansion

Average overall dimensional change (from 3 specimens) = 0.088%

Conclusion: ISO sets that the average dimensional change of the material should not exceed 1.0% shrinkage or 0.1% expansion. Thus it is concluded that the material fulfilled the requirements standardized by ISO, considering each sample individually, as well as the average change in the material adding all samples tested.*

The setting expansion of the material decreases apical leakage, as demonstrated by the work below:

Average results of apical leakage



IN VITRO EVALUATION OF APICAL LEAKAGE OF ENDODONTICS CEMENTS: MTA-Fillapex®, ENDO-CPM-SEALER® E SEALAPEX®. Moreira J.V, Gomes Filho, J.E., Watanabe,S, Rodrigues, G.B. – Campus de Araçatuba – Faculdade de Odontologia de Araçatuba – 2010.

*Internal Bench Test

5.4. Solubility

The solubility test was performed in 3 samples accoding test ISO 6876:2012.

Results:

SPECIMEN	MTA-FILLAPEX (%)
1	0,10
2	0,05
3	0,05
Average	**0,07**
SD	**0,03**

MTA-FILLAPEX presented solubility of 0,07 (± 0,03) %, as can be seen in Table 04. The specimens showed no disintegration when observed visually.

Conclusion: MTA-FILLAPEX presented solubility of 0,07 (± 0,03) %. As expected, the solubility was determined in accordance with EN ISO 6876:2012, did not exceed 3% by mass and show no disintegration, when observed visually.

*Internal Bench Test

5.5. Antimicrobial Action

The use of materials that provide high alkalinity favors hard tissue mineralization as well as offers good antimicrobial activity. MTA-based sealers present alkaline pH and high calcium ion releasing (KUGA,MC, 2011).

Mean and standard deviation
of the pH regarding to the analysis time period

TIME PERIOD	MTA FILLAPEX
24 hours	9.39 (0.30)
7 days	7.68 (0.23)
14 days	8.89 (0.54)

Mean concentration and standard deviation of
calcium releasing regarding to analysis time period

TIME PERIOD	MTA FILLAPEX
24 hours	9.15 (4.03)
7 days	8.95 (2.43)
14 days	9.68 (3.00)

5.6. Ease of removal

MTA-Fillapex can be removed with chemical or mechanical intervention or a combination of both. Solvents based on citrus oils and chloroform substances can be used.

Research on removal of lateral condensation root canal fillings with files and eucalyptol has shown that MTA-Fillapex is easier to remove than other cements (AH Plus, Sealapex, Real Seal e Endofill) (SANTOS , LGP, 2011).

5.7. Radiopacity ISO 6876:2012 Test

1. MTA-Fillapex was mixed according to the manufacturer's instructions and placed in the mold.
2. The covers on the top and bottom were pressed to make a 1mm thick sample.
3. The sample was placed in the center of an X-ray film adjacent to the step wedge.
4. The system was irradiated in accordance with ISO 6876:2012.
5. After developing, fixing and drying the exposed film, the densities of the image of the sample and the step wedge were compared using Image J.
6. The results were expressed in millimeters of aluminum.

Results:

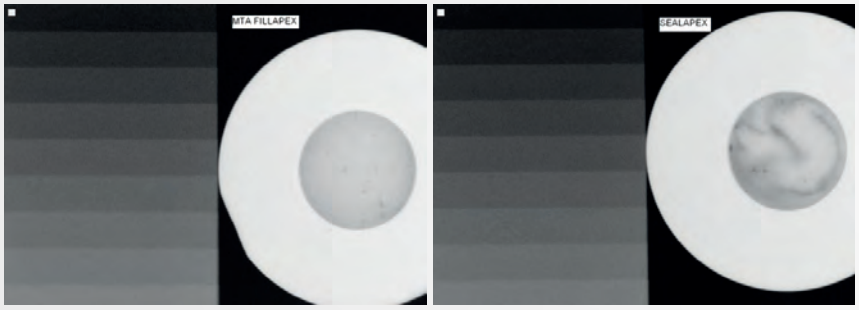


Figure with X-ray images of MTA-Fillapex and Sealapex compared to the aluminum scale

X-ray after the use of Fillapex in extracted roots.

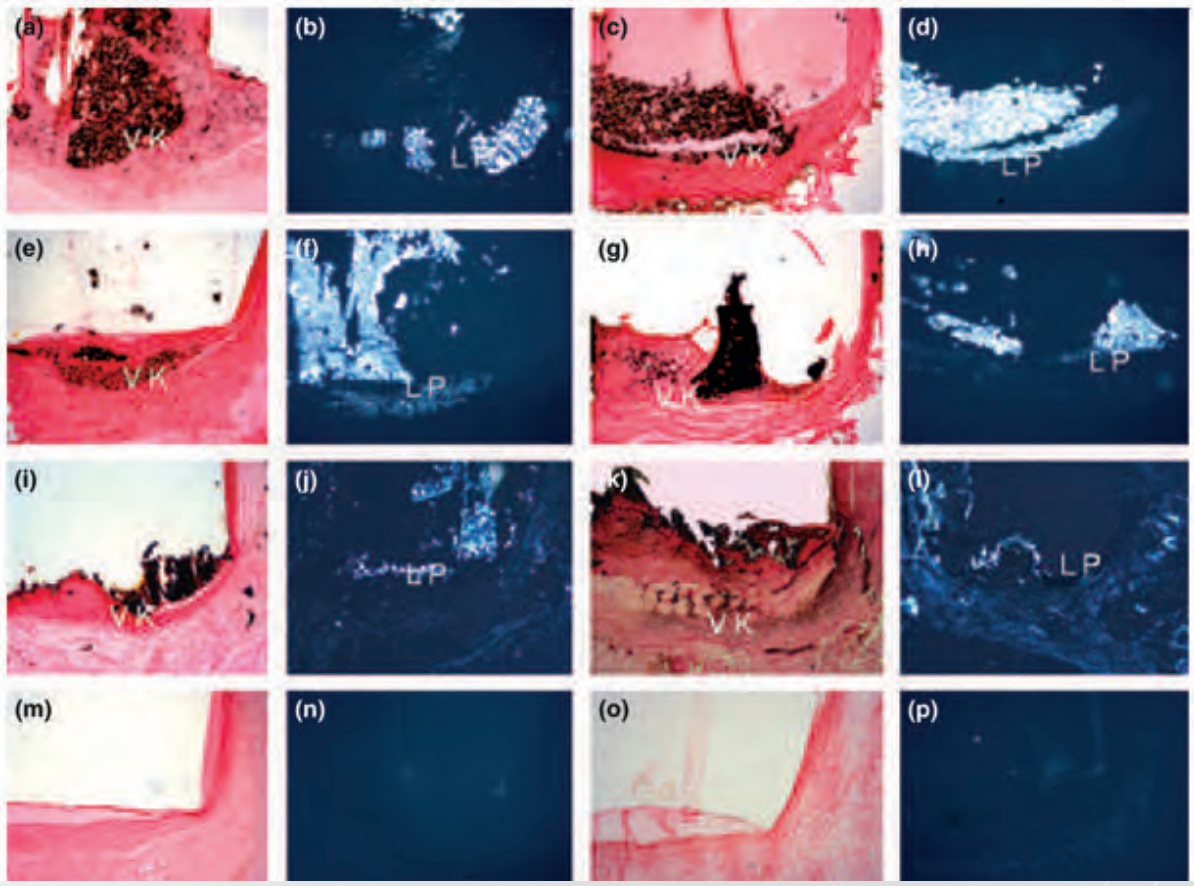
MTA-FILLAPEX presented radiopacity of 4-5 mm compared to Al scale

Conclusion: MTA-FILLAPEX is in accordance with EN ISO 6876 (2012), presenting radiopacity greater than 3 mm.

5.8. Biocompatibility

The biological properties inherent to conventional MTA used for treatment of root perforations replicates in MTA-Fillapex. When in contact with water, CaO can be converted into $Ca(OH)_2$ and dissociated into Ca^{+2} and OH. The diffusion of hydroxyl ions from the root canal increases the pH at the surface of the root adjacent to the periodontal tissues, possibly interfering with osteoclastic activity and promoting alkalinization in the adjacent tissues, which favors healing. Calcium ions participate in the activation of calcium-dependent adenosine triphosphatase and react with carbonic gas to form calcium carbonate crystals (birefringent to polarized light), which serve as a nucleus for calcification and favor mineralization. A rich extracellular network of fibronectin in close contact with these crystals strongly supports the role of calcite crystals and fibronectin as an initiating step in the formation of a hard tissue. Calcium is also needed for cell migration and differentiation. Because MTA-Fillapex and MTA have similar chemical composition and elicit similar tissue reactions, it is expected that MTA-Fillapex will act similarly to MTA when used in clinical situations, but be easier to handle because of its paste/paste presentation.

MTA-Fillapex is considered a great material for root canal treatment. MTA-Fillapex clearly shows the ability to stimulate nucleation sites for the formation of apatite crystals in human osteoblast-like cell culture.



After 30 and 90 days, note the presence of dystrophic calcification on the tube opening with Sealapex® (a,c, respectively), FILLAPEX® (e,g), Angelus MTA® (i,k), but not with Control (m,o). Von Kossa 100x. After 30 and 90 days, observe the presence of birefringent structures to polarized light, confirming the mineralization induction with Sealapex® (b,d, respectively), FILLAPEX® (f,h), Angelus MTA (j,l), but not with Control (n,p). Polarized light 100x. Rat tissue reaction to MTA-Fillapex - Dental Traumatology 2011; doi: 10.1111/j.1600-9657.2011.01096. Gomes-Filho, J.E ET al Department of Endodontics, Araçatuba School of Dentistry, University of Estadual Paulista, São Paulo, Brazil

5.9 Working Time and Setting Time

5.9.1 Working time Test ISO 6876:2012

1. The catalyst and base paste of MTA-FILLAPEX was dispensed in equal proportion in a glass plate and mixed for 60 seconds.
2. Approximately 0.05 ml (0,087 g) of the homogeneous moisture was dispensed between two glass plates (40x40mm).
3. The load (1,5 N) was applied 15 seconds before the working time of 23 minutes (stated by the manufacturer), finishes.
4. The weight was removed, and the diameter of compress disc formed was measured.
5. The diameter should not less than 17,00 mm 15 s before the end of working time.

Results: MTA-FILLAPEX presented flow, 15 seconds before the end of working time, of 24.88 (±0.26) mm, as can be seen in the Table below .

SAMPLES	FLOW (millimeters)
1	24.74
2	24.72
3	25.18
Average	24.88
SD	0.26

Conclusion: MTA-FILLAPEX meets the requirements of EN ISO 6876 (2012), presenting flow higher than 17 mm, confirming the manufacturer's working time specification of 23 minutes. *

*Internal Bench Test

5.9.2. Setting Time Test ISO 6876:2012.

1. Three samples of the MTA-FILLAPEX material were prepared. The catalyst and base paste of MTA-FILLAPEX was dispensed in equal proportion in a glass plate and mixed for 60 seconds.

2. As the material needs to come into contact with moisture to set, gypsum molding (according to ISO 6873 Type 2) was used.

3. The plaster cast was maintained in a climatic chamber at (37 ± 1 oC) and 95% U.R for 24 hours.

4. After this time, the cavity in the pre-conditioned plaster cast was filled with the material.

5. In a second moment, the set was stored in a climatic chamber at (37 ± 1 oC) and 95% of U.R for a certain time.

Results: MTA-FILLAPEX presented setting time 100 (± 35) minutes (Table below).

SAMPLES	SETTING TIME (minutes)
1	120
2	120
36	0
Average	100
SD	35

Conclusion: MTA-FILLAPEX complies with the acceptance criteria established for the product manufacturer (until 150 minutes) and meets the EN ISO 6876 (2012) requirements, presenting setting time in 100 (± 35) minutes.*

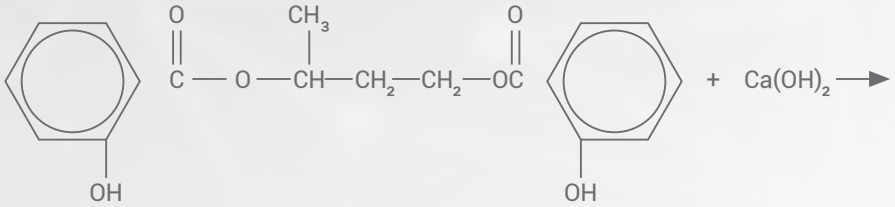
*Internal Bench Test

5.9.3. Complexation Reaction

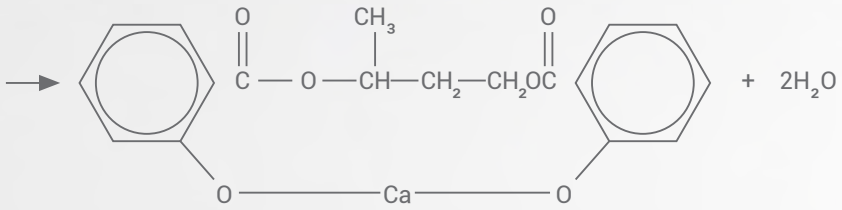
For the understanding of the chemical process that provides the setting of MTA-Fillapex, it is necessary to understand the complexation reaction.

Complexation is an electrostatic attraction between an ion and a chelating agent so that occurs no electron transfer between them. In this process the final structure will charge the sum of the individual charges for each participant of the complex.

Complexation reaction in MTA-Fillapex



(1,3 Butylene Glycol Disalicylate) (Calcium Hydroxide)



(Calcium Disalicylate)

H. R. Stanley, T. Lundy: Dycal therapy for pulp exposures, Oral Surg. Vol. 34 Number 5: 818-827, 1972.

The chemical reaction that promotes setting in MTA-Fillapex is not a polymerization reaction between pastes but a complexation reaction.

The complexation reaction is an autocatalytic process. To get started, there must be a molecule of water from the external medium which, when forming the first complex, promotes a chain reaction and a new water molecule is generated (acid reaction + base = salt + water). Therefore the reaction has an intrinsic process of self-acceleration. The complexation reaction is also a chelation reaction where $Ca(OH)_2$ contacts the disalicylate resin, resulting in the entrapment of calcium ions in the compound.

Therefore, for this reaction, besides the salicylate, another component is fundamental: $Ca(OH)_2$. The major source of $Ca(OH)_2$ responsible for the MTA-Fillapex reaction is from the hydration of free CaO which is in a high concentration in the formula.

It is therefore concluded that the moisture present in the dentin tubules hydrates free CaO, forming $Ca(OH)_2$ which will react with the salicylate and promote the setting.

6. CLINICAL EVALUATION

Clinical studies with MTA-Fillapex demonstrated the absence of post-operative pain after a short period of time, in different clinical situations, as shown below:

Post-op in different periods of time (%)
MTA-Fillapex single visit (126 cases)
Irreversible pulpitis with painful symptoms

	IMMEDIATE	24 HOURS	72 HOURS	1 WEEK
Without pain	66%	84%	98%	100%
Moderate pain	24%	12%	2%	
Severe pain	10%	4%		

Internal clinical data compiled from the Dental Clinic of the Universidade Estadual de Londrina (UEL).

Post-op in different periods of time (%)
MTA-Fillapex single visit (84 cases)
Necrosis without painful symptoms

	IMMEDIATE	24 HOURS	72 HOURS	1 WEEK
Without pain	84%	92%	98%	100%
Moderate pain	16%	8%	2%	
Severe pain				

Internal clinical data compiled from the Dental Clinic of the Universidade Estadual de Londrina (UEL).

Quick recovery of pre¬existing periapical lesions (before endodontic treatment) has also been observed after use of MTA-Fillapex.

Clinical case with MTA-Fillapex: Initial RX (Photo 1), 4 months P.O (Photo 2) 14 months P.O (Photo 3) (SELLERA, D.P, 2011).

7. TECHNIQUE FOR USE

1. **Root canal preparation:** Prior to insertion of MTA-FILLAPEX, the root canal should be prepared and cleaned according to the selected endodontic technique. The device requires an isolated dry field; therefore, moisture found in the canal or in the ambient humidity is sufficient to initiate MTA-FILLAPEX hardening;

2. **Mixing:**

- **Dual syringe:** The dual syringe ensures equal mixing in a 1:1 ratio. Press plunger to extrude material directly onto a glass slab, mixing pad or into the tooth canal. The cement should be used immediately after mixing;

- **Tubes:** Mix equal volume units (1:1). Mix for 30 seconds to a homogeneous consistency;

3. **Insertion:** Use MTA-FILLAPEX with gutta-percha or silver points, coating them with a thin layer of the cement and filling the root canal according to the selected technique. MTA-FILLAPEX can be applied in the root canal with a Lentulo spiral or, directly, with an applicator tip adapted to the self-mixing tip;

ATTENTION: *The auto-mixing tip or the intracanal applicator mixing tip must be discarded after use in accordance with national laws and local authorities' recommendations for proper disposal.*

4. Take a radiograph for control.

WARNINGS

- Contact with eyes or skin: you must avoid contact of both the separate and already mixed pastes with eyes or skin. In case of accidental contact, wash abundantly with water;

- Avoid contact with oral mucosa. In case of contact, rinse with water and avoid ingesting the product. If any sensitivity persists, seek medical attention immediately.

PRECAUTIONS

- During the use of this product, it is recommended the patient and professional use suitable protective clothing, eye protection and gloves

- Use the product only after controlling the infection or the material will not function correctly due to the acidic pH of the environment;

- • Ensure that the covers of the base and catalyst pastes are not interchanged, because replacing them

- incorrectly can cause the hardening of the product inside the tube;
- If the syringe is contaminated with saliva or blood during the application, dispose of the syringe and do not use it on other patients;
- The syringe and tube must be cleaned immediately after use with alcohol and instruments must be sterilized;
- Federal law restricts the sale of this medical device only to dental surgeons.

STORAGE

- Keep in dry and cool place, away from humidity and sources of heat.
- Do not store in the refrigerator.
- Keep the product thightly capped.

DISPOSAL METHOD

- The product must be disposed of in accordance with local regulations.

8. PUBLICATIONS

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Sealability of MTA and calcium hydroxide-containing sealers

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ABSTRACT

Objectives: The aim of this study was to evaluate the apical sealability of Fillapex®, Endo-CPM-Sealer® and Sealapex®. Material and Methods: Ninety-four freshly extracted single-rooted teeth were selected and decoronated. All teeth were radiographed to confirm the existence of a single and straight root canal, which was prepared using Protaper Universal and 2.5% sodium hypochlorite. The teeth were randomly divided in groups of 10 specimens each according to the sealer, and the canals were filled using the single cone technique and one of the sealers. Four additional teeth were used as controls. The teeth were submitted to dye leakage with Rhodamine B for 24 h but using vacuum on the initial 15 min. Thereafter, they were cut longitudinally and the leakage was measured in a linear fashion from apex to crown. Data were analyzed by ANOVA and Tukey's tests at 5% significance level. Results: Fillapex® and Sealapex® showed significantly less dye leakage than Endo-CPM-Sealer® ($p<0.05$). Conclusions: It was concluded that Fillapex® and Sealapex® were able to prevent apical dye leakage differently from Endo-CPM-Sealer®.

Key words: Root canal filling material. Leakage. Fillapex.

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Original Research Article

Hydrogen ion and calcium releasing of MTA Fillapex® and MTA-based formulations

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MTA; pH; calcium; sealer.

Abstract

Introduction: MTA is composed of various metal oxides, calcium oxide and bismuth. It has good biological properties and is indicated in cases of endodontic complications. Several commercial formulations are available and further studies are necessary to evaluate these materials. **Objective:** To evaluate pH and calcium releasing of MTA Fillapex® compared with gray and white MTA. **Material and methods:** Gray and white MTA (Angelus) and MTA Fillapex® (Angelus) were manipulated and placed into polyethylene tubes and immersed in distilled water. The pH of these solutions was measured at 24 hours, 7 days and 14 days. Simultaneously, at these same aforementioned periods, these materials' calcium releasing was quantified, through atomic absorption spectrophotometry. The results were submitted to ANOVA, with level of significance at 5%. **Results:** Concerning to pH, the materials present similar behaviors among each other at 24 hours ($p > 0.05$). At 7 and 14 days, MTA Fillapex® provided significantly lower pH values than the other materials ($p < 0.05$). Regarding to calcium releasing, at 24 hours and 7 days, MTA Fillapex® provided lower releasing than the other materials ($p < 0.05$). After 14 days, differences were found between MTA Fillapex® and gray MTA ($p < 0.05$). **Conclusion:** All materials showed alkaline pH and calcium releasing, with significantly lower values for MTA Fillapex® sealer.

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Comparison of MTA Fillapex radiopacity with five root canal sealers

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Keywords: obturation; root canal sealer; radiopacity.

Abstract

Introduction: The endodontic sealer is a filling material whose physicochemical properties are mandatory for the achievement of endodontic therapy final goal. An ideal endodontic sealer should have some properties, including radiopacity. **Objective:** This study compared MTA Fillapex™ radiopacity with the radiopacity of five others endodontic sealers: Endométhasone-N™, AH Plus™, Acroseal™, Epiphany SE™ and RoekoSeal™. **Material and methods:** Five cylindrical samples of each sealer were used, constructed with the aid of a matrix. On an occlusal film, a sample of each sealer was placed along with an aluminum stepwedge and five radiographic shots were taken. The radiographic images were digitized and each sample's gray scales were compared with each shade of the aluminum stepwedge, by using software. **Results:** The results, in decreasing order of radiopacity, were: AH Plus™ was statistically the most radiopaque sealer (9.4 mm Al), followed by Epiphany SE™ (7.8 mm Al), MTA Fillapex™ (6.5 mm Al), RoekoSeal™ (5.8 mm Al), Endométhasone-N™ (4.5 mm Al), and Acroseal™, the least statistically radiopaque (3.5 mm Al). **Conclusion:** It can be concluded that MTA Fillapex™ was the third most radiopaque sealer among all tested sealers. Also, MTA Fillapex™ has the radiopacity degree in agreement with ADA specification No. 57 (1983).

Dental Traumatology

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Rat tissue reaction to MTA FILLAPEX®

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Accepted 6 November, 2011

Abstract – The aim of this study was to evaluate the rat subcutaneous tissue reaction to implanted polyethylene tubes filled with mineral trioxide aggregate (MTA) FILLAPEX® compared to the reaction to tubes filled with Sealapex® or Angelus MTA®. These materials were placed in polyethylene tubes and implanted into the dorsal connective tissue of Wistar rats for 7, 15, 30, 60, and 90 days. The specimens were stained with hematoxylin and eosin or Von Kossa or left unstained for examination under polarized light. Qualitative and quantitative evaluations of the reaction were performed. All materials caused moderate reactions after 7 days, which decreased with time. The reactions were moderate and similar to that evoked by the control and Sealapex® on the 15th day. MTA FILLAPEX® and Angelus MTA caused mild reactions beginning after 15 days. Mineralization and granulation birefringent to polarized light were observed with all materials. It was concluded that MTA FILLAPEX® was biocompatible and stimulated mineralization.

Basic Research—Biology

Mineral Trioxide Aggregate–based Endodontic Sealer Stimulates Hydroxyapatite Nucleation in Human Osteoblast-like Cell Culture

Loise Pedrosa Salles, MSc,† Ana Lívia Gomes-Cornélio, MSc,* Felipe Coutinho Guimarães, MSc,† Bruno Schneider Herrera, PhD,‡ Sonia Nair Bao, PhD,† Carlos Rossa-Junior, PhD,‡ Juliane Maria Guerreiro-Tanomaru, PhD,* and Mario Tanomaru-Filho, PhD**

Abstract

Introduction: The main purpose of this study was to evaluate the biocompatibility and bioactivity of a new mineral trioxide aggregate (MTA)-based endodontic sealer, MTA Fillapex (MTA-F; Angelus, Londrina, Brazil), in human cell culture. **Methods:** Human osteoblast-like cells (Saos-2) were exposed for 1, 2, 3, and 7 days to MTA-F, Epiphany SE (EP-SE; SybronEndo, Orange, CA), and zinc oxide–eugenol sealer (ZOE). Unexposed cultures were the control group (CT). The viability of the cells was assessed by MTT assay and the morphology by scanning electron microscopy (SEM). The bioactivity of MTA-F was evaluated by alkaline phosphatase activity (ALP) and the detection of calcium deposits in the culture with alizarin red stain (ARS). Energy-dispersive X-ray spectroscopy (EDS) was used to chemically characterize the hydroxyapatite crystallites (HAP). Saos-2 cells were cultured for 21 days for ARS and SEM/EDS. ARS results were expressed as the number of stained nodules per area. Statistical analysis was performed with analysis of variance and Bonferroni tests ($P < .01$). **Results:** MTA-F exposure for 1, 2, and 3 days resulted in increased cytotoxicity. In contrast, viability increased after 7 days of exposure to MTA-F. Exposure to EP-SE and ZOE was cytotoxic at all time points. At day 7, ALP activity increase was significant in the MTA-F group. MTA-F presented the highest percentage of ARS-stained nodules (MTA-F > CT > EP-SE > ZOE). SEM/EDS analysis showed hydroxyapatite crystals only in the MTA-F and CT groups. In the MTA-F group, crystallite morphology and chemical composition were different from CT. **Conclusions:** After setting, the cytotoxicity of MTA-F decreases and the sealer presents suitable bioactivity to stimulate HAP crystal nucleation. *(J Endod 2012;■:1–6)*

Key Words

Bioactivity, biocompatibility, hydroxyapatite, mineral trioxide aggregate sealer

Mineral trioxide aggregate (MTA) emerged as the material of choice for root perforation repairs and root-end fillings in the 90s, a revolutionary period marked by many advances in endodontics (1). MTA was developed at Loma Linda University and received approval from the Food and Drug Administration for human use in 1998 (2, 3). Since then, MTA has shown excellent biological properties in several *in vivo* and *in vitro* studies (4–9). In cell culture systems, for example, MTA has been shown to enhance proliferation of periodontal ligament fibroblasts (6), to induce differentiation of osteoblasts (7, 8), and to stimulate mineralization of dental pulp cells (9). This biocompatibility and bioactive potential raised the interest of scientists worldwide to improve the handling characteristics and some physicochemical properties of MTA with the intention of expanding its applicability in endodontics. Consequently, new MTA-based root-end filling cements and root canal sealers have been proposed (10–12), such as MTA Fillapex (MTA-F; Angelus, Londrina, Brazil).

The new MTA-based sealers reflect a current requirement to have materials for endodontic therapy that are able to stimulate the healing process of periapical tissues, instead of merely biocompatible or inert materials. As a result, MTA-F represents the effort in combining a material of excellent biological properties as MTA with resins and other components to improve diverse required properties of an endodontic sealer including adhesiveness, dimensional stability, working time, radiopacity, flow, and antibacterial effects. According to the manufacturer's information, MTA-F is composed of salicylate resin, resin diluent, natural resin, bismuth oxide as radiopacifying agent, silica nanoparticles, MTA, and pigments. The MTA itself consists of fine hydrophilic particles of tricalcium silicate, tricalcium aluminum oxide, tricalcium oxide, gypsum (calcium sulfate dihydrate), and other mineral oxides (3). Gypsum is an important determinant of setting time. MTA cements generally contain less gypsum to allow more handling time. Unfortunately, MTA-F data sheet lacks details about the natural resin, pigments, and diluents composition.

It is important to investigate if the combination of these resins and other constituents influence the bioactive potential of MTA in the new endodontic sealer. Therefore, the main purpose of this study was to evaluate the biocompatibility and the bioactivity of MTA-F in stimulating mineralization in Saos-2 cell culture compared with Epiphany SE

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721 Evaluation of a MTA-based sealer histocompatibility in subcutaneous tissue

Thursday, June 21, 2012: 11:45 a.m. - 1 p.m.
Location: Poster Hall (Convention Center)
Presentation Type: Poster Session

***R.V. FERINO**, M. TANOMARU-FILHO, G.F. SILVA, E. SASSO-CERRI, J.M. GUERREIRO-TANOMARU, and P.S. CERRI, Dentística Restauradora, FACULDADE DE ODONTOLOGIA DE ARARAQUARA, UNESP Univ Estadual Paulista, Câmpus Araraquara, Araraquara / SP, Brazil*

Objective: Mineral Trioxide Aggregate (MTA) has been widely used in endodontic treatment due to its good marginal adaptation and biocompatibility. In attempt to associate physicochemical properties of a root canal sealer with MTA biocompatibility, some modifications have been made with the aim to improve its use as a root canal sealer. Thus, the tissue reaction promoted by a MTA-based sealer (MTA-Fillapex) in rat subcutaneous was investigated by morphological and morphometric analyses

Method: Eighty rats were distributed into 4 groups (n=20); in each animal, a polyethylene tube filled with MTA-Fillapex, MTA, AH-Plus or Fill Canal was implanted in the dorsal subcutaneous. After 7, 15, 30 and 60 days, the tubes surrounded by connective tissue were removed, fixed and embedded in paraffin. In the HE-stained sections, the numerical density of inflammatory cells (IC) in the capsule was evaluated and statistical analyses were performed using ANOVA and Tukey's test ($p \leq 0.05$). Sections were also submitted to von Kossa method for detection of calcified structures

Result: At 7 and 15 days, the number of IC was significantly higher in the capsule of the MTA-Fillapex in comparison to other materials. However, significant reduction in the number of IC was verified in the capsule of the MTA-Fillapex in the 30 and 60 days when compared to the initial periods. At 60 days, the inflammatory reaction promoted by MTA-Fillapex was similar to MTA and significantly lower than Fill Canal. Otherwise, a gradual and significant increase was observed in the number of IC in the capsule adjacent to the Fill Canal. von Kossa-positive structures were observed in the capsule adjacent to the MTA-Fillapex, MTA and AH-Plus; positive strucutres were not seen in the capsule surrounding the Fill Canal

Conclusion: The results indicate that the biocompatibility of MTA-Fillapex is similar to MTA

Keywords: Biocompatibility, Dental materials, Endodontics and Root canal fillings

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See more of: Dental Materials 5: Biocompatibility and Biologic Effects

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89TH GENERAL SESSION & EXHIBITION OF THE IADR • SAN DIEGO CONVENTION CENTER • SAN DIEGO, CALIFORNIA, USA

1164 MTA FILLAPEXÂ® STIMULATED MINERALIZATION

Thursday, March 17, 2011: 3:30 p.m. - 4:45 p.m.
Location: Hall C (San Diego Convention Center)
Presentation Type: Poster Session

***J.E. GOMES-FILHO**[1], S. WATANABE[1], L.T.A. CINTRA[1], C.S. LODI[2], E. DEZAN, Jr.[3], M.J. NERY[4], and P.F.E. BERNABÉ[1], [1]Endodontics, Universidade Est. Paulista Julio Mesquita, Araçatuba, Brazil, [2]Pediatric Dentistry, Universidade Est. Paulista Julio Mesquita, Araçatuba, Brazil, [3]Endodontics, Universidade Est. Paulista Julio Mesquita, Aracatuba, Brazil, [4]Endodontis, Universidade Est. Paulista Julio Mesquita, Araçatuba, Brazil*

Objectives: The aim of this study was to evaluate the rat subcutaneous tissue response to implanted polyethylene tubes filled with MTA Fillapex® (Angelus, Londrina, Brazil) compared Endo-CPM-Sealer® (Portland Cement Modified Sealer) (EGEO S.R.L., Buenos Aires, Argentina) and Sealapex® (SybronEndo, Glendora, CA). Methods: These materials were placed in polyethylene tubes and implanted into dorsal connective tissue of Wistar rats for 7, 15, 30, 60, and 90 days. The specimens were prepared to be stained with hematoxylin and eosin or Von Kossa or not stained for polarized light. Qualitative and quantitative evaluations of the reaction were performed. Results: All materials caused moderate reactions at 7 days that decreased with time. The response was similar to the control on the 15th day with Endo-CPM-Sealer® and Sealapex®. MTA Fillapex® caused mild reactions from 15 days on. Mineralization and granulations birefringent to the polarized light were observed with all materials. Conclusions: It was possible to conclude that MTA Fillapex® was biocompatible and stimulated mineralization. Supported by FAPESP#2009/11194-5 and #2009/00380-2

Keywords: Animal, Endodontics, MTA, Root canal fillings and Wound healing

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See more of: Dental Materials 5: Biocompatibility and Biologic Effects

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