UNIVERSIDADE FERNANDO PESSOA

Ex-vivo coronal dye leakage analysis of polytetrafluoroethylene tape thickness as endodontic acess cavity spacer

[Análise ex-vivo de infiltração coronal por corante da espessura da fita de politetrafluoroetileno como espaçador de cavidade de acesso endodôntico]

Dissertação de Mestrado

Mestrado Integrado em Medicina Dentária

Alfonso Maria Franza

Orientador:

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Primeiramente a mim, por todo o esforço, coragem, dedicação e força de vontade.

Dedico esta conquista aos meus amados pais, Giovanni e Fabiola, que com o seu amor e apoio iluminaram cada passo da minha jornada.

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ABSTRACT

Temporary restorations, used when the procedure requires multiple visits, aim to avoid contamination of the root canal space while maintaining function and aesthetics. In addition to the temporary restoration, it is recommended to place a spacer that will prevent the entry of unwanted materials and the blockage of the root canal space. Other reasons to advocate the use of a spacer are its ease of removal, which reduces the time it takes to access the root canal system, and the reduced risk of tooth damage during the removal of the temporary material. To overcome some of the problems of cotton as an endodontic spacer, doctors began to use other materials, such as polytetrafluoroethylene tape. This is an endodontic spacer that fully fulfills the ideal characteristics such as non-fibrous, inorganic, and ribbon-like material. Because it is not fibrous, it reduces the chances of impregnation in the temporary restoration and by not being spongy it better supports the excessive propagation of the temporary restoration. The objective of this study is to evaluate infiltration in monoradicular teeth using different thicknesses of polytetrafluoroethylene tape . The teeth used in this study was collected from clinics located in Italy and was selected according to inclusion criteria: (1) monoradicular teeth, (2) teeth without signs of fracture and caries and (3) teeth with absence of dental anomalies. The entire procedure was carried out by a single operator to reduce intra-operator error. A total of tweenty teeth were separated into two distinct groups according to the coronal cut performed. The results of the study showed that the thickness of the polytetrafluoroethylene tape influence the leakage in the teeth. So, 2mm polytetrafluoroethylene tape a good thickness to maintain the root canal patency and to provide a sterile environment by preventing the microbial growth under the provisional restoration as an endodontic spacer material in between the appointments.

Keywords: “endodontic treatment”, “multiple visit”, “endodontic spacer”, “polytetrafluoroethylene tape”

RESUMO

As restaurações temporárias, utilizadas quando o procedimento requer múltiplas visitas, visam evitar a contaminação do espaço do canal radicular, mantendo a função e a estética. Além da restauração temporária, recomenda-se colocar um espaçador que impeça a entrada de materiais indesejados e o bloqueio do espaço do canal radicular. Outras razões para defender o uso de um espaçador são a sua facilidade de remoção, que reduz o tempo necessário para acessar o sistema de canais radiculares, e a redução do risco de danos dentários durante a remoção do material temporário. Para superar alguns dos problemas do algodão como espaçador endodôntico, os médicos começaram a usar outros materiais, como a fita de politetrafluoroetileno . Este é um espaçador endodôntico que cumpre plenamente as características ideais, como material não fibroso, inorgânico e semelhante a fita. Por não ser fibrosa, reduz as chances de impregnação na restauração temporária e, por não ser esponjosa, suporta melhor a propagação excessiva da restauração temporária. O objetivo deste estudo é avaliar a infiltração em dentes monoradiculares utilizando diferentes espessuras de fita de politetrafluoroetileno. Os dentes utilizados neste estudo foram coletados em clínicas localizadas na Itália e selecionados de acordo com os critérios de inclusão: (1) dentes monoradiculares, (2) dentes sem sinais de fratura e cárie e (3) dentes com ausência de anomalias dentárias. Todo o procedimento foi realizado por um único operador para reduzir o erro intraoperador. Um total de dentes de interpolação foi separado em dois grupos distintos de acordo com o corte coronal realizado. Os resultados do estudo mostraram que a espessura da fita de politetrafluoroetileno influencia o vazamento nos dentes. Assim, a fita de politetrafluoroetileno de 2mm tem uma boa espessura para manter a permeabilidade do canal radicular e proporcionar um ambiente estéril, impedindo o crescimento microbiano sob a restauração provisória como material espaçador endodôntico entre as consultas.

Keywords: “endodontic treatment”, “multiple visit”, “endodontic spacer”, “fita de politetrafluoroetileno”

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1. INTRODUCTION

Endodontics is a branch of Dentistry which is responsible for studying pulp and periapex pathologies and whose main objective is the preservation of teeth that were once considered lost (AAE, 2020).

The morphological and anatomical characteristics of human teeth, although they have common characteristics, differ between individuals and ethnicities. (Alrahabi & Zafar, 2015)

The place where the dental pulp is lodged inside the tooth structure is called the root canal system. This system consists of two distinct areas, the pulp chamber and root canals. The pulp chamber is located in the anatomical part of the tooth, with the coronary pulp and the root canals are located in the anatomical root, with the root pulp (AAE, 2020).

However, while ethnicity has been shown to be an important factor in differentiation found in the number and root morphology, the same does not necessarily occur with regard to the internal configuration of the root canal (De Pablo et al., 2010).

The purpose of endodontic treatment is to promote an environment conducive to the the body can repair the periapical tissues after the therapeutic intervention, allowing the tooth to return to its functions. To achieve this goal, it is necessary to establish cleaning and conformation for disinfection of root canal systems, filling and coronary sealing.

The objective of endodontics is all aimed at obtaining a reparative process in the shortest period of time after the intervention and that has its epilogue in a normal way, allowing the tooth to return to its specific tasks - aesthetic and functional as if nothing had happened to it.

According to the International Conference on Endodontics, there are ten important principles to be followed when a dentist performs endodontic treatment on his/her patient. First, endodontic treatment should be conducted using an aseptic technique. Second, the instruments should be confined to the root canal of the treated tooth. Third, the root canal should be prepared using fine and smooth instruments. Fourth, the root canal should be enlarged regardless of its original size, to enable the removal of contaminated dentinal debris and filling of the root canal. Fifth, the root canal should be copiously irrigated with an antiseptic solution during instrumentation. Sixth, the antiseptic irrigation or agents used should be nonirritating to the periapical tissues. Seventh, the sinus tract, if present,

should subside after root canal treatment and should not require surgical intervention (however, an incision of the soft tissue can be performed for cases of acute periapical abscess, to allow drainage). Eighth, the canal should be aptly shaped and hermetically obturated. Ninth, a negative culture should be obtained prior to obturation. Finally, the root canal filling should be biocompatible (cit in Wong, Zhang & Chu, 2014).

According to the American Association of Endodontics, endodontic treatment consists of:

• Removal of infected dental pulp;

• Cleaning of the root canal system of this tooth, by mechanical action using manual or mechanical endodontic files combined with chemical action of irrigation;

• Form from the soil of the pulp chamber to the apical foramen, using hand files or

mechanized so that the irrigation solution penetrates the entire root canal system;

• Dry the root canal system;

• Perform the root canal system filling, usually with heated or cold gutta-percha, with obturator cement.

The success or failure of this treatment is assessed by the clinical signs and symptoms, as well as the radiological results of the treated tooth. The symptoms and clinical signs that define success are the absence of pain, the disappearance of inflammation and fistulas (if they exist before treatment) and the maintenance of the functional tooth in its socket. Radiographically, the complete healing of the periapical bone lesion and the normal appearance of the lamina lasts for a period of 6 months to 24 months, will define will define success. Histologically, however, complete repair of periapical structures with the absence of inflammatory cells should be produced (Prada et al., 2019).

At the beginning of the execution of a diagnosis, the Dentist must take a good clinical, medical and dental history, which must include a careful intra and extraoral examination. During the intraoral examination, it may be necessary to resort to several tests, such as palpation, mobility test, occlusal analysis, percussion, transillumination, evaluation periodontal, tooth fracture screening, selective local anaesthesia, vitality testing pulp and radiography (European Society of Endodontology, 2006). Radiography should be performed using a parallelizer, and should contain the entire tooth root and periapical area within its limits.

Root canal instrumentation is one of the most important phases for the success of the endodontic treatment (Karatas et al., 2015). The reduction of microorganisms is achieved through chemical-mechanical preparation, however, there is currently no instrument that can clean the entire root canal, and cleaning is particularly limited in the apical portion of the root canal (Burklein et al., 2012).

Root canal preparation procedures are not easy to perform due to their anatomical complexity and limitations of endodontic instruments, which often results in an increased risk of root canal failure and iatrogenic errors. In most cases, dentin fragments, tissue pulp fragments, necrotic tissue, microorganisms, and pulp irritants may be deposited to apical during instrumentation. This becomes a concern because it can lead to inflammation of the periapical tissue, post-treatment pain and/or flare-up (Gambarini et al., 2013).

With the introduction of Nickel-Titanium instrumentation systems and their elasticity, flexibility and memory, allowed the development of making instrumentation faster (Carvalho et al., 2015).

However, the instrumentation alone can be done in the main root canals where the files arrive, but it is evident that the great challenge of the dentist is to make a good cleaning of the areas that cannot be instrumented, such as the accessory and lateral canals. This can only be achieved with irrigation (Ruksakiet et al., 2020).

Microorganisms are the main infectious agents that adhere to tooth surfaces inside the oral cavity and quickly form a biofilm that protects them. In cases of infected root canals, when it comes to teeth with complex morphologies such as accessory channels, lateral channels, and isthmus, these biofilms are particularly problematic because these areas are inaccessible to instrumentation (Macedo et al., 2014).

The instrumentation of the root canal produces a residual layer composed of organic and inorganic components, the Smear Layer. This layer includes dentinary, predentinary, necrotic or vital debris, microorganisms; contaminated as uncontaminated debris, which adheres to the dentin surface (Kanaan et al., 2020).

This extracellular polysaccharide matrix has the main advantage of imparting to the biofilm viscoelastic properties which give the biofilm the ability to deform and adapt to chemical and mechanical stresses caused by instrumentation procedures acting as well as protection (Macedo et al., 2014).

Residual debris and smear layer can act as a barrier and promote bacterial invasion of dentin tubules. Microorganisms can survive and multiply in the smear layer and enter the tubules directly. In addition, smear layer may reduce antimicrobial efficacy of intra-canalar drugs and the sealing capacity of filling materials (Urban et al., (2017). The bacteria that exist in the canal can be Gram positive or Gram negative. Gram negative bacteria have endotoxins in their cell walls that can trigger an inflammatory response such as pulpitis and, if left untreated, this can progress to apical periodontitis or, in a more severe phase, apical abscess (Chubb, 2019).

Currently, irrigation is the best method to remove tissue remnants and dentin debris during instrumentation. In order to simultaneously remove the organic tissues and the smear layer, the combination of sodium hypochlorite and other irrigants is used. Of all irrigants, sodium hypochlorite is probably the most widely used irrigating solution in endodontics. It effectively destroys detached and necrotic pulp tissue and has excellent antimicrobial efficacy (Farag et al., 2015).

The sodium hypochlorite solution used in root canal irrigation can be cytotoxic to periradicular tissues, particularly in high concentrations. As such, post-treatment pain is a concern when highly concentrated solutions are used in one-session treatments on non-vital teeth. A suggested alternative is chlorhexidine gel in non-vital teeth, due to its antimicrobial action and low toxicity, but it is also associated with allergic reactions (Almeida et al., 2012).

Essential criteria for an optimal irrigant include: potent antimicrobial activity, ability to dissolve organic and inorganic components, to disinfect and eliminate debris from non-instrumented areas of the canals, to provide lubrication, and not to cause adverse effects on periradicular tissues or the structural integrity of the canal. However, currently, there are no irrigators who can sufficiently fulfill all the necessary functions (Wu et al, 2017).

Ethylenediaminetetraacetic acid is an artificial amino acid, biocompatible with pH 7 (Sarkees et al., 2020), chelating agent used in root canal system irrigation, due to its ability to remove the smear layer containing bacteria, dentin debris, and inflamed pulp tissue – smear layer; this effect allows for more effective disinfection (Liu et al., 2020).

It is able to destabilize the outer membrane of Gram negative bacteria, which can increase the activity of other antimicrobials. In addition, it is able to reduce the strength of the biofilm matrix by sequestering cations, thus increasing the detachment of bacterial cells

from the biofilm. ethylenediaminetetraacetic acid is used to remove inorganic components at root canal system produced during root canal preparation (Pinheiro et al., 2021) that sodium hypochlorite does not remove. For this reason, these two irrigators have to be coupled.

Citric acid can be used as a final irrigant in place of ethylenediaminetetraacetic acid, after irrigation with sodium hypochlorite to remove the smear layer. When compared to ethylenediaminetetraacetic acid, citric acid has a higher demineralization power. Concentrations range from 1% and 50%, with the concentration of 10% being the most common. Both irrigants can be found in liquid or gel form (Haapasalo et al., 2014).

There are other methods to have even more effective irrigation. During positive pressure root canal irrigation, i.e., syringe irrigation, a vapor block is created that makes it very difficult to change irrigants in the apical third of the root canal. To overcome this situation, the concept of negative pressure irrigators was introduced. These irrigants can be activated using sonic, ultrasonic, and rotary brush techniques. The advantages of negative pressure irrigation techniques include greater root canal cleaning and better antimicrobial property than conventional syringe irrigation (Nagendrababu et al., 2018).

Another method that could be very useful for dentists to achieve the complete removal of bacteria inside the root canal by making the irrigants reach the accessory canals is laser-activated root canal irrigation. It is a recently introduced technique and is increasingly used, as its effectiveness has been shown to be superior to conventional techniques (Dioguardi et al., 2018).

Regardless of the placement of intracanal medication between sessions, irrigation is an essential part of root canal treatment, as it allows for effective cleaning and disinfection of the root canal system, penetrating to the dentin and its dentin tubules (Gupta, Nikhil and Jha, 2014)

Because the presence of residual bacteria adversely alters the outcome of treatment, the use of intracanal medication between visits has been recommended in order to complement the antibacterial effects of mechanical chemical procedures and maximize bacterial reduction (Vera et al., 2012).

Calcium hydroxide is an intracanal drug that is widely used in dentistry. Its antibacterial capacity is linked to its high pH (12.5 to 12.8). The existence of an alkaline medium occurs by the release of hydroxyl ions (OH-), and this alkalinity makes the medium less

susceptible to the development of microorganisms. It should be used for at least seven days, reaching maximum pH levels after 3-4 weeks (Athanassiadis et al., 2007; Kawashima, Wadachi, & Suda, 2009).

The ultimate goal of an endodontic treatment is to completely seal the root canal system to prevent the infiltration of toxins and bacteria, thus preventing inflammation (Wolf, Willems, & Briseño-Marroquín, 2021).

Filling is also considered an important step in endodontic treatment, with the main objective of permanently sealing the root canal after it has been cleaned and instrumented, in order to prevent infection or re-infection of root canals, providing an unfavorable environment for the growth of microorganisms (Piati et al., 2013; Alshehri et al., 2015).

The use of filling cement aims to fill the anatomical irregularities between the dentin walls and the gutta percha, providing a better sealing, but on the other hand, its decomposition and contraction over time of time causes a limitation in its use (Piati et al., 2013).

It is common to fill the root canal with gutta-percha combined with a endodontic cement. Among the various types of filling cements, calcium silicate is a good choice due to its biocompatibility, excellent sealing between gutta-percha and root canal walls, and has a high success rate (Kim et al., 2019).

While there are several advancements in the endodontic field, including new concepts, materials, devices, and approaches; microbial eradication remains the main target of endodontic treatment. Therefore, efforts are directed toward achieving this target through proper chemical and mechanical treatment of the root canal space followed by hermetically sealing the disinfected space by utilizing biocompatible materials. These treatment procedures might be performed in single or multiple visits. For several reasons, including time limitation, presence of pain, or placement of intracanal medicaments, the multiple-visit approach has been very common in endodontic practice. In such cases, placing a temporary restoration is needed between the appointments. Temporary restorations are also commonly placed after the completion of endodontic treatment and before the placement of the definitive restoration (Prabhakar, Dixit & Raju, 2018; Alkadi & Alsalleeh, 2019; Alkadi et al., 2023).

In single-session treatments, it is believed that infection control, by means of cleaning, conformation and filling with gutta-percha and antiseptic cements, would be sufficient to

achieve successful treatment, in addition to indisputably ensuring less time to re-establish the functions of the tooth element and its aesthetics. The followers of the treatment in multiple sessions believe in the need for intracanal medication between sessions, with the aim of enhancing the disinfection obtained during the chemical-mechanical preparation, for a better postoperative period and a higher success rate in the prevention and repair of periradicular pathologies (Rosso et al., 2012).

In cases of vital noninfected teeth, endodontic treatment can be completed in a single visit, eliminating the need for temporization. However, in many situations, a one-visit treatment may not be feasible because of time limitation, case complexity, persistent bacteria, and/or patient-related factors. Moreover, despite the large body of evidence indicating no difference in the outcome of endodontic treatment performed in either single or multiple visits, many endodontists still prefer the multiple-visit approach to ensure the absence of pain or complications and for dressing infected canals with antibacterial intracanal medicaments (Moreira et al., 2017; Alkadi & Alsalleeh, 2019).

Temporisation of a tooth undergoing multiple-visit root canal treatment requires a restoration that would ideally hermetically seal the access cavity, preventing ingress of saliva and bacteria. A barrier material below the temporary restoration prevents unwanted dental materials entering the root canal system during placement, with the additional benefit of being readily removable when required (Algahtani et al., 2021; Alkadi et al., 2023).

In case of multiple visit procedure, the state of sterility must be maintained in between the appointments until a definitive coronal restoration is placed following root-canal obturation. So it is mandatory to place an endodontic spacer under a provisional restoration to maintain the patency of the root canals and prevention of the microbial growth (Somani et al., 2022).

Temporary coronal sealing materials are used between endodontic treatment sessions when it is decided to perform the treatment in multiple sessions and between the end of the treatment and the placement of the final restoration. The purpose of these restorations is to ensure a good coronary seal between appointments in order to prevent the penetration of oral fluids and bacteria from the oral cavity into the root canal system (Sivakumar et al., 2013; Srivastava et al., 2017).

These materials should be easy to remove, inexpensive and have inferior aesthetics (which can also be a disadvantage) as it allows for easier removal and does not remove additional tooth structure during its removal (Eliyas et al., 2015). Therefore, its role should not be minimized and its importance in endodontic treatment should be highlighted (Sivakumar et al., 2013).

When selecting a temporary material for root canal procedures, it is crucial to choose one that can effectively prevent contact between the root canal system and the oral environment. Additionally, the material should be able to withstand abrasion and compression while exhibiting low porosity, dimensional stability, and good sealing properties. It should also possess reasonable aesthetics and have the ability to protect the canal system from contamination by saliva, fluids, and microorganisms. Currently, the most commonly used temporary materials in clinical practice are Cavit™, a calcium sulfate-based cement, , and IRM®, a reinforced zinc-oxide-eugenol cement. The choice of which material to use depends on various clinical factors, including the duration of use, dimensional stability, abrasion resistance, stabilization of intracanal medication, and adaptation to complex access cavity formats (Paulo et al., 2023).

Sterile environment must be ensured between appointments up to the placement of permanent restoration during root-canal procedure, who provide a fluid-tight coronal seal. An important consideration in the seal provided by temporary restoration is its thickness. A thickness of more than 4 mm of the interior of restoration is a prerequisite for an effective seal (Prabhakar, Dixit & Raju, 2018). Also sometimes, the kind of endodontic spacer used below the temporary restoration, can also cause microbial contamination. Apart from that endodontic spacers also help easy removal of provisional restoration by avoiding the chances of unwanted intact tooth structure loss, perforation on floor of pulp chamber, prevent provisional restorative materials entrapment into the root-canals which results in canal blockage (Paranjpe et al., 2012).

Cavit™ is a ready-to-use self-curing substance that consists of synthetic resins and zinc oxide, excluding eugenol. Cavit™ is available in three variations: Cavit™(pink), Cavit™-W (white), and Cavit™-G (grey). Cavit™ and Cavit™-W differ in the levels of zinc sulfate and zinc oxide they contain, resulting in increased hardness for Cavit™ and improved adhesion for Cavit™-W. Cavit™ possesses advantageous qualities for sealing crowns, including the ability to expand hygroscopically through water absorption (Djouiai & Wolf, 2021).

On the other hand, it is known for its limited mechanical strength and gradual hardening process.

IRM® is a self-curing substance comprised of eugenol and zinc oxide. While it may be more challenging to handle, it demonstrates moderate levels of penetration. The infiltration capabilities of IRM® compared to CavitTM have yielded conflicting findings in various studies. Some suggest that IRM® outperforms Cavit™ in terms of sealing ability during shorter evaluation periods, while others indicate that IRM® falls short in this regard (Paulo et al., 2023).

Polytetrafluoroethylene tape, commonly known as Teflon tape, is a polymer material that possesses several unique properties and has been used in different dental applications including endodontic access spacers. It is non-biodegradable, nonfibrous, hydrophobic and autoclavable (Olsson et al., 2017; Alkadi & Alsalleeh, 2019; Somani et al., 2022). Additionally, it is firm when condensed; thus, it has been thought to allow for better compaction and increased thickness of the provisional restoration, compared with the soft cotton pellet. Moreover, it lacks the fibers that may interfere with the adequate adaptation of the restorative material to the walls of the access cavity (Prabhakar, Dixit & Raju, 2018; Alkadi & Alsalleeh, 2019; Alkadi et al., 2023).

Polytetrafluoroethylene tape is relatively inert; as such it is capable of resistance to solvents and acids, therefore will not degrade when used with dental etchants. Polytetrafluoroethylene tape also has a low static and kinetic coefficient of friction (0.1) ensuring a 'non-stick' application and removal without leaving behind a residue. Due to Polytetrafluoroethylene tape's 'high break elongation' it is capable of being stretched up to 400% of its original length without tearing. As such the material can be stretched and adapted closely to different surfaces and manipulated without the risk of being destroyed. Despite the material being available in thin sections (30–120 μm) it does not significantly lose its shear strength. In addition to excellent insulating properties, Polytetrafluoroethylene tape has a high melt viscosity (approximately six times that of most fluoropolymers) which allows the tape to be sterilised for dental purposes in an autoclave (Sattar, Patel & Alani, 2017).

Polytetrafluoroethylene tape has been investigated as an alternative endodontic access spacer to the cotton pellet, both clinically and in laboratory studies, and showed promising results. The Polytetrafluoroethylene tape spacer was consistently associated with lower

levels of microbial contamination (Olsson et al., 2017; Prabhakar, Dixit & Raju, 2018; Alkadi & Alsalleeh, 2019; Somani et al., 2022).

Polytetrafluoroethylene tape can be used as an alternative to cotton wool or foam pellets below temporary endodontic restorations. Olsson et al. investigated the PTFE spacer clinically in permanent molars. After pulp space debridment, the patients received either cotton pellet or Polytetrafluoroethylene tape spacers under the Cavit restoration. In the second appointment, the spacers were retrieved and evaluated for microbial growth by culturing on agar plates. Cotton pellet spacers were significantly more frequently contaminated (15/24, 63%) compared with Polytetrafluoroethylene tape spacers (2/24, 8%) (Olsson et al., 2017).

However there are not studies evaluating the influence of the thickness of Polytetrafluoroethylene tape in the endodontic treatment. So the objective of this study is to evaluate infiltration in monoradicular teeth using different thicknesses of polytetrafluoroethylene tape.

2. MATERIALS AND METHODS

Bibliographic research

A bibliographic search was conducted online using the PubMed and Web of Science databases. The search terms used were: "endodontic treatment," "multiple visits," "endodontic spacer," "PTFE," combined using the Boolean operator AND. Filters applied included a time limit of the last 15 years (2009-2024), free full text availability, and articles published in English, Italian, and Portuguese languages. For the literature review, some articles outside the specified time limits were included if deemed relevant to this scientific work. Duplicate or irrelevant articles were excluded. In total, the review comprised 34 articles.

Objective

The objective of this study was to evaluate infiltration in single-rooted teeth using different thicknesses of polytetrafluoroethylene tape.

Study type

The proposed research work corresponds to an "Ex vivo" quantitative study, involving data collection through the observation method.

Study location

The proposed preclinical study involved a physical study location at the Fernando Pessoa University clinic (FCS-UFP). The researcher personally conducted each clinical step at the study sites. The working and data collection period was set for a duration of two months from the outset. Given the favorable assessment, both verbal and written, by the FCS-UFP institution for the conduct of the scientific work, a meeting was scheduled with the work coordinator to establish a timeline for the planned activities, aiming to avoid disrupting the normal functioning of the university clinic's activities.

Ethical considerations

Before conducting the research, a detailed project was prepared containing all necessary information for submission to the Ethics Committee of Fernando Pessoa University. The key components of this document included: introduction, study objectives, methodology, informed consent, bibliographic references, and all annexes appended to the project. The committee's opinion was favorable (approval number FCS/MMED – 505/23) (Appendix

A). The adopted methodology complies with current ethical standards, ensuring the integrity of all materials used.

Informed consent

To conduct the study, a free and clarified informed consent form was prepared for the Italian clinic from which the teeth for the experiment were sourced, whose acceptance by the study was mandatory. This step was an essential component of research ethics. Within the document, written in both Italian and Portuguese, all the objectives and purposes were described, ensuring that the participants were fully aware and voluntarily consented to their participation in the study. This declaration aimed to protect the rights and privacy of the participating clinic (Appendix B).

Sample

A total of 24 teeth were selected according to the inclusion criteria established for this study: (1) monoradicular teeth; (2) teeth without signs of fractures and root caries; (3) teeth with closed apex; (4) teeth with no dental anomalies.

Data collection instruments

The teeth used in this study were collected from dental clinics located in Italy. After extraction, they were placed for 5 minutes in a solution of 3% sodium hypochlorite (Coltene®), and then stored at a temperature of 5ºC in saline solution (Braun®), until the beginning of the execution of the experimental protocol.

All procedures were performed by the same operator, in order to reduce interoperator error.

For the selection of the teeth and verification of the inclusion criteria, the visual evaluation of the teeth was performed.

The teeth were separated into two distinct groups according to the coronal cut performed. This cut was made perpendicular to the major axis of the tooth, with a Cutting Disc – Dynex 0.4x40 mm (Renfert®) attached to an HP Disc chuck (Edenta®) using a high rotation handpiece (Sigma Air Dentflex®) cooled, until the length was defined for each of the groups:

Group 1: coronal cut to 5 mm;

Group 2: coronal cut to 4 mm.

In the preparation of the access cavities, the following were used: a spherical diamond core drill (E 0123 014 Dentsply Maillefer) and then an Endo-Z® drill (Dentsply Malleifer), coupled to a turbine (Dentflex®) with cooling, in order to have an access cavity that would allow a perfect visualization of the root canal, removing only the necessary dental tissue and avoiding perforations. After the execution of the access cavity, the permeability of the root canal was verified through irrigation with 3% sodium hypochlorite solution and using a K 10 file (Dentsply Malleifer) until the tip was visible in the apical foramen.

For the root canal instrumentation, the root canal was pre-widened using K-type manual files, from the K10 file to the K20 file (Dentsply Maillefer), then the ProTaper® Gold mechanized instrumentation system was used to the F3 file, using the X-Smart Plus® endodontic micromotor, with speed and torque, according to the manufacturer's instructions.

Between each file, the RC was irrigated with 2 mL of 3% sodium hypochlorite using a 5 mL syringe (Ultradent®) and a needle (BD Microlance 3™, 27G, 25mm).

In group 1, 2 mm of Polytetrafluoroethylene tape was inserted following by placing 3 mm of the temporary restoration, cavit (Oralfil-G®), while in group 2, 1 mm of Polytetrafluoroethylene tape was inserted following by placing 3 mm of the temporary restoration, cavit.

All the teeth surfaces in the two experimental groups were coated with two layers of nail polish, first was used a red colour one and the second was a blue color one, in order to garantee that all surfaces were doble coated. The totality of the tooth was doble coated except for the access openings of cavit.

Positive control teeth were not filled, in order to ensure correct infiltration of the canal along its entire length through the apical route.

The teeth in negative control have not been filled and have been painted completely to ensure that the nail polishes prevent filtration through the root walls.

After drying the nail polish, the teeth were dipped in 1% methylene blue, with pH 7, and stored in a dry environment and controlled temperature for 7 days.

After a week in methylene blue the teeth are removed and passed in water quickly, then with a turbine the crown was cut at the same height as the Polytetrafluoroethylene tape.

From here we were wearing to see how much the methylene blue was able to penetrate and the mm penetration was recorded for both groups.

Statistical analysis

The data collected were processed using the IBM SPSS Statistics vs. 26.0 software. The Shapiro-Wilk test was applied to verify data normality. Accordingly, to non-normal distribution, Mann-Whitney U test was applied. The significance level was 5% for all statistical tests ($p<.05$).

3. RESULTS

The total distance of coronal dye leakage is shown in Table 1. The group with 2 mm of Polytetrafluoroethylene tape presented the least amount of coronal dye leakage, with statistically significant differences to the group with 1 mm of Polytetrafluoroethylene tape ($p<.05$).

Table 1: Total distance of coronal dye leakage

Data	***Total distance of coronal dye leakage (mm)***	
1 mm	Mean ± SD	2,70 ± 0,675
	Median	3,00
2 mm	Mean ± SD	0,30 ± 0,483
	Median	0,00

Legenda: mm: (millimetres)

The positive control group presented total distance of the root with coronal dye leakage. The negative control group presented total absence of coronal dye leakage.

Ex-vivo coronal dye leakage analysis of polytetrafluoroethylene tape thickness as endodontic acess cavity spacer

4. DISCUSSION

When it comes to noninfected teeth that are vital, it is possible to complete endodontic treatment in just one visit, which eliminates the need for temporary measures. However, there are instances where a single-visit approach may not be feasible due to various factors such as limited time, complexity of the case, presence of persistent bacteria, or patient-related considerations (Moreira et al., 2017; Alkadi & Alsalleeh, 2019).

Despite numerous studies showing no difference in the outcome between single and multiple visits for endodontic treatment, some endodontists still prefer the multiple-visit approach. This is done to ensure a pain-free experience, minimize complications, and apply antibacterial intracanal medicaments to infected canals. As a result, a temporary restoration is necessary to seal the access cavities and prevent recontamination from oral fluids between appointments.

Temporary coronal sealing materials are used between endodontic treatment sessions when it is decided to perform the treatment in multiple sessions and between the end of the treatment and the placement of the final restoration. The purpose of these restorations is to ensure a good coronary seal between appointments in order to prevent the penetration of oral fluids and bacteria from the oral cavity into the root canal system (Sivakumar et al., 2013; K Srivastava et al., 2017).

These materials should be easy to remove, inexpensive and have inferior aesthetics (which can also be a disadvantage) as it allows for easier removal and does not remove additional tooth structure during its removal (Eliyas et al., 2015).

IRM® is a zinc-eugenol oxide cement reinforced with polymethyl methacrylate (Lai et al., 2007). In endodontics, IRM® is one of the most widely used temporary materials because of its high compressive strength. (Pieper et al., 2009). Manufacturers recommend its use for up to 1 year for cavities, with a powder-to-liquid ratio of 6:1. (Sivakumar et al., 2013; Devika Warrier et al., 2016). Setting occurs within 5 minutes of starting mixing.

However, due to its dimensional instability, IRM®, when exposed to heat stress, is subject to infiltration (Devika Warrier et al., 2016). In addition, the mixing process can result in poor homogeneity that can produce variations in the volume of the IRM® mixture (Shanmugam et al., 2020).

Due to the uncertainty regarding the efficacy of IRM® in preventing the passage of bacteria into the root canal system, it was recommended to combine it with another temporary restoration material - Cavit®. This association is justified by the price, ease of use and the fact that, when used together, a better adaptation to dentin has been observed compared to IRM® alone. (Eliyas et al., 2015; Naoum et al., 2002; Martin, 2004).

Cavit® it's an already mixed temporary filling material, containing zinc oxide, triethanolamine, calcium sulfate, glycol acetate, zinc sulfate, polyvinyl chloride acetate, polyvinyl acetate resins, and pigments (Lai et al., 2007). Cavit® has a low compressive strength (Naoum et al., 2002; Martin, 2004). Cavit® has certain advantages, such as the fact that it has a high coefficient of linear expansion during fixation. (Sivakumar et al., 2013; Eliyas et al., 2015; Srivastava et al., 2017), A good marginal seal (Eliyas et al., 2015; Srivastava et al., 2017), Good water absorption characteristics (Eliyas et al., 2015; Srivastava et al., 2017), Good resistance to bacterial penetration (Martin, 2004) and it is easy to use due to its premixed form.

Due to their water absorption characteristics, they have a good marginal seal (Eliyas et al., 2015). However, it requires a restoration thickness of 3 to 4 mm over a period of up to 3 weeks to prevent bacterial penetration and thus achieve an adequate seal (Sivakumar et al., 2013; Eliyas et al., 2015; Shanmugam et al., 2020).

The objective of the study of Paulo et al (2023) was to compare the effectiveness of various temporary restorative materials used in endodontic treatment in terms of their ability to seal. To conduct the experiment, a total of eighty sheep incisors were collected and standardized in length. Access cavities were then created in all teeth, except for the negative control group, which remained intact. The teeth were divided into six different groups for further analysis. In the positive control group, the access cavities were made but left empty. In the experimental groups, the access cavities were restored using three different temporary materials: IRM®, Ketac™ Silver, and Cavit™. Additionally, a definitive restorative material called Filtek Supreme™ was used as a comparison. To assess the sealing ability of these materials, the teeth underwent thermocycling. After two and four weeks, the teeth were infiltrated with $^{99m}TcNaO_4$, and nuclear medicine imaging was conducted. The results revealed that Filtek Supreme™ exhibited the lowest infiltration values, indicating superior sealing ability. Among the temporary materials, Ketac™ Silver demonstrated the lowest infiltration values at two weeks, followed by IRM®, while Cavit™ exhibited the highest infiltration. After four weeks, Ketac™ Silver

maintained the lowest infiltration values, and Cavit™ showed a decrease in infiltration, comparable to that of IRM® (Paulo et al., 2023).

In the study of Babu et al (2019) a total of sixty caries-free primary molars were used in this study, with standardized access cavities measuring 3 × 3 mm being prepared. These teeth were randomly divided into four groups, each consisting of 14 teeth. The temporary restorative materials used in each group were IRM, Cavit G, Orafil-G, and Dia-Temp, applied in accordance with the manufacturer's instructions. To assess microleakage, the teeth underwent thermocycling and were then immersed in a 0.5% basic fuchsin solution for 24 hours. Subsequently, the specimens were sectioned and examined under a digital microscope at 20× magnification, with microleakage being scored. Among the temporary restorative materials tested, Dia-Temp exhibited the lowest microleakage values. On the other hand, IRM had the highest microleakage score, followed by Orafil-G and Cavit-G. Statistical analysis revealed a significant difference between the IRM and Dia-Temp groups (p value = 0.009), as well as between the Orafil-G and Dia-Temp groups (p value = 0.025) (Babu et al., 2019).

In the study of Markose et al (2016) Cavit-W showed lowest mean leakage than IRM. To ensure consistency across all experimental groups, as well as the positive control group, a three-layer application of nail varnish was administered to the roots, excluding the coronal orifice region. Conversely, teeth in the negative control group were fully coated with nail polish, including the coronal orifice. Following this preparation, the teeth were submerged in a solution containing 2% methylene blue dye for a period of three days. Carefully, all sealing materials and Gutta-percha were removed from the canal walls, allowing for a thorough examination of the entire circumference of the canal wall for any signs of dye infiltration. The measurement from the canal orifice to the deepest point of dye penetration was meticulously recorded and calculated in millimeters (Markose et al., 2016).

In this study we use Cavit as temporary coronal sealing material.

To ensure the preservation of sterility during multiple visit procedures, it is crucial to maintain a state of sterility between appointments until a permanent coronal restoration is placed after root-canal obturation. In order to achieve this, it is necessary to use an endodontic spacer beneath a temporary restoration. This spacer serves two important purposes: maintaining the patency of the root canals and preventing the growth of microorganisms. These spacers are typically placed between endodontic appointments or

after the completion of endodontic therapy, serving as a temporary measure until a permanent restoration is placed. The primary objectives of using a spacer are to facilitate the removal of temporary fillings and to aid in the identification of canal orifices. When selecting an ideal material for this purpose, several factors come into play. It should be easy to place and remove, minimize bacterial leakage, and discourage bacterial growth. Furthermore, it should be cost-effective, inorganic, readily available, autoclavable, and occupy minimal volume (Somani et al., 2022).

Historically, the cotton pellet has served as the prevailing choice for endodontic spacers. Nevertheless, its utilization has been linked to significant complications that can undermine its intended sealing properties. A notable drawback of this material is its fibrous and organic composition, which has the potential to exacerbate microbial leakage and facilitate the proliferation of bacteria (Alkadi & Alsalleeh, 2019).

As a substitute for cotton wool or foam pellets, polytetrafluoroethylene tape can be utilized beneath temporary endodontic restorations. Laboratory studies have demonstrated that polytetrafluoroethylene tape outperforms other materials in reducing bacterial contamination. This superior performance can be attributed to the non-fibrous nature of polytetrafluoroethylene tape, which decreases the likelihood of bacterial uptake through wicking. Additionally, when compacted, polytetrafluoroethylene tape creates a sturdy foundation that may minimize the risk of marginal breakdown in temporary materials when subjected to occlusal loading, thereby providing a more stable sub-structure (Alkadi & Alsalleeh, 2019; Somani et al., 2022).

This polymer material is widely utilized in various medical and dental applications due to its versatility. Polytetrafluoroethylene tape offers similar advantages to cotton pellets as a spacer material, while also providing additional benefits. Its inert, nonbiodegradable, and nonfibrous properties make it capable of overcoming the limitations associated with cotton pellets (Olsson et al., 2017; Alkadi & Alsalleeh, 2019; Somani et al., 2022).

Previous studies, both in the laboratory and clinical settings, have examined the potential of Polytetrafluoroethylene tape as an alternative spacer to conventional cotton pellets and have reported promising results (Olsson et al., 2017; Prabhakar, Dixit & Raju, 2018; Alkadi & Alsalleeh, 2019; Somani et al., 2022).

The study of Alkadi and Alsalleeh pretend to assess the effectiveness of a polytetrafluoroethylene tape access spacer in preventing microbial leakage compared to

a cotton pellet. A total of 52 single-rooted premolars were divided into two experimental groups (n = 20) based on the type of endodontic spacer used: cotton pellet or polytetrafluoroethylene tape. Two control groups (n = 6) were also included. After standardized access cavity preparation, cleaning, and shaping procedures, the access cavities were filled with a standardized thickness of the spacer material, followed by a Cavit restoration in all teeth except for the positive controls, which remained empty. The root surfaces of the negative controls were completely sealed with nail polish. To evaluate microbial leakage, a dual-chamber model was utilized, with *Enterococcus faecalis* as the test strain. Samples of the lower chamber solution were collected at days 7 and 30 and analyzed using quantitative real-time polymerase chain reaction to determine bacterial levels. Additionally, broth turbidity in the lower chambers was recorded weekly. The experimental groups exhibited similar levels of microbial leakage as indicated by broth turbidity at days 7 and 14. However, at days 21 and 30, a significantly higher number of cotton pellet samples demonstrated microbial leakage. Quantitative real-time polymerase chain reaction analysis demonstrated that the levels of E. faecalis counts were higher in cotton pellet samples than in polytetrafluoroethylene tape samples. This disparity was found to be statistically significant on day 7, but not on day 30. The utilization of a polytetrafluoroethylene tape spacer exhibited enhanced sealing capability in comparison to the conventional cotton pellet, suggesting its potential as an alternative endodontic access cavity spacer (Alkadi & Alsalleeh, 2019).

Due to its organic composition, cotton wool is prone to bacterial absorption through wicking. Additionally, if cotton fibers become trapped in cavity walls, it can lead to a compromised coronal seal and subsequent leakage into the disinfected root canal system. This has been observed in the apical migration of cotton wool fibers, which have been found in apical granulomas accompanied by an inflammatory infiltrate (Gidwani et al., 2014).

Paranjpe et al (2012) evaluate microbiologically the efficacy of cotton and polytetrafluoroethylene tape as spacer materials in endodontic treatment. Under a standardized provisional restorative material called Cavit, 26 human molars were restored using either cotton or polytetrafluoroethylene tape as spacers. Following restoration, the teeth were subjected to a 7-day incubation period in a culture of Streptococcus gordonii or in liquid media alone. After removal, the spacers were examined for any presence of bacterial contamination. Additionally, the access cavities were assessed for bacterial

contamination. Out of the 10 teeth that had cotton spacers, 9 of them tested positive for the growth of *S. gordonii*. Additionally, these 9 teeth also showed contamination in the access cavities. This suggests that even in ideal circumstances, cotton spacers can lead to leakage into the access cavities. The presence of cotton fibers may serve as a pathway for bacterial contamination in both the access cavities and the root canal space. On the other hand, the use of polytetrafluoroethylene tape did not allow for any bacterial contamination in all the teeth.

While previous in-vitro studies have highlighted the advantages of utilizing polytetrafluoroethylene tape instead of cotton, there has been a lack of in-vivo studies to support these findings. As a result, the objective of the Olsson's study was to determine which spacer exhibited lower levels of bacterial leakage in endodontic treatments. A total of fifty patients were enrolled in the study and randomly assigned to either the cotton or polytetrafluoroethylene group. Root canal treatments were conducted over two appointments, with the cotton and polytetrafluoroethylene spacers being collected after a 2- to 4-week interval between appointments. The collected samples were then incubated on agar plates for 48 hours and assessed for the presence of microbial growth. Colony forming units were counted for each sample, and the data was analyzed using nonparametric statistical tests. Out of the 24 cotton spacers, 15 tested positive for bacterial growth, whereas only 2 out of the 24 polytetrafluoroethylene spacers showed the same result. The use of cotton spacers may potentially introduce contaminants into the pulp chamber due to its exposure to the oral environment. Furthermore, the tendency of cotton to distort under the forces of mastication may compromise the marginal seal of the temporary material. After analyzing the findings of this research, it is highly recommended to utilize polytetrafluoroethylene as an endodontic spacer material instead of cotton. In this particular in-vivo microbial study, polytetrafluoroethylene demonstrated superior performance compared to cotton (Olsson et al., 2017).

A few years later, a study aimed to assess the effectiveness of using cotton and Polytetrafluoroethylene tape as spacers under temporary filling material during root canal treatment. A total of forty infected primary molars from twenty children were included in the study. The root canal treatment was conducted in two visits, with the application of either cotton or Polytetrafluoroethylene tape as spacers randomly on each side. Microbiological analysis was performed after pulpectomy, with samples taken from the coronal portion of the cavity at different time points: immediately after pulpectomy, and

at seven days follow-up for both the cavity and the spacer material. The results showed that the cotton fibers group exhibited bacterial contamination in both the cavity and the spacer material, while the Polytetrafluoroethylene tape group had the least bacterial growth in their samples. The majority of samples from the cotton group were contaminated, whereas only a minimal amount of the Polytetrafluoroethylene tape samples showed bacterial contamination (Khatab & Abdelhafez, 2020).

The purpose of the Somani's study was to assess the microbiological properties of cotton, polytetrafluoroethylene tape, and foam pellets when used as endodontic spacers in primary teeth. A total of thirty primary second molars that required pulpectomy were included in the study. Following the completion of pulpectomy, ten teeth each were randomly assigned to receive cotton, polytetrafluoroethylene tape, or foam pellets as endodontic spacers. Samples were collected from the pulp chamber at baseline and after seven days to evaluate microbial contamination. After seven days, both the cotton and foam pellet groups exhibited a statistically significant increase in colony forming units, indicating higher levels of contamination. In contrast, the polytetrafluoroethylene tape group showed minimal contamination of the pulp chamber after seven days. Based on the findings of this study, it can be concluded that polytetrafluoroethylene tape is a superior alternative to cotton as an endodontic spacer (Somani et al., 2022).

Based on the microbial analysis of the various studies, the use of Polytetrafluoroethylene tape as a spacer material under provisional restoration yielded excellent results and may serve as a potential alternative to cotton in future endodontic practices.

In a systematic review conducted by Mathew et al, the efficacy of polytetrafluoroethylene tape and cotton pellet as endodontic spacers under provisional restorations was compared. The review included three laboratory studies and three clinical studies, each with varying levels of bias. The laboratory studies consistently showed that cotton pellets had higher bacterial counts and more positive samples compared to polytetrafluoroethylene tape. However, there were some discrepancies in the results when different recall times were assessed. None of the studies reported higher contamination levels for polytetrafluoroethylene tape in any recall or experimental set-up. On the other hand, the clinical studies consistently indicated that polytetrafluoroethylene tape was associated with a significantly lower incidence of microbial contamination and positive cultures (Mathew et al., 2021).

Alkadi recently conducted a study to assess how two different spacer materials, cotton pellet and polytetrafluoroethylene, impact the formation of gaps and voids in Cavit restorations used for endodontic temporization. The study involved thirty-four extracted human single-rooted premolars that were divided into two groups, with each group consisting of seventeen teeth. The allocation of teeth into the groups was based on the type of spacer material used in the access cavity, either cotton pellet or polytetrafluoroethylene tape. All the teeth underwent standardized endodontic access cavity preparation. Micro-computed tomography scans were then performed to measure the volume of the access cavities. Afterward, the teeth were temporized by placing either cotton pellet or polytetrafluoroethylene tape as spacer materials on the canal orifices, followed by the application of the Cavit restoration. A second Micro-computed tomography scan was conducted after the temporization procedure to determine the percentage volume of gaps along the margins and voids within the Cavit restoration. The results revealed that the use of polytetrafluoroethylene tape as a spacer material resulted in significantly less gap formation between the Cavit restoration and the access cavity walls compared to the cotton pellet ($P < 0.05$). However, there was no significant difference in void formation between the two groups ($P > 0.05$). The results of this study suggest that the type of spacer material used under the Cavit restoration can have an impact on the overall quality of the restoration. In comparison to the cotton pellet, the use of polytetrafluoroethylene tape as a spacer material resulted in fewer gaps and demonstrated superior performance during endodontic treatment (Alkadi et al., 2023).

The objective of the research from Olcay et al (2015) was to evaluate and compare the efficacy of various temporary restorative materials in terms of their sealing ability after 24 hours and 1 week. The study focused on endodontic access cavities. A total of 56 lower incisor-teeth were extracted and utilized for the experiment, which were then divided into 5 groups consisting of 10 teeth each. The restoration of cavities was carried out using different materials in each group: Group 1 utilized temporary restorative material (Ceivitron), Group 2 used glass ionomer cement (Fuji II), Group 3 employed zinc oxide-eugenol cement (IRM), Group 4 opted for zinc phosphate cement (Adhesor), and Group 5 utilized polytetrafluoroethylene tape. The fluid transport model was utilized to measure the effectiveness of coronal sealing in each specimen, both after 24 hours and one week. Significant differences were observed among the groups at all time-points ($p<0.05$), including the 24-hour mark. polytetrafluoroethylene tape exhibited comparable levels of

leakage to Ceivitron, IRM, and Fuji II, but it demonstrated greater leakage than Adhesor. After a week, Ceivitron displayed higher levels of leakage than the other materials. There was no significant difference in leakage observed with polytetrafluoroethylene tape compared to IRM, Fuji II, and Adhesor ($p>0.05$). Based on the findings of this study, it can be concluded that polytetrafluoroethylene tape exhibits a satisfactory short-term sealing capability when compared to other temporary restorative materials commonly used, as observed in the 1-week measurements (Olcay et al., 2015).

Therefore, the objective of the present study ex vivo study is to further explore the potential of Polytetrafluoroethylene tape as a spacer material evaluating the better thickness. So, this is the first study, as we know, in this conditions and no one in literature is possible to compare directly with our results.

The literature suggests that a 3 to 4-mm thickness of Cavit should prevent bacterial ingress for at least 2 weeks, (Wester et al., 2008). In this study the temporary thickness was 3 mm, and the teeth were prepared for reach this objective.

Numerous studies have evaluated the efficacy of Polytetrafluoroethylene tape compared to cotton as an endodontic spacer using various methodologies. In this study, the technique used was dye filtration.

The dye used is actually a very important variable to take into consideration. In the literature, the most used dyes are Indian ink and Methylene Blue. However, the average size of the particles that make up these dyes is much smaller than the of the bacterial flora that surrounds the endodontic structures. Therefore, by using these dyes, it is possible to obtain filtration values that overestimate the actual size of the filtration, which is a disadvantage of this technique (Oliver & Abbott, 2001; (Camps & Pashley, 2003).

To carry out this study, the technique of penetration of Methylene blue dye with neutral pH was used, as it is a simple technique, the use does not require a large learning curve on the part of the operator or specific materials, not even a laboratory.

The results of this study showed that the group with 2 mm of Polytetrafluoroethylene tape presented the least amount of coronal dye leakage.

The negative control group demonstrated that the two layers of nail varnish have the ability to prevent bacterial filtration inside the canal, attesting that if there is filtration in the other groups, it will only be through the apical foramen of the tooth and not through the tooth walls.

The positive control group showed a total filtration of the solution inside the channel, occupying all the empty spaces present. This group was used to evaluate the ability of the dye to completely penetrate the empty spaces present in the root (Oliver and Abbott, 2001).

Final reflection and limitations of the study

This study highlights the crucial role of Polytetrafluoroethylene tape spacer thickness in enhancing the seal integrity of endodontic access cavities. The clear superiority of the 2 mm Polytetrafluoroethylene tape spacer over the 1 mm spacer underscores the importance of meticulous material selection and adaptation to prevent coronal dye infiltration. However, given the study's focus on only two thicknesses, further exploration across a broader range of Polytetrafluoroethylene tape thicknesses is necessary to validate these findings.

To ensure the continuity of this study and expand research while maintaining the adopted methodological approach, it is essential to identify its intrinsic limitations. Future recommendations include conducting comprehensive investigations involving various Polytetrafluoroethylene tape thicknesses combined with different temporary restorative materials. This expanded research scope should encompass clinical scenarios that replicate real-world conditions, including thermo-mechanical cycles and diverse access cavity designs. Such studies would not only validate our findings under more realistic conditions but also promote the development of refined protocols for endodontic sealing.

Other limitations of this study were: the size of the sample. It´s used only twenty teeth wich were randomized allocated in the groups. This situation can originate a heterogeneous group for each thickness.

Through advancing our understanding and refining techniques based on empirical data, we can significantly reduce the risks of bacterial infiltration and enhance the long-term effectiveness of endodontic treatments. Ultimately, this pursuit of excellence in sealing methodologies aims to optimize outcomes for patients and uphold standards in modern endodontic practice.

Clinical significance

In case of multiple visit procedure, the state of sterility must be maintained in between the appointments until a definitive coronal restoration is placed following root-canal obturation. So, it is mandatory to place an endodontic spacer under a provisional

restoration to maintain the patency of the root canals and prevention of the microbial growth. The Polytetrafluoroethylene tape is inorganic, nonfibrous material which can be tightly packed without any voids under the provisional restoration. The thickness of the Polytetrafluoroethylene tape influenced the leakage in the teeth. So, 2mm Polytetrafluoroethylene tape a good thickness to maintain the root canal patency and to provide a sterile environment by preventing the microbial growth under the provisional restoration as an endodontic spacer material in between the appointments.

Ex-vivo coronal dye leakage analysis of polytetrafluoroethylene tape thickness as endodontic acess cavity spacer

5. CONCLUSION

The results indicate that the Polytetrafluoroethylene tape spacer with a thickness of 2 mm demonstrated better sealing compared to the 1 mm thickness, suggesting that material adaptation is critical for the success of endodontic access cavity sealing.

However, it is essential to consider that this study examined only two thicknesses of Polytetrafluoroethylene tape, which limits the generalization of the results. Further research should explore a broader range of Polytetrafluoroethylene tape thicknesses and assess their effectiveness in combination with various temporary restorative materials. Additionally, including studies that replicate more realistic clinical conditions, such as thermo-mechanical cycling and different access cavity designs, would be beneficial.

These insights could provide a more robust foundation for improving endodontic sealing techniques, thereby contributing to the reduction of bacterial infiltration and enhancing the long-term reliability of endodontic therapies.

Ex-vivo coronal dye leakage analysis of polytetrafluoroethylene tape thickness as endodontic acess cavity spacer

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7. APPENDICES

Appendix A - Authorization obtained from the Ethics Committee of Fernando Pessoa University

UNIVERSIDADE FERNANDO PESSOA

Exma. Senhora
Prof. Doutora Sandra Gavinha
Diretora da FCS

Nº	Data
FCS/MMED – 505/23	23 de Janeiro de 2024

Exma. Senhora Professor Doutora,

A Comissão de Ética apreciou o projeto de investigação apresentado por Alfonso Antonio Maria Franza, intitulado "*Ex-vivo* coronal dye leakage analysis of polytetrafluoroethylene tape thickness as endodontic access cavity spacer", a realizar no âmbito do Mestrado Integrado em Medicina Dentária.

O objetivo deste estudo é avaliar a infiltração em dentes monoradiculares utilizando diferentes espessuras de politetrafluoroetileno (PTFE).

A Comissão de Ética considera que todos os aspetos éticos estão salvaguardados, e, deste modo, nada tem a opor quanto à sua realização.

Com os melhores cumprimentos,

A Presidente da
Comissão de Ética da UFP
Inês Lopes Cardoso

Autorizo-se

este

24-11-24

Appendix B - Informed consent

Formulário de consentimento informado

Está convidado a participar, como voluntário, no projeto de investigação "Ex vivo coronal dye leakage analysis of polytetrafluoroethylene tape thickness as endodontic access cavity spacer ". Para o efeito, pedimos a sua autorização para recolher, depositar, armazenar e utilizar material biológico humano do seu dente. Nesta investigação, pretendemos avaliar o efeito da espessura do espaçador utilizado tem na infiltração coronária, através da utilização de azul de metileno. O dente utilizado será arquivado sob a minha responsabilidade por um período máximo de 5 (cinco) anos e depois será destruído. A investigação contribuirá para o conhecimento da espessura máxima que se poderá utilizar de um espaçador sem que exista comprometimento para a qualidade do tratamento endodôntico. Para participar neste estudo, não terá quaisquer custos nem receberá quaisquer benefícios financeiros. Será informado do estudo da forma que desejar e terá a liberdade de participar ou recusar-se a participar e, a qualquer momento e sem qualquer prejuízo, poderá retirar o seu consentimento para a conservação e utilização do material biológico armazenado, sendo a retirada válida a a partir da data de formalização. A sua participação é voluntária e o facto de se recusar a participar não implicará qualquer penalização ou alteração dos cuidados que lhe são prestados. Os resultados obtidos pela investigação, utilizando o seu material biológico, ser-lhe-ão facultados quando estiverem concluídos. Não será identificado em nenhuma publicação que possa resultar deste trabalho. Este formulário de consentimento é impresso em dois exemplares originais, um dos quais será guardado pelo diretor da Clínica Médica e o outro ser-lhe-á entregue. Os investigadores tratarão a sua identidade de acordo com as normas profissionais de confidencialidade e utilizarão a informação apenas para fins académicos e científicos.

Eu,
_____
_____, portador do documento _____, fui informado dos objectivos do projeto de investigação " Ex vivo coronal dye leakage analysis of polytetrafluoroethylene tape thickness as endodontic access cavity spacer ", de forma clara e detalhada e esclareci as minhas dúvidas. Estou ciente de que posso solicitar informações adicionais em qualquer altura e alterar a minha decisão de participar, se assim o desejar. Declaro que concordo em participar neste estudo. Recebi uma cópia original deste formulário de consentimento informado e tive a oportunidade de o ler e esclarecer as minhas dúvidas.

_____,_____de _____de_____.

Assinatura do participante

Nome :

Data :