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INFLUENCE OF IRRIGATION NEEDLE DESIGN ON THE REMOVAL OF HARD TISSUE DEBRIS

INFLUÊNCIA DO DESENHO DA AGULHA DE IRRIGAÇÃO NA REMOÇÃO DE RESÍDUOS DE TECIDO DURO

DISSERTAÇÃO DE MESTRADO

ALESSANDRA CRISTINA BAASCH CARDOZO

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Orientadores:
Prof. Dr. Jose Freitas Siqueira Junior
Profa. Dra. Isabela das Neves Rôças Siqueira

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Banca examinadora

Maria Kaline Romeiro Teodoro

Prof. (a) Dr. (a) Maria Kaline Romeiro Teodoro
UNIFACOL

Cristine da Silva Furtado Amaral

Prof. (a) Dr. (a) Cristine da Silva Furtado Amaral
UNIGRANRIO

Prof. (a) Dr. (a) Jose Freitas Siqueira Junior
UNIGRANRIO

Prof. (a) Dr. (a) Isabela das Neves Rôças Siqueira
UNIGRANRIO

DEDICATION

To my family for their unconditional support.

Eternally grateful.

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I thank God and the Virgin Mary for the blessings received and for guiding me in this new professional life.

To my parents Hermann Eduard and María Cristina for giving me life and for instilling in me and always supporting me to grow. For always being by my side. For their eternal and unconditional love that has always been my greatest impulse.

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RESUMO

Vários fatores influenciam a eficácia da irrigação, como o alargamento apical do canal radicular, a presença de curvatura, o desenho e a distância de penetração da agulha, bem como o fluxo e o volume do irrigante. A inserção da agulha de irrigação mais próxima do ápice permite uma rotação mais eficiente da solução, resultando em melhor limpeza e desinfecção do canal. Além disso, as características relacionadas ao design da agulha influenciam a taxa de fluxo do irrigante, sua tensão contra as paredes da dentina, o padrão de fluxo e a rotação do irrigante. **Objetivos.** Avaliar a remoção de debris de tecidos duros do sistema de canais radiculares usando diferentes designs de agulha para irrigação endodôntica. **Materiais e métodos.** Três agulhas de irrigação diferentes (ponta fechada CanalPro com saída lateral, ponta aberta Navitip, TrueNatomy) foram avaliadas em primeiros molares inferiores extraídos. Os volumes de detritos de tecido duro remanescentes no canal radicular após o preparo químico mecânico foram analisados usando os três tipos diferentes de agulhas. **Resultados.** A quantidade de volume de resíduos de tecido duro no grupo da agulha fechada foi de 13,83%; no grupo da agulha TruNatomy 8,06% e no grupo da agulha aberta foi de 10,35%. Não houve diferenças estatisticamente significativas entre os grupos (P > 0,05). **Conclusão**. Não é possível eliminar completamente os resíduos de tecido duro encontrados em isthmuses communicating the two mesial canals.

Palavras-chave: Agulha de irrigação; Desenho de agulha de irrigação; Ponta.

ABSTRACT

Several factors influence the effectiveness of irrigation, such as the apical widening of the root canal, the presence of curvature, the design and penetration distance of the needle, as well as the flow and volume of the irrigant. Inserting the irrigating needle closer to the apex allows for more efficient turnover of the solution, resulting in better cleaning and disinfection of the canal. In addition, characteristics related to needle design influence the flow rate of the irrigant, its tension against the dentin walls, the flow pattern and the turnover of the irrigant. **Objectives.** To evaluate the removal of hard tissue debris of the root canal system using different needle designs for endodontic irrigation. **Materials and methods.** Three different irrigation needles (CanalPro closed tip with lateral exit, Navitip open tip, TrueNatomy) were evaluated in extracted mandibular first molars. The volumes of hard tissue debris remaining in the root canal after mechanical chemical preparation were analyzed using the 3 different types of needles. **Results.** The amount of hard tissue debris volume in the closed-ended needle group was 13.83%; in the TruNatomy needle group the amount was 8.06%, and in the open-ended needle group it was 10.35%. There were no statistically significant differences between groups ($P > .05$). **Conclusion**. It is not possible to completely eliminate the hard tissue debris found in anatomical areas such as the isthmuses communicating the two mesial canals.

Keywords: Irrigation needle; Irrigation needle design; Tip.

LIST OF FIGURES

LIST OF ABBREVIATIONS, SYMBOLS AND ACRONYMS

DNA	Deoxyribonucleic acid
G	Gauge
ISO	International Standards Organization
mCT	Computerized microtomography
NaOCl	Sodium hypochlorite
Niti	Nickel titanium
RNA	Ribonucleic acid
RCS	Root canal system
UFC	Colony Forming Units

1. INTRODUCTION AND LITERATURE REVIEW

Reduction of the microbial population within the root canal system (RCS) is achieved by chemomechanical cleaning and shaping with the use of hand and/or rotary instruments. A significant portion of the RCS cannot be reached during instrumentation, so large areas of the root canal may remain untouched, filled with organic and inorganic tissue debris and bacterial biofilm within. In addition, the apical area of the root canal is a critical area for proper disinfection, because bacteria located in that region are conceivably the most important ones associated with the pathogenesis of apical periodontitis. As a consequence, mechanical debridement and adequate irrigation of the root canal are essential for the reduction of the bacterial load in the apical canal and irregularities. Several techniques and instruments have been developed to improve the limitations of conventional syringe irrigation, among which different types of irrigation needles have been designed. Therefore, it is important to analyze the different types of needles designs available in endodontic practice to achieve greater efficiency of root canal treatment.

1.1 APICAL PERIODONTITIS AS AN INFECTIOUS DISEASE

The evidence of the role played by microorganisms in endodontic infections dates back to the late 1800's when Miller in 1891 began to study dental pulp disease after caries formation, evaluating more than 250 dental pulps from sectioned extracted teeth using light microscopy and bacterial culture. In 1894, he finally published a study that marks the beginning of endodontic microbiology, in which he shows in detail the results observed in 50 different pulp samples, identifying for the first time the presence of the bacterial morphologies of *cocci, bacillus and spirochetes*. However, the results

of the culture analyses did not show the evaluations observed in the microscope, since the microscopic evaluation of the necrotic pulp revealed a mixed infection and most of the cultures showed only *cocci* or only *bacilli*, due to the fact that at that time there were no adequate resources to isolate anaerobic microorganisms. In abscess samples of, *spirochetes* were repeatedly observed in the microscopic evaluation and although these were not cultivable, their importance in the etiology of the purulent process could be suggested.

Kakehashi *et al.* (1965) observed the pathological changes in pulp exposures in germ-free and conventional rats, the latter presenting a normal microbiota. The rats free of microorganisms that underwent pulp exposure formed a dentin bridge at 28 days, while the rats that underwent pulp exposure in the presence of microorganisms developed pulp necrosis with associated periapical infection, demonstrating that the presence or absence of microorganisms is the main determinant in the healing of pulp exposures (Kakehashi *et al*., 1965).

Sundqvist, in 1976, evaluated teeth that had suffered trauma and presented necrotic pulps and periapical destruction, but with intact clinical crowns, by means of anaerobic culture techniques. He managed to isolate 88 bacterial strains, more than 90% of these being anaerobic. His findings confirmed that the etiology of periapical disease is clearly bacterial, and that it occurs when the pulp tissue is infected.

Once the microorganisms come in contact with the pulp tissue, an inflammatory response begins with the presence of inflammatory cells with polymorphonuclear leukocytes (Cvek *et al.,* 1982). Within 3 to 4 weeks, necrosis of the pulp tissue and widening of the tissue in the periapical area develops, and after 3 months the periapical tissues are altered with connective tissue proliferation or suppuration (Tagger & Massler 1975). This is how the bacteria in the apical canal are

the protagonist of the infection entering in contact with the periradicular tissues through the apical foramen or foramina, causing damage to these tissues and initiating the inflammation process. The inflammatory exudate seeps into the apical canal to create a fluid phase and provides the bacteria with nutrients in the form of glycoproteins and proteins. Representing an optimal condition for biofilm formation in the apical canal, especially in primary endodontic infections, in which untreated root canals may allow more space for exudate seepage and stagnation within the canal (Ricucci & Siqueira 2010).

This is why the objective of endodontic treatment is based on avoiding the introduction of new bacteria into the root canal during treatment; whereas if there is an already established apical periodontitis, the objective of treatment should be the elimination of causative microorganisms found inside the root canal system (Siqueira & Rôças 2008).

1.2 **NEED FOR DISINFECTION**

The root canal system presents anatomical characteristics such as ramifications, apical deltas and lateral and accessory canals, where microorganisms can lodge in a planktonic form and as a sessile community called biofilm, which is embedded in a polysaccharide membrane, responsible for the formation and maintenance of apical periodontitis. Culture and molecular studies have identified at least 1000 different taxa of bacterial species inhabiting the oral environment, although no specific etiological agent has been identified for endodontic infections. However, a group of 10-20 species predominates in most studies (Siqueira & Rôças 2017).

The oral microbiota has been traditionally studied through studies of culture samples using an artificial growth medium, establishing a set of species that

play an important role in oral diseases, which have now been confirmed and complemented with molecular microbiology techniques. More than 50% of microorganisms fail to be fully cultured and characterized by culture studies, leaving the possibility that uncultured and uncharacterized species may play an important role in the pathogenesis of disease in the oral cavity (Paster *et al.,* 2001, Kazor *et al.,* 2003); although it allows the identification of a wide variety of microbial species in a sample, including those that are not sought, making it possible to determine antimicrobial susceptibility and to study the physiology and pathogenicity of the isolated bacteria (Siqueira & Rôças 2005 [a], Siqueira & Rôças 2010). In contrast, nucleic acid or molecular microbiology techniques can detect culturable and even non-culturable species or strains (including dead microorganisms) that can be taken directly from clinical samples with high specificity and sensitivity, without requiring controlled anaerobic conditions for sample collection, transportation or handling. The detection of dead cells can be an advantage as well as a limitation, as it allows the detection of hitherto uncultured bacteria or bacteria that may die during sampling, transport or isolation procedures; but it may lend itself to misinterpretation of their role in the habitat (Siqueira & Rôças 2005 [a], Siqueira & Rôças 2010).

1.3 **CLINICAL STUDIES EVALUATING DISINFECTION**

The success or failure of endodontic treatment may be related to the presence or absence of microorganisms at the time of obturation. Treatment success has been observed when the culture sample is negative (Zeldow & Ingle, 1963) or less than 10^3 - 10^4 Colony Forming Units (CFU) (Siqueira & Rôças, 2008). Sjögren *et al.* (1997) evaluated 55 single-rooted teeth with apical periodontitis, using advanced anaerobic

bacteriological techniques for culture sampling after chemomechanical preparation and immediate obturation, obtaining as results in the 5-year follow-up clinical evaluations that the teeth that presented a negative CFU or less than 10^2 presented periapical healing. These findings emphasize the importance of reducing SCR microorganisms to tolerable quantities for the host before obturation. This objective is difficult to achieve in a single endodontic treatment appointment, because it is not possible to eradicate the microorganisms present in the root canal without the use of intra-canal medications.

Peters & Wesselink (2002), evaluated the healing of periapical lesions in teeth with negative and positive cultures at the time of obturation, and the periapical healing of teeth treated in one appointment and in 2 appointments with intra-oral calcium hydroxide medication. They obtained no significant differences in healing outcomes over 4.5 years of follow-up between teeth treated at 1 or 2 appointments, but noted that healed cases had a negative culture or less than 10^2 CFU at the time of obturation.

Zandi *et al.* (2018) evaluated by the pyrosequencing method the microbiota in teeth with treated canals with post-treatment apical periodontitis before and after instrumentation and irrigation with 1% NaOCl and 2% chlorhexidine. They observed a high bacterial diversity in the initial samples of the obturated teeth which were drastically reduced after chemomechanical preparation, with some species remaining in the samples taken after treatment, demonstrating that persistent taxa have the potential to influence the outcome of retreatment.

Recently, Zandi *et al.* (2019) compared the clinical and radiographic outcome with 4-year follow-up of endodontic retreatments in teeth with apical periodontitis using 1% NaOCl or 2% chlorhexidine and intra-canal medication with calcium hydroxide using the molecular qPCR method, demonstrating the correlation

between molecular findings and treatment outcomes. The findings showed that bacteria present at the time of obturation significantly impaired treatment prognosis, demonstrating that all cases in which the bacterial load was reduced and remained at levels below 3.12 x 10^3 CFU healed.

Reducing intracanal bacterial counts to levels undetectable by culture procedures, i.e. less than 10^3 CFU, increases the chance of better treatment results. Studies show that chemomechanical preparation is of utmost importance because it eliminates the greatest amount of microorganisms that are found in greater volume in the main canal, although instrumentation and irrigation alone is not enough to keep the root canals free of culturable bacteria, so the use of intra-canal medication with calcium hydroxide is recommended to supplement the antibacterial effects of the chemomechanical preparation and to keep the root canals free of culturable bacteria before obturation. Because these persistent microorganisms lodge in the anatomical variations, they may not be reached by disinfection methods or irrigant solutions and may remain in direct contact with the periradicular tissues, having access to a sustainable source of nutrients that can maintain periradicular inflammation and impair healing. Therefore, all efforts should be exhausted towards the maximum elimination of bacteria from the root canals before obturation (Siqueira & Rôças, 2008).

1.4 **MICRO-COMPUTED TOMOGRAPHY**

Micro-computed tomography produces true 3D reconstructions of the target object with cubic voxels and isotropic resolution. It is non-invasive; therefore, samples can remain intact during instrumentation studies and be evaluated in different time periods. A large amount of information can be obtained, slices can be recreated in any

plane, and the data can be represented as 2D or 3D images. Internal and external anatomy can be displayed simultaneously or separately. Images can be evaluated qualitatively and quantitatively (Rhodes *et al*., 1999). Peters *et al*. (2000) demonstrated detailed 3D models of the root canal system using high-resolution computed tomography. It can be used to monitor the accumulation and, theoretically, also the removal of radiopaque structures in the root canal during and after instrumentation. This method is quantitative, three-dimensional and can be applied to teeth with complex anatomy (Paqué *et al.,* 2010).

Paqué *et al*. (2009) conducted the first study to evaluate debris accumulation after instrumentation. They did not use irrigants, therefore they suggest future studies investigating the effect of irrigation. As it is a non-destructive method, the same specimens can be scanned several times to see and compare the debris after each treatment step.

Despite the advantages of micro-CT, it also has limitations in that it can only detect the inorganic aspects of accumulated debris, not the organic counterpart, with the idea that the debris may maintain microorganisms, or inhibit the activity of antiseptics. Therefore, the chemical effects of proteolytic solutions such as NaOCl cannot be determined (Paqué *et al.,* 2011).

1.5. **IRRIGATION**

Irrigation is an essential procedure for the treatment of the root canal system, which can be seen as a micro-scale flow of a liquid (irrigant) into an irregularly shaped space of very small dimensions (the root canal system) (Ram, 1977; Abou-Rass & Patonai, 1982; Chow, 1983; Zhender, 2006). As soon as the irrigant is carried into the

root canal, the chemically active particles are rapidly transported by fluid movement, a process referred to as convection, and in areas of the root canal where flow cannot be created, transport of the irrigant can be accomplished by the process of diffusion which is the random movement of particles in a fluid (Boutsioukis & Van der Sluis, 2015). Despite the convection and diffusion processes, a significant part of the root canal system cannot be reached during instrumentation, large areas of bacterial biofilm may remain within the root canals in untouched areas, isthmuses, accessory and lateral canals (Siqueira *et al*., 1997; Peters *et al.,* 2004; Ricucci *et al.,* 2013; Siqueira *et al.,* 2018) and pulp tissue debris, especially in the apical third (Siqueira *et al.,* 2018; Zhao *et al.,* 2019). Therefore, together with the mechanical preparation, the application of an irrigating solution is necessary, which should have disinfectant and organic debris dissolving properties. The syringe irrigation method continues to be the most commonly used method for distributing irrigants in root canals.

1.6 **SODIUM HYPOCHLORITE (NaOCl)**

The most widely used irrigant to date is sodium hypochlorite, a halogenated compound that has antimicrobial activity, organic matter solvent, lubricant and low surface tension properties. When sodium hypochlorite (NaOCl) contacts tissues, peptide bonds are broken to dissolve the proteins. During this process, hydrogen from the imine groups (-NH-) is replaced by chlorine (-N.Cl-) forming chloramines, which plays an important role in antimicrobial effectiveness (Dutner *et al*., 2012). Therefore, necrotic tissue and pus are dissolved and the antimicrobial agent can better reach and clean the infected areas (Basrani & Haapasalo, 2012).

Tawakoli *et al.* (2017) investigated whether clinical concentrations of NaOCl and other irrigants could dissolve the polysaccharide matrix of the biofilm. They

demonstrated that NaOCl has the unique property among all irrigants to chemically reduce biofilm-related matter by breaking glycosidic bonds, dissolving glycoconjugates in the biofilm matrix and generating bacterial cell lysis.

The literature recommends the use of NaOCl in concentrations from 0.5% to 5.25%. A study by Alves *et al.* (2011) showed that the time that NaOCl remains in the canal has a greater influence on the elimination of bacterial population than high concentrations, since a high concentration does not necessarily cause the solution to penetrate to greater depths while a longer time can increase the chances of reaching the bacteria lodged in the anatomical irregularities. Similarly, Verma *et al*. (2019) demonstrated through a randomized controlled study that the use of 1% NaOCl as an endodontic irrigant is adequate and that high concentrations do not provide any additional benefit. Therefore, more important than the concentration of NaOCl is the continuous replacement of the solution in the root canal by irrigation and aspiration (Siqueira *et al.,* 2000).

When organic matter comes into contact with NaOCl, it consumes available chlorines and reduces antibacterial activity. Siqueira *et al.* (2000) compared in vitro bacterial reduction after instrumentation and irrigation with 1%, 2.5% and 5.25% NaOCl, and observed no significant differences in antibacterial effects among the three NaOCl concentrations used. Suggesting that copious and frequent irrigation with a low concentration of NaOCl can maintain a sufficient pool of chlorine to eliminate a significant number of bacterial cells.

Gazzaneo *et al.* (2019) evaluated different concentrations and volume of NaOCl used with instrumentation systems employing multiple files and single file systems. They conclude that the use of multiple instruments, all up to the working length, can favor the replacement of irrigant in the apical zone, which is associated with a greater volume of NaOCl and increased time of NaOCl remaining inside the canal, thus

improving the effectiveness of disinfection. Using a single file system by increasing the concentration of NaOCl does not provide any improvement in the effectiveness of disinfection, therefore when using these rotary instruments with a single file, a greater volume of NaOCl should be used than if rotary systems with multiple files were being used, since a high volume of irrigation and more time for the irrigant to remain in the canal during chemomechanical preparation has a positive influence on the disinfection of the root canal.

Despite the antibacterial properties of NaOCl, Rôças *et al.* (2014) showed that a large percentage of root canals remain contaminated. They evaluated the prevalence of bacterial taxa not yet cultured (that have not yet grown in artificial media and are only known from a 16S RNA genetic sequence) and culture-difficult bacterial taxa (species already characterized but unable to grow in ordinary media or conditions) in root canals of teeth before and after chemomechanical procedures using qPCR. They conclude that chemomechanical preparation using NiTi rotary instruments and 2.5% NaOCl irrigation significantly decreases the amount of bacteria by 98.5%, even though 64% of the canals remained harboring detectable bacteria.

1.7 **ETHYLENEDIAMINETETRAACETIC ACID (EDTA)**

During mechanical preparation, the metal instrument abrades the mineralized dentin walls of the root canal, forming a thin amorphous layer of approximately 0.5-2 micrometers thick of dentin smear that obliterates the dentin tubules. In addition to being composed of mineralized dentin, this layer also contains predentin, remnants of pulp tissue, bacteria and biofilm (Haapasalo *et al.,* 2012).

This layer, being composed of organic and inorganic matter, cannot be removed by a single irrigant, since no chemical solution has been found that presents

both properties (Yamada *et al.,* 1983). Therefore, in addition to the use of sodium hypochlorite, which has the capacity to dissolve organic matter, it is necessary to use a demineralizing chelating agent as an irrigant in the final irrigation procedure (Goldman *et al.,* 1982).

EDTA is a neutral or slightly alkaline solution, usually used in concentrations of 17% or 15%, with an action time between 2 and 3 minutes (Yamada *et al.,* 1983, Haapasalo *et al.,* 2014) that removes calcium ions from mineral tissue, including dentin (Quian *et al.,* 2011). This solution neutralizes the tissue-dissolving effect of NaOCl and therefore should not be used until the end of treatment at the time of final irrigation (Haapasalo *et al.,* 2012).

1.8 CHEMICAL AND MECHANICAL EFFECTS

Proper irrigation complements instrumentation by combining chemical and mechanical effects, although there is no consensus on the relative importance of each of these effects for the overall success of root canal treatment. Both effects are primarily produced by the flow of a chemically active irrigant and require its penetration throughout the entire length of the root canal system (Boutsioukis & Van der Sluis, 2015).

1.8.1 Mechanical Effect

The mechanical effect is the application of forces on the root canal walls (wall shear force) by the flowing irrigant, causing mechanical disruption and removal of microorganisms, remaining pulp tissue, and dentin debris from the root canal walls (Boutsioukis & Van der Sluis, 2015). Baker *et al.* (1975) suggested that the greater the

amount of irrigant flowing into the root canal, regardless of the type of irrigant, the greater the removal of organic tissue, debris, and microorganisms. Lee *et al.* (2004) confirm this study by Baker *et al.* (1975), demonstrating in an ex vivo study that there is greater removal of debris the greater the speed and volume of irrigant in the root canal.

The shear stress on the canal wall will influence the mechanical detachment of debris, tissue debris, isolated microbes, and biofilm. Although there is no quantitative data on the minimum shear stress required, the distribution of shear stress along the canal wall provides an indication of the debridement efficacy of each type of needle. It should be emphasized that rupture or detachment of biofilm or debris cannot ensure its removal unless there is a favorable irrigant flow that carries it into the canal orifice, a reverse flow (Boutsioukis *et al.,* 2010 [a]).

1.8.2 **Chemical Effect**

The chemical effect occurs due to the frequent replacement of the irrigant, to retain a high concentration of its active components at the site of interest and compensate for its rapid consumption, which applies only to chemically active irrigants. The chemically active chemical components of the irrigant chemically break down or inactivate the biofilm, killing microorganisms and inactivating endotoxins, diluting the remaining pulp tissue, dentin debris and debris layer (Boutsioukis & Van der Sluis, 2015). The constant replacement of NaOCl is considered essential as chlorine which is the element responsible for tissue dissolution and antimicrobial effect, is rapidly consumed upon contact with tissue or organic matter inactivating NaOCl (Moorer & Wesselink, 1982).

1.9 **IRRIGATION NEEDLES**

Irrigation needles are manufactured in stainless steel and comply with ISO 9626:1991 and 9626:1991/Amd 1:2001 specifications, concerning both external and internal diameter and use the Gauge (G) system units. NiTi needles are also available but are not included in the specifications, and exceed the outer limits of the ISO specifications (Boutsioukis *et al.,* 2007). Several needle tip designs and irrigation techniques have been developed to improve the limitations of chemical-mechanical disinfection (Goldman *et al*., 1976; Goldman *et al.,* 1979; Moser & Heuer, 1982; Kahn *et al*., 1995; Vinothkumar *et al*., 2007; Hüllsmann *et al*., 2009). Based on the needle design and the resulting flow, the available needle types can be categorized into 2 main groups, namely, open-tip and closed-tip needles. Open-tip needles include flat, beveled, and notched needles; and closed-tip needles include side-vented, closed-tip with double side-vented, and closed-tip with multiple exits (Fig. 1) (Boutsioukis *et al.,* 2010 [b]).

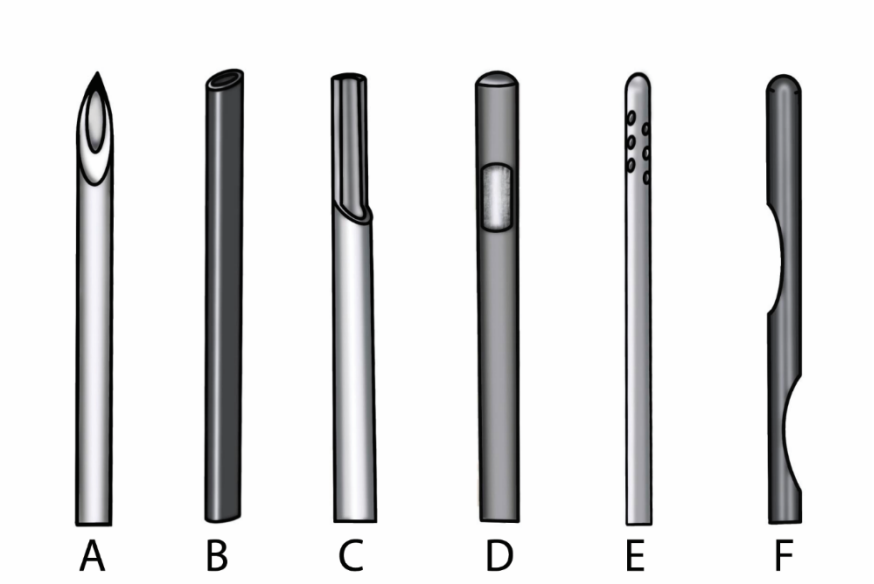


Fig. 1. Representation of endodontic needle types. Open-ended (A) beveled, (B) flat, and (C) notched. Closed-ended (D) side-vented, (E) with multiple exits, (F) double side-vented.

The main objectives of endodontic irrigation needle design are to maximize efficacy and safety. The classic irrigation needle has the outlet at the end with a variety of modifications to the needle tip, such as a bevel or notch. Side-vented needles have a rounded tip and side port that allow some of the pressure to be transmitted directly and some to vent laterally. They should bend easily so that they can follow the curvatures of the canal and allow the irrigating solution to be delivered to all areas of the root canal. The 27- to 30-G gauge needles are currently the most commonly used needle sizes for root canal irrigation because they are small enough to allow solution flow in most canals (Shen *et al.*, 2010).

Recently, needles made of plastic with a closed tip and two lateral outlets have been introduced, which according to the manufacturer can be easily bent and flexed, reaching the difficult anatomies of the root canal system which have not yet been evaluated.

Boutsioukis *et al.* (2010) designed Computational Fluid Dynamic Models to evaluate endodontic irrigation needles and their influence on the irrigant flow behavior within the root canal (Boutsioukis *et al.,* 2010 [c]). In one of the studies they suggest that a flow rate of 0.01-0.26 mL sec -1 combined with irrigation needle placement within 1 mm of the working length should be exerted in order to achieve acceptable irrigant exchange (Boutsioukis *et al*., 2009). However, in another study simulating apical foramina prepared up to a #45 file, they evaluated 6 different 30G needles, 3 mm short of the working length, and observed that the irrigant exchange achieved by the side-venting needle is limited and clearly inferior to the flat, beveled, and notched needles. Confirming that the shear stress developed by these needles is significantly higher on the wall facing the outlet, and that in all cases studied the area of high shear stress is identified in the apical part of the canal, relatively close to the tip of the needle.

Resulting in more irrigant turnover in front of the open needle but also a higher apical pressure (Boutsioukis *et al.,* 2010 [c]).

According to the results of another study, Boutsioukis *et al.* (2010 d) show that the side-exit needle develops less apical pressure than the flat needle at the same preparation size. The relatively low pressure for larger preparation sizes suggests that to decrease the risk of irrigant extrusion, root canals should be prepared at larger #25 file sizes. When using the side-exit needle, they observed irrigant turnover limited to 1-1.5 mm apical to the needle tip, even when the root canal was widened to 55 taper .06, while the flat needle achieves irrigant turnover almost at working length even when placed 3 mm from the working length when the root canal is widened to at least 35 taper .06. Clinically suggesting that side-exit needles should be placed 1 mm from the working length and flat-ended needles should be placed 2-3 mm from the working length, to decrease the risk of extrusion without compromising irrigant turnover (Boutsioukis *et al.,* 2010 [d]). Regarding taper, an increase in root canal taper improves irrigant turnover despite decreasing the shear force of the walls and reducing the risk of irrigant extrusion. Irrigant flow in a root canal with minimal taper and wide apical preparation also improves irrigant turnover and wall shear force and reduces the risk of irrigant extrusion, compared to root canals with large taper and small apical preparation (Boutsioukis *et al.,* 2010 [e]).

Taking into account the needle penetration depth and irrigant flow rate, it is recommended that closed-end needles should be placed 1 mm from the working length, while open-end needles should be placed 2 to 3 mm from the working length (Boutsioukis et al., 2010 [a]) (Fig. 2). When a 30-G needle is used, the apical preparation should be made to diameters larger than #25 to ensure adequate cleaning of the apical area, since an increase in the size and taper of the preparation improves solution turnover.

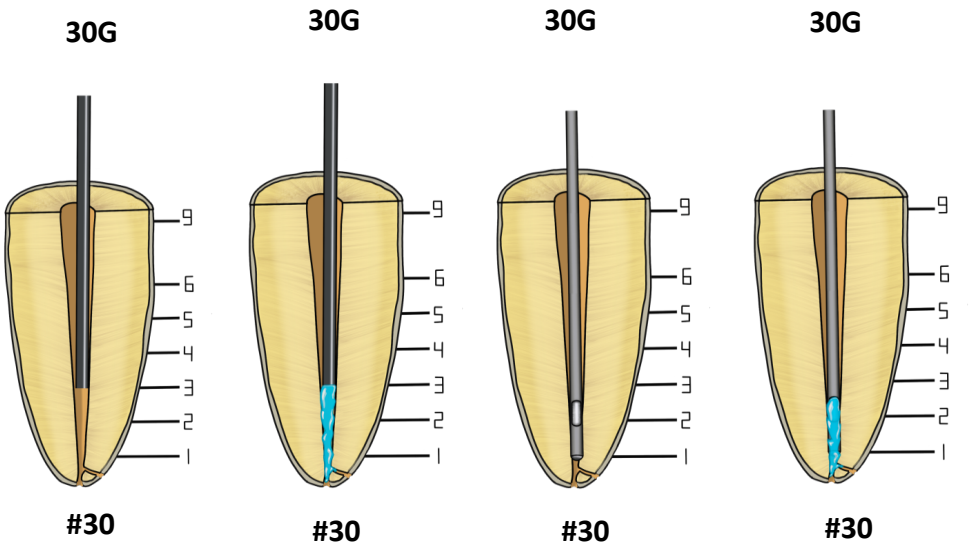


Fig. 2. Representation of needle penetration depth and irrigant flow rate according to tip design. Flat (A); closed end with side outlet (B)

2. JUSTIFICATION

There are no studies evaluating the effect of the endodontic irrigation needle on the cleaning of the root canal system. Therefore, the present study can contribute to the application of an effective irrigation method in the elimination of debris from the root canal system, which may harbor residual microorganisms and interfere with the obturation quality.

3. HYPOTHESIS

Null hypothesis (H0): Different needle designs for endodontic irrigation will not influence the cleaning of the root canal system.

Alternative hypothesis (H1): Different needle designs for endodontic irrigation are going to influence the cleaning of the root canal system.

4. OBJECTIVES

To evaluate the cleaning of the root canal system using different needle designs for endodontic irrigation, by quantifying the accumulated hard tissue debris as determined by micro-CT analysis.

5. METHODOLOGY

The protocol for this ex vivo study was approved by the Ethics Committee of the Faculty of Dentistry of the Universidad Central de Venezuela under number CB-177-2023 and the following methodology was applied (Appendix 1).

5.1 Sample Selection and Preparation

The sample size was calculated using STATISTICA v8.0 software (StatSoft, Tulsa, OK), which revealed that at least 20 teeth per group were required. Eighty-seven lower first molars with two independent canals joining apically through an isthmus in the mesial root (Vertucci type II) extracted from humans for reasons unrelated to this study were selected by periapical radiography.

Inclusion Criteria:

* Extracted lower first molars of humans

* Do not present any type of previous endodontic treatment

* Teeth with fully formed apex

* Teeth free of calcifications and resorptions

Access preparation and exploration of the mesial canals was performed with #8 or #10 files (FKG Dentaire, La Chaux-de-Fonds, Switzerland) until their tip was visualized in the apical foramen using a microscope, establishing this length as the patency length, and the working length 1 mm less than the patency length established for each tooth above.

All samples were subjected to SkyScan 1174v2 micro-CT study (Bruker, Kontich, Belgium) operated at 50 kV, 800 mA, isotropic resolution of 18.99 μm, 180°

rotation about the vertical axis, 1.0 rotation step and 0.5 mm thick aluminum filter. Images were reconstructed with NRecon software (v1.6.1.0, Bruker, micro-CT) with the same patterns. The images of the samples were reconstructed and evaluated in the programs CTAn (v.1.6.6.0, Bruker, micro-CT) for 3D evaluation of the root canal with respect to volume and surface area; and CTvol (Bruker, micro-CT) for visualization and qualitative evaluation of the configuration of the root canal system. This procedure was performed again at the end of the chemomechanical preparation process to compare the initial preoperative samples superimposed with the postoperative ones. A color-coded standard was defined in which green was used for preoperative specimens and red for postoperative specimens (Lacerda et al., 2017; Pérez et al., 2020).

Based on the anatomy and surface area of the root canals, the specimens were grouped into trios, one specimen from each trio was randomly assigned to each experimental group.

Root canals were prepared up to a 20/.02 manual file (FKG Dentaire) to the patency length to standardize the initial canal diameter. Canals were irrigated with 17% EDTA using a Navitip 30-G needle (Ultradent, South Jordan, UT), and then the specimens were immersed in the same solution with ultrasonic agitation for 3 minutes to remove the debris. The specimens were then subjected to sequential ultrasonic baths using distilled water, 2.5% NaOCl, and finally 10% sodium thiosulfate.

5.2 Root canal preparation

The samples were distributed in 3 groups of 20 teeth each (Appendix 2. Flowchart):

1. Closed-ended side-vented irrigation needle (MK Life, Porto Alegre, Rs, Brazil): the needle was used at 1 mm from the established working length.

2. Open-ended flat needle (NaviTip 30-G Ultradent, South Jordan, UT) : the needle was used at 3 mm from the established working length.

3. Closed-ended plastic needle with two lateral outlets (TruNatomy): the needle was used at 1 mm from the established working length.

All of the following procedure was performed by the same operator. All apical foramen was sealed using TopDam (FGM, Joinville, SC, Brazil) to simulate the vapor lock effect. The canals were prepared to the Working Length using the Reciproc R25 (25.08) system (VDW, Munich, Germany), operated on a VDW Silver motor using reciprocating motion. For canal shaping, the R25 instrument was placed in the canal until it presented resistance and was then activated with inward and outward pecking movements towards the apical of approximately 3 mm amplitude. After 3 pecking movements, the instrument was removed and cleaned. This was considered as one instrumentation cycle, and as such, each subject underwent 3 cycles until the instrument reached working length. Irrigation was performed before and after each instrumentation cycle with 2.5% NaOCl with different irrigation tip designs at 1 mm and 3 mm working length depending on the needle design. All canals were irrigated with 2 ml of NaOCl during preparation between each instrument, checking patency with a #10 K-file, and final irrigation with 5 ml. The irrigation flow was controlled by a pump at 4 mL per minute (Vatea irrigation pump, ReDentNOVA, Ra'anana, Israel).

The final irrigation was performed respecting the penetration length established for each needle with 5 mL of NaOCl, followed by 5 mL of EDTA 17% and 5 mL of NaOCl, and finally irrigated with 1 mL of 10% sodium thiosulfate for 1 minute to inactivate the NaOCl.

All procedures were performed under strict aseptic conditions inside a heated cabinet (800-Heater; PlasLabs, Lansing, MI) that maintains inside temperature at 37 C.

5.3 Micro-CT evaluation

After preparation, all samples were scanned once again on the micro-CT with the same parameters as above. The images were reconstructed and geometrically co-registered with their preoperative counterpart using 3D Slicer 4.4.0 software (http://www.slicer.org) with a customized combination of a rigid registration module based on image intensity similarity with an accuracy of better than 1 voxel (CTAn v.1.12 Bruker Micro-CT software) to calculate the volume (mm^3) and surface area (mm^2) of the root canal segment. The surface area of the unprepared canals was evaluated using ImageJ 1.50 software (National Institute of Health) by calculating the number of static voxels. All values were calculated by subtracting the values of the treated canals from their untreated counterparts and then converted to percentages. The analyses included the 5 mm of the apical portion of the prepared canals. The evaluation of hard tissues debris was performed by counting the volume of areas that in the image of the initial sample showed an empty space and in the final sample was filled with debris material, quantifying the volume of each area and then adding all these results to get the final value of each sample.

5.4 Statistical Analysis

The Shapiro-Wilk test was applied to verify the normality of the data. In the intergroup analyses, the Kruskal-Wallis test was used to compare the groups with respect to canal volume and debris volume after chemomechanical preparation. For intragroup analyses, Mann-Whitney t-tests were used to verify the differences in canal volume before the procedure and after preparation and irrigation with the different types of needles. For the evaluation of debris volume, the Mann-Whitney test was used for the before and after debris volume. The significance level was set at 5% for all statistical tests ($P<0.05$).

6. RESULTS

Measurements of the volume of the canal and the accumulated hard tissue debris after chemomechanical preparation are shown in Table 1.

Table 1. Canal volume and accumulated hard tissue debris after chemomechanical preparation

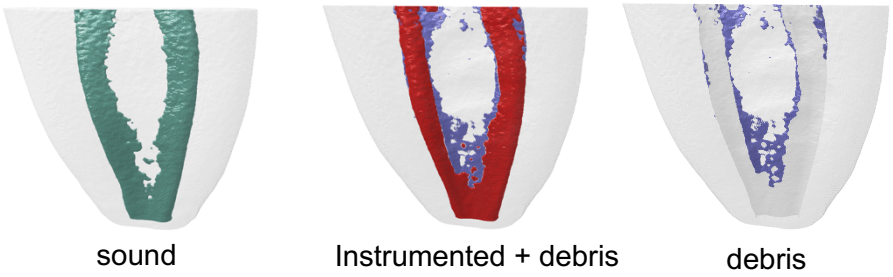
Needle Design	Volume	Means	Median	Range
Closed-Ended	Canal Volume (mm3)	1.67	1.59	0.30 - 4.69
	Debris Volume (mm3)	0.19	0.09	0.02 - 0.83
	% Debris Volume	13.83	8.46	2.27 - 78.38
TruNatomy	Canal Volume (mm3)	3.01	2.95	1.03 - 7.40
	Debris Volume (mm3)	0.18	0.20	0.00 - 0.51
	% Debris Volumen	8.06	6.95	0.03 - 21.27
Open-Ended	Canal Volume (mm3)	2.76	2.08	0.49 -7.56
	Debris Volume (mm3)	0.21	0.23	0.00 - 0.36
	% Debris Volume	10.35	9.42	0.03 - 24.62

No statistically significant differences were observed between the different needles evaluated. The amount of hard tissue debris volume in the closed-ended needle group was 13.83%; in the TruNatomy needle group the amount was 8.06%, and in the open-ended needle group it was 10.35%. Although the TruNatomy needle presented a lower percentage of accumulated hard tissue debris, there were no statistically significant differences between groups ($P > .05$).

Figures 3 through 5 (A and B) shows representative examples of the overlapping root canals before and after chemomechanical preparation in each group. Changes in canal shape are shown as overlapping unprepared areas (green) and prepared areas (red), and hard tissues debris (purple). Overlapping areas are shown in red.

Figure 3. Overlapping root canals before and after chemomechanical preparation with open ended needle

A.



B.

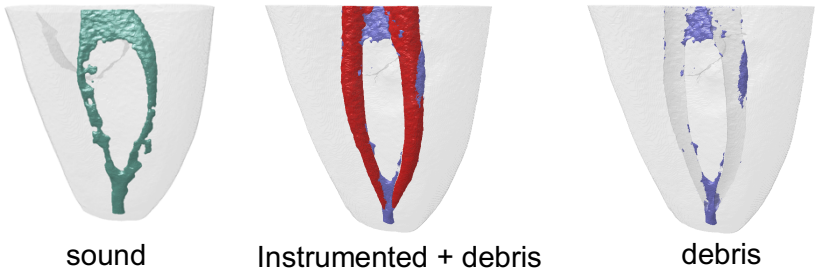
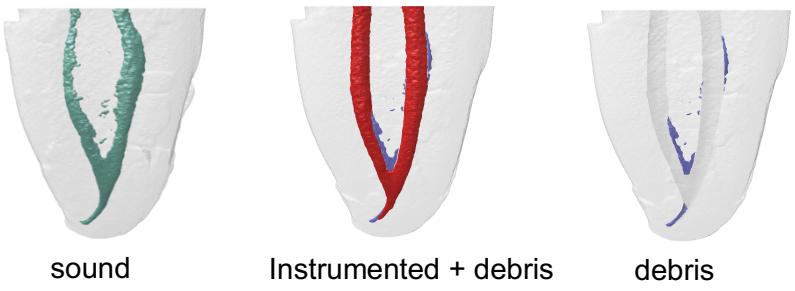


Figure 4. Overlapping root canals before and after chemomechanical preparation with closed ended needle.

A.



B.

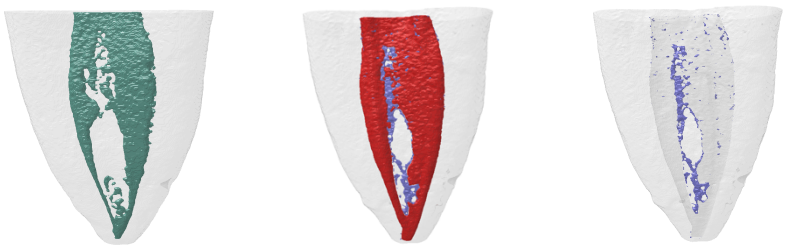
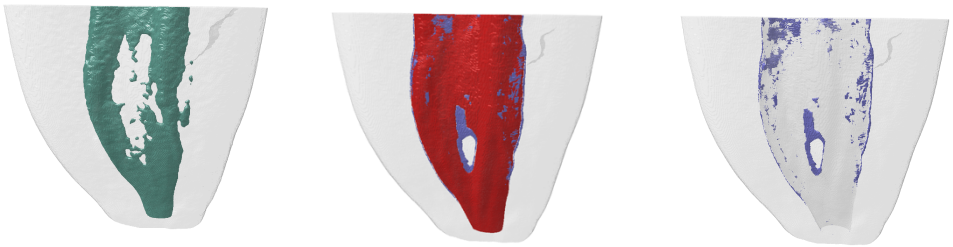
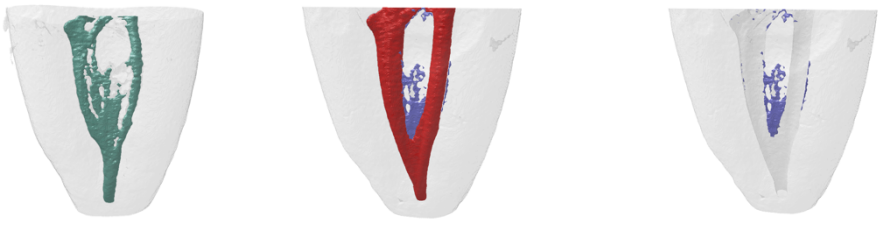


Figure 5. Overlapping root canals before and after chemomechanical preparation with TrueNatomy

A.



B.



7. DISCUSSION

Syringe and needle irrigation continues to be the most widely used method of delivering irrigant to the root canal system and its effectiveness depends on the level of needle penetration into the root canal, the space available in the apical third for irrigant replacement to occur and the flow rate of the irrigant (Boutsioukis *et al* 2022). Therefore, shaping, through mechanical preparation, of the root canal and the diameter of the needle is of utmost importance.

Since the 1970's, research has been done on the size of root canal preparation and its influence on cleaning, showing that canals are not cleaned until prepared to at least a #30 file and improve when prepared to a #40 file (Senia *et al.,* 1971; Ram *et al.,* 1977; Salzgeber *et al.,* 1977; Teplitsky *et al.,* 1987). This may be due to the depth of penetration of the needle, since cleaning occurs only slightly beyond the tip of the needle (Chow *et al.,* 1983) and at the time the most commonly used needles were 22-23-G in diameter.

The different diameters of stainless steel endodontic needles follow the ISO 9626:1991/ Amd 1:2001 specifications, and their external diameters, expressed according to the Gauge system, have been related to the diameter of the different sizes of endodontic hand files. The 22-23-G needles correspond to #90 and #70 files, while the 27-G and 30-G needles, which are the most commonly used at present, correspond to the diameter of #40 and #30 files, respectively (Boutsioukis *et al*., 2007). In the present study, 2 different designs of 30-G stainless steel needles and a flexible polypropylene needle of diameter 25 at the tip with .04 taper were evaluated.

A study by Kahn *et al* (1995), using resin block stains simulating curved canals prepared to different diameters, evaluated closed-endedMaxi-i Probe needles 30-G,

28-G and 25-G diameters and open notch Monojet needles of 27-G and 23-G diameters. Concluding that the 23-G needles cannot be placed more than 5-6 mm from the apex when the canal is prepared up to a #30 and #35 file, unlike the 27-G needles which can be introduced up to 1 to 2 mm from the apex.

For successful irrigation in a canal prepared apical up to a #30 to #40 file, a 27-G needle is required to be placed 3 mm from the apex. Irrigation flow approaches the apex in wide root canals and when the tip of the irrigation needle is placed close to the root apex (Hsieh *et al.,* 2007). However, preparation to a file larger than 0.60 diameter has been observed to cause turbulence and incomplete irrigation of the root canal (FALK *et al.,* 2007). Therefore, the needle size should be selected according to the size of the apical preparation. In cases where wide canals are present, a larger diameter irrigation needle should be used to obtain a good replacement of the irrigant, although an adequate space between the needle and the canal wall should be ensured to allow an effective reverse flow of the irrigant towards the main canal entrance, also not an extremely wide space as this way the irrigant decreases its shear force capacity against the canal walls and thus decreases the effectiveness of the mechanical effect (Boutsioukis *et al.,* 2010 b).

Microbiological study methods are often destructive for sample analysis. Sedgley *et al*. (2004) developed a nondestructive method for quantifying bacteria in the root canal using real-time imaging and bioluminescent bacteria reporting. They performed apical shaping up to a #60 file with a .04 taper and used various volumes of irrigant, finding that the greater the volume, the greater the bacterial removal. An irrigation with 6 ml of NaOCl at 1 mm of the working length removes up to 92% of microorganisms, leaving a bacterial load of $4x10^5$ cells inside the canal, enough to maintain the infection. Regarding the mechanical effect and penetration of the needle, using a closed needle with a 28-G lateral outlet, they demonstrate that at 1 mm there

is less bacteria remaining within the root canal system than at 5 mm working length. They therefore suggest that irrigation may be more effective in wide canals using smaller needle diameters, as well as producing better currents within the root canal system (Sedgley *et al*. 2005).

Currently, several in vitro studies have promoted ultra-conservative access and shaping of the tooth to preserve as much tooth structure as possible while avoiding weakening the tooth. Thus, many manufacturers offer instrumentation systems for a maximum apical preparation of 0.25 diameter, which can compromise the penetration of the needle and therefore the effectiveness of irrigation. In the present study the mechanical preparation was performed with a single file reciprocating system up to a #25 file with 0.08 taper (Reciproc R25 VDW, Munich, Germany), therefore at 1 mm of the working length a preparation diameter of 33, at 2 mm of 41 and at 3 mm of 49.

The apical taper of the root canal preparation influences the insertion depth of the needle tip (Bronnec *et al.,* 2010 [b]). In a study performed on extracted teeth prepared to a diameter 0.20 and taper 0.07 by placing intra-canal hypaque and then performing irrigation protocols with a 27-G needle and corroborating the results radiographically, they observed that complete renewal of the solution in the apical third is impossible to achieve with passive irrigation at the end of the preparation (Bronnec *et al.,* 2010 [a]). A #20/0.07 preparation at 2 mm apical has a diameter of 0.34 mm and at 3 mm of 0.41 mm and the 27-G needle corresponds to a #40 diameter file, perhaps the needle diameter did not reach the adequate length for an optimal replacement of the irrigant. The same occurred when evaluating curved canals, despite performing the preparation apically up to #25 0.08 file, the preparation used in the present study, and #30 0.09 with the notched Monoject needle as the curvature prevented needle placement at 3 mm from the working length, due to the stiffness of the needle alloy and intra-canal constraints, while the shaft of the flat open-ended Navitip tip easily bends

around the curvature (Bronnec *et al.,* 2010 [b]). Increasing the curvature of the root canal impedes the flow of the irrigant, thus reducing its cleaning ability and decreasing its mechanical efficacy (Nguy *et al.,* 2006).

Although both apical flaring diameter and taper are directly associated with increased residual collagen removal (Huang *et al.,* 2008), increasing apical flaring mechanically removes more contaminated dentin without the need to weaken the cervical third. Efficient chemical disinfection is achievable by performing apical flaring using a #35 file (Hockett *et al.,* 2008). However, the flow of irrigant in a root canal with minimal taper and wide apical preparation seems more advantageous than a root canal with wide taper and small apical preparation. Although, a 30-G needle cannot be placed close to the working length with a #30 0.02 preparation (Boutsioukis *et al.,* 2010 [d]), an increase in preparation size leads to a decrease in average speed, cutting force and apical pressure and an increase in irrigant turnover in the apical part of the root canal (Boutsioukis *et al.,* 2010 [b]).

In terms of refill efficiency, an irrigant flow rate of 0.01-0.26 ml sec-1 should be combined with needle placement within 1 mm of the working length. Clinical flow rate achieved with a 30-G needle and exerting force on a 5 ml syringe, which allows for irrigant replacement less than 1 mm apically from the needle tip. A higher flow rate of 0.53-0.79 ml sec-1 offers an additional 0.5 mm advantage but cannot be considered as an average clinical condition, as it is a flow rate rarely encountered in clinical practice (Boutsioukis *et al*., 2009). To reproduce the clinical flow rate in the present study, pump-controlled irrigation was used with a flow rate of 4 ml/min, which corresponds to 0.07 ml/sec (Park *et al*., 2013).

Goldman *et al* (1979) and Kahn *et al* (1995) evaluated irrigant flow macroscopically, limited by the limited ability of x-ray or visual assessment to detect dynamic fluid movements, providing an approximate and incomplete view of irrigant

flow. Boutsioukis *et al.,* (2010 [a]), performed a computational fluid dynamics study simulating a #45 taper 0.06 preparation using an open tip and closed tip needle with side outlet, placed at 3 mm from the working length with a flow rate representing that used in a clinical situation of 0.26 mL/s. It was observed that the irrigant turnover achieved by the closed tip needle with lateral outlet is limited and clearly inferior to that of the flat, beveled or notched open tip needles, the latter 3 without significant advantages among themselves, although they lead to an increase in pressure in the apical foramen, indicating an increased risk of irrigant extrusion into the periapical tissues.

Computational fluid dynamics represents a powerful tool to investigate flow patterns and physical and chemical phenomena by means of mathematical modeling and computer simulation (Boutsioukis *et al.,* 2009). Thanks to these models it has been possible to evaluate the behavior of the irrigant and the different needle designs used in endodontics, despite being theories and simulations carried out in straight ducts which in practice could have a different behavior to that observed in these representations. However, according to computational theories, the open-endedneedle achieves a more extensive irrigant replacement compared to the lateral outlet needle. The closed-tip, side-vented needle exhibits adequate irrigant exchange only at 1 mm of the working length, while the open-ended needle at 2 mm. When the needle is placed far from the working length, the increased number of vortices causes a delay in irrigant replacement, even though less apical pressure develops. Therefore, it is recommended to place the closed-tip needle at 1 mm from the working length and the open-ended needle at 3 mm (Boutsioukis *et al.,* 2010 [c]) as was done in the present study.

A study on extracted teeth, in which they cultured *E. faecalis* and evaluated by single tube luminometers apical preparations up to 0.60 diameter with 0.04 taper and

saline irrigation, 3 different needle designs all 25-G (closed tip with side vented, closed tip with double side vented, hypodermic needle), placed at 1 mm from the working length. They determined that the closed-ended, side-vented needle removed significantly more bacteria compared to the other two (Vinothkumar *et al.,* 2007). According to Kahn *et al* (1995), the needle with a single lateral outlet and closed tip produces coronal turbulence that enhances complete cleaning of the root canal. The presence of an additional lateral outlet at a higher level of the needle reduces the pressure on the needle tip by partial extrusion of the irrigant through the needle, thus removing significantly less bacteria than the closed-tip needle with a single lateral outlet. (Vinothkumar *et al.,* 2007) The propylene needle, evaluated in the present study, has dual lateral exits but these are at the same distance from the needle tip. Therefore, it cannot be considered that there is a partial extrusion of the irrigant through any of the outlets, but on the contrary, as they are at the same level, they probably present the same pressure.

Some studies have evaluated the implication of needle design on the mechanical effect of the irrigant by nondestructive methods. In a study in which they introduced organic collagen solution into the canal and performed irrigation techniques with a closed-ended needle and side vented, they show that the surface of the canal facing the needle outlet is significantly cleaner than the opposite surface, reinforcing the notion of the benefit of the physical cleaning effect in addition to the chemical effect of the irrigant (Huang *et al* 2008). In the present study, we did not evaluate the wall where the needle outlet was located, but in general there was no greater cleanliness using the different needle designs.

Several studies have evaluated the effect of irrigant on hard tissue debris accumulation by micro-CT analysis (Paqué *et al*., 2010; Siqueira *et al*., 2013; De-Deus *et al*., 2014). In a study performed in mesial canals of lower molars, irrigants were

administered up to the working length using thin needles with side vented and final irrigation with ultrasonically activated NaOCl. They established 4 high resolution scans for each tooth: before treatment, after preparation and irrigation with 1% NaOCl, after irrigation with EDTA 17% and after PUI. The results demonstrated that half of the debris accumulated during instrumentation cannot be removed by the subsequent irrigation steps (Paqué *et al.,* 2010).

Siqueira *et al.* (2013) designed a study protocol to allow a paired analysis of the ability of 3 instrumentation techniques in shaping and disinfecting mesial canals of lower molars, evaluating the shaping ability using micro-CT analysis of the same teeth that were then subjected to bacteriological analysis. Observing that many areas of the main canal remain unprepared (20%-35%), and that the isthmuses are not mechanically affected by the instrumentation and possibly not even by the irrigants. The effect of the irrigants could not be evaluated by micro-CT analysis and the bacteriological procedure was performed by sampling using paper tips, limiting the analysis to evaluate the permanence of bacteria in isthmuses. Thus, it is recommended to perform histobacteriological analysis or cryopulverization.

Conventional irrigation with needle and syringe is not effective in the removal of debris lodged in the isthmuses present in the root canal system (Endal *et al.,* 2011). In the present study, it was observed that regardless of the design of the irrigation needle used, debris remains in the anatomical variations of the root canal system. According to De-Deus *et al*. (2014), after performing an irrigation protocol with a total of 40 ml of NaOCl 5.25% for 30 minutes and 3 ml of EDTA 17% for 3 minutes, using a notched open-ended needle placed 2 mm from the working length, the volume of hard tissue debris accumulation is 11.3% in the main canal. In agreement with the results obtained in the present work, since the amount of hard tissue debris volume in the closed-ended

needle group was 13.83%; in the TruNatomy needle group the amount was 8.06%, and in the open-ended needle group it was 10.35%.

8. CONCLUSION

Regardless of the design of the needle used for irrigant delivery, when following recommendations for use based on previous computational fluid analysis studies, no significant differences were observed in the amount of accumulated hard tissue debris. Therefore it can be concluded that as long as it is possible to bring the irrigation needle to the desired length, the irrigant will have the opportunity to penetrate the entire main root canal possibly improving the disinfection of the critical apical third. However, according to previous studies and the present study, it has been demonstrated that it is not possible to completely eliminate the hard tissue debris found in anatomical areas such as the isthmuses communicating the two mesial canals.

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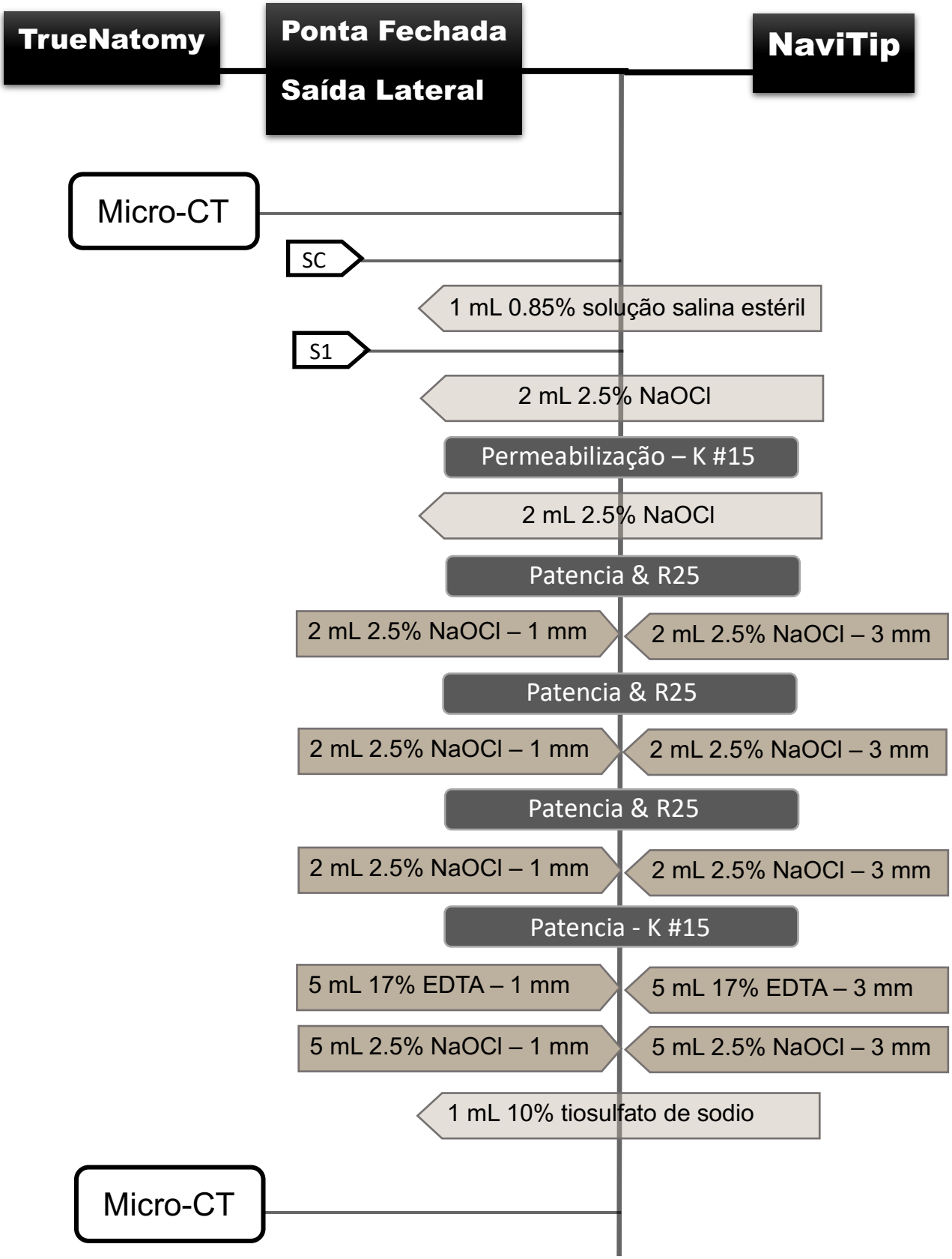
TrueNatomy
Ponta Fechada
Saída Lateral
NaviTip
Micro-CT
SC
1 mL 0.85% solução salina estéril
S1
2 mL 2.5% NaOCl
Permeabilização – K #15
2 mL 2.5% NaOCl
Patencia & R25
2 mL 2.5% NaOCl – 1 mm
2 mL 2.5% NaOCl – 3 mm
Patencia & R25
2 mL 2.5% NaOCl – 1 mm
2 mL 2.5% NaOCl – 3 mm
Patencia & R25
2 mL 2.5% NaOCl – 1 mm
2 mL 2.5% NaOCl – 3 mm
Patencia - K #15
5 mL 17% EDTA – 1 mm
5 mL 17% EDTA – 3 mm
5 mL 2.5% NaOCl – 1 mm
5 mL 2.5% NaOCl – 3 mm
1 mL 10% tiosulfato de sodio
Micro-CT

COMITE BIOETICA
FACULTAD DE ODONTOLOGÍA - UCV

Caracas, 24 de julio 2023.

CB-177-2023

Ciudadano (a):
Od. Alessandra Cristina Baasch Cardozo
Facultad de Odontología
Universidad Central de Venezuela
Presente.

Nos dirigimos a usted en la oportunidad de informarle que el Comité de Bioética de esta Facultad, una vez analizado su proyecto de investigación bajo el título: **"INFLEUNCIA DEL DISEÑO DE LAS AGUJAS DE IRRIGACIÓN EN LA EFICACIA DE DESINFECCIÓN DEL SISTEMA DE CONDUCTOS RADICULARES".** decide aprobar el protocolo de investigación presentado por usted, para el otorgamiento del aval inicial, el cual tiene validez de dos años apartir de la fecha de esta comunicación. Se le informa además que debe presentar un informe sobre los resultados parciales o finales de la investigación durante el lapso antes mencionado, ya que el aval es indispensable para defender su presentación o para publicarla. En caso de no concluir la investigación, deberá consignar un informe con los resultados parciales para prorrogar el aval o en el mejor de los casos un informe con los resultados finales de su investigación y poder concluir el seguimiento de la investigación por parte del Comité de Bioética.

El Comité no subroga, ni reemplaza de responsabilidad a quienes han solicitado su aval pararealizar un proyecto de investigación o asesoramiento. Las resoluciones no son amparo jurídico directo, ya que la ejecución debe estar en manos del profesional responsable.

Sin otro particular a que hacer referencia, atentamente;

Dra. Belkis Rodrígues de Galarraga
Coordinadora del Comité de Bioética