UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

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Clinical and laboratory study of two different stages of biomechanical preparation

Estudo clínico e laboratorial de duas diferentes etapas do preparo biomecânico

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Orientador: Prof. Dr. Clovis Monteiro Bramante

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“Somente quando temos coragem suficiente para explorar a escuridão, descobrimos o poder infinito de nossa própria luz.”

Brené Brown

RESUMO

Constantemente novos instrumentos são desenvolvidos para o preparo biomecânico. As evoluções são observadas desde os procedimentos de acesso ao canal radicular até os procedimentos finais de irrigação, os quais visam remover a camada de detritos formada durante o preparo e alcançar áreas não tocadas pelos instrumentos. O objetivo deste trabalho foi: 1- avaliar, in vitro, o desempenho de dois sistemas de instrumentos reciprocantes para glide path em canais mesiais de molares inferiores; 2- avaliar por um estudo clínico randomizado, a dor pós-operatória após o uso de dois protocolos de ativação da irrigação. No estudo in vitro, sessenta canais radiculares mesiais de molares inferiores foram divididos em dois grupos: um instrumentado com o sistema WaveOne Gold Glider e o outro com R-Pilot. Avaliou-se o tempo de preparo, a frequência no ganho de patência apical, a deformação plástica dos instrumentos, o transporte do canal, a capacidade de centralização do preparo e a fadiga torcional dos instrumentos após o uso. Os testes Exato de Fisher e U de Mann-Whitney, com significância de 5%, não mostraram diferenças significativas entre os grupos em relação ao tempo para realizar o glide path, a frequência no ganho de patência apical e a deformação plástica dos instrumentos após o uso. Não foram observadas diferenças significativas entre os grupos quanto ao grau de transporte do canal e capacidade de centralização. Os Instrumentos R-Pilot apresentaram valores de torção significativamente maiores do que os WaveOne Gold Glider. Os instrumentos WaveOne Gold Glider após o uso, apresentaram maior deflexão que os WaveOne Gold Glider novos. Foi encontrada diferença significativa no percentual de perda de deflexão angular dos instrumentos WaveOne Gold Glider em relação ao R-Pilot. No ensaio clínico randomizado, sessenta e seis dentes unirradiculados com necrose pulpar foram distribuídos aleatoriamente em 2 grupos experimentais quanto ao protocolo de ativação da irrigação: irrigação ultrassônica passiva e EasyClean. Os níveis de dor pós-operatória foram avaliados por uma escala de avaliação verbal após o intervalo de 24, 48 e 72 horas. A quantidade de uso de analgésicos foi registrada no mesmo intervalo de tempo. Os dados foram analisados por meio dos testes t de Student, U de Mann-Whitney e exato de Fisher, com significância de 5%. Os níveis de dor pós-operatória e a frequência de uso de analgésicos não mostraram diferenças significativas quando comparados os 2 protocolos de ativação de irrigação. A prevalência de dor pós-operatória foi de 3,1% a 25,8% entre todos os participantes

dos 2 grupos. Concluindo, este trabalho observou que os instrumentos WaveOne Gold Glider e R-Pilot tiveram o mesmo desempenho em relação ao tempo de preparo, deformação plástica, ganho de patência, grau de transporte do canal e capacidade de centralização. Os instrumentos R-Pilot apresentaram maior resistência à torção, menor deflexão angular e menor percentual de perda na deflexão angular do que os intrumentos WaveOne Gold Glider. O grupo WaveOne Gold Glider usados apresentou os maiores valores de deflexão angular. No ensaio clínico randomizado, os protocolos de ativação da irrigação, irrigação ultrassônica passiva e EasyClean, foram considerados equivalentes em relação a dor pós-operatória e uso de analgésicos.

Palavras-chave: instrumentos odontológicos; endodontia; preparo de canal radicular.

ABSTRACT

CLINICAL AND LABORATORY STUDY OF TWO DIFFERENT STAGES OF BIOMECHANICAL PREPARATION

New instruments are constantly being developed for biomechanical preparation. Evolutions are observed from root canal access procedures to final irrigation procedures, which aim to remove the layer of debris formed during preparation and reach areas not touched by instruments. The objective of this study was: 1- to evaluate, in vitro, the performance of two reciprocating instrument systems for glide path in mesial canals of mandibular molars; 2 - to evaluate, in a randomized clinical trial, postoperative pain after using of two irrigation activation protocols. In the in vitro study, sixty mesial root canals of mandibular molars were divided into two groups: one instrumented with the WaveOne Gold Glider system and the other with R-Pilot. The preparation time, the frequency of apical patency gain, the plastic deformation of instruments, the transport of the canal, the ability to centralize the preparation, and the torsional fatigue of the instruments after use were evaluated. Fisher's Exact and Mann-Whitney's U tests, with a significance of 5%, did not show significant differences between the groups in relation to the time to perform the glide path, the frequency of apical patency gain, and the plastic deformation of the instruments after use. No significant differences were found between the groups regarding the degree of canal transport and centralization ability. The R-Pilot Instruments showed significantly higher maximum torque values than the WaveOne Gold Glider. After use, the WaveOne Gold Glider instruments showed greater deflection than the new WaveOne Gold Glider. A significant difference was found in the percentage of angular deflection loss of the WaveOne Gold Glider instruments in relation to the R-Pilot. In the randomized clinical trial, sixty-six single-rooted teeth with pulp necrosis were randomly assigned to 2 experimental groups according to the irrigation activation protocol: passive ultrasonic irrigation and EasyClean. Postoperative pain levels were assessed by a verbal rating scale after 24, 48 and 72 hours. The amount of analgesic intake was recorded at the same time interval. Data were analyzed using Student's t, Mann-Whitney U and Fisher's exact tests, with a significance level of 5%. Postoperative pain levels and analgesic intake frequency did not show significant differences when comparing the 2 irrigation activation protocols.

The prevalence of postoperative pain ranged from 3.1% to 25.8% among all participants in the 2 groups. In conclusion, this study observed that the WaveOne Gold Glider and R-Pilot instruments had the same performance in terms of preparation time, plastic deformation, patency gain, degree of canal transport and centering ability. The R-Pilot instruments showed greater resistance to torsion, less angular deflection and a lower percentage of loss in angular deflection than the WaveOne Gold Glider instruments. The used WaveOne Gold Glider group had the greatest angular deflection values. In the randomized clinical trial, the irrigation activation protocols, passive ultrasonic irrigation and EasyClean, were found to be equivalent in terms of postoperative pain and analgesic intake.

Keywords: dental Instruments; endodontics; root canal preparation.

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LISTA DE ABREVIATURA E SIGLAS

PUI	Irrigação passiva ultrasônica
Micro-CT	Microtomografia computadorizada
NaOCl	Hipoclorito de sódio
NiTi	Níquel-titânio
EDTA	Ácido etilenodiamino tetra-acético
ABS	Acrilonitrila butadieno estireno
min	Minutos
mm	Milímetro
µm	Micrometro
mL	Mililitro
mg	Miligrama
n	Número
P	Significância estatística
rpm	Rotações por minuto
%	Porcentegem
=	Igual
º	Grau
mA	Miliampere
kV	Quilovolt
ISO	Organização Internacional de Padronização
3D	Tridimensional

SUMÁRIO

1 **INTRODUÇÃO**

1 **INTRODUÇÃO**

O preparo biomecânico é provavelmente a etapa mais importante do tratamento endodôntico pois está diretamente relacionado com o objetivo principal de desinfecção do canal radicular (MARKS DUARTE *et al.*, 2018). A desinfecção é alcançada por desbridamento mecânico com os instrumentos endodônticos, uso de irrigantes e medicamentos, assim como a ampliação do espaço do canal radicular é essencial para facilitar o fluxo dos agentes irrigantes e também para a inserção dos materiais obturadores (ZHAO *et al.*, 2013). Porém, o sistema de canais radiculares é anatomicamente complexo e deficiências técnicas durante o preparo biomecânico podem resultar em erros processuais de preparo, limpeza e desinfecção insuficientes, e levar à persistência bacteriana no canal radicular. (SIQUEIRA JR e*t al.*, 2018)

Assim, novos protocolos de preparo biomecânico do sistema de canais radiculares são constantemente desenvolvidos com instrumentos de níquel-titânio (NiTi) de diferentes desenhos e conicidades variáveis, bem como diferentes tratamentos de liga e tipos de movimento, os quais até recentemente totalizavam mais de 150 sistemas desenvolvidos (SOUSA-NETO e*t al.*, 2018).

Apesar da diversidade de sistemas disponíveis, pode-se destacar duas etapas adjuntas ao preparo biomecânico, onde uma parte dos desenvolvimentos tecnológicos está voltada para negociação inicial dos canais radiculares, denominada glide path, a qual é considerada o primeiro passo do preparo biomecânico (ÖZYÜREK *et al.*, 2017), enquanto que outra parte dos desenvolvimentos tecnológicos se dedica aos procedimentos finais do preparo, denominados protoclolos de ativação da irrigação, os quais buscam melhorar a distribuição de irrigantes dentro do sistema de canais radiculares, no intuito de alcançar áreas não instrumentadas e aumentar a desinfecção (LIAPIS *et al*., 2021).

Dentro da negociação inicial dos canais radiculares, o glide path é um importante procedimento clínico com o propósito de pré-modelagem do canal radicular (WEST, 2010; ALCALDE *et al.*, 2018), o que facilita o acesso à região apical com instrumentos de maior conicidade durante o preparo biomecânico e pode reduzir a incidência de erros operatórios como desvios e fratura de instrumentos (ELNAGHY *et al.*, 2015; ÖZYÜREK *et al.*, 2017). O glide path pode ser realizado com limas manuais de aço inoxidável ou com limas mecanizadas NiTi de baixa conicidade (ALCALDE *et al*., 2018). As limas de NiTi eliminam as desvantagens do uso de limas manuais, como

o tempo consumido durante o preparo, principalmente em canais radiculares curvos, e simplificam a realização desta etapa clínica (BERUTTI *et al*., 2009, D'AMARIO *et al*., 2013; ÖZYÜREK *et al*., 2017).

Durante os procedimentos de modelagem do canal radicular ou a criação do glide path, parte do instrumento pode se travar na dentina do canal radicular e o restante continuar a se mover, resultando em fratura por torção (KAPAR *et al*., 2015). Os instrumentos glide path são suscetíveis a um risco aumentado à fratura por serem utilizados no início do procedimento, em canais radiculares atrésicos e não instrumentados (ALCALDE *et al*., 2018; İNAN & KESKIN, 2019; PEDULLÀ *et al*., 2020).

Existem vários tipos de instrumentos de NiTi, com diferentes diâmetros de pontas, desenhos, métodos de fabricação, ligas metálicas e cinemática do movimento, para a realização do glide path (CAPAR *et al*., 2015; ÖZYÜREK *et al*., 2018; TOPÇUOĞLU *et al*., 2018). Alguns autores demonstraram que o movimento reciprocante prolonga a vida útil de um instrumento de NiTi e, portanto, a resistência à fadiga em comparação com a rotação contínua (GAMBARINI *et al*., 2012; PEDULLÀ *et al*., 2013; AHN *et al*., 2016). Atualmente, o tratamento térmico dos instrumentos de NiTi melhorou as propriedades mecânicas, como maior flexibilidade e aumento da resistência à fratura por fadiga cíclica e por torção (İNAN & KESKIN, 2019). Neste contexto, novos instrumentos reciprocantes de glide path foram introduzidos no mercado com diferentes ligas metálicas de NiTi. O R-Pilot é um instrumento feito de liga metálica MWire, com um diâmetro de ponta de 0,125 mm, conicidade constante de 4% e seção transversal em forma de "S", e o WaveOne Gold Glider é outro instrumento de glide path feito de uma liga metálica tratada termomecanicamente, denominada "Gold" pelo fabricante, com um tamanho de ponta de 0,15 mm, conicidade de 2% que aumenta progressivamente até 6% e possui uma seção transversal em forma de paralelogramo (ÖZYÜREK *et al*., 2018; PEDULLÀ *et al*., 2020).

Dentro dos procedimentos finais do preparo biomecânico, atualmente as técnicas de ativação da irrigação são o propósito de várias investigações (ESTEVEZ *et al.*, 2017; RODRIGUES *et al.*, 2017; DUQUE *et al.*, 2017; CĂPUTĂ *et al.*, 2019). Está postulado que algunas áreas do canal radicular não são tocadas por instrumentos durante o preparo biomecânico (TOPÇUOĞLU *et al.*, 2018; SIQUEIRA JR *et al.*, 2018). Consequentemente, várias técnicas de ativação de soluções

irrigadoras têm sido descritas a fim de melhorar sua eficácia (RODRIGUES *et al*., 2017). Os protocolos buscam levar soluções irrigadoras para áreas que não podem ser alcançadas por instrumentos. Dentre as técnicas, a irrigação ultrassônica passiva (PUI) é bastante popular (ESTEVEZ *et al*., 2017), e tem sido descrita como uma excelente técnica auxiliar no processo de limpeza do sistema de canais radiculares (JUSTO *et al*., 2014). A PUI consiste na oscilação de uma ponta ultrassônica fina, livremente no centro do canal radicular, que induz a formação de microcorrente acústica e/ou cavitação hidrodinâmica de uma solução (VAN DER SLUIS *et al*., 2010; RODRIGUES *et al*., 2017; ESTEVEZ *et al*., 2017). Vários autores relataram o potencial de limpeza do PUI e sua capacidade de aumentar a eficácia dos irrigantes para remover a smear layer e detritos de áreas inacessíveis do canal radicular (ESTEVEZ *et al*., 2017). Recentemente, novos dispositivos de agitação mecânica da irrigação foram desenvolvidos. Dentre estes, o EasyClean é um instrumento feito de plástico (ABS), com seção transversal de forma biconvexa, com possibilidade de uso em rotação contínua em baixa velocidade ou em movimento reciprocante, com risco mínimo de deformação das paredes do canal radicular (RODRIGUES *et al*., 2017). Em um estudo recente, o dispositivo EasyClean com rotação contínua em baixa velocidade, em raízes mesiais de molares inferiores, demonstrou ser um método de agitação capaz de proporcionar uma melhor limpeza das áreas do canal radicular e istmo (DUQUE *et al*., 2017).

Apesar do volume e frequência de irrigação, bem como a capacidade de atingir as regiões apicais ser necessária para uma desinfecção eficaz (GONDIM *et al*., 2010), a pressão apical positiva gerada durante a irrigação pode gerar a extrusão de pequenas quantidades do irrigante para os tecidos periapicais e, posteriormente, levar à dor pós-operatória (RAMAMOORTHI *et al*., 2015). A dor pós-operatória, geralmente atribuída a causas mecânicas, químicas e microbianas (MIDDHA *et al*., 2017), é uma sensação indesejada, mas infelizmente comum após o tratamento endodôntico. A incidência de dor pós-operatória tem sido relatada com uma prevalência altamente variável, variando de 3% a 58% (GONDIM *et al*., 2010). Um sistema de irrigação seguro é desejável para evitar danos aos tecidos periapicais e, assim, diminuir a dor pós-operatória. Tradicionalmente, as soluções irrigadoras são entregues no espaço do canal radicular por meio de seringas e agulhas metálicas de diferentes tamanhos e desenhos de pontas (RAMAMOORTHI *et al*., 2015). Vários dispositivos e protocolos agitação da irrigação, desenvolvidos com o objetivo de melhorar a distribuição de

irrigantes dentro do canal radicular, foram avaliados em relação à dor pós-operatória (GONDIM *et al*., 2010; RAMAMOORTHI *et al*., 2015; MIDDHA *et al*., 2017 ; TOPÇUOĞLU *et al*., 2018).

No entanto, não há na literatura afirmação se a agitação da irrigação com o dispositivo EasyClean proporciona resultados mais ou menos favoráveis em relação a dor pós-operatória, e também, devido à falta de investigações que comparem a capacidade de instrumentos reciprocantes para realização do glide path. O objetivo deste trabalho foi avaliar in vitro o desempenho de dois sistemas de instrumentos reciprocantes para realizar o glide path em canais mesiais de molares inferiores; e em um estudo clínico randomizado, avaliar a dor pós-operatória após o uso de duas diferentes técnicas de ativação da irrigação, PUI e EasyClean.

2 **ARTIGOS**

2 **ARTIGOS**

2.1 **ARTIGO 1**

Pereira RP, Alcalde MP, Duarte MAH, Vivan RR, Bueno CES, Duque JA, Calefi PHS, Bramante CM. A laboratory study of the scouting ability of two reciprocating glide path instruments in mesial root canals of extracted mandibular molars. Int Endod J. 2021 Jul;54(7):1166-1174. Available from: http://dx.doi.org/10.1111/iej.13492.

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A laboratory study of the scouting ability of two reciprocating glide path instruments in mesial root canals of extracted mandibular molars

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Abstract

Pereira RP, Alcalde MP, Duarte MAH, Vivan RR, Bueno CES, Duque JA, Calefi PHS, Bramante CM. A laboratory study of the scouting ability of two reciprocating glide path instruments in mesial root canals of extracted mandibular molars. *International Endodontic Journal*, **54**, 1166–1174, 2021.

Aim To evaluate in a laboratory setting the performance of two reciprocating glide path systems, WaveOne Gold Glider (WO) and R-Pilot (RP), to create a glide path in mesial root canals of mandibular molars and to assess the torsional resistance of instruments after performing the glide path.

Methodology A total of 60 mesial root canals of extracted human mandibular molars were divided into two groups (n = 30) according to the glide path system to be used. The data from the volume of each canal, acquired by microcomputed tomography (micro-CT), were validated statistically for the anatomical pairing of the groups. Preparation time, frequency in gaining apical patency, plastic deformation rate of instruments, and canal transportation and centring ability were recorded and compared statistically. The torsional fatigue of the instruments after use was also evaluated. Data were analysed using Fisher's exact test and Mann–Whitney U-test with a 5% significance level.

Results No significant differences were found between groups regarding the time required to perform the glide path, the frequency distributions of the canals classified as patent and the instruments with plastic deformation after use ($P > 0.05$). No significant differences were found between groups regarding the degree of canal transportation and centring ability at the cervical, middle and apical thirds ($P > 0.05$). The RP groups had significantly greater maximum torsional strength values compared with the WO groups ($P < 0.05$). The used WO group had greater angular deflection to fracture when compared to the new WO group ($P < 0.05$). A significant difference was also found in the percentage of loss of angular deflection in a comparison of the WO group with the RP group ($P < 0.05$).

Conclusions The WO and RP instruments performed the same in terms of preparation time, plastic deformation, gaining apical patency, degree of canal transportation and centring ability. The RP instruments had greater torsional strength, less angular deflection and lower percentage of loss in angular deflection than the WO. The used WO group had the greatest angular deflection values.

Keywords: glide path, nickel-titanium, root canal preparation, torsional resistance.

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Introduction

A glide path is considered an important clinical procedure for pre-shaping root canals (West 2010, Alcalde *et al.* 2018) as this allows easier access to the apical region of canals during preparation with instruments with greater taper and reduce the incidence of operative errors such as deviations and fracture of

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instruments (Elnaghy & Elsaka 2015, Özyürek *et al.* 2017). A glide path can be performed with stainless-steel hand-files and with low-taper nickel-titanium (NiTi) mechanized instruments (Alcalde *et al.* 2018). NiTi files reduce the disadvantages of using hand-files, such as time consumed, especially in curved root canals and simplify the creation of the glide path (Berutti *et al.* 2009, D'amario *et al.* 2013, Özyürek *et al.* 2017).

Glide path instruments are susceptible to an increased risk of fracture because they are used at the beginning of the procedure in narrow and uninstrumented root canals. Therefore, these instruments are more susceptible to torsional fracture (Alcalde *et al.* 2018, İnan & Keskin 2019, Pedullà *et al.* 2020). During root canal shaping procedures or glide path creation, part of the instrument can bind to the dentine, whilst the rest of the file continues to move, resulting in fracture through torsional fatigue (Capar *et al.* 2015).

There are various types of NiTi instruments with different apical sizes, designs, manufacturing processes, alloys and movement kinematics to create the glide path (Capar *et al.* 2015, Özyürek *et al.* 2018, Topçuoğlu *et al.* 2018). Previous studies have reported that the design of the instruments and the type of NiTi play a role on the effect of the cyclic and torsional properties of the instruments, affecting the susceptibility of instruments to fracture. In addition, reciprocating motion reduces the cyclic and torsional stress in comparison with continuous rotation (Gambarini *et al.* 2012, Pedullà *et al.* 2013, Ahn *et al.* 2016). In this context, new reciprocating glide path instruments have been introduced with various NiTi metal alloys. The R-Pilot (VDW GmbH, Munich, Germany) is an instrument made from M-Wire alloy that has a 0.125-mm-diameter tip, 4% constant taper and an S-shaped cross-section. The WaveOne Gold Glider (Dentsply Sirona, Ballaigues, Switzerland) is another glide path instrument made from a thermomechanically treated alloy labelled 'Gold' by the manufacturer, with a tip size of 0.15 mm and a 2% taper that progressively increases up to 6% and has a parallelogram-shaped cross-section (Özyürek *et al.* 2018, Pedullà *et al.* 2020).

The advantages of glide path preparation before shaping root canals are evident in decreasing the incidence of instrument fractures during preparation (Elnaghy & Elsaka 2015). However, due to a lack of investigations comparing the ability of reciprocating instruments to create a glide path, the purpose of this study was to evaluate the performance of two reciprocating instrument systems, the WaveOne Gold Glider and the R-Pilot, in preparing a glide path in mesial root canals of extracted mandibular molars in relation with preparation time, frequency in gaining apical patency, plastic deformation rate, canal transportation and centring ability by micro-CT. The torsional fatigue (maximum torque load and angular deflection) of the two systems was also evaluated following their use. The null hypothesis tested was listed as follows: there are no differences in performance between the two reciprocating glide path systems in regard to reaching patency, preparation time, plastic deformation rate, torsional resistance, canal transportation or centring ability.

Materials and methods

Sample selection

Following approval by the institutional research ethics committee (Protocol no 3.284.709), 60 mesial root canals of 30 mesial roots of extracted mandibular molars with moderate curvature (10° to 20°), according to the method proposed by Schneider (1971), were selected from a pool of teeth extracted for unknown reasons. Digital periapical radiographs at different angles were used to preselect only roots with two independent root canals and ending as two separate foramina.

Before glide path preparation, the teeth were scanned using a micro-CT device (SkyScan 1174; Bruker-micro-CT, Kontich, Belgium) at 50 kV and 800 μA, an isotropic resolution of 14.1 μm and 360° rotation around the vertical axis with a rotation step of 0.8°. After image reconstruction (NRecon v1.6.9; Bruker- micro-CT), 3D models were created with the CTAn v1.12 program (Bruker-micro-CT) in order to analyse the internal anatomy of the specimens, as described in a previous study (Pinheiro *et al.* 2018).

The 60 root canals were randomly divided (www.random.org) into two groups of 30 according to the glide path system to be used, that is a WaveOne Gold Glider group and an R-Pilot group. The allocation was conducted guaranteeing one group per root canal of each mesial root. After allocation, the data from the volume of each canal were analysed statistically using the Mann–Whitney *U*-test, which validated the statistical similarity between the two groups ($P > 0.05$).

Glide path preparation

For the sample calculation of the torsional test, the G*Power v3.1 for Mac (Heinrich Heine, Düsseldorf, Germany) was used and the *T*-Student test of the *T*-test family was selected. The data of a previous study, which evaluated torsional test of reciprocating glide path instruments (Santos *et al.* 2019), were used and the effect size in the present study was established (=2.0). The alpha type error of 0.05, a beta power of 0.95 and a ratio N2/N1 of 1 were also stipulated. A total of seven instruments per group were indicated as the ideal size required for noting significant differences. A total of 10 instruments were used, considering of risk of fracture of instrument during the glide path preparation. Therefore, a total of 10 R-Pilot instruments and 10 WaveOne Gold Glider instruments were used to perform the glide path of the 60 mesial root canals (n = 30). Each instrument was used for three root canals, simulating the use of the system in a multi-rooted tooth. Before being used, all instruments were inspected for defects or deformities under a stereomicroscope (Stemi 2000C; Carl Zeiss, Jena, Germany) and no instruments were discarded. In order to avoid interoperator variability, a single operator carried out the preparations following the manufacturer's recommendations for each reciprocating system, using the pre-set programs 'WaveOne ALL' mode and 'Reciproc ALL' mode, respectively, to perform the procedure. The instruments were coupled to a 6 : 1 reduction hand-piece powered by a torque-controlled motor (VDW Gold Reciproc; VDW).

After conventional endodontic access cavity preparation, each tooth was placed in a tooth holder for endodontic training (IM do Brasil, São Paulo, Brazil) that simulated the alveolar socket and allowed the connection of the cable of the apex locator integrated in the VDW motor (De-Deus *et al.* 2016). An initial exploration of the root canals was performed using a size 08 K-file, at the level of the cervical third, in order to determine the appropriate insertion angle for the instruments. The reciprocating glide path instruments were applied using an in-and-out motion of about 2-mm amplitude to the full working length, as described by De-Deus *et al.* (2016). The procedures were carried out on the benchtop and not in a phantom head. After three pecking motions, the root canals were then irrigated with 2 mL of 5.25% sodium hypochlorite, and the instruments were cleaned. Through the 'Apical Auto Stop' mode, the movement stopped when apical patency was established, indicating that the tip of the instrument had been through apical foramen. The frequency in gaining apical patency and the time required to complete glide path preparation were recorded using a chronometer. The root canals that offered resistance, preventing the instrument from being introduced any farther as determined by the automatic activation of the autoreverse mode, were counted as failures after three attempts. After glide path preparation, all instruments were cleaned ultrasonically to remove debris and inspected again under a stereomicroscope (Stemi 2000C; Fig. 1).

Canal transportation and centring ability

After glide path preparation, the teeth were scanned by micro-CT following the same parameters described previously. DataViewer v.1.5.1 software (Bruker-micro-CT) was used. The reconstructed images captured before and after glide path preparation were geometrically aligned in the sagittal, coronal and axial planes, ensuring accurate superposition of the images before and after preparation as previously reported (Marks Duarte *et al.* 2018). One examiner, who was blinded to the glide path system used to prepare the canals, evaluated cross-sectional images of the apical, middle and coronal thirds (Hwang *et al.* 2014) and measured root canal transportation and centring ability using the CTAn v1.12 software (Bruker-micro-CT). The formulas used to calculate the canal transportation and centring ability were as follows: $(m1 - m2) - (d1 - d2)$ and $(m1 - m2)/(d1 - d2)$ or $(d1 - d2)/(m1 - m2)$, respectively (Gambill *et al.* 1996). Therefore, m1 and m2 were the shortest distances from the mesial edge of the root to the mesial edge of the root canal before and after glide path preparation, respectively, and d1 and d2 were the shortest distances from the distal edge of the root to the distal edge of the root canal before and after glide path preparation, respectively. A positive value meant that transportation occurred in the mesial direction, and a negative value indicated that transportation occurred in the distal direction. A value equal to zero meant that no transportation occurred. The numerator for the centring ratio formula was the smaller of the 2 numbers $(m1 - m2)$ or $(d1 - d2)$ whether these numbers were unequal. A result other than 0 indicated canal transportation, and a result equal to 1 indicated perfect centring (Gambill *et al.* 1996).

Figure 1 Stereomicroscopy view of instrument surfaces before and after glide path preparation. (a) Intact WaveOne Gold Glider. (b) WaveOne Gold Glider showing deformation of helical structure, after glide path preparation. (c) Intact R-Pilot. (d) R-Pilot showing deformation of structure, after glide path preparation.

Torsional test

The instruments assigned to perform the glide path were used to establish the mean values of torque and maximum angular deflection necessary until rupture. Another 10 new instruments from each system were incorporated as control groups. Thus, the groups tested were listed as follows: new RP, used RP, new WO and used WO. Based on ISO 3630-1 (1992) and by means of a specifically designed torsion-testing machine (Analógica, Belo Horizonte, MG, Brazil), the torsion test followed as described in previous studies (Alcalde *et al.* 2017, 2018). Three millimetres of the instrument tip were clamped to a chuck with brass jaws to prevent sliding, and the another end of the instrument was clamped in another chuck connected to a reversible-geared motor. Each instrument handle was removed at the point where the handle was attached to the shaft before testing. At a rotation speed of 2 rpm in a counter-clockwise direction, the rotation angle was measured and controlled by a resistive angular transducer connected to a process controller, and the torque values were assessed by measuring the force exerted on a small load cell by a lever arm linked to the torsion axis. The values of the ultimate torsional strength and angular deflection (°) were provided by a computer program designed specifically for the torsion-testing machine. The percentage of loss in the angular deflection values for the instruments used was also compared.

Fractured instruments were examined under a scanning electron microscope (JSM-TLLOA; JEOL, Tokyo, Japan) to assess the topographic features of the fractured surface of the instruments. The photomicrographs (Fig. 2) were obtained at different magnifications (×50, ×350 and ×1000).

Statistical analysis

The Mann–Whitney *U*-test was then performed to analyse the data statistically. The frequencies obtained in reaching patency and plastic deformation were analysed using Fisher's exact test. The level of significance was set at 5%.

Results

The mean and standard deviation values of the time required to complete glide path preparation, as well

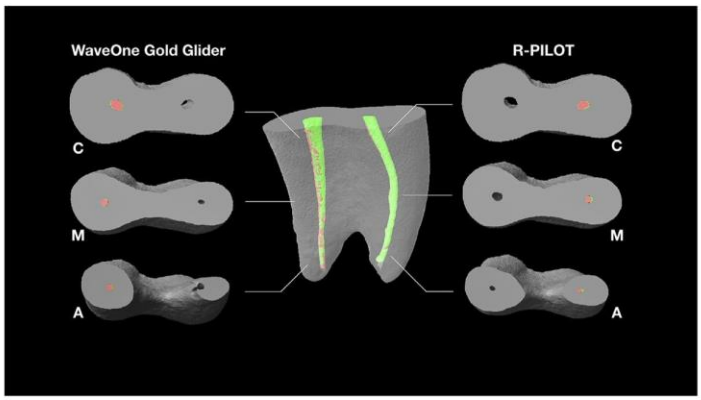

Figure 2 Representative reconstruction and cross-sections of the superimposed mesial root canals of a mandibular molar from each experimental group, before (red) and after (green) glide path preparation at the cervical (C), middle (M) and apical (A) thirds.

as the frequency distributions of the canals classified as patent and the instruments with plastic deformation after use are presented in Table 1. No significant differences were found between groups ($P > 0.05$). No instruments fractured during testing. The surface stereomicroscope images revealed deformation of the helical structures of the instruments after glide path preparation (Fig. 1).

No significant differences were found between the groups regarding the degree of canal transportation and centring ability at the cervical, middle and apical thirds ($P > 0.05$; Table 2). Representative images are presented in Fig. 2.

The mean and standard deviation of torque and maximum angular deflection are presented in Table 3. The RP groups had significantly greater values for maximum torsional strength when compared to the WO groups, new instruments ($P = 0.017$) and used instruments ($P = 0.001$). The used WO group had greater angular deflection to fracture when compared to the used RP group ($P < 0.001$). Comparing the used WO group with the used RP group ($P = 0.028$) also revealed a significant difference in the percentage of loss of angular deviation. The scanning electron microscope images revealed typical features of torsional failure such as the ductile type for all groups (Fig. 3).

Table 1 The time required in seconds to prepare glide path, absolute and percentages frequency of the success in gaining apical patency, and absolute and percentages frequency of plastic deformation of the glide path instruments

	Time (s)	Apical patency		Deformation	
Group	Mean (SD)	PC, *n* (%)	NP, *n* (%)	WD, *n* (%)	ND, *n* (%)
WaveOne Gold Glider	10.64 (7.02)	28 (93.33)	2 (6.66)	5 (50)	5 (50)
R-Pilot	10.40 (6.27)	27 (90)	3 (10)	1 (10)	9 (90)

ND, no plastic deformation; NP, not patent canal; PC, patent canal; SD, standard deviation; WD, with plastic deformation.

Table 2 Root canal transportation and centring ability values in millimetres observed after glide path preparation

	Third	WaveOne gold glider Mean ± SD	R-Pilot Mean ± SD
Canal transportation (mm)[a]	Apical	0.015 ± 0.045	0.001 ± 0.025
	Middle	0.003 ± 0.023	0.005 ± 0.023
	Cervical	0.001 ± 0.066	−0.019 ± 0.023
centring ability (mm)	Apical	0.612 ± 0.268	0.501 ± 0.261
	Middle	0.513 ± 0.266	0.595 ± 0.254
	Cervical	0.462 ± 0.272	0.450 ± 0.259

SD, standard deviation.
[a]Negative values indicate transportation towards the distal side (furcation area).

Discussion

It has been reported that instruments manufactured from heat-treated NiTi have improved material properties that increase their fatigue resistance and flexibility compared with superelastic NiTi (Plotino *et al.* 2014, Topçuoğlu *et al.* 2018, İnan & Keskin

Table 3 Torque, angular deflection and percentage of loss angular deflection values of glide path instruments tested

Group		Torque (Ncm) mean ± SD	Angular deflection (°) mean ± SD	Loss angular deflection (%) mean ± SD
New	WaveOne Gold Glider	0.13 ± 0.04^{aA}	299.1 ± 51.44^{aA}	−16.76 ± 24.64^{A}
Used	WaveOne Gold Glider	0.13 ± 0.04^{aA}	340.9 ± 50.58^{aB}	
New	R-Pilot	0.22 ± 0.09^{aB}	267.8 ± 17.60^{aA}	−0.27 ± 7.70^{B}
Used	R-Pilot	0.24 ± 0.05^{aB}	267.4 ± 9.35^{aA}	

Different superscript lowercase letters in the same column means significant intragroup differences of the same brand (new WO x used WO; new RP x used RP), and different superscript uppercase letters in the same column means significant intergroup differences (new WO x new RP; used WO x used RP) according to Mann–Whitney test ($P < 0.05$).
SD, standard deviation.

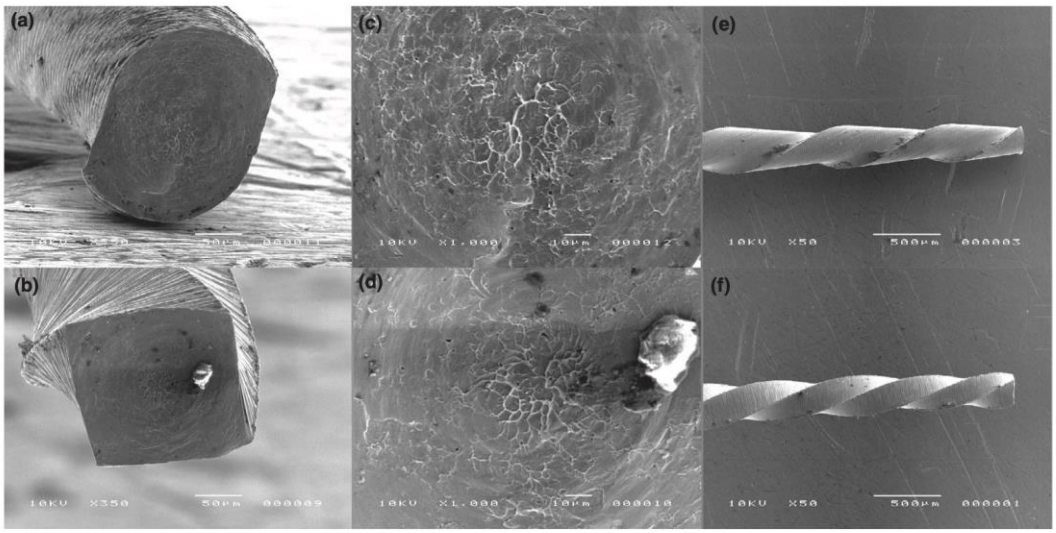

Figure 3 Scanning electron microscopy of the glide path instruments after the torsional test. View of the fracture surface (a) R-Pilot and (b) WaveOne Gold Glider. High-magnification view of (c) R-Pilot and (d) WaveOne Gold Glider shows concentric abrasion marks, typical features of torsional failure. View of the spiral flutes (e) R-Pilot and (f) WaveOne Gold Glider.

2019). In addition, reciprocating motion increases fatigue resistance in comparison with continuous rotation. Increased fatigue resistance is believed to occur because of the release of reaction stresses built up in the material by reversing the direction of rotation (Gambarini *et al.* 2012, Pedullà *et al.* 2013, Ahn *et al.* 2016). Recently, two new reciprocating glide path instruments were launched with alloys of different heat treatments and designs (WO; Gold heat-treated and RP; M-Wire), and for this reason, these two systems were used in this study. In relation the sample selected, a previous study (De-Deus *et al.* 2016) recommended the use of molars with a moderate curvature, which represent the type of root canal configuration most commonly observed clinically, and that the complex anatomy of the mesial root canals of mandibular molars make the procedure difficult for clinicians during the preparation phase (Aydın *et al.* 2019). Sample homogeneity was ensured by selecting specimen molars with two distinct mesial canals with two separate foramina (Freire *et al.* 2012). Each independent canal of the same mandibular molar mesial root was randomly assigned to one of two different groups, guaranteeing two systems per tooth, as in the study by Arias *et al.* (2017).

The present study evaluated various factors of the glide path preparations produced by two reciprocating systems with thermal treatment. In relation to success in gaining apical patency, time required to complete glide path preparation and plastic deformation rate,

both instruments achieved similar results. Although not significant, half of the WaveOne Gold Glider instruments had plastic deformation compared with only one R-Pilot instrument. According to Santos *et al.* (2019), the R-Pilot instruments had fewer deformations when compared with the WaveOne Gold Glider instruments, and fracture might occur without any previous deformation. The greater angle of rotation values, as found in the WaveOne Gold Glider groups, were considered a safety factor and an advantage because, clinically, they result in visible deformation of the instrument, which serves to warn clinicians that the instrument may fracture with further loads (Pedullà *et al.* 2020). This indicates that glide path instruments need to be inspected during use because they are usually more susceptible to torsional stress (Arias *et al.* 2017).

No instrument fractures were observed during the tests; thus, the findings of the present study disagree with those of another study (De-Deus *et al.* 2016) where the observed fracture rate was 3.3% to 11.6% between groups using instruments in continuous rotation. A possible explanation for this disagreement is in the movement kinematics of the instruments analysed in the two studies, that is. reciprocating and continuous rotation, respectively.

Glide path preparation is considered an important step, as it provides guidance for the large instruments used to prepare root canals and reduces the risk of iatrogenic errors, such as instrument fracture, transportation and ledge formation (Alcalde *et al.* 2018, Özyürek *et al.* 2018, İnan & Keskin 2019). Therefore, it is important that the instruments preserve the original canal anatomy and the position of the apical foramen (Vorster *et al.* 2018). To investigate canal transportation and centring ability, pre- and post-procedure micro-CT images of the same sample were combined and revealed no significant differences between the groups at the cervical, middle and apical thirds. Only a few studies have assessed the shaping ability of reciprocating glide path instruments. According to the results obtained by Aydın *et al.* (2019), the WaveOne Gold Glider and R-Pilot systems had better centring ability and less canal transportation (middle and coronal thirds) than the ProGlider system. The authors also found no differences between the two reciprocating systems, WaveOne Gold Glider and R-Pilot. Moreover, the results of the present study might be more linked to the small diameter and taper of the glide path instruments (Aydın *et al.* 2019). These instruments are usually extremely flexible (De-Deus *et al.* 2016).

Using the torsional test, this study evaluated the torque and maximum angular deflection necessary until rupture of the WaveOne Gold Glider and R-Pilot instruments, after use in three root canals compared with new, unused instruments. This strategy aimed to simulate a single clinical use in a multi-rooted tooth. For comparison, another 10 new instruments from each system were used as controls. The results demonstrated that the RP group had a significantly greater maximum torque than the WO group ($P < 0.05$). In agreement with these results, it has been reported that the R-Pilot had greater torsional resistance compared to the WaveOne Gold Glider (Santos *et al.* 2019). Torsional fracture occurs when the tip or another part of the instrument locks into the root canal (Alcalde *et al.* 2018, Zupanc *et al.* 2018, Santos *et al.* 2019), so the greater torsional resistance found in the RP group suggests an advantage for the glide path instruments of this group since they are the first mechanized instruments to negotiate the root canal, with the potential for a lower fracture rate when the R-Pilot is used clinically (Santos *et al.* 2019).

In addition, a probable limitation for the study, a continuous slow speed rotation was used to measure the torque and maximum angular deflection necessary until rupture, whilst these instruments are activated under reciprocating kinematics. However, even reciprocating instruments complete 360° rotation after several asymmetric clockwise (CW) and CCW movements and are, therefore, vulnerable to torsional stress. The results suggest that the two reciprocating instrument systems are able to withstand clinical use, with less chance of fracture (Santos *et al.* 2019).

The use of a martensitic alloy results in more flexible instruments. The Gold heat-treatment gives instruments a greater amount of stable martensite than M-Wire, leading to a softer and more ductile NiTi alloy (Zupanc *et al.* 2018). This might be explained by the higher ductility of the WaveOne Gold Glider compared with the R-PILOT, adding to the differences in the design such as tip diameter, taper and cross-section of the WaveOne Gold Glider and R-Pilot instruments (Santos *et al.* 2019). The R-Pilot has M-Wire alloy with a 0.125-mm tip, 4% taper, S-shaped cross-section and WaveOne Gold Glider has gold alloy with a 0.15-mm tip, variable taper from 2% to 6% and cross-section in the form of a parallelogram (Özyürek *et al.* 2018, Pedullà *et al.* 2020). In the present study, a significant difference was found for maximum angular deflection only in the used WO group compared

with the used RP group. Half of the used WaveOne Gold Glider instruments already had plastic deformations before the torsional test, which may be a possible explanation for the increase in maximum angular deflection values found in the used WO group. This may also explain the significant difference found in the percentage of loss of angular deviation compared with the RP group ($P < 0.05$).

Despite similarities in the performance of the two glide path systems evaluated in this study, the results allow inferences to be made as considered by several authors (Zupanc *et al.* 2018). The austenitic instruments such as M-Wire alloy have high torque values at fracture. Thus, these glide path instruments are appropriate for shaping straight or slightly curved root canals, whilst martensitic instruments should be preferred in cases of severely curved root canals due to their superior flexibility, greater rotation angle at fracture and design. Thereby, laboratory studies of instruments with new characteristics are recommended in order to suggest directions for the use of a safer and more effective clinical application (Arias *et al.* 2017).

Given the fact that the study was performed under laboratory conditions and on the benchtop, care must be taken when adapting the results to clinic conditions (Aydın *et al.* 2019), and further studies are needed to confirm the findings of the present study.

Conclusions

In this laboratory study with extracted molar teeth, WaveOne Gold Glider and R-Pilot instruments had similar preparation times, plastic deformation, success in gaining apical patency and degree of canal transportation and centring ability. The R-Pilot had higher torsional strength, less angular deflection and a lower percentage of loss in angular deflection than the WaveOne Gold Glider. Used WaveOne Gold Glider instruments had the highest angular deviation values.

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Conflict of interest

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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2.1 **ARTIGO 2**

The article presented in this thesis was written according to **Journal of Endodontics** instruction and guidelines for article submission

Postoperative pain after using passive ultrasonic irrigation and EasyClean device, irrigation activation techniques: a randomized clinical trial

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ABSTRACT

Introduction: This randomized clinical trial aimed to compare postoperative pain after the use of two different irrigation activation techniques, passive ultrasonic irrigation and the EasyClean device. **Methods:** Sixty-six single-rooted teeth diagnosed with asymptomatic pulp necrosis and apical periodontitis were randomly assigned to two experimental groups (n=33), which differed in the irrigation activation technique. Postoperative pain levels were assessed after 24, 48, and 72 hours using a verbal rating scale; the ibuprofen intake amount was recorded at the same time intervals. Data were analyzed using Student's t-test, Mann-Whitney U and Fisher's exact tests, with a significance level of 5%. **Results:** Postoperative pain levels and analgesic intake frequency were not significantly different across the two irrigation activation techniques ($P > .05$). The frequencies obtained in relation to the prevalence of postoperative pain were 3.1-25.8% for all participants of the two studied groups. **Conclusion:** The irrigation activation techniques of passive ultrasonic irrigation and the EasyClean device were found to be equivalent in terms of postoperative pain and analgesic intake.

KEY WORDS

Dental Instruments; endodontics; root canal preparation

Chemical-mechanical preparation is an important phase of root canal treatment, as it is responsible for the removal of pulp tissues, debris, microorganisms, and their byproducts through the use of endodontic instruments and irrigating solutions. However, several studies have shown that some areas of the root canal are not touched by instruments during the chemical-mechanical preparation[1]; consequently, several irrigation solution activation techniques have been described in order to improve effectiveness[2]. The techniques seek to bring irrigation solutions to areas that

cannot be reached by instruments. One of the more popular of these techniques is passive ultrasonic irrigation (PUI)[3], which has been described as an excellent auxiliary technique in the root canal system cleaning process[4]. PUI consists of the free oscillation of a thin ultrasonic metal tip in the center of the root canal, which induces the formation of acoustic microcurrent and/or hydrodynamic cavitation of a solution[2,3,5]. Several authors have reported the cleaning potential of PUI and its ability to increase the effectiveness of irrigants in removing the smear layer and debris from inaccessible areas of the root canal[3].

In addition, new mechanical irrigation activation devices recently have been developed, among them the EasyClean: an instrument made of plastic (ABS) with a cross-section similar to a biconvex lens, it can be used with continuous rotation and low speed or in reciprocating motion, with minimal risk of deformation of the root canal walls[2]. In a previous study, used in mesial roots of mandibular molars, the EasyClean system with continuous rotation and low speed proved to be an activation method that was capable of providing better cleaning of the root canal and isthmus areas in comparison with conventional irrigation, moreover, according to the authors at the 2mm level in the apical third, EasyClean with continuous rotation was the only agitation method that showed significantly better cleaning compared to conventional irrigation[6].

Although the volume and frequency of irrigation, as well as its ability to reach the apical third, are necessary for effective disinfection[7], the positive apical pressure generated during irrigation can generate the extrusion of small amounts of the irrigant into the periapical tissues and thus lead to postoperative pain[8]. Postoperative pain – usually attributed to mechanical, chemical, and microbial causes[9] – is an unwanted but unfortunately common sensation after endodontic treatment. The incidence of

postoperative pain has been reported with a highly variable prevalence, ranging from 3% to 58%[7].

A safe irrigation system is needed to prevent periapical tissue damage and thus decrease postoperative pain. Traditionally, irrigating solutions are delivered into the root canal space through syringes and metallic needles of different sizes and tip designs[8]. Several irrigation devices and techniques, developed with the goal of improving the distribution of irrigants inside the root canal, have been evaluated for their relationship to postoperative pain[1,7-9]; however, the literature does not state whether irrigation with the EasyClean device provides more or less favorable results in terms of postoperative pain. Therefore, the objective of this study was to compare postoperative pain after the use of two different irrigation activation techniques: PUI and EasyClean. The null hypothesis was that the incidence of postoperative pain will not be affected by of irrigation activation technique used.

MATERIALS AND METHODS

This prospective, double-blind, single-center, parallel-group, randomized clinical trial and its informed consent format were approved by the institutional research ethics committee (Protocol no. CAAE 16144919.6.0000.5417) and were registered with the Brazilian Clinical Trials Registry (https://ensaiosclinicos.gov.br; Identifier: RBR-32b22n). Study reporting procedure followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines[10]. All included patients signed a written informed consent from explaining the nature of the study, its objectives, procedures, benefits, and potential risks.

Sample size calculation

A sample size calculation was performed using the G*Power 3.1 software (Heinrich-Heine, Düsseldorf, Germany), with an alpha error of 0.05 and a beta power of 0.95,

based on the data of a previous study[11]. Sample size calculation estimated the desired size at 30 individuals per group. The sample was adjusted to account for approximately 10% of patients who may not respond to the questionnaire. Therefore, the first 66 patients who met the inclusion and exclusion criteria were invited to participate in this randomized clinical trial.

Eligibility criteria

Patients had been referred for endodontic treatment to the public dental health service. Patients who were eligible for inclusion in this study were 18-60 years old and systemically healthy. Only single-rooted teeth with a single canal with a diagnosis of pulp necrosis and evidence of apical periodontitis, with radiolucency not exceeding 4 mm in diameter, were included in the study, from October 2019 to November 2022. The individual diagnosis was confirmed through dental history, radiographic examination, periodontal evaluation, percussion and palpation tests, and cold thermal pulp sensitivity test. The findings were verified by comparison with adjacent vital teeth. Patients were excluded if they had one or more of the following conditions: patients with any chronic or acute systemic disease; pregnancy; allergies to local anesthetics; presence of severe or acute pain; acute apical abscess; use of analgesic, anti-inflammatory, or antibiotic medication for 7 days before treatment; a periodontal pocket of the referred tooth greater than 4 mm; teeth with subgingival caries that make absolute isolation difficult; and a history of unfinished endodontic treatment[9,11].

Randomization and endodontic procedures

A simple randomization procedure (www.random.org) was used in order to randomly assign a list of patients to either the PUI protocol group or the EasyClean device treatment group (Easy Equipamentos Odontológicos, Belo Horizonte, Brazil) before the patients came in. Once a patient who was verified of fulfilling the inclusion criteria,

the list was checked by the endodontic procedure operator to determine the group to which the patient would be assigned. Patient-related factors, such as tooth location, age, and sex, were registered.

For all of the patients, the endodontic procedure was performed in a single visit by a single operator with over 10 years of experience in endodontics. After the administration of local anesthesia with 2% lidocaine with 1:100.000 epinephrine solution (Alphacaine; DFL, Rio de Janeiro, Brazil) and rubber dam isolation, the access cavity was performed with round diamond burs. To shape the root canals, the X1-Blue 25.06 and X1-Blue 40.06 reciprocating instrument system (MKLife - Medical and Dental Products Brazil, Porto Alegre, Brazil), along with the Hyflex EDM finishing 50.3 and 60.2 continuous rotation system (Coltene, Altstatten, Switzerland) in an endodontic motor (E-Connect S; MK Life - Medical and Dental Products Brazil), were used in accordance with the manufacturer's instructions. The initial exploration of the canals was performed with a #15 stainless steel hand file and preparation with the X1-Blue 25.06 instrument at 2/3 of the estimated tooth length on the preoperative radiograph. The working length was established with a hand file #15, checked for full reading of the apex locator integrated in the endodontic motor system (MK Life - Medical and Dental Products Brazil) at level zero (beyond the constriction, into the periapical tissues), and then adjusted to remain within the root canal. For both groups, apical preparation was performed 1 mm below the zero level (as determined by the apical locator) with the X1-Blue 25.06 and X1-Blue 40.06 instruments. Depending on the individual characteristics of each tooth, a final apical enlargement was performed with the Hyflex EDM finishing 50.3 and/or 60.2 continuous rotation instruments.

The irrigation with 2.5% NaOCl was dispensed through a 27-G needle up to 2 mm short of the working length between each file, and the irrigant remained in the root canal throughout the procedure. The same volume of irrigant was used on all teeth.

Irrigation activation techniques

In the PUI group, the E1-Irrisonic insert with a size 20 tip, 0.01 taper, and without a cutting blade (Helse Dental Technology, Santa Rosa de Viterbo, Brazil), coupled to the dental ultrasonic (Newtron Booster; Satelec, Merignac, France) at 20% power, was inserted 1 mm from the working length and used for 3 cycles of 20 seconds, totaling 1 minute for each irrigating solution. The solutions used during the three activation cycles were 2.5% sodium hypochlorite (NaOCl), 17% ethylenediamine tetra-acetic acid (EDTA), and 2.5% NaOCl; 2 mL of each solution per cycle was applied in the canal using a syringe with a 27-G needle[5]. The irrigating solution was renewed each time a cycle of 20 seconds was carried out. After this irrigation activation technique, a final flush was performed with 2 mL of saline with no activation.

In the EasyClean group, the EasyClean device (Easy Equipamentos Odontológicos) was coupled to a micromotor and a contra-angle at low speed at approximately 20.000 rotations per minute (KaVo Kerr Group, Charlotte, NC). It was inserted 1mm from the working length, and the same sequence of irrigating solutions and irrigation times described for the PUI group was used.

After each patient underwent the irrigation activation technique, the tooth was dried with paper points and filled with gutta-percha cones and AH Plus endodontic cement (Dentsply, Konstanz, Germany) using the vertical compaction technique with a heated obturation system (FastPack; MK Life - Medical and Dental Products Brazil). After the treatments, all patients received postoperative instructions to take analgesics in case of pain at a dosage of 1 tablet (400 mg ibuprofen) every 6 hours[7,11].

Postoperative pain assessment

All participants were instructed to verbally answer about their incidence of pain 24, 48, and 72 hours after the root canal treatment, using a verbal rating scale in the form of a questionnaire. An evaluator who did not know the technique used during the irrigation activation procedure telephoned the research subjects to monitor postoperative pain 24, 48, and 72 after treatment and to fill in the verbal descriptive scale as follows: 0 – absence of pain or discomfort; 1 – mild pain: feeling pain, but not taking oral medication (analgesics); 2 – moderate pain: feeling pain and taking oral medication (analgesics); and 3 – severe pain: feeling pain and no longer able to perform any type of activity, feeling the need to lie down and rest (i.e., analgesics have little or no effect on pain relief). The frequency of analgesic intake was recorded by the number of ibuprofen tablets taken by the patient from 0 to 72 hours[11,12].

Statistical analysis

A statistical analysis was performed on the collected data. Age was handled as a continuous variable, normally distributed, and analyzed using Student's t-test. Tooth type was handled as a categorical variable and analyzed using Pearson's chi-square test. The Mann-Whitney U-test was used to compare the postoperative pain and analgesic intake between groups for each time interval. Intragroup comparisons were analyzed using Dunn's post-hoc test. The frequencies obtained in relation to gender, perception of pain, and analgesic use were analyzed using Fisher's exact test. The level of significance was set at 5%.

RESULTS

The flow diagram of participants in the different phases of the study is shown in Fig. 1. A total of 66 patients were recruited for this study and received their designated treatment from October 2019 to December 2022; the study ended with the recruitment

of the 66th individual. Sixty-three patients verbally answered the questionnaire, for a recall rate of 95.4%. Three patients, two from the PUI group and one from the EasyClean group, could not be found at the phone numbers provided and were thus lost to follow-up.

Demographic data did not show significant differences between the groups in terms of age, sex, and tooth type ($P > .05$). No significant difference was found in the incidence of postoperative pain when comparing the two groups at 24, 48, and 72 h interval. In the PUI group, 23 (74.2%) patients reported no pain after the first 24 h, 5 (16.1%) reported mild pain, 3 (9.7%) reported moderate pain, and none reported severe pain; after 48 h, 29 (93.5%) patients reported no pain and 2 (6.5%) individuals reported moderate pain; and at 72 h, 29 (93.5%) patients did not report any kind of pain and 2 (6.5%) individuals reported moderate pain. In the EasyClean group, 25 (78.1%) patients reported no pain after the first 24 h, 6 (18.8%) reported mild pain, one moderate pain (3.1%), and none reported severe pain; after 48 h, 28 (87.5%) patients reported no pain and 4 (12.5%) individuals reported mild pain; and at 72 h, 31 (96.9%) patients did not report any kind of pain, and only 1 (3.1%) individual reported mild pain. Only 5 patients in the PUI group and 3 patients in the EasyClean group reported the need for postoperative rescue analgesics. Table 1 shows the demographic data, the postoperative pain scores, and the analgesic intake amount associated with each irrigation activation technique at the different time intervals.

Postoperative pain was present from 3.1% to 25.8% of all participants in the two studied groups after the endodontic treatments and the irrigation activation techniques (Fig. 2). In the intragroup comparison, from 24 h to 72 h the postoperative pain prevalence significantly reduced when comparing the time intervals 24 h with 48 h (*P*

<.05), and 24 h with 72 h (*P* <.05), within the PUI group, and when comparing the time interval 24 h with 72 h within the EasyClean group (*P* <.05).

No instrument fractures occurred in either group. The only adverse effect observed throughout the trial was post-treatment discreet swelling in one patient of the PUI group.

DISCUSSION

The present study sought to compare the EasyClean irrigation activation device with the PUI technique in terms of postoperative pain. Traditionally, irrigants are delivered to the root canal using syringes and metallic needles, and as a result, several irrigation protocols haves been developed with the aim of improving the delivery of irrigating solutions throughout the root canal system[8,9]. Among all proposed techniques, PUI is probably the most widely used adjunct method, and it has been compared with syringe irrigation in several studies[13,14,15]. In terms of the benefits expected from the use of ultrasound irrigation, the authors of a systematic review report that it is not yet clear whether ultrasonic irrigation activation can reduce the microbial load further than in vitro syringe irrigation does[14], but it is more effective in the removal of organic tissue remnants[3,14,16] and the removal of hard tissue debris in vitro[4,14]. In addition, recent studies have shown that the EasyClean device in continuous rotary produces turbulence of the irrigating solution, also benefiting root canal cleaning[2,6,15,17,18].

Irrigation activation techniques used to increase the efficiency of the irrigation solution in removing debris from the root canals may stimulate an inflammatory response through extrusion of the solution into the periapical region, thereby causing pain[19]; however, it remains unclear whether these intra-treatment factors alone induce postoperative pain or whether they should be considered in combination with pre-treatment conditions[20]. Only asymptomatic patients diagnosed with pulp necrosis were

enrolled in the present study, since preoperative pain is a strong predictor of postoperative pain[21,22]. Intra-treatment factors may influence postoperative pain, including local anesthetic injection, rubber dam clamp impingement on soft tissues, or muscle fatigue. It should be taken into account that the two groups studied here had similar preoperative clinical conditions, and all patients underwent the same treatment protocol by a single operator, with the only difference being the final irrigation activation technique[8,12]. Standardizing the study protocol can help minimize known and unknown effects on the study findings, by specifying eligibility criteria and randomly assigning patients to groups[10,23].

In another recent systematic review, the authors concluded that the evidence indicates that ultrasonic irrigation of root canals has a lower incidence of postoperative pain than conventional needle irrigation[24]. This finding can be explained by the fact that most irrigation activation techniques normally require prior delivery of the irrigant – often via syringe irrigation – which is passively agitated. During passive ultrasonic irrigation, the irrigant volume is limited to the small amount of irrigate contained in the root canal and mainly generates a lateral flow toward the root canal walls; in contrast, conventional needle irrigation generates an irrigant pressure in the apical direction, limited to the volume dispensed through the syringe into the root canal[25].

The results of the present study showed no significant differences in postoperative pain in a comparison of the EasyClean device with the PUI in the time interval of 24-72 h post treatment. The results suggest that, in terms of postoperative pain, the EasyClean device is safe as a final activation technique for irrigants. These results corroborate other authors who compared other irrigation activation devices with the PUI[18,19,26]. In intragroup comparisons, the incidence of pain gradually reduce over the time, corroborating prior studies[23,27]. The time interval evaluated, 24-72 hours,

normally coincides with the acute phase of the inflammatory response, and for some authors, the occurrence of postoperative pain is frequently reported in the initial period after the endodontic treatment (up to 48 h), which is considered a critical period for painful sensation[24].

Pain sensation is subjective and strongly dependent on the patient's cultural, individual, and economic background[28], so the design of the questionnaire must ensure that the questions will be fully understood by patients and the answers will be easily interpreted by researchers[11]. In this study, based on others' publications, the questionnaire evaluated the incidence, duration, and intensity of pain through a simple verbal categorization of intensity (mild, moderate, and intense)[11,12,28,29], which was defined by the need for and relief with an analgesic. However, Relvas et al[12] considered postoperative pain, as moderate pain since the patient did not require the use of oral medication.

Other data evaluated included the frequency of analgesics use, since ibuprofen was prescribed for all patients, to be administered in case of pain. Rescue medication is recommended in clinical trials evaluating pain, and it should be administered in case of pain after treatment regardless of the quality of the intervention[23]. In this study, the frequency of analgesic intake was low and did not differ significantly between the two groups. These results can be explained by the low pain perception in the present study. The average level of pain prevalence was from 3.1% to 25.8% among all participants of both studied groups.

It has been suggested that variables such as age, sex, and tooth type could play a significant role in postoperative pain[21]. However, the demographic data in the present study showed no significant differences in sex, age distribution, and tooth type.

Therefore, the effects of these variables were minimized, as both groups had similar baseline characteristics, indicating successful randomization[23].

As it was a double-blind study, where neither the observed nor the observer knew who was which intervention group, a probable limitation of this study is the fact that the patients were not totally blinded to the irrigation activation technique used during the application phase, since this was tenuous. Although the patient did not know and was a layman about the two irrigation activation techniques described in the consent form, it was likely possible to differentiate the EasyClean, continuous rotation plastic device, used in the handpiece connected to of the dental chair unit from an ultrasound device used with the PUI technique. Knowing the method that was applied may have caused a difference in the patients' subjective pain perception[19,20]. At the same time, while administering the questionnaire by telephone, the evaluator was totally blinded to the irrigation activation technique used.

Another consideration is that the generalization of the results should not be extended to other clinical situations that were not evaluated in the present study. To reduce the risk of bias, only single-rooted teeth were included; for some authors, multi-rooted teeth like mandibular molars have the highest incidence of postoperative pain[28]. In addition, the inclusion criteria used in the present study did not take into account situations other than single-visit treatments, such as the use of intra-canal medication. Multiple-visit treatments most probably affect the development of inflammatory processes[28]. Therefore, further trials in different clinical scenarios are recommended.

CONCLUSION

Within the limits of this study, the irrigation activation techniques of PUI and the EasyClean device resulted in the same levels of postoperative pain and analgesic intake.

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The authors deny any conflicts of interest related this study.

I affirm that we have no financial affiliation (e.g., employment, direct payment, stock holdings, retainers, consultantships, patent licensing arrangements or honoraria), or involvement with any commercial organization with direct financial interest in the subject or materials discussed in this manuscript, nor have any such arrangements existed in the past three years. Any other potential conflict of interest is disclosed.

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TABLE 1. Demographic data, pain levels, and number of analgesic intakes according to groups.

	PUI	EasyClean	*P* value
Demographic data			
Age (mean ± SD)	33.29 ± 11.73	35.72 ± 9.95	.37
Gender, *n* (%)			
Male	11 (35.48)	6 (18.75)	.16
Female	20 (64.52)	26 (81.25)	
Tooth type *n* (%)			
incisors	20 (66.70)	25 (78.13)	
canines	3 (10)	0 (0)	.17
premolars	8 (23.33)	7 (21.87)	
Pain (mean score ± SD)			
Postoperative pain at 24 h	0.35 ± 0.66	0.25 ± 0.50	.63
Postoperative pain at 48 h	0.12 ± 0.49	0.12 ± 0.33	.67
Postoperative pain at 72 h	0.12 ± 0.49	0.03 ± 0.17	.36
Analgesic intake (mean ± SD)			
Post-op 24 h	0.32 ± 0.83	0.15 ± 0.57	.38
Post-op 48 h	0.22 ± 0.76	0.15 ± 0.51	.77
Post-op 72 h	0.19 ± 0.74	0.00 ± 0.00	.23

PUI, passive ultrasonic irrigation; SD, standard deviation

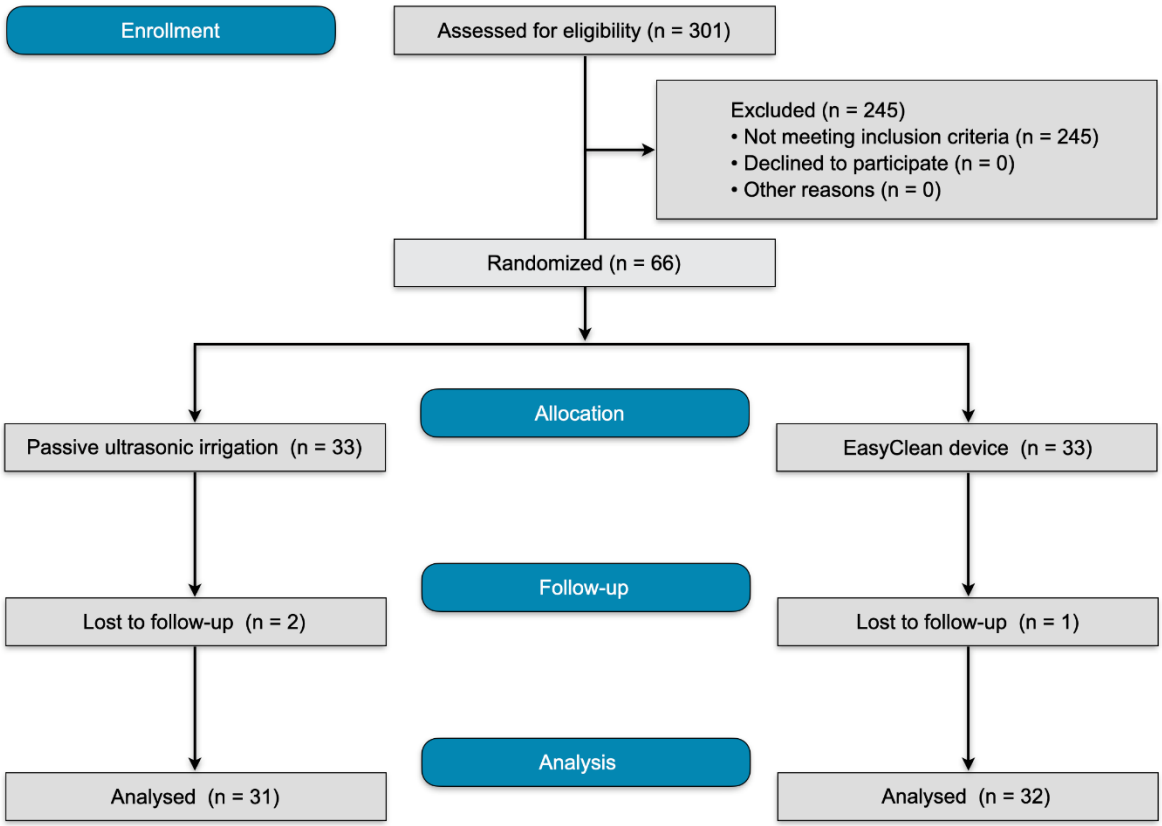

FIGURE 1. CONSORT flowchart showing flow of participants along the study.

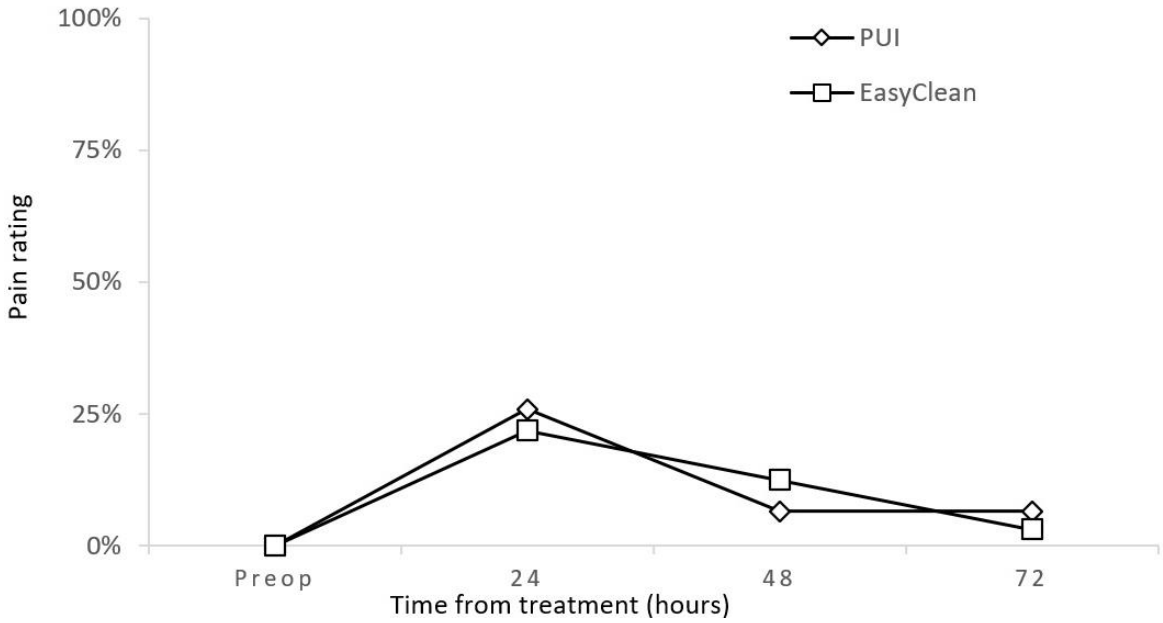

FIGURE 2. Baseline and percentage of postoperative pain reported by all participants, measured according to the assessment time interval and irrigation activation protocol.

3 **DISCUSSÃO**

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Este trabalho buscou responder dois objetivos importantes sobre o uso de diferentes instrumentos utilizados em fases distintas do preparo biomecânico, os quais possuem o propósito de facilitar o acesso e consequente a desinfecção dos condutos radiculares. Constantemente são apresentados no mercado novos sistemas voltados a etapa de preparo do canal radicular os quais buscam serem mais eficientes no que tange o acesso a complexidade anatômica do sistema de canais radiculares (SIQUEIRA JR et al., 2018).

O primeiro objetivo, a comparação entre dois instrumentos de glide path reciprocantes disponíveis no mercado, WaveOne Gold Glider e R-Pilot, levou em consideração que intrumentos de NiTi tratados termicamente possuem maior resistência à fadiga e flexibilidade em comparação com NiTi convencionais (PLOTINO et al. 2014, TOPÇUOĞLU et al. 2018, INAN & KESKIN 2019), além do que, a cinemática reciprocante aumenta resistência à fadiga em comparação com rotação contínua. Acredita-se que o aumento da resistência à fadiga ocorrem devido à liberação de tensões de reação construídas no material invertendo o sentido de rotação (GAMBARINI et al. 2012, PEDULLA et al. 2013, AHN et al. 2016, SOUSA-NETO et al. 2018). Os amostra selecionada para este estudo, raizes mesiais de molares inferiores, também foi utilizada em um estudo anterior (DE-DEUS et al. 2016) onde os autores sugerem que molares com curvatura moderada representam o tipo de configuração do canal radicular mais comumente observado clinicamente, e que a anatomia complexa dos canais radiculares mesiais de molares inferiores dificultam o procedimento clínico durante a fase do preparo biomecânico (AYDIN et al. 2019). A homogeneidade da amostra foi garantida selecionando espécimes molares com dois canais mesiais distintos com dois forames separados (FREIRE et al. 2012). Cada canal independente de uma mesma raiz mesial foi atribuído aleatoriamente a um do dois diferentes grupos de instrumentos reciprocante de glide path, garantindo dois sistemas por dente, como no estudo de ARIAS et al. (2017).

Vários fatores relacionados a realização do glide path pelos instrumetos reciprocantes foram avaliados. Os resultados foram semelhantes em relação ao sucesso na obtenção da patência apical, ao tempo necessário para realizar o glide path e taxa de deformação plástica dos instrumetos após o uso. Embora não

significativo, metade dos instrumentos WaveOne Gold Glider deformaram em comparação com apenas um instrumento R-Pilot. De acordo com o estudo de SANTOS et al. (2019), os instrumentos R-Pilot apresentaram menos deformações quando comparados aos instrumentos WaveOne Gold Glider, podendo ocorrer fratura sem qualquer deformação anterior. Os resultados de deflexação angular maiores, encontrados nos grupos com WaveOne Gold Glider, foram considerados por alguns autores como um fator de segurança, pois, clinicamente resultam em deformação visível do instrumento, o que serve para alertar o clínico que o instrumento pode fraturar com cargas adicionais (PEDULLA et al. 2020). Isso indica que instrumentos de glide path precisam ser inspecionados durante uso porque geralmente são mais suscetíveis ao estresse por torção (ARIAS et al. 2017). Não foram observadas fraturas de instrumentos durante o testes; assim, os achados do presente estudo discordam de outros autores (DE-DEUS et al. 2016) onde a taxa de fratura observada foi de 3,3% a 11,6% entre grupos usando instrumentos com rotação contínua. Uma possível explicação para essa discordância está na cinemática de movimento dos instrumentos analisados nos dois estudos, ou seja, recíprocante e rotação contínua, respectivamente.

Outro dados avaliado foi o transporte e a capacidade de centralização dos dois sistemas reciprocantes de glide path. O glide path é considerado um importante passo, pois fornece orientação para instrumentos mais calibrosos durante o preparo biomecânico e reduz o risco de erros iatrogênicos, como fratura de instrumentos e formação de desvios (ALCALDE et al. 2018, ÖZYÜREK et al. 2018, INAN & KESKIN 2019), assim, é importante que os instrumentos preservem a anatomia original do canal e a posição do forame apical (VORSTER et al. 2018). Para investigar o transporte e a capacidade de centralização, imagens de micro-CT pré e pós-procedimento da mesma amostra foram combinadas e não revelaram diferenças significativas entre os grupos nos terços cervical, médio e apical. Apenas alguns estudos avaliaram o preparo de instrumentos reciprocantes de glide path. De acordo com resultados obtidos por AYDIN et al. (2019), os sistemas WaveOne Gold Glider e R-Pilot tiveram melhor capacidade centralização e menor transporte do canal (terços médio e coronal) do que o sistema ProGlider. Os autores também não encontraram diferenças entre os dois sistemas reciprocantes, WaveOne Gold Glider e R-Pilot. Além disso, os resultados do presente estudo podem ser explicados pelos diâmetros e

conicidades pequenas dos dois sistemas de instrumentos reciprocantes de glide path avaliados (AYDIN et al. 2019). Esses instrumentos geralmente são extremamente flexíveis (DE-DEUS et al. 2016).

Por meio do deste de resistência torcional, também foram avaliados o torque e a deflexão angular máxima necessários até a ruptura dos instrumentos WaveOne Gold Glider e R-Pilot após o uso em três condutos radiculare. Essa estratégia visou simular um único uso clínico em um dente multirradicular. Para efeito de comparação, outros 10 novos instrumentos de cada sistema foram utilizados como controle. Os resultados demonstraram que os grupo R-Pilot mostrou valores maiores de torque máximo que os grupos WaveOne Gold Glider ($p < .05$). Esses resultados concordam com outros autores (SANTOS et al. 2019). A fratura por torção ocorre quando a ponta ou outra parte do instrumento trava no canal radicular (ALCALDE et al. 2018, ZUPANC et al. 2018, SANTOS et al. 2019), então a maior resistência à torção encontrada nos grupos R-Pilot sugere uma vantagem para os instrumentos de glide path deste grupo, uma vez que são os primeiros instrumentos mecanizados a negociar o canal radicular, com potencial para uma fratura inferior quando o R-Pilot é usado clinicamente (SANTOS et al.2019).

Uma provável limitação do estudo foi o teste de fadiga torcional ter sido realizado em rotação contínua de baixa velocidade, enquanto esses instrumentos são acionados sob cinemática reciprocante. No entanto, mesmo instrumentos reciprocantes completam uma rotação de 360°após vários movimentos assimétricos nos sentidos horário e anti-horário, portanto, vulneráveis à fadiga por torção (SANTOS et al. 2019).

O uso de uma liga martensítica resulta em instrumentos mais flexíveis. O tratamento térmico Gold fornece aos instrumentos uma quantidade maior de martensita estável do que o tratamento M-Wire presente nos instrumentos R-Pilot, levando a uma liga de NiTi mais macia e dúctil (ZUPANC et al. 2018). Isso pode ser explicado pela maior ductilidade do sistema WaveOne Gold Glider em comparação com o R-PILOT, somando-se às diferenças no design, como diâmetro da ponta, conicidade e seção transversal (SANTOS et al. 2019).

No presente estudo, uma diferença estatisticamente significante foi encontrada para a deflexão máxima angular apenas no grupo WaveOne Gold Glider quando comparado com R-Pilot após o uso em três condutos radiculares. Metade dos

instrumentos WaveOne Gold Glider já apresentavam deformações plásticas após o uso, o que pode ser uma possível explicação para o aumento dos valores deflexão máxima angular encontrados neste grupo. Apesar das semelhanças no desempenho dos dois sistemas de instrumentos de glide path avaliados neste estudo, os resultados permitir que inferências sejam feitas conforme considerado por vários autores (ZUPANC et al. 2018). Os instrumentos austeníticos como a liga M-Wire possuem altos valores de resistência à fratura por torção, assim, esses instrumentos são apropriados para realizar o glide path em condutos retos ou ligeiramente curvos, enquanto os instrumentos martensíticos devem ser preferidos em casos de canais radiculares severamente curvos devido à sua flexibilidade superior e maiores valores de deflexão angular.

Um segundo objetivo estudado foi a segurança do uso do dispositivo de agitação da irrigação, EasyClean, já respaldado por outras invstigação a respeito da eficácia associado a limpeza do canal radicular (RODRIGUES et al., 2017; DUQUE et al., 2017), porém sem evidencias científicas em relação à dor pós-operatória. Para a investigação, o dispositivo EasyClean foi comparado, em estudo em paralelo ao PUI por meio de um ensaio clínico randomizado.

Tradicionalmente, os irrigantes são entregues ao canal radicular por meio de seringas e agulhas metálicas, porém, diversos protocolos de irrigação têm sido desenvolvidos com o objetivo de melhorar a entrega de soluções irrigadoras em todo o sistema de canais radiculares (RAMAMOORTHI et al., 2015; MIDDHA e outros, 2017). Entre todos os protocolos propostos, a ativação irrigadora ultrassônica é provavelmente o método adjunto mais utilizado, e tem sido comparado com a irrigação por seringa em um grande número de estudos (PLOTINO et al., 2007; CĂPUTĂ et al., 2019). Sobre os benefícios esperados com o uso da irrigação por ultrassom, os autores de uma revisão sistemática relatam que ainda não está claro se a ativação por ultrassom pode reduzir a carga microbiana ainda mais do que a irrigação com seringa e agulas convenionais (CĂPUTĂ et al., 2019), mas é mais eficaz na remoção de restos de tecidos orgânicos (GUTARTS et al., 2005; ESTEVEZ et al., 2017; CĂPUTĂ et al., 2019), e também é mais eficaz na remoção de restos de tecido mineralizados, em trabalhos “in vitro” (JUSTO et al. al., 2014; CĂPUTĂ et al., 2019).

Os métodos de ativação da irrigação utilizados para aumentar a eficiência da solução de irrigação na remoção de detritos dos canais radiculares podem iniciar a

resposta inflamatória por extrusão da solução na região periapical e causar dor (ERKAN et al., 2022), no entanto, não está claro se esses fatores intratratamento sozinhos podem induzir dor pós-operatória ou se devem ser combinados com condições pré-tratamento (LIAPIS et al., 2021). Apenas pacientes assintomáticos com diagnóstico de necrose pulpar foram incluídos no presente estudo, uma vez que a dor pré-operatória é um forte preditor de dor pós-operatória (ALI et al., 2016; FERREIRA et al., 2020). Fatores intratratamento também podem influenciar a dor pós-operatória, incluindo injeção de anestésico local, pinçamento de dique de borracha em tecidos moles ou fadiga muscular. Deve-se levar em consideração que os dois grupos estudados apresentavam condições clínicas pré-operatórias semelhantes, e todos os pacientes foram submetidos ao mesmo protocolo de tratamento, por um único operador, selecionados pelo critérios de elegibilidade e distribuidos aleatoriamente. (RAMAMOORTHI et al. 2014 ; RELVAS et al. 2016; MOSTAFA et al. 2020).

Os resultados do presente estudo não mostraram diferenças significativas na dor pós-operatória ao comparar o dispositivo EasyClean com o PUI, no intervalo de tempo de 24-72 h. Os resultados sugerem que o dispositivo EasyClean é seguro como ativação final para irrigantes em relação à dor pós-operatória. Esses resultados corroboram outros autores que compararam outros dispositivos de ativação de irrigação com a PUI (GÜNDOĞAR et al., 2021; ERKAN et al., 2022). O intervalo de tempo avaliado, 24-72 horas, normalmente coincide com a fase aguda da resposta inflamatória. Para alguns autores, a ocorrência de dor pós-operatória é frequentemente relatada nos períodos iniciais após o tratamento endodôntico, até 48 h, considerado um período crítico para a sensação dolorosa (CHALUB et al., 2022). A sensação de dor é subjetiva e fortemente dependente da origem cultural, individual e econômica do paciente (ARIAS et al. 2013), portanto, o desenho do questionário objetivou garantir que as perguntas fossem totalmente compreendidas pelos pacientes e facilmente interpretadas pelos pesquisadores (COMPARIN et al., 2017). Neste estudo, o questionário utilizado avaliou a incidência, duração e intensidade da dor por meio de uma simples categorização verbal de intensidade (leve, moderada e intensa) com base em outras publicações (SILVA et al. 2013, ARIAS et al. 2013, RELVAS et al. al. 2016, COMPARIN et al. 2017), que foi definida pela necessidade e alívio de um analgésico. No entanto, divergiu de Relvas et al. (2016) os quais

consideraram que a dor pós-operatória categorizada como dor moderada não necessita do uso de medicação oral.

Os autores de um recente trabalho de revisão sistemática concluíram que as evidências sugerem que a irrigação ultrassônica dos canais radiculares tem menor incidência de dor pós-operatória do que a irrigação convencional por agulha (CHALUB et al., 2022). Esse achado pode ser explicado pelo fato de que a maioria das técnicas de ativação da irrigação normalmente requer a entrega prévia do irrigante, muitas vezes por irrigação com seringa, e o irrigante é agitado passivamente. Durante a irrigação ultrassônica passiva, o volume de irrigante limitado à pequena quantidade de irrigante contido no canal radicular gera principalmente um fluxo lateral em direção às paredes do canal radicular, enquanto a irrigação convencional por agulha gera uma pressão de irrigação na direção apical, limitada ao volume dispensado através a seringa no canal radicular (BOUTSIOUKIS et al., 2014).

Outro dado avaliado no presente estudo foi a frequência do uso de analgésicos, uma vez que o ibuprofeno foi prescrito para todos os pacientes, para ser administrado em caso de dor. A medicação de resgate é recomendada em ensaios clínicos que avaliam a dor. Este deve ser administrado em caso de dor após o tratamento, independentemente da qualidade da intervenção (MOSTAFA et al. 2020). A frequência de ingestão de analgésicos foi baixa e não diferiu significativamente entre os dois grupos estudados. Estes resultados podem ser explicados pela baixa percepção da dor no presente estudo. O nível médio de percepção da dor ficou entre 1,92% a 13,46% entre todos os participantes de todos os grupos estudados.

Tem sido afirmado que variáveis como idade, sexo e tipo de dente podem desempenhar um papel significativo na dor pós-operatória (ALI et al., 2016). Em contraste, os dados demográficos do presente estudo mostraram que não houve diferenças significativas entre sexo, distribuição etária e tipo de dente. Portanto, os efeitos dessas variáveis foram minimizados, pois ambos os grupos apresentaram características basais semelhantes, indicando sucesso na randomização (MOSTAFA et al. 2020).

Como provável limitação deste estudo, duplo-cego, onde o observado e o observador não conheciam a intervenção nos grupos, foi o fato de os pacientes não estarem totalmente cegos quanto ao método de ativação da irrigação durante a fase de aplicação, pois embora o paciente não conhecesse e fosse leigo sobre os dois

métodos de ativação da irrigação descritos no termo de consentimento, provavelmente era possível diferenciar o dispositivo plástico EasyClean utilizado na conexão da peça de mão com a unidade da cadeira odontológica de um dispositivo metálico ligado a um aparelho de ultrassom para a ralização do PUI. Conhecer o método a ser aplicado pode causar diferença na percepção subjetiva da dor dos pacientes (LIAPIS et al., 2021; ERKAN et al., 2022). Por outro lado, o avaliador desconhecia totalmente o procedimento de ativação da irrigação alocado, durante a aplicação dos questionários por telefone.

Apesar deste trabalho adicionar ao conhecimento científico respostas frente aos dois objetivos relacionados as duas fases estudas do preparo biomecânico, considerações devem ser feitas sobre os dois estudos. O estudo sobre o uso dos intrumentos reciprocantes de glide path, em raizes mesiais de molares inferiores, foi realizado sob condições laboratoriais, em bancada. Avaliar outras propriedades e outros instrumentos com novas características são recomendados para confirmar os achados do presente estudo. Deve-se tomar cuidado ao adaptar os resultados às condições clínicas (Aydın et al. 2019), apesar de estudos laboratoriais serem recomendados a fim de sugerir direções para o uso clínico de forma mais segura (Arias et ai. 2017). Outra consideração sobre o estudo clínico randomizado, os resultados não devem ser estendidos de forma generalizada para outras situações clínicas não avaliadas no presente estudo. Para reduzir o risco de viés, apenas os dentes uniradiculares foram incluídos. Para alguns autores, dentes multirradiculares como molares inferiores apresentam a maior incidência de dor pós-operatória (ARIAS et al., 2013). Ressalta-se, ainda, que os critérios de inclusão utilizados no presente estudo não levaram em consideração outras situações além de tratamentos em sessão única, como o uso de medicação intracanal. Os tratamentos com múltiplas visitas provavelmente afetam o desenvolvimento de processos inflamatórios (ARIAS et al., 2013). Portanto, mais ensaios em diferentes cenários clínicos são recomendados.

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ANEXOS

ANEXO A - Carta de permissão para incluir nesta tese o artigo “A laboratory study of the scouting ability of two reciprocating glide path instruments in mesial root canals of extracted mandibular molars”, publicado no International Endodontic Journal

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Renato Piai Pereira <rppiai@usp.br>

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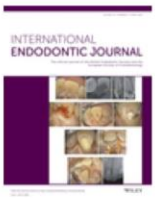
Para: rppiai@usp.br



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ANEXO B - Carta de aceite do manuscrito “Postoperative pain after using passive ultrasonic irrigation and EasyClean device, irrigation activation techniques: a randomized clinical trial”, para publicação Journal of Endodontics

09/04/2023 16:09

BOL MAIL

Acceptance of JOE Manuscript

De:
Para: rppiai@bol.com.br
Cópia:
Cópia oculta:
Assunto: Acceptance of JOE Manuscript
Enviada em: 07/04/2023 | 11:15
Recebida em: 07/04/2023 | 11:15

Ref.: Ms. No. JOE-23-111R2
Postoperative pain after using passive ultrasonic irrigation and EasyClean device, irrigation activation techniques: a randomized clinical trial

Dear Dr. Pereira,

I am pleased to inform you that your manuscript has now been accepted for publication in Journal of Endodontics.

You will soon be contacted by our publisher to review the galley proofs.

Thank you for submitting this manuscript. I look forward to seeing it published soon.

With kind regards,

Ken Hargreaves
Editor
Journal of Endodontics

Comments to Authors:

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/joe/login.asp?a=r). Please contact the publication office if you have any questions.

ANEXO C – Registro de ensaios clínicos

Estudo publicado

RBR-32b22n Comparison of the effect of two different irrigation methods on pain that occurs after root canal treatment

Data de registro: 04/03/2020 (dd/mm/yyyy)
Última data de aprovação: 04/03/2020 (dd/mm/yyyy)

Tipo de estudo:

Intervenções

Título científico:

en
Postoperative Pain after use of two different Final Irrigation protocols: A randomized controlled trial

pt-br
Dor Pós-operatória após o uso de dois diferentes protocolos de Irrigação Final: Um ensaio clínico randomizado

Identificação do ensaio

- **Número do UTN:** U1111-1240-3349
- **Título público:**

en
Comparison of the effect of two different irrigation methods on pain that occurs after root canal treatment

pt-br
Comparação do efeito de dois métodos diferentes de irrigação sobre a dor que ocorre após o tratamento de canal

- **Acrônimo científico:**
- **Acrônimo público:**
- **Identificadores secundários:**
  - **16144919.6.0000.5417 CAAE**
    Orgão emissor: Plataforma Brasil
  - **3.518.616**
    Orgão emissor: CEP - Faculdade de Odontologia de Bauru da USP

Patrocinadores

- **Patrocinador primário:** Universidade de São Paulo - Faculdade de Odontologia de Bauru
- **Patrocinador secundário:**
  - **Instituição:** Centro Especializado de Odontologia - Prefeitura Municipal de Vitória da Conquista

- **Fontes de apoio financeiro ou material:**
  - **Instituição:** Universidade de São Paulo - Faculdade de Odontologia de Bauru
  - **Instituição:** Centro Especializado de Odontologia - Prefeitura Municipal de Vitória da Conquista

Condições de saúde

- **Condições de Saúde:**

en	pt-br
Chronic apical periodontitis	Periodontite apical crônica

- **Descritores gerais para condições de saúde:**

en	pt-br	es
C06 Digestive system diseases	**C06** Doenças do sistema digestório	**C06** Enfermedades del sistema digestivo

- **Descritores específicos para condições de saúde:**

Intervenções

- **Intervenções:**

en	pt-br
The levels of postoperative pain will be evaluated, through a questionnaire, with a verbal classification scale, in the period of 24, 48 and 72 hours after the endodontic treatments, of 70 volunteer patients who need endodontic treatment, distributed in a randomization in two groups, according to two different root canal final irrigation protocols. Group 1: 35 patients will receive the final irrigation treatment with passive ultrasonic irrigation. Group 2: 35 patients will receive the final irrigation treatment with activation of the Easyclean device. The data will be collected by a researcher blind to the treatments, through telephone calls	Serão avaliados os níveis de dor pós-operatória, por meio de um questionário, com uma escala de classificação verbal, no período de 24, 48 e 72 horas após os tratamentos endodônticos, de 70 pacientes voluntários que necessitem de tratamento endodôntico, distribuídos de forma aleatória em dois grupos, de acordo com dois diferentes protocolos de irrigação final do canal radicular. Grupo 1: 35 pacientes receberão o tratamento de irrigação final com irrigação ultrassônica passiva. Grupo 2: 35 pacientes receberão o tratamento de irrigação final com ativação do dispositivo Easyclean. Os dados serão coletados por um pesquisador cego aos tratamentos, através de ligações telefônicas.

- **Descritores para as intervenções:**

en	pt-br	es
K04.1 Necrosis of pulp	**K04.1** Necrose da polpa	**K04.1** Necrosis de la pulpa
en	**pt-br**	**es**
K04 Diseases of pulp and periapical tissues	**K04** Doenças da polpa e dos tecidos periapicais	**K04** Enfermedades de la pulpa y de los tejidos periapicales

Recrutamento

- **Situação de recrutamento:** Recrutando

- **Países de recrutamento**
  - Brasil

- **Data prevista do primeiro recrutamento:** 01/09/2019 (dd/mm/yyyy)
- **Data prevista do último recrutamento:** 30/09/2020 (dd/mm/yyyy)
-

Tamanho da amostra alvo:	Gênero para inclusão:	Idade mínima para inclusão:	Idade máxima para inclusão:
70	-	18 Y	60 Y

- **Critérios de inclusão:**

en

Single root canals teeth; diagnosed with pulp necrosis and evidence of apical periodontitis; with radiolucency not exceeding 4 mm in diameter

pt-br

Dentes unirradiculares com canal único; com diagnóstico de necrose pulpar e evidência de periodontite apical; com radiolucidez não excedendo 4mm de diâmetro.

- **Critérios de exclusão:**

en

Patients who have one or more of the following conditions: systemic disease; pregnant women; allergies to local anesthetics; presence of severe or acute pain; acute apical abscess; use of analgesic, anti-inflammatory, or antibiotic for 7 days prior to treatment; periodontal pockets greater than 4 mm associated with the referred tooth; teeth with subgingival caries that make absolute isolation difficult; and a history of unfinished endodontic treatment.

pt-br

Pacientes que apresentarem uma ou mais das seguintes condições: doença sistêmica; gestantes; alergias à anestésicos locais; presença de dor severa ou aguda; abscesso apical agudo; uso de analgésico, anti-inflamatório, ou antibiótico durante 7 dias antes do tratamento; bolsa periodontal maior que 4 mm associada ao dente referido; dentes com cáries subgengivais que dificultem o isolamento absoluto; e histórico de tratamento endodôntico não finalizado.

Tipo de estudo

- **Desenho de estudo:**
-

Programa de acesso expandido	Enfoque do estudo	Desenho da intervenção	Número de braços	Tipo de mascaramento	Tipo de alocação	Fase do estudo
	Prognóstico	Paralelo	2	Unicego	Randomizado controlado	N/A

Desfechos

- **Desfechos primários:**

en

The presence or the absence of postoperative pain after the use of two different final irrigation protocols, PUI and EasyClean, which will be verified by means of a verbal classification scale, 24, 48 and 72 hours after endodontic treatments. It is expected that there are no differences between the techniques, and thus determine the clinical application of final irrigation protocols safely.

pt-br

Presença ou ausência de dor pós-operatória após o uso dos dois diferentes protocolos de irrigação final, PUI e EasyClean, que será verificado por meio de uma escala de classificação verbal, 24, 48 e 72 horas, após os tratamentos endodônticos. Espera-se não haver diferenças entre as técnicas, e assim determinar a aplicação clínica de protocolos de irrigação final de forma segura.

- **Desfechos secundários:**

en

Influence of predictor variables (dental group, age and gender) on the primary outcome variable.

pt-br

Influência das variáveis preditoras (grupo dental, faixa etária e gênero) sobre a variável de desfecho primário.

Contatos

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