Universidade de Lisboa

Faculdade de Medicina Dentária

COMPARATIVE ANALYSIS OF CYCLIC FATIGUE OF HYFLEX EDM^{TM} INSTRUMENTS WITH AND WITHOUT SODIUM HYPOCHLORITE

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Dissertação

Mestrado Integrado em Medicina Dentária

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Dissertação orientada pelo Prof. Doutor António Ginjeira e
co-orientada pelo Prof. Doutor Rui Martins (FCT-UNL/DEMI)

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RESUMO

INTRODUÇÃO: A Endodontia estuda a forma, a função, a saúde e as doenças da polpa e da região perirradicular, bem como a sua prevenção e tratamento. Tradicionalmente a instrumentação canalar era feita com limas de aço inoxidável. Contudo, o uso destes instrumentos foi associado a alterações indesejáveis da morfologia do sistema do canal radicular durante a preparação. Para tentar superar estas características indesejáveis, foram introduzidas limas de Níquel-Titânio (NiTi). A sua superelasticidade e memória de forma oferecem uma maior flexibilidade e resistência, o que faz com que exista uma melhoria na geometria dos canais preparados e uma diminuição no tempo da instrumentação. Apesar destas melhorias, os instrumentos de NiTi parecem exibir um maior risco de fratura, especialmente após o uso prolongado.

A fratura de instrumentos é uma complicação imprevisível para os clínicos e parece ocorrer principalmente no terço apical do canal radicular. Diversas variáveis podem contribuir para a falha dos instrumentos endodônticos rotativos, tais como o raio e o ângulo de curvatura, o tamanho do instrumento, a geometria e a área na secção crítica, entre outros. Contudo, as duas principais causas de falha são a fadiga cíclica e a torção. A torção ocorre quando o limite elástico do metal é ultrapassado, por exemplo quando a ponta da lima fica presa no canal enquanto o motor continua a rodar. A fadiga cíclica ocorre com a lima livre na curvatura de um canal, sujeita a ciclos de tensão/compressão. Estes ciclos de tensão/compressão repetidos irão causar alterações macro-estruturais cumulativas que podem levar à fratura do instrumento, a qual ocorre no ponto de carregamento máximo. Clinicamente, a fadiga parece ser a causa mais prevalente de fratura.

O sistema HyFlex EDM™ (Coltene, Switzerland) é uma nova ferramenta para a preparação de canais, que utiliza a técnica de lima única em rotação contínua. As limas HyFlex EDM™ OneFile são submetidas a um processo de fabrico inovador que usa máquinas de eletroerosão, o que resulta numa maior resistência à fratura por fadiga. Estas possuem o efeito memória controlada e propriedades regenerativas, que respeitam e mantêm a anatomia original do canal. Após a esterilização em autoclave voltam à sua forma original.

OBJETIVO: Comparar a resistência à fadiga entre limas Hyflex EDM™ na presença e ausência de hipoclorito de sódio.

MATERIAIS E MÉTODOS: Foram analisadas 20 limas endodônticas, com 25 mm de comprimento, do sistema Hyflex EDM^{TM} OneFile sem pré-utilização. A amostra foi dividida em 2 grupos. No seguimento dos estudos que têm vindo a ser desenvolvidos na parceria estabelecida entre o Departamento de Endodontia da Faculdade de Medicina Dentária da Universidade de Lisboa e o Departamento de Engenharia Mecânica da Faculdade de Ciências e Tecnologia da Universidade Nova de Lisboa, foi criado um sistema mecânico em que as limas são submetidas a forças que se assemelham ao canal radicular. De forma a comparar os resultados obtidos com estudos anteriormente realizados, os mesmos parâmetros foram seguidos: o raio de curvatura foi de 4,7 mm, o ângulo de curvatura de 45º, a velocidade de rotação de 400 rpm (a indicada pelo fabricante) e um binário de 2,5 N.cm. Cada instrumento foi inserido no contra-ângulo acoplado ao micromotor WaveOne^{TM} e submetido ao teste de fadiga. O tempo que a lima demorou a fraturar foi registado com um cronómetro digital, sempre pelo mesmo operador. No primeiro grupo (n=10) fez-se este procedimento sem adição de hipoclorito de sódio e no segundo grupo (n=10) adicionou-se hipoclorito de sódio ao longo da experiência. Mediu-se ainda a temperatura dos instrumentos (n=2) e da montagem no início, aos 5 e aos 10 minutos. Em seguida foi calculado o Número de Ciclos à Fratura (NCF), multiplicando o tempo de vida à fadiga pela velocidade de rotação.

A análise descritiva dos resultados incluiu média, desvio padrão, mediana, valores máximos e mínimos para as variáveis contínuas de cada grupo, de acordo com a presença/ ausência de hipoclorito de sódio. Após testar a normalidade com o teste Shapiro-Wilk e a homocedasticidade com o teste de Levene, as diferenças entre os grupos em relação ao NCF/tempo de fratura foram analisadas usando um teste *t-student* para variâncias desiguais. O teste Mann-Whitney foi utilizado para analisar as diferenças entre os grupos em relação ao comprimento da fratura, uma vez que este rejeitou uma distribuição normal. Foi também calculado o coeficiente de correlação de Spearman entre o comprimento do fragmento e NCF para a amostra global e para cada um dos grupos de fatores. A análise estatística foi feita através do programa SPSS 23, com um nível de significância estabelecido em 0,05.

RESULTADOS: As limas testadas na ausência de hipoclorito de sódio apresentaram uma média de tempo até à fratura, e consequentemente de NCF, inferior às limas usadas com hipoclorito de sódio, contudo sem diferenças estatisticamente significativas (p=0,638). O local de fratura não mostrou diferenças estatisticamente significativas entre os dois

grupos, com um valor de *p*=0,495. Existe uma associação linear entre o tamanho do fragmento e o número de ciclos à fratura, que é confirmado pelo coeficiente de correlação de Spearman, em que existe uma correlação significativamente moderada (r =-0.554, *p*= 0.011).

DISCUSSÃO: Nesta experiência, os instrumentos Hyflex EDM™ lubrificados com hipoclorito de sódio apresentaram maior resistência do que os instrumentos utilizados em condições secas, apresentando um valor médio de tempo de fratura e NCF ligeiramente maior, mas não estatisticamente significativo (*p*=0,638). O hipoclorito de sódio foi utilizado para minimizar o atrito entre o canal artificial e os instrumentos e prevenir o aumento de temperatura. Neste estudo foi possível verificar a variação de temperatura aos 5 e aos 10 minutos, sendo que a temperatura atingiu valores superiores no grupo em que não se utilizou hipoclorito de sódio.

Outro parâmetro estudado foi o comprimento de fratura, onde os comprimentos dos fragmentos foram semelhantes entre os grupos, não mostrando significância estatística (*p*=0,495), possivelmente porque os instrumentos testados foram posicionados corretamente dentro da curvatura do canal e as tensões induzidas foram semelhantes em ambos os grupos.

Ainda foi estudada uma correlação entre o comprimento da fratura e o NCF. Ambos os grupos mostraram que quanto maior o NCF, menor o comprimento da fratura, apresentando um resultado estatisticamente significativo (r =-0,554, *p*=0,011). Neste caso, a hipótese nula foi rejeitada. Esta correlação poderá fornecer informações para os clínicos, identificando a parte mais frágil do instrumento, mas existe conhecimento limitado sobre este assunto.

Comparando o presente estudo com Fernandes (2013), os resultados mostram que as limas Hyflex EDM™ apresentam maior resistência à fadiga do que as limas Hyflex CM™, com base na média de NCF. Embora ambos os instrumentos sejam fabricados com a mesma memória controlada, a Hyflex EDM™ é fabricada com o procedimento de eletroerosão que aumenta consideravelmente a resistência à fadiga dos instrumentos.

Outro estudo testou a fadiga cíclica das limas Hyflex EDM™ OneFile sem pré-utilização. Embora as condições de teste sejam diferentes do presente estudo, os resultados também mostraram que as limas Hyflex EDM™ são as mais resistentes à fadiga cíclica.

É de salientar que o tamanho da amostra obtido é pequeno, o que pode introduzir viéses no estudo. A análise de uma amostra maior de instrumentos, com um uso mais controlado deve ser considerada, de modo a fornecer uma maior evidência científica. Outro fator a ter em conta é a utilização de um teste estático de fadiga cíclica. Foi reportado por estudos que testes de fadiga cíclica estáticos apresentam menores resultados em comparação com testes dinâmicos. Sendo assim, futuramente, deve ser considerada a possibilidade de realizar testes dinâmicos, pois são mais próximos dos movimentos clínicos que se efectuam durante a instrumentação.

CONCLUSÃO: Dentro das limitações deste estudo *in vitro*, os resultados sugerem que a resistência à fadiga é semelhante nos instrumentos, quer estejam na presença ou ausência de hipoclorito de sódio. No entanto, o estudo mostrou que quanto maior o NCF, menores são os comprimentos dos fragmentos dos instrumentos. É importante referir que os dados obtidos neste estudo não podem ser diretamente extrapolados para condições clínicas.

Uma vez que estes instrumentos são amplamente utilizados, é necessária uma padronização dos testes de fadiga cíclica para obter resultados mais consistentes. A uniformização da metodologia e comparabilidade de resultados também são necessários para um uso clínico mais seguro.

PALAVRAS-CHAVE: Hyflex EDM; resistência à fadiga; intrumentos níquel-titânio; hipoclorito de sódio; endodontia.

ABSTRACT

INTRODUCTION: Nickel-titanium files were introduced to overcome some undesirable features of stainless steel instruments. These flexible rotary instruments have enhanced endodontic practice. Shaping and cleaning with sodium hypochlorite are responsible for eliminating microorganisms in an infected root canal system. The aim of this study was to compare cyclic fatigue resistance between, as fabricated, files in presence and absence of sodium hypochlorite.

MATERIAL AND METHODS: Twenty Hyflex EDM^{TM} files were divided in 2 groups: 10 files were tested in presence of sodium hypochlorite and 10 files were tested in its absence. A mechanical device was used to simulate the root canal system, and, to compare our data with a previous study, the same experimental parameters were followed. The testing time was registered with a digital chronometer until fracture occurred. The temperature of the files (n=2) was measured at the beginning of the essays and after 5 and 10 minutes. The number of cycles to fracture (NCF) was calculated by multiplying time by rotational speed. The normality was tested with the Shapiro-Wilk and the Levene tests, differences between groups regarding NCF were analysed using a t-student test for unequal variances. A Mann-Whitney U test was used to analyse differences between groups regarding fracture length. Additionally, Spearman's correlation coefficient was computed after plotting fracture length against NCF. The level of statistical significance was set at 0.05.

RESULTS: There was no statistically difference related to NCF/time to fracture between groups. Length of the fractured fragments was also similar between groups. Both groups showed that the higher the NCF was, the smaller the length of fracture, presenting a statistically significant result.

DISCUSSION AND CONCLUSION: Within the limitations of this study, results suggest that fatigue life is similar in both groups. A standardisation in cyclic fatigue tests is required to obtain consistent results and for a safer clinical use.

KEYWORDS: Hyflex EDM; cyclic fatigue; nickel-titanium instruments; sodium hypochlorite; endodontics.

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1. INTRODUCTION

Endodontology studies the form, function, health and diseases of the dental pulp and periradicular region and their prevention and treatment (European Society of Endodontology, 2006).

Endodontic treatment is achieved by cleaning and shaping procedures that use irrigants; therefore mechanical enlargement of the root canal space and properly shaped canals are essential for adequate flow of irrigating agents, as well as for placement of root filling (Al-Hadlaq *et al*., 2010; Fife *et al*., 2004).

The aim of the treatment is to preserve or restore to health periradicular tissues and prevent future infections (European Society of Endodontology, 2006).

1.1 Use of sodium hypochlorite as irrigant

Root canal preparation and the use of irrigating solutions, such as sodium hypochlorite, are responsible for eliminating the majority of microorganisms in an infected root canal system (Estrela *et al*., 2002).

An endodontic irrigant should ideally exhibit powerful antimicrobial activity, dissolve organic tissue remnants, disinfect the root canal space, flush out debris from the instrumented root canals, provide lubrication, have no cytotoxic effects on the periradicular tissues, among other properties. Sodium hypochlorite solution has many of these properties (Vianna *et al*., 2004). It is widely used in dental practice during root canal treatment because it is an effective antimicrobial, has tissue-dissolving capabilities, has low viscosity, allowing easy introduction into the canal architecture, and it is inexpensive (Spencer *et al*., 2007; Vianna *et al*., 2004).

Sodium hypochlorite reacts with fatty acids and amino acids in dental pulp resulting in liquefaction of organic tissue. Even though there is no universally accepted concentration of sodium hypochlorite for use as an endodontic irrigant, the antibacterial and tissue dissolution action of hypochlorite increases with its concentration, although this leads to an increase in toxicity. Concentrations used vary down from 5.25% depending on the dilution and storage protocols of individual practitioners (Spencer *et al*., 2007).

The toxicity of its action to vital tissues and corrosion of metals are its main disadvantages in dental use.

1.2 Nickel-Titanium endodontic instruments

Cleaning and shaping have been executed, traditionally, by using stainless steel files; nonetheless, the use of these files is associated with undesirable changes of the root canal system morphology during root canal preparation that made proper filling of the root canal system difficult (Al-Hadlaq *et al*., 2010; Yao *et al*., 2006).

To overcome some of these undesirable characteristics, nickel-titanium (NiTi) files were introduced in 1988 (Al-Hadlaq *et al*., 2010; Yao *et al*., 2006). These files demonstrated a significant gain in flexibility that enabled them to be used in conjunction with automated rotary handpieces, increasing the efficiency of root canal preparation and reducing the time for chemo-mechanical preparation (Al-Hadlaq *et al*., 2010).

1.2.1 Microstruture of Nickel-Titanium alloy

NiTi alloy has special characteristics of superelasticity and shape memory (Shen *et al*., 2011). The crystalline structure of NiTi alloy at high temperature ranges is a stable, face-centered cubic lattice, which is referred to as the Austenite Phase or Parent Phase (Figure 1). When it is cooled through a critical transformation temperature range (TTR), there is a change in the crystallographic structure which is known as the martensitic transformation that originates the Martensitic or Daughter Phase (Figure 1).

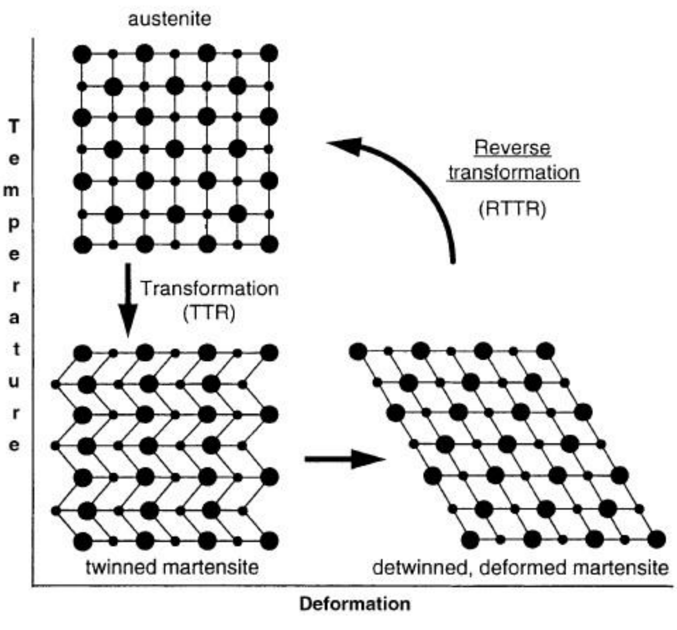

Figure 1 – Diagrammatic representation of the martensitic transformation and shape memory effect of NiTi alloy (Thompsom, 2000)

The phenomenon causes a change in the physical properties of the alloy and gives rise to the shape memory characteristic and the superelastic behavior (Thompson, 2000). The martensite shape can be deformed easily to a single orientation by a process known as de-twinning. The NiTi alloy is more ductile in the martensitic phase than in the austenite phase. The deformation can be reversed by heating the alloy above the TTR (Figure 1) and the properties of the NiTi alloy revert to their previous higher temperature characteristic values. The transition from the austenitic to martensitic phase (superelasticity) can also occur as a result of application of stress, such as occurs during root canal preparation (Thompson, 2000).

Phase composition and transition temperatures have an important impact on the clinical performance of the instruments. That is, files with a 'martensitic' microstructure are soft, ductile, and have shown a higher flexibility and an improved fatigue resistance when compared with conventional 'austenitic' NiTi instruments (Shen *et al*., 2013). Therefore, during the last decade, NiTi rotary instruments, have been gaining popularity among dentists practicing endodontic therapy. Adittionally, rotary nickel-titanium files are believed to produce more predictable root canal preparations, with better maintenance of the original canal morphology while minimizing procedural errors associated with hand instrumentation, specially in curved canals (Al-Hadlaq *et al*., 2010; Pirani *et al*., 2016; Yao *et al*., 2006). However, endodontic instruments sometimes fracture and visible inspections are not a reliable method for the evaluation of the physical integrity of NiTi instruments; therefore an increasing concern about the structural integrity of instruments during clinical procedure is present (Lopes *et al*., 2009).

1.3 Separation of the endodontic files

Despite higher strength and flexibility, fracture is still a concern with NiTi instruments, specially after extended use. Many of these fractures happen unexpectedly without any visible signs of permanent deformation (Al-Hadlaq *et al*., 2010; Fife *et al*., 2004; Li *et al*., 2002; Yao *et al*., 2006). Therefore, one of the biggest concerns in endodontic practice is the occurrence of instrument separation (Lee *et al*., 2011).

Instrument's fracture is an unpredictable and troublesome complication for clinicians (Fife *et al*., 2004) and can jeopardise the outcome of the root canal treatment. It seems to occur mostly in the apical third of the root canal and the complications most commonly reported in literature are excessive removal of tooth structure, ledges, canal transportation and even root perforation (Castelló-Escrivá *et al*., 2012). The removal of the broken fragments may not be feasible, and, when possible, it is a challenging and a time consuming procedure (Fife *et al*., 2004; Kaval *et al*., 2016).

Several variables may contribute to failure of rotary endodontic instruments but the two main causes are torsional fatigue and cyclic flexural fatigue. More frequently, it is a combination of these two factors that cause fracture in clinical situations (Li *et al*., 2002).

Studies have determined that the radius of curvature is the most important factor in cyclic fatigue. Other significant factors include instrument's size, its design and cross sectional area, metal surface thermo treatments, metallurgical characterisation of the NiTi alloys, as well as angle of canal curvature (Yao *et al*., 2006). The rotational speed, technique and operator's experience, torque, sterilisation procedures and clinical use, also influence the mechanic behaviour of NiTi instruments (Aydin *et al*., 2010; Bhagabati *et al*., 2012). Although these factors are often described individually, they act collectively (Bhagabati *et al*., 2012).

1.3.1 Torsional fatigue

Torsional failure occurs when the tip of the instrument binds in the canal while the shank continues to rotate (Al-Hadlaq *et al*., 2010). Hence, the elastic limit of the metal is exceeded by torque exerted by the handpiece and fracture of the tip becomes inevitable. Frequently, signs of plastic deformation are visible (Plotino *et al*., 2009).

1.3.2 Cyclic fatigue

Cyclic fatigue is caused by the repeated application of cyclic tensile and compressive stresses. Rotation subjects an instrument to both tensile and compressive stresses in the area of the curve (Fife *et al*., 2004; Li *et al*., 2002). When the file is bent, the metal at the point of flexure on the outer fibre undergoes tension while the metal on the inner region of the curve undergoes compression (Li *et al*., 2002). This repeated tension/compression cycle will cause cumulative microstructural changes that may lead to the fracture of the instrument, that occurs at the point of maximum stresses applied (Al-Hadlaq *et al*., 2010) and may be the most crucial factor in instrument's separation (Li *et al*., 2002).

It has been suggested that cyclic fatigue has accounted for 50% to 90% of mechanical failures. Therefore, the use of a back and forth movement during instrumentation by NiTi engine-driven rotary instruments would be expected to significantly extend the lifespan of the instrument (Li *et al*., 2002).

The incidence of nickel-titanium file's fracture has been recently reported to be around 5%, and 70% of the those fractures were due to flexural fatigue fracture, whereas 30% were due to torsional fatigue (Al-Hadlaq *et al*., 2010).

1.3.2.1 Cyclic fatigue tests

The fatigue resistance comprises the number of cycles that an instrument is able to resist under cyclic loading conditions (Lopes *et al*., 2012). Because the number of cycles to fracture is cumulative, it can be calculated by multiplying the rotational speed by time elapsed until fracture occurs (Lopes *et al*., 2010). Fatigue life is usually tested by measuring the number of rotations of the instrument in an artificial root canal until fracture (Lee *et al*., 2011).

The greater the value of Number of Cycles to Fracture (NCF), the greater is its resistance to fracture. Cyclic fatigue tests can be "static" or dynamic. In "static" tests the instrument rotates at a fixed length without axial movement, whereas in the dynamic model the instrument moves back and forth within the canal (Rodrigues *et al*., 2011). In addition, several factors can influence the cyclic fatigue resistance of an endodontic instrument subjected to rotational movement, namely:

a) Surface finishing

Surface roughness resulting from the machining process used for manufacturing NiTi instruments is one of the factors that influence cyclic fatigue. The surface defects inherent to machining are mostly grooves that work as stress concentration factors. Once fatigue cracks initiates on the instrument's surface, stress concentration factors favor nucleation, growth, and propagation of cracks (Lopes *et al*., 2010). Initiation of fatigue cracks usually occurs at the surface of a working part and it is especially vulnerable if the area with the highest stress coincide with the machining grooves (Kim *et al*., 2008).

b) Angle and radius of curvature

Resistance of rotary instruments to cyclic fatigue depends on the angle and radius of canal curvature and other factors (Grande *et al*., 2006). Studies have determined that the radius of curvature is the most importante factor in cyclic fatigue - the shorter the radius, the higher the risk. The radius of curvature represents how abruptly or severely a specific angle of curvature occurs as the canal deviates from a straight line and NCF significantly increase as radius increases (Grande *et al*., 2006; Yao *et al*., 2006).

In figure 2 there are two lines drawn along the long axes of the root canal and two lines that are perpendicular to these. The angle formed by these two perpendicular lines, which are intersected at the circle’s center, is called the angle of curvature, expressed in degrees and the length of these lines is the radius. The circle's radius is the radius of the the curved portion of the root canal space and defines how abruptly are the canal curves. Therefore, the smaller the radius, the more abrupt the canal deviation.

The parameters of angle of curvature and radius of curvature are independent, so canals can have the same angle of curvature while having different radii of curvature, resulting in more abrupt curves (Pruett *et al*., 1997).

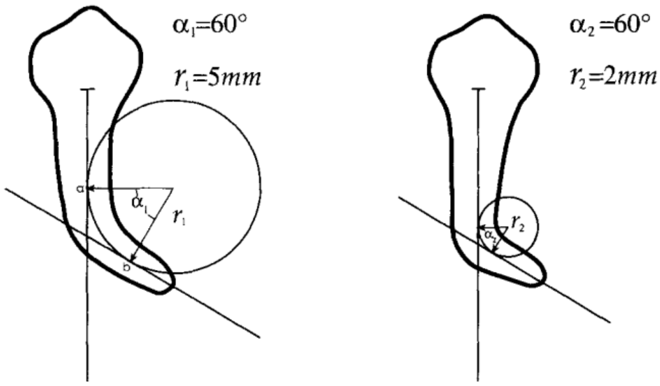

Figure 2 – Pruett’s method to demonstrate the influence of radius (r) and angle of curvature (α) in canal geometry (Pruett *et al.,* 1997).

c) Rotational speed

Contradictory results on the influence of rotational speed on cyclic fatigue of NiTi instruments were described. Some studies found rotational speed did not impact the cyclic fatigue, while others reported that a higher rotational speed decreased cyclic fatigue resistance of endodontic NiTi instruments (Grande *et al*., 2006). Few scientific data have been published regarding the life cycle of NiTi rotary instruments while being activated at different rotational speeds (Li *et al*., 2002); however, the effect of rotational speed on instrument fracture is related to the generation of heat. Therefore, higher speeds produce more heat and thereby induce a faster increase in the instrument’s temperature. This rise of temperature leads to a fast increase in surface tension, causing precocious fatigue fracture (Lopes *et al*., 2009).

d) Controlled Memory

Controlled memory - thermal treatment in the NiTi alloy - was recently introduced to Hyflex EDM™ to shift the austenite/martensite transition temperature, so that a stable martensitic microstructure is obtained at body/room temperature. This imparts to the file a high fatigue resistance, ease of bending and the ability to recover its original shape by heating above the transformation temperature (Iacono et al., 2017). The files made of controlled memory were reported to have higher cyclic fatigue resistance than those made of the conventional NiTi alloy (Gündoğar & Özyürek, 2017).

1.4 Hyflex EDM™ (Coltene, Switzerland) system

Hyflex EDM™ OneFile is a single-file system recently introduced in the market. These instruments are manufactured from the same controlled memory wire as HyFlex CM™. However, these are produced via electro-discharge machining (EDM), a non-contact thermal erosion process that partially melts and evaporates the wire by high-frequency spark discharges (Iacono *et al*., 2016; Özyürek *et al*., 2017). Although EDM is a common fabrication process for miniaturised components in medical technology and micro-engineering, and already used for NiTi alloys in surgical applications, Hyflex EDM™ are the first endodontic instruments manufactured with this procedure (Iacono et al., 2017).

A normal autoclaving process (with the manufacturer's recommended settings) is enough to return the files to their original shape and fatigue resistance. Should the file fail to regain its shape after heat treatment, risk of fracture is increased, and the file should not be used after visual inspection (Coltene, 2016).

Figure 3 – Regeneration by thermal treatment (Coltene, 2016).

Hyflex EDM^{TM} has a 0.25 mm apical diameter. In addition, throughout the file's shaft, it uses 3 different cross sections: square in the apical third, trapezoidal in the middle third, and almost triangular in the coronal third. The hardened surface plus controlled memory behavior improves its cutting efficiency. This system has six files available for shaping canals with different sizes: Orifice opener (tip size 25 with a taper of 0.12), Glidepath file (tip size 10 with a taper of 0.05), Hyflex Onefile (tip size 25), optional Finishing files (tip size 40 with a taper of 0.04; tip size 50 with a taper of 0.03; tip size 60 with a taper of 0.02) (Figure 4).

All Hyflex EDM^{TM} files can be used at 400 rpm and at a torque of up to 2.5 N.cm (25 mN.m) except he Glidepath Files, wich can be used with 300 rpm and a torque of up to 1.8 N.cm (18 mN.m).

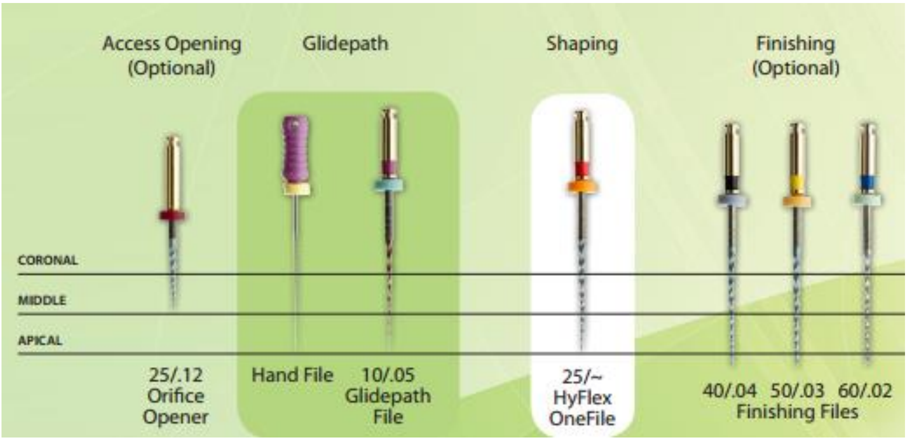

Figure 4 – Hyflex EDM^{TM} system (Coltene,2017)

2. AIMS

The aim of this *in vitro* study is to compare the fatigue life of Hyflex EDM™ instruments, as fabricated, tested in a simulated canal, with and without sodium hypochlorite.

Specific goals:

1 – To compare the fatigue life of Hyflex EDM™ OneFile instruments tested in the presence and absence of sodium hypochlorite.

H0: the number of cycles to fracture is alike in all instruments.

H1: the number of cycles to fracture is different for all instruments.

2 – To compare the mean of fragments lengths in Hyflex EDM™ OneFile instruments in presence and absence sodium hypochlorite.

H0: the fragment's length is alike in all instruments.

H1: the fragment's length is different for all instruments

3 – To study the correlation between lenght of the fractured fragment and the NCF:

H0: No correlation exists between length of the fractured fragment and the number of cycles to fracture when using Hyflex EDM™ files.

H1: A significant correlation exists between length of the fractured fragment and the number of cycles to fracture when using Hyflex EDM™ files.

3. MATERIAL

In this study, one type of rotary endodontic instruments, with a file's length equal to 25 mm, was tested; hence, Hyflex EDM^{TM} OneFile constituted two experimental groups and all instruments had no pre-use. Files were grouped according to instrument type as shown in chart 1:

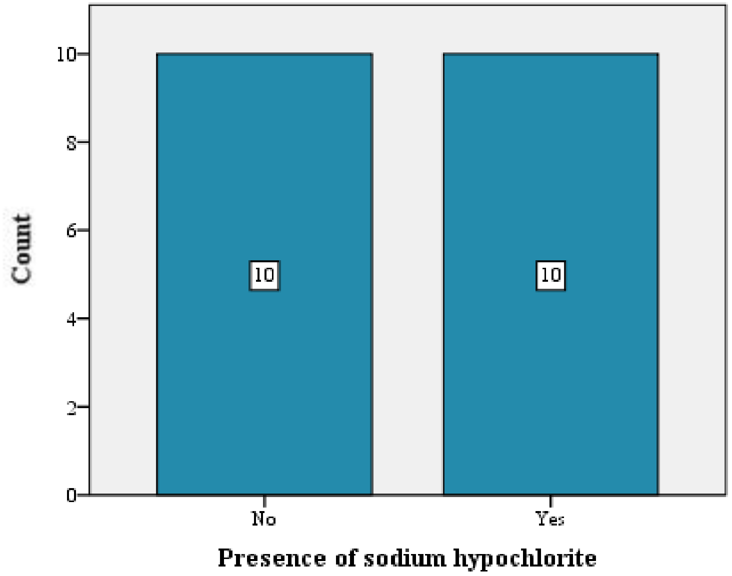

Chart 1 – Distribution of Hyflex EDM^{TM} OneFile regarding presence of sodium hypochlorite during testing.

Twenty Hyflex EDM^{TM} files were provided by the manufacturer Coltene with no further influence in this study. The motor used was a WaveOne^{TM} (Denstply Maillefer) motor in "My program" setting, at 400 rpm continuous rotary motion and an input torque of 2.5 N.cm.

Figure 5 – The WaveOne ^{TM} (Denstply Maillefer) motor used in this study.

4. METHODS

This study was constituted by two experimental groups:

In the **first group**, the fatigue life of endodontic rotary instruments was tested in a mechanical system previously designed due to a partnership between the Department of Endodontics of Faculdade de Medicina Dentária da Universidade de Lisboa (Lisbon Faculty of Dentistry) and the Department of Mechanical and Industrial Engineering of Faculdade de Ciências e Tecnologia da Universidade Nova de Lisboa. The system tries to simulate a root canal, recreating the bending forces applied to an endodontic file during clinical treatment. The two parameters related to these bending forces are: the radius and angle of the curvature, namely 4.7 mm and 45º, respectively.

Figure 6 shows a schematic drawing of the mechanical system used in the herein research. In (a) the instrument enters in the canal and it is forced to bend and adjust to the curvature. Point W represents the place where the extremity of the instrument should be in each test to standardise instrument placement, which corresponds to a distance of 5 mm from the beginning of the curvature of the simulated root canal to file's tip. To guarantee that the whole system was static, except the instrument to be tested, it was necessary to use three bolts very well tightened, to prevent the different pieces from moving apart. The reproducibility of the tests is guaranteed by these parameters.

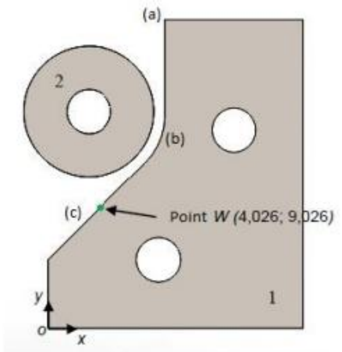

Figure 6 – Schematic representation of the mechanical system adapted, from Fernandes (2013)

The piece number 1 (block) was manufactured by a Computerized Numerical Control machine (CNC) and piece number 2 (washer) was manufactured from a rod of stainless steel that was machined to a diameter of 4.7 mm and hole-drilled. The stand structure is a stainless-steel sheet with 1.5 mm thick with several folding, cutting and welding (Figures 7 and 8). The contra-angle of the motor WaveOne^{TM} (Dentsply Maillefer) was fixed to the metallic stand structure with two plastic pieces that were also tightened with the aid of two bolts. The system was supported by a screen of teflon which was fixed to the table with two staples (Figure 7). Testing time was registered with a digital chronometer manually operated, and started at the moment the motor was turned on and stopped as fracture was visually detected.

Figure 7 – The Wave-One^{TM} (Denstply Maillefer) motor and the experimental apparatus.

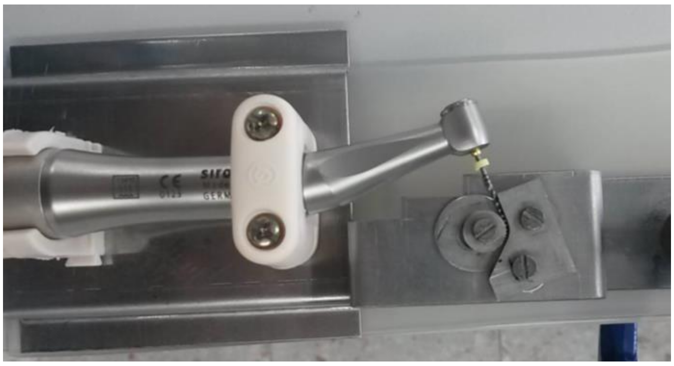

Figure 8 – The experimental apparatus: detail view of headpiece and file.

4.1 Experimental procedure

The following experimental procedure was used in all instruments:

1- Place the motor in the fixed system;
2- Place the instrument to be tested in the contra-angle and rotate the head of the contra-angle until the instrument is parallel to the table;
3- Make sure that the instrument is between pieces no. 1 and 2;

4- Ensure that the extremity of the file is well positioned at point W and that it is perpendicular to the upper part of the block;
5- Turn on the WaveOne^{TM} motor and select the "My program";
6- Get the chronometer set up and ready to use;
7- Step on the pedal initiating the chronometer at the same time until separation of the instrument occurs, which was detected visually;
8- Stop the chronometer when the tip of the instrument fractures;
9- Remove the instrument off the contra-angle and measure the length of the instrument;
10- Repeat every step for each instrument.

In the **second group,** every step described above was repeated for each instrument by the same operator adding sodium hypochrolite 5,25% with a syringe during the experiment until fracture of the file occurred.

The temperatures of 2 files (one from each group) was measured at the beginning of the essays, after 5 and 10 minutes, by the same operator, with an infrared thermometer (Table 5).

a b

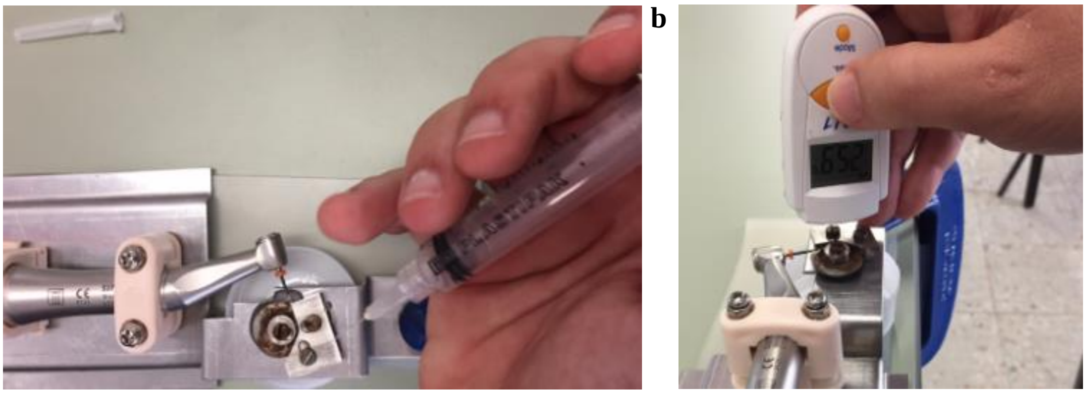

Figure 9 – Experimental procedure: a) sodium hypochlorite addition by the operator; b) temperature measuring by the operator.

All instruments were tested under the same conditions and by the same operator. The time until fracture was registered in each test (t). The Number of Cycles to Fracture (NCF) for each file was calculated by multiplying the time to failure, in seconds, by the rotational speed, which in this study was 400 rpm:

$$NCF = \frac{400t}{60} \Leftrightarrow NCF = 6{,}67t$$

The point of fracture in relation to the tip of the instrument was determined by measuring the fractured file with a Vernier caliper.

Additionally, to complement further knowledge, a bibliographic research was made between January and August 2017 using database Pubmed/Medline with a combination of the following keywords: Hyflex EDM, cyclic fatigue, nickel-titanium instruments, rotary preparation, sodium hypochlorite and endodontics. Through evaluation of the abstract, relevant content articles were selected.

4.2 Statistical analysis

All statistical analysis was performed using SPSS 23 (IBM, Armonk, NY, USA) with the level of statistical significance set at 0.05.

Descriptive data were reported as mean, standard deviation, median, minimum and maximum for the continuous variables for each group, according to presence/absence of sodium hypochlorite. The respective graphic representations were computed as well. After testing for normality with the Shapiro-Wilk test and for unequal variances with the Levene test, differences between groups regarding NCF/time to fracture were analysed using a t-Student distribution for unequal variances. A Mann-Whitney U test was used to analyse differences between groups regarding fracture length since the latter rejected a normal distribution. Additionally, and after plotting fracture length against NCF, Spearman's correlation coefficient was computed for the overall sample and for each of the factor groups.

4.3 SEM observations

A scanning electron microscope Jeol JSM-T330A (Figure 11) was used to observe the fracture surfaces of the endodontic instruments tested.

Figure 10 – SEM JEOL JSM-T330A, similar to the one used in this experiment, from JEOL website.

5. RESULTS

Variables	Presence of sodium hypochlorite						
	No			Yes			
	Mean	Std. Deviation	Median	Mean	Std. Deviation	Median	p value
Time to fracture (sec)	652.00	249.00	665.00	694.00	119.00	708.00	0.638 [a]
Number of cycles to fracture	4348.60	1659.30	4432.20	4628.70	795.70	4722.30	0.638 [a]
Fracture length (mm)	5.55	1.09	5.95	5.52	0.66	5.80	0.495[b]

[a] t-Student test for unequal variances

[b] Mann-Whitney U test

Table 1 – Comparison of means and median values between groups for time to fracture, number of cycles to fracture and fracture lengths.

In table 1, it can be observed that the specimens tested without sodium hypochlorite presented the smallest mean regarding time to fracture – 652 sec (SD 249) vs. 694 sec (SD 119), and, consequently, also presented the smallest mean regarding number of cycles to fracture – 4348.60 cycles (SD 1659.30) vs. 4628.70 cycles (SD 795.70), when compared to the specimens tested with sodium hypochlorite (Charts 2 and 3).

It is also noteworthy that the group tested without presented a higher variation of values regarding these two variables, when compared to the sodium hypochlorite group (Charts 2 and 3). However, differences between group means were not statistically significant (p= 0.638).

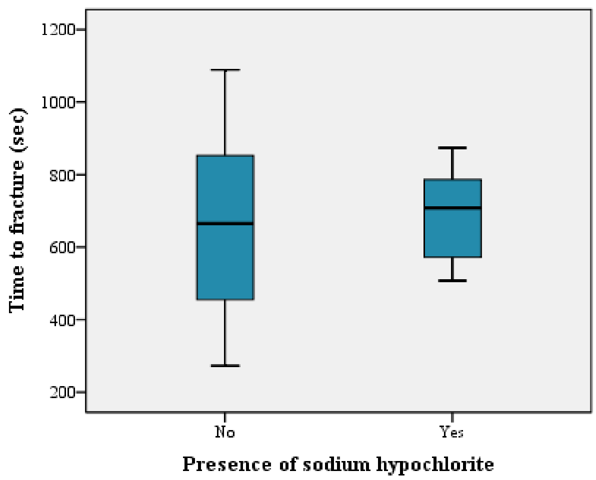

Chart 2 – Distribution of time to fracture in the presence/absence of sodium hypochlorite.

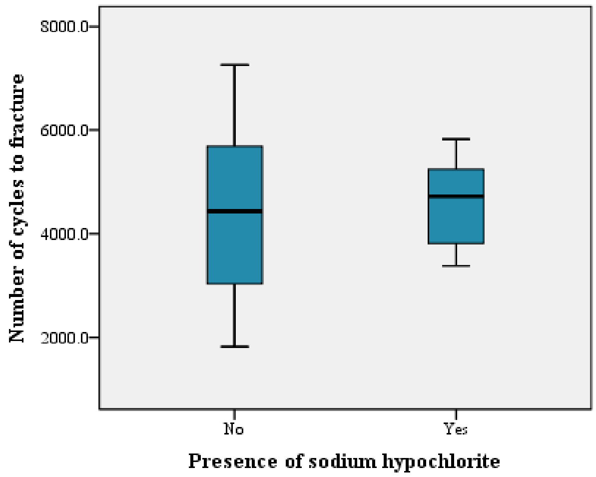

Chart 3 – Distribution of number of cycles to fracture in the presence/absence of sodium hypochlorite.

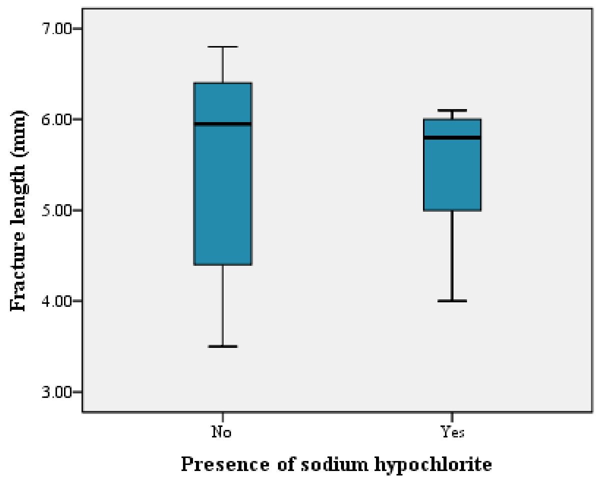

Chart 4 – Distribution of file's fracture length in the presence/ absence of sodium hypochlorite.

Length of the fractured fragments was very similar between groups – 5.55 mm (SD 1.09) vs. 5.52mm (SD 0.66) – and, as such, no statistically significant differences were found between specimens tested with or without sodium hypochlorite (p=0.495). Additionally, chart 4 also illustrates a wider range of values in the group where no sodium hypochlorite was used.

Observing chart 5, there appears to be a negative linear association between fracture length and number of cycles to fracture, which is confirmed by Spearman's correlation coefficient as a significant moderate negative correlation (r =-0.554, p= 0.011), in table 2.

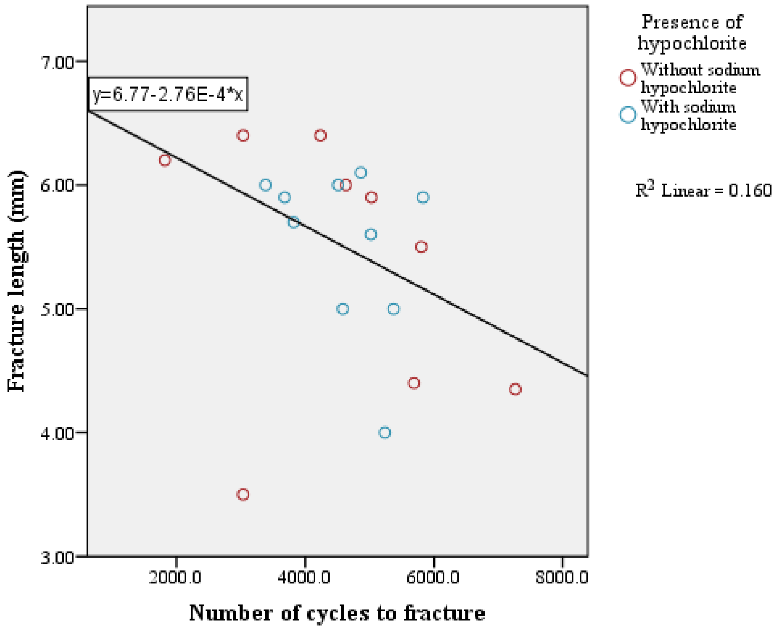

Chart 5 – Fracture length plotted against number of cycles to fracture.

		Number of cycles to fracture	Fracture length (mm)
Spearman's rho	Number of cycles to fracture	1.000	**-0.554***
	Fracture length (mm)	**-0.554***	1.000

* Correlation is significant (p = 0.011). Note: when correlations were performed separately for each hypochlorite presence/absence group were not statistically significant.

Table 2 – Correlation between fracture length and number of cycles to fracture.

Figures 11a and b show two representative SEM pictures taken to fracture surfaces of endodontic files tested. It can be clearly seen the geometrical critical cross sections of endodontic files tested and the similitude of the fracture surfaces obtained during experimental tests in the presence (Figure 11b) and in the absence of sodium hypochlorite (Figure 11a).

a **b**

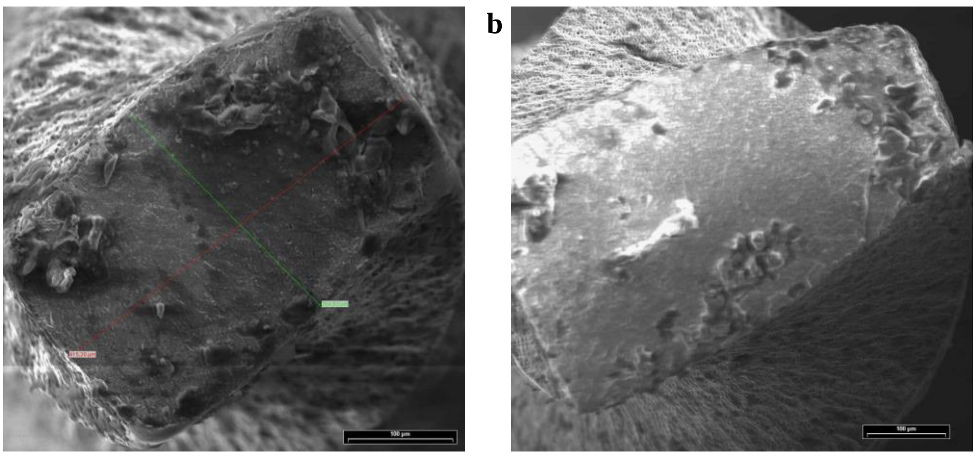

Figure 11 – Fracture surfaces of endodontic files under study: a) in the absence of sodium hypochlorite; b) in the presence of sodium hypochlorite.

6. DISCUSSION

Despite the advantages related to the superelasticity, fracture of NiTi files, due to torsional overloading or flexural fatigue, remains a concern in clinical practice (Gündoğar & Özyürek, 2017). Instrument fracture is an unpredictable and troublesome complication for clinicians (Kaval *et al*., 2016).

The main aim of this study was to evaluate the cyclic fatigue resistance of Hyflex EDM^{TM} instruments, as fabricated, in the presence/absence of sodium hypochlorite, through the calculation of NCF.

In this experiment, the Hyflex EDM^{TM} instruments lubricated with sodium hypochlorite were more resistant than instruments used in dry conditions, presenting a mean value of time to fracture and NCF slightly higher, but not statistically significant (p=0,638). The group tested without sodium hypochlorite also presented a higher variation of values regarding these two variables (Charts 2 and 3) and higher values of standard deviation, showing that the use of sodium hypochlorite improves the repeatability of the experiments. This can be explained by the effect of the generation and dissipation of heat; therefore, rotational speeds produce heat and thereby induce a faster increase in the instrument's temperature. This rise of temperature leads to a fast increase in surface tension, causing precocious fatigue fracture (Lopes *et al*., 2009). Hence sodium hypochlorite 5,25% was used in this experiment in order to minimise the friction between the canal and files (Gündoğar & Özyürek, 2017), and to maximise the release of heat.

Another parameter studied was the fractured length, where the fragment's lengths were very similar between groups, showing no statistically significance (p=0,495), possibly because the tested instruments were correctly positioned within the canal curvature and that similar stresses were being induced in both groups. However, chart 4 illustrates a wider range of values in the group in absence of sodium hypochlorite, which can be explained by the lack of lubrication (Vianna *et al*., 2004).

Adittionally, a correlation between fracture's lengths and number of cycles to fracture was studied. Both groups (in presence and absence of sodium hypochlorite) showed that the higher the NCF was, the smaller the length of fracture, presenting a statistically significant result (r =-0.554, p=0.011). In this case the null hypothesis was rejected. This correlation could provide information for clinicians by identifying the most fragile portion of the instrument, yet limited knowledge exists on this subject. However, instruments with larger diameters have been found to fracture earlier than those with smaller diameters (Gambarini *et al*., 2011). It is worth to note that when the correlations were performed separately, for each group, they were not statistically significant, which means this correlation is independent of the presence of sodium hypochlorite.

Fernandes (2013) used the same angle of curvature and radius as this experiment with non-used Hyflex CM^{TM} instruments. Comparing the present study with Fernandes (2013) (Table 3), the results showed that Hyflex EDM^{TM} files have higher fatigue resistance than Hyflex CM^{TM} files, based on the NCF mean. Similarly, Pirani reported the cyclic fatigue resistance of Hyflex EDM^{TM} files to be higher than HyFlex CM^{TM} files. Although these files are manufactured with the same controlled memory, Hyflex EDM^{TM} OneFile are produced with the electrodischarge machining procedure, which greatly increases the resistance of the instruments (Pedullà *et al*., 2015; Pirani *et al*., 2016). In fact, during this research, mean NCF equal to 4348.6 and 4628.7 cycles, which could be compared with the values obtained by Fernandes (2013) (1540.7 cycles for 20/.04 files and 3181.3 cycles for 20/.06 files).

Another study (Gündoğar & Özyürek 2017) researched the cyclic fatigue for this system with Hyflex EDM^{TM} files with no pre-use (Table 3). Although test conditions of both studies differ from the present studies (Table 3), the results also showed that Hyflex EDM^{TM} OneFile is the most resistant file to cyclic fatigue. In addition, according to Plotino (2010), the increase of angle and radius of curvature results in shortened lifespan of the instruments, which is confirmed by results included in Table 3 (Plotino *et al*., 2010).

Even though the rotational speed was different in all studies, each recommended by the manufacturer at the time, the sodium hypochlorite used in this study prevented the rise of temperature in Hyflex EDM^{TM} OneFile and promoted an increase in NCF (Table 4). Table 4 shows the results of the temperature measurements with an infrared thermometer, at the beginning of the essays and after 5 and 10 minutes.

Study	Instruments/ Testing conditions	Presence of sodium hypochlorite	Number	Rot. Speed	NCF (mean/st. Dev)	Mean time (sec)	Fracture length (mm)
Present study	Hyflex EDM (25/~) 45º 4,7 mm	No	10	400	4628.70 ± 795.70	694	5.52
		Yes	10	400	4348.60 ± 1659.30	652	5.55
Fernandes 2013	Hyflex CM (04/20) 45º 4,7 mm	No	8	500	1540 ± 73.88	793	–
	Hyflex CM (06/20)	No	8	500	3181 ±77.44	1004,3	–
Gündoğar & Özyürek 2017	Hyflex EDM (25/~) 60º 4,7 mm	No	30	500	3456.33 ± 633.37	–	5.77

Table 3 – Summary of the testing conditions, results and conclusions of the studies considered.

Presence of sodium hypochlorite	Initial temperature (ºC)	Temp. after 5 min. rotating (ºC)	Temp. after 10 min. rotating (ºC)
No	24,5	25,9	26,7
Yes	24,5	25,4	25,2

Table 4 – Results for the temperature of Hyflex EDM^{TM} instruments in presence/absence of sodium hypochlorite.

However, it should be noted that the sample size obtained is small, which can introduce bias in this study. The analysis of a larger sample of instruments with a more controlled use should be considered to provide stronger scientific evidence of the conclusions.

Another factor to consider is that this experiment engages a static cyclic fatigue test. It has been reported that static cyclic fatigue tests showed lower results compared with dynamic tests in which endodontic instruments are subjected to axial movements (Pérez-Higueras *et al*., 2014).

In future studies, the possibility to do a dynamic test should be evaluated, because this would be closer to the real movement that the instrument is submitted to during preparation. Besides, one study showed that back and forth movement may be a crucial factor in preventing the fracture of NiTi rotary instruments (Li *et al*., 2002). In addition, cyclic fatigue tests are laboratory studies that represent a pure mechanical test that extrapolate only one characteristic of the instruments. This condition is far from the clinical setting, in which the fracture occurs due to several factors that act together in the same moment (Plotino *et al*., 2010). The need for a standardisation in cyclic fatigue tests is mandatory to obtain consistent results to compare the cyclic fatigue resistance of the different instruments. It is required to ensure the uniformity of methodology and comparable results for a safer, efficient clinical use (Plotino *et al*., 2010). Further studies are needed to create specifications, to minimise uncontrolled variables and to reproduce the same conditions between researchers.

Finally, although one study reported that reusing NiTi files up to four times did not increase separation incidence, there has been no consensus on how many times or how long a file could be used for root canal preparation (Pedullà *et al*., 2015). In addition, according to Pirani (2016), Hyflex EDM^{TM} files presented low degradation after multiple canal preparation and it could be considered that these instruments could be used more safely in severely curved canals because of their higher flexural fatigue. The low degradation after multiple uses and the improved mechanical properties, due to the innovative fabrication process, could have an important clinical relevance in order to minimise the risk of fracture of the instruments (Iacono et al., 2017; Pirani et al., 2016).

7. CONCLUSION

The knowledge of the mechanical behavior of endodontic instruments is very important for clinicians to predict clinical performance. Hyflex EDM^{TM} instruments have been gaining popularity in endodontic treatment. The aim of this study was to evaluate the fatigue life of these instruments.

Within the limitations of this *in vitro* study, the results suggest that resistance to fatigue life is similar wether the instruments are used in presence or absence of sodium hypochlorite. However, the study showed that the higher the number of cycles, the smaller the fractured lenghts of the files. It is important to refer that the data obtained in this study cannot be directly extrapolated to clinical conditions.

Because rotary endodontic instruments are widely used, a standardisation in cyclic fatigue tests is needed to obtain consistent results. The uniformity of methodology and comparable results are also required for a safer and efficient clinical use.

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APPENDICES

APPENDIX A

Abbreviations

CNC – Computerized Numerical Control

NCF – Number of Cycles to Fracture

NiTi – Nickel-Titanium

TTR – Transformation Temperature Range

Symbols

% – Percentage

n – Number of sample

p – Significance

TM – Unregistered trademark

Units

º – Degrees

ºC – Degree Celsius

mm – Millimeters

N.cm – Newton centimeter

rpm – Rotations per minute

APPENDIX B

Table 5 shows the results of the experimental procedure: time to fracture in seconds, fracture length in millimeters and number of cycles to fracture for each type of file.

Sodium hypochlorite	Type of file	Time (sec)	Fracture length (mm)	NCF
Yes	EDM_1	634,8	6,4	4234,1
	EDM_2	1089	4,35	7263,6
	EDM_3	272,4	6,2	1816,9
	EDM_4	454,8	6,4	3033,5
	EDM_5	455,4	3,5	3033.5
	EDM_6	694,2	6	4630,3
	EDM_7	442,8	6,8	2953,5
	EDM_8	853,2	4,4	5690,8
	EDM_9	753,6	5,9	5026,5
	EDM_{10}	870	5,5	5802,9
No	EDM_{11}	752,4	5,6	5018,5
	EDM_{12}	676,2	6	4510,2
	EDM_{13}	729	6,1	4862,4
	EDM_{14}	551,4	5,9	3677,8
	EDM_{15}	687	5	4582,2
	EDM_{16}	873,6	5,9	5826,9
	EDM_{17}	785,4	4	5238,6
	EDM_{18}	805,2	5	5370,7
	EDM_{19}	507	6	3381,7
	EDM_{20}	572,4	5,7	3817,9

Table 5 - Results for each instrument's test for time to fracture (seconds), length of the fractured tip (mm) and Number of Cycles to Fracture.

APPENDIX C

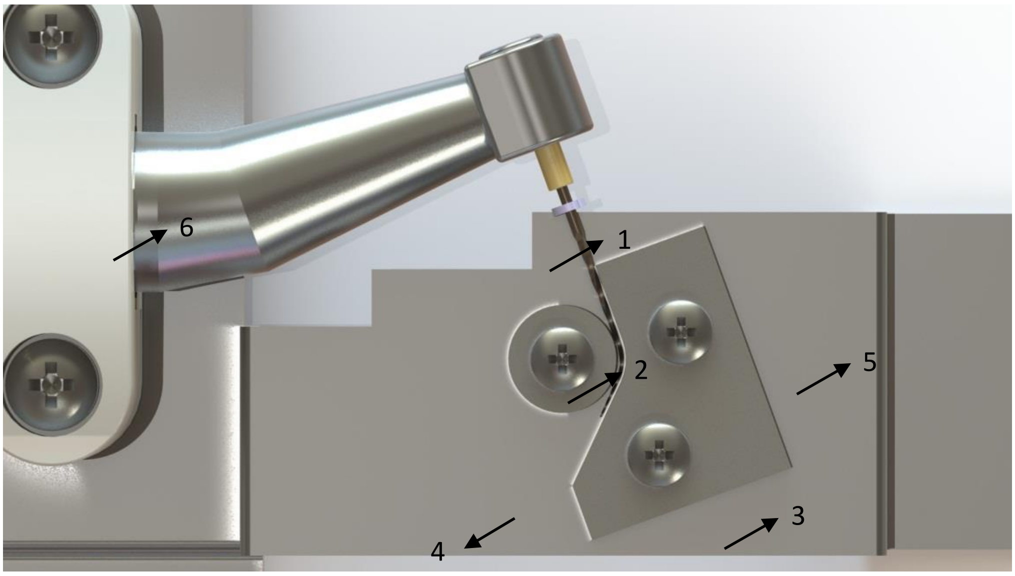

Figure 12 - The experimental apparatus close-up: headpiece and file, from Fernandes (2013)

Figure 12 caption:

1 – Micromotor;

2 – Testing instrument;

3 – Meeting peace;

4 – Contact washer;

5 – Support structure;

6 – Motor attachment setting.

APPENDIX D

Figure 13 – Infrared thermometer used in the experimental procedure.

Figure 14 – Hyflex EDM™ OneFile kit and LOT number, from Hyflex EDM™ system.