



[DOI]10.12016/j.issn.2096-1456.2024.02.003

· 基础研究 ·

## 3种镍钛锉预备弯曲根管时抗循环疲劳性能的体外研究

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**【摘要】目的** 探究不同角度的弯曲根管模型中, 不同尖端直径的Woride KS(WKS)、Protaper Gold(PTG)及Hyflex CM(HCM)机用镍钛器械抗循环疲劳性能的差异, 为临幊上预备弯曲根管时有针对性地选用合适的镍钛器械提供参考。**方法** 选取不同尖端直径20#、25#(0.20 mm、0.25 mm)的3种全新镍钛锉,WKS(20/0.06)、WKS(25/0.06)、PTG(20/0.07)、PTG(25/0.08)、HCM(20/0.06)、HCM(25/0.06)各20支。根据推荐设置马达的转速和扭矩,于30°和60°的不锈钢根管模型中测试镍钛锉的抗循环疲劳性能,用摄像机及计时器记录镍钛锉从开始旋转到疲劳折断的时间(time from rotation to fatigue fracture, TTF),用游标卡尺测量并记录折断碎片的长度(fragment length, FL)。**结果** 同种锉的TTF比较,①WKS:尖端同直径锉在30°弯曲根管中的TTF均长于60°( $P < 0.05$ ),同角度弯曲根管中25#锉的TTF均长于20#锉( $P < 0.05$ );②PTG:20#锉在30°弯曲根管中的TTF长于60°( $P < 0.05$ ),25#锉在30°弯曲根管中的TTF与60°无统计学差异( $P > 0.05$ ),在30°弯曲根管中的20#锉TTF长于25#锉( $P < 0.05$ ),在60°弯曲根管中20#锉的TTF与25#锉无统计学差异( $P > 0.05$ );③HCM:尖端同直径锉在30°弯曲根管中的TTF均长于60°( $P < 0.05$ ),同角度弯曲根管中20#锉的TTF均长于25#锉。不同锉的TTF比较:在30°弯曲根管中,3种20#锉的TTF无统计学差异( $P > 0.05$ ),25#WKS的TTF长于其他锉( $P < 0.05$ );在60°弯曲根管中,20#HCM的TTF长于尖端同直径的其他锉( $P < 0.05$ ),25#WKS的TTF长于尖端同直径的HCM( $P < 0.05$ )。20#PTG、25#PTG、20#HCM在30°的弯曲根管模型中FL均分别显著长于60°( $P < 0.05$ ),20#WKS、25#WKS、25#HCM在30°及60°的弯曲根管模型中FL无统计学差异。**结论** WKS镍钛锉的抗循环疲劳性能在30°模拟弯曲根管内较PTG及HCM镍钛锉有明显优势;而在60°模拟弯曲根管内,20#镍钛锉中HCM镍钛锉的抗循环疲劳性能较其他锉有明显优势,25#镍钛锉中仅WKS镍钛锉的抗循环疲劳性能较HCM镍钛锉有明显优势。

**【关键词】** 镍钛器械; 抗循环疲劳; 热处理; 弯曲度; 弯曲根管; 器械分离; Woride KS; Protaper Gold; Hyflex CM



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**【中图分类号】** R78 **【文献标志码】** A **【文章编号】** 2096-1456(2024)02-00101-07

**【引用著录格式】** 王渝鑫, 焦任天, 赵莹, 等. 3种镍钛锉预备弯曲根管时抗循环疲劳性能的体外研究[J]. 口腔疾病防治, 2024, 32(2): 101-107. doi:10.12016/j.issn.2096-1456.2024.02.003.

**In vitro study on cyclic fatigue resistance of three types of nickel titanium files in preparation for bending root canals** WANG Yuxin<sup>1</sup>, JIAO Rentian<sup>1</sup>, ZHAO Ying<sup>2</sup>, WANG Tianqi<sup>1</sup>, LIANG Guangzhi<sup>1,2</sup>. 1. Weifang Meidical University of stomatology, Shandong 261000, China; 2. Department of Endodontics, Affiliated Hospital, Weifang Meidical University, Shandong 261000, China

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**[Abstract]** **Objective** The purpose of this study was to investigate the differences in the anti cyclic fatigue performance of Woride KS (WKS), Protaper Gold (PTG), and Hyflex CM (HCM) nickel titanium instruments with different tip diameters in curved root canal models, and to provide reference for the targeted selection of suitable nickel titanium in-

**【收稿日期】** 2023-09-17; **【修回日期】** 2023-11-22

**【基金项目】** 潍坊市科学技术局科技发展项目(2021YX084)

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struments in clinical preparation of curved root canals. **Methods** Three kinds of new nickel titanium files with 20# and 25# (0.20 mm and 0.25 mm) tip diameters were selected, including WKS (20/0.06), WKS (25/0.06), PTG (20/0.07), PTG (25/0.08), HCM (20/0.06), and HCM (25/0.06), each with 20 files. According to the recommended speed and torque of the motor, the anti cycle fatigue performance of the nickel titanium file was tested in 30° and 60° stainless steel root canal models. The time from rotation to fatigue fracture (TTF) of the nickel titanium file was recorded with a camera and timer, and the fragment length (FL) was measured and recorded with a Vernier scale. **Results** Comparison of TTF of the same type of file. ① WKS: the TTF of files with the same tip diameter in a 30° curved root canal was longer than 60° ( $P < 0.05$ ); The TTF of 25# nickel titanium files in the same angle curved root canal was longer than that of 20# nickel titanium files ( $P < 0.05$ ). ② PTG: the 20# nickel titanium files had a TTF longer than 60° in a 30° curved root canal ( $P < 0.05$ ), while the 25# nickel titanium files had no statistically significant difference in TTF between the 30° curved root canal and 60° curved root canal ( $P > 0.05$ ); In a 30° curved root canal, the TTF of 20# nickel titanium files was longer than that of 25# nickel titanium files ( $P < 0.05$ ). In a 60° curved root canal, there were no statistically significant difference between the TTF of 20# nickel titanium files and 25# nickel titanium files ( $P > 0.05$ ). ③ HCM: the TTF of files with the same tip diameter in a 30° curved root canal was longer than 60° ( $P < 0.05$ ); The TTF of 20# nickel titanium files in the same angle curved root canal is longer than that of 25# nickel titanium filea. Comparison of TTF of different files: in a 30° curved root canal, there was no statistically significant difference in TTF among the three types of 20# nickel titanium files ( $P > 0.05$ ). The TTF of 25# WKS was longer than that of other files ( $P < 0.05$ ); In a 60 ° curved root canal, the TTF of 20# HCM was longer than other files with the same tip diameter ( $P < 0.05$ ), and the TTF of 25# WKS was longer than HCM with the same tip diameter ( $P < 0.05$ ). The FL of 20# PTG, 25# PTG, and 20# HCM in the 30° curved root canal model is significantly longer than that of 60° ( $P < 0.05$ ), while there is no statistical difference in FL among 20# WKS, 25# WKS, and 25# HCM in the 30° and 60° curved root canal models. **Conclusion** The anti cyclic fatigue performance of WKS is significantly superior to PTG and HCM in a 30° curved root canal. In a 60° curved root canal, 20# HCM had a significant advantage in terms of anti cyclic fatigue performance compared to other files, while only 25# WKS had a significant advantage in anti cyclic fatigue performance compared to HCM.

**【Key words】** nickel titanium instruments; anti cyclic fatigue; heat treatment; curvature; curved root canals; instrument separation; Woride KS; Protape Gold; Hyflex CM

**J Prev Treat Stomatol Dis, 2024, 32(2): 101-107.**

**【Competing interests】** The authors declare no competing interests.

This study was supported by Weifang Science and Technology Bureau Science and Technology Development Project (No. 2021YX084).

镍钛器械较传统不锈钢器械能更高效完善地预备弯曲根管,逐步成为临幊上根管治疗的主流选择<sup>[1-2]</sup>。但镍钛器械在术中发生折断的概率较高<sup>[3]</sup>,循环疲劳是造成镍钛器械意外折断的主要原因<sup>[4]</sup>。循环疲劳是因重复的压缩和拉伸应力引起的增量裂纹扩展导致的器械断裂<sup>[5]</sup>。在弯曲根管中,急剧的角度变化会增加镍钛器械受到的应力<sup>[6]</sup>,影响镍钛器械的循环疲劳效应。为了提高镍钛锉的抗循环疲劳性能,热处理工艺是常用的方法之一<sup>[7]</sup>。传统的镍钛合金器械在室温和体温下通常存在于奥氏体相中<sup>[8]</sup>,较高的硬度及较低的抗疲劳能力限制了其在重度弯曲根管中的使用,而热处理工艺通过影响镍钛合金相变温度能产生更稳定的晶体结构增加镍钛锉循环疲劳时的耐受性<sup>[9]</sup>,现国内外已成功研制出多种工艺应用于近年

新型热处理型镍钛锉的制作,如国产CM Wire工艺制作的Woride KS(WKS)、Gold Wire工艺制作的Protape Gold(PTG)以及进口CM Wire工艺制作的Hyflex CM(HCM)。已有研究证明,CM Wire制造的HCM表现出比传统镍钛制造的Hyflex NT(HNT)更好的循环疲劳折断圈数<sup>[10]</sup>;PTG比前代材料Protape Next及Protape Universal(PTU)的性能更优异<sup>[11-12]</sup>。本研究旨在分析WKS、PTG和HCM两种尖端直径20#、25#(0.20mm、0.25mm),在不同弯曲角度(30°、60°)的根管中抗循环疲劳性能的差异,为治疗弯曲根管时根管预备器械的选择提供参考。

## 1 材料与方法

### 1.1 主要仪器和材料

WKS(20/0.06、25/0.06,批号:221220,山东欧力



德医疗器械有限公司,中国);PTG(20/0.07,25/0.08,批号:1764177,登士柏西诺德公司,美国);HCM(20/0.06、25/0.06,批号:K83414,康特公司,瑞士);EDTA(朗力生物医药武汉有限公司,中国);光学显微镜(AO-HD228S,深圳市奥斯微光学仪器有限公司,中国);Denjoy扭矩控制马达(DY220604,长沙得悦科技发展有限公司,中国);6:1减速手机(DY220604,长沙得悦科技发展有限公司,中国);数码相机(Olympus EosII,奥林巴斯株式会社,日本)。

## 1.2 实验装置

循环疲劳实验装置根据Keleş等<sup>[13]</sup>改良制作了模型,其由两层组合而成,层间采用可拆卸螺丝固定。上层为一块透明的有机玻璃板,能够直观地观察器械的折断情况;下层为一块耐磨的不锈钢金属板,模拟根管的总长度为19 mm,弯曲点以上的根管内径为1.5 mm,弯曲点以下的内径为0.7 mm,曲率半径为5 mm,弯曲角度分别为30°和60°,弯曲中心位于距模拟根管的末端5 mm处,见图1。



The cyclic fatigue experimental device is equipped with a simulated root canal with a length of 19 mm and a curvature radius of 5 mm. The angle of group A is 30°, and the angle of group B is 60°. The inner diameter of the root canal above the bending point is 1.5 mm, and the inner diameter below the bending point is 0.7 mm. The bending center is located 5 mm from the end of the simulated root canal.

Figure 1 Cyclic fatigue experimental device

图1 循环疲劳实验装置

## 1.3 实验分组

根据镍钛锉的种类及不同尖端直径将实验分为6组,即WKS 20组(20/0.06)、WKS 25组(25/0.06)、PTG 20组(20/0.07)、PTG 25组(25/0.08)、HCM 20组(20/0.06)、HCM 25组(25/0.06),每组的全新镍钛锉各取20支,长度均为21 mm。研究比较30°及60°弯曲模拟根管中,20#和25#的3种镍钛锉的抗弯曲疲劳性能的差异性。

## 1.4 实验方法

体视显微镜放大40倍下,确认镍钛锉的刃部完整无损。将镍钛锉安装于6:1减速手机上,将手

机连接于Denjoy扭矩控制马达,确定镍钛锉进入根管的长度为19 mm,调整位置与根管中心,固定根管马达及金属模拟根管,数码相机垂直于模拟根管照相。按厂家建议设置转速和扭矩,WKS 20组、25组均设置为转速500 rpm、扭矩2.5 N·cm;PTG 20组设置为转速300 rpm、扭矩1.5 N·cm,PTG 25组设置为转速300 rpm、扭矩2 N·cm;HCM 20组、25组均设置为转速500 rpm、扭矩2.5 N·cm。

涂布足量的EDTA于金属模拟根管管壁,以减少镍钛锉与模拟金属根管壁之间的摩擦。根据实验分组依次将WKS 20、WKS 25、PTG 20、PTG 25、HCM 20、HCM 25各20支均分在2种角度的根管模型中,即30°及60°弯曲根管模型中每种锉各10支。启动摄像机及马达,同时使用计时器计时,待镍钛锉旋转至折断后,计时及录像停止。折断时间的记录采用0.25倍速放慢录像,由同一人观看3遍,获取从开始旋转到疲劳折断的时间平均值为最终疲劳折断时间(time from rotation to fatigue fracture, TTF),精确到0.01 s;使用游标卡尺测量出镍钛锉折断碎片的长度(fragment length, FL),精确到0.01 mm。

## 1.5 统计学分析

采用SPSS 27.0软件进行统计学分析。各组数据均符合正态分布,以均数±标准差表示,两组间比较采用独立样本t检验;多组间比较采用Kruskal-Wallis H检验,P<0.05为差异有统计学意义。

## 2 结 果

### 2.1 不同根管弯曲角度时镍钛锉的TTF比较

WKS 20组、WKS 25组、PTG 20组、HCM 20组、HCM 25组镍钛锉在30°的弯曲根管模型中,TTF均长于在60°的弯曲根管模型中的TTF( $P < 0.05$ );而PTG 25组在30°及60°的弯曲根管模型中,组间TTF无统计学差异( $P > 0.05$ ,图2)。

### 2.2 不同尖端直径时镍钛锉的TTF比较

在30°的弯曲根管模型中,WKS 20组镍钛锉的TTF短于WKS 25组,PTG 20组及HCM 20组的TTF均分别长于PTG 25组及HCM 25组( $P < 0.05$ )。在60°的弯曲根管模型中,WKS 20组镍钛锉的TTF短于WKS 25组,HCM 20组的TTF长于HCM 25组( $P < 0.05$ ),而PTG 20组和PTG 25组间无统计学差异( $P > 0.05$ ,图3)。

### 2.3 不同工艺时镍钛锉的TTF比较

在30°的弯曲根管模型中,WKS 20组、PTG 20

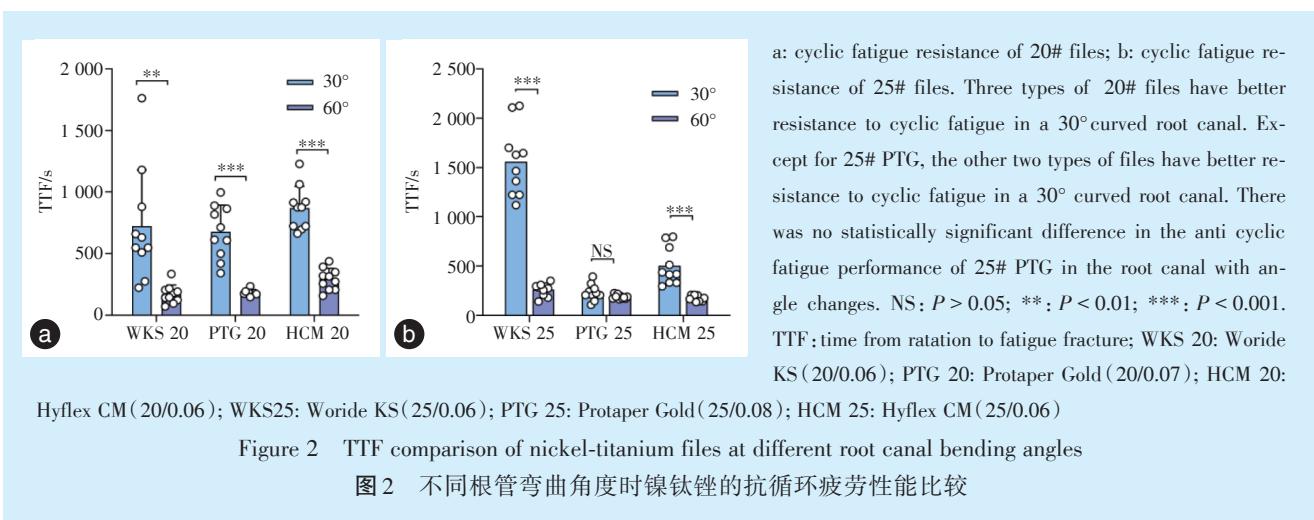


Figure 2 TTF comparison of nickel-titanium files at different root canal bending angles

图2 不同根管弯曲角度时镍钛锉的抗循环疲劳性能比较

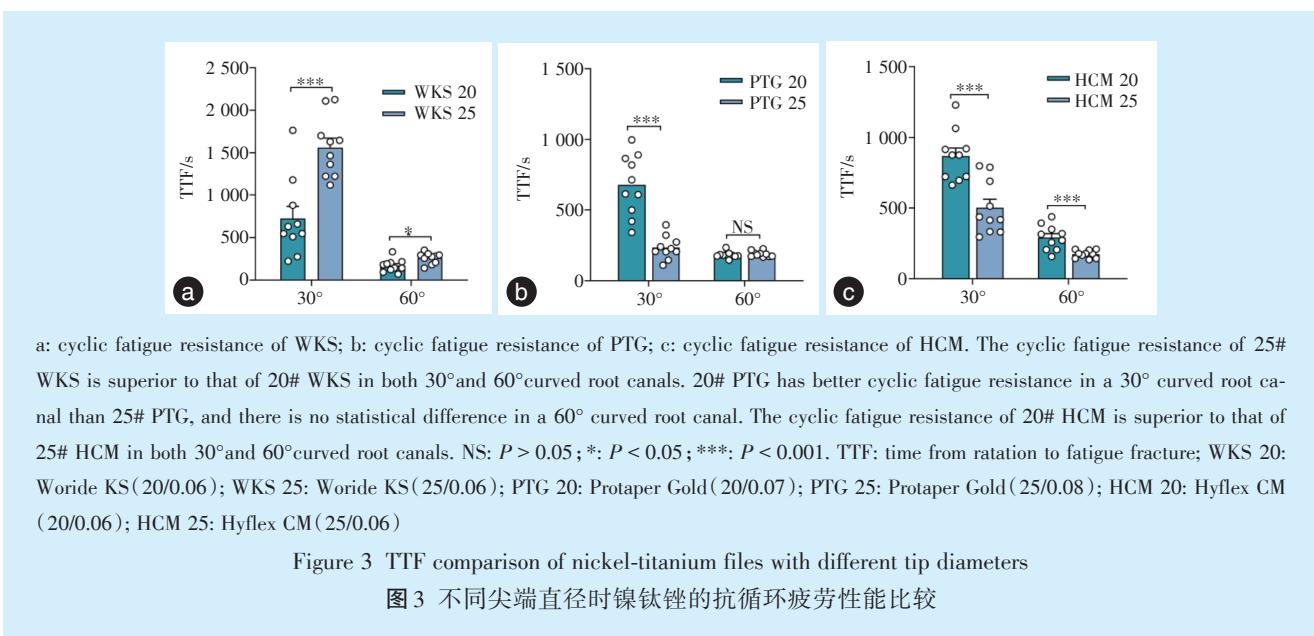


Figure 3 TTF comparison of nickel-titanium files with different tip diameters

图3 不同尖端直径时镍钛锉的抗循环疲劳性能比较

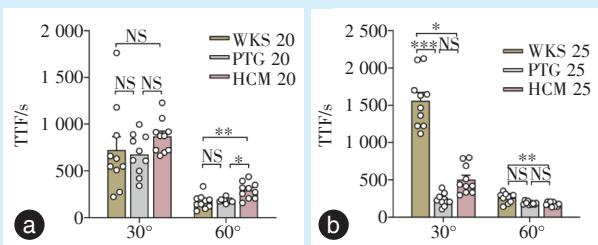
组及 HCM 20 组间 TTF 差异无统计学意义 ( $P > 0.05$ )；WKS 25 组镍钛锉的 TTF 明显长于 PTG 25 组及 HCM 25 组 ( $P < 0.05$ )，而 PTG 25 组与 HCM 25 组间无统计学差异 ( $P > 0.05$ )。在 60° 的弯曲根管模型中，HCM 20 组镍钛锉的 TTF 最长 ( $P < 0.05$ )，而 WKS 20 组及 PTG 20 组间无统计学差异 ( $P > 0.05$ )；WKS 25 组镍钛锉的 TTF 长于 HCM 25 组 ( $P < 0.05$ )，但 WKS 25 组与 PTG 25 组间，PTG 25 组与 HCM 25 组间无统计学差异 ( $P > 0.05$ ，图 4)。

#### 2.4 各组镍钛锉的折断碎片的长度

PTG 20、PTG 25、HCM 20 在 30° 的弯曲根管模型中 FL 长于 60° ( $P < 0.05$ )，WKS 20、WKS 25、HCM 25 在 30° 及 60° 的弯曲根管模型中 FL 无统计学差异 ( $P > 0.05$ ，表 1)。

### 3 讨论

器械分离是根管治疗过程中亟待解决的一个并发症<sup>[14]</sup>。许多因素都可能影响到镍钛锉的抗循环疲劳性能，比如根管角度的变化、器械的尖端直径、热处理工艺、横截面设计、直径、螺距、锥度等<sup>[15-18]</sup>。为降低牙髓疾病治疗过程中镍钛锉的断裂风险，本研究量化分析了弯曲根管角度、锉的尖端直径以及加工工艺对 WKS、PTG 及 HCM 机用镍钛器械的疲劳寿命的影响。天然牙根管的曲率角、半径、根尖直径、横截面和硬度等多种变量的存在使其无法成为理想的研究模型，因此，镍钛锉的测试循环疲劳性能多采用体外模拟弯曲根管研究。循环疲劳试验可以静态或动态进行<sup>[19]</sup>。有研究表明，动态循环疲劳试验装置在模拟临床环境



that of HCM. NS:  $P > 0.05$ ; \*:  $P < 0.05$ ; \*\*:  $P < 0.01$ ; \*\*\*:  $P < 0.001$ . TTF: time from rotation to fatigue fracture; WKS 20: Woride KS (20/0.06); PTG 20: Protaper Gold (20/0.07); HCM 20: Hyflex CM (20/0.06); WKS 25: Woride KS (25/0.06); PTG 25: Protaper Gold (25/0.08); HCM 25: Hyflex CM (25/0.06)

Figure 4 TTF comparison of nickel-titanium files in different technological requirements

图4 不同工艺镍钛锉的抗循环疲劳性能比较

表1 不同根管弯曲角度镍钛锉的FL比较

Table 1 FL comparison of nickel titanium files with different canal curvatures  $\bar{x} \pm s, n=10$

Groups	FL of 30°canal curvature/mm	FL of 60°canal curvature/mm	$t$	$P$
WKS 20	$5.36 \pm 0.31$	$5.58 \pm 0.61$	-1.008	0.327
WKS 25	$5.04 \pm 0.22$	$4.79 \pm 0.71$	1.063	0.311
PTG 20	$5.48 \pm 0.19$	$4.23 \pm 0.32$	10.636	< 0.001
PTG 25	$4.90 \pm 0.13$	$3.35 \pm 0.24$	17.723	< 0.001
HCM 20	$5.04 \pm 0.25$	$4.37 \pm 0.23$	6.389	< 0.001
HCM 25	$5.09 \pm 0.30$	$4.73 \pm 0.78$	1.369	0.188

FL: fragment length; WKS 20: Woride KS (20/0.06); WKS 25: Woride KS (25/0.06); PTG 20: Protaper Gold (20/0.07); PTG 25: Protaper Gold (25/0.08); HCM 20: Hyflex CM (20/0.06); HCM 25: Hyflex CM (25/0.06)

时效果不好,但在静态测试中,仪器在人工根管内以固定长度旋转,不进行轴向运动<sup>[20]</sup>。故本研究采用了静态实验装置,且选用了定制的不锈钢材料,以保证试验条件的可重复性。本实验中所用的模拟根管将弯曲点以下的根管内径缩窄至镍钛锉进入模拟根管的弯曲段时恰好能自由旋转,使器械在根管内的弯曲弧度与模拟根管更贴合,能较真实客观地反映测试器械的抗循环疲劳性能。

根管预备的成功取决于根管的弯曲角度和半径。研究表明,如果根管弯曲角度超过30°,在根管预备过程中更有可能发生并发症<sup>[21]</sup>,而5 mm的曲率半径是在根尖曲率上观察到的常见值<sup>[22]</sup>。因此本研究选用了30°和60°作为模拟根管的弯曲角度,据此曲率半径设计了根管模型,更好地模拟临床环境。20#和25#的镍钛根管锉是临床中常用的型号,据此设计了实验分组;选用了推荐使用的转

a: cyclic fatigue resistance of three kinds of 20# files; b: cyclic fatigue resistance of three kinds of 25# files. In the 30° curved root canal, there is no significant difference between the three types of 20# files, but in the 60° curved root canal, 20# HCM has a significant advantage in terms of cyclic fatigue resistance among the three types of files. 25# WKS has a significant advantage in the anti cyclic fatigue performance of the 30° curved root canal compared to three types of files, and the anti cyclic fatigue performance of the 60° curved root canal is better than

that of HCM. NS:  $P > 0.05$ ; \*:  $P < 0.05$ ; \*\*:  $P < 0.01$ ; \*\*\*:  $P < 0.001$ .

速和扭矩参数,更好地贴近镍钛锉临床中实际使用上的抗循环疲劳效果,避免了自定义设置转速和扭矩导致的人为误差。

本研究结果显示,当根管角度变化时,WKS、HCM 及 20#PTG 的抗循环疲劳性能随着根管角度的增大而降低,弯曲根管的角度越大,曲线越陡峭,即根管角度变化会影响镍钛锉的抗循环疲劳性能,与 Pedullà 等<sup>[23]</sup>研究结果相似。当镍钛锉的尖端直径变化时,HCM 的抗循环疲劳性能在30°及60°弯曲模型根管中随着锉的尖端直径的增大而降低,而同样条件下,WKS 的抗循环疲劳性能在30°及60°弯曲模型根管中随着锉的尖端直径的增大而提高。PTG 在30°的弯曲模型根管中抗循环疲劳性能随着锉的尖端直径的增大而降低,但在60°的弯曲根管模型中两者无统计学差异。Fukumori 等<sup>[24]</sup>发现,锉的尖端直径越大,其抗循环疲劳性能越差;但 Thu 等<sup>[25]</sup>研究结果与此结论相异。这可能与锉的加工工艺不同有关,WKS 和 HCM 由 CM-Wire 热处理工艺制成,与 M-Wire 和其他传统镍钛合金仪器相比,CM-Wire 具有更高的灵活性及抗疲劳性<sup>[26]</sup>。而 PTG 的设计与传统镍钛金属制成的 Protaper Universal 的理念完全相同,其使用 M-Wire 为基础制造。三者的表面处理工艺不同,WKS 外观为铂金色的涂层,而 HCM 外观为彩色的涂层,PTG 外观为金色的涂层,工艺参数上的差异可能对锉的抗循环疲劳性能造成影响。

在不同工艺的镍钛锉中,20#的 WKS、PTG、HCM 在30°弯曲模拟根管中3种锉之间无显著差异,但在60°弯曲模拟根管中20#HCM 的抗循环疲劳性能在三者之间有显著优势。即在弯曲角度更



大的模拟根管中,锉的抗循环疲劳性能差异越明显。而20#HCM较好的抗循环疲劳性能可能是受生产工艺的影响。除了不同工艺的影响外,WKS及HCM镍钛锉的横截面形状为正三角形,PTG镍钛锉的横截面为正方形,三角形几何结构比方形截面具有更好的抗疲劳性能<sup>[27]</sup>,横截面设计也影响了三者之间的抗循环疲劳性能。当镍钛锉的尖端直径增大时,25#WKS在30°弯曲模拟根管的抗循环疲劳性能在3种锉之间有显著优势且在60°弯曲模拟根管时的抗循环疲劳性能优于HCM。这可能与锉的合金种类不同有关,WKS在重度弯曲根管中有着更好的弹性和柔韧性,使25#WKS的抗循环疲劳性能比20#时更优越。而25#PTG在30°弯曲模拟根管的抗循环疲劳性能与HCM无显著差异,在60°弯曲模拟根管的抗循环疲劳性能与WKS、HCM无显著差异。这可能与PTG为变锥度根管器械,在最大曲率点时2种锉的横截面大小相同有关<sup>[28]</sup>。

本研究表明25#WKS比PTG、HCM的抗循环疲劳性能好。WKS镍钛锉是采用碳氧含量低的高纯镍钛制作的锉,有一定的可预弯性、超柔韧性及热激活记忆性,其螺纹从锉尖开始逐步拉长,尖端为无切削功能的无刃圆形的安全导向尖,独特的三角形横截面,三个锋利的切削刃,大而深的容屑空间,这些特性较好地提高了WKS镍钛锉的抗循环疲劳性能。但同时,WKS镍钛锉的抗循环疲劳性能不够稳定,这可能与镍钛合金的机械性能受成分、杂质、温度、表面加工、几何参数等因素的影响有关<sup>[29-31]</sup>。

同种锉折断端的平均长度在不同弯曲角度的模型中存在差异,可能是随着弯曲严重程度和突然性的增加,器械上的应变及其对牙本质壁的压力也会增加,使器械在与管壁接合时的最大弯曲点不同。在弯曲根管中的牙体预备是困难的,并且所有的预备技术都有使预备好的根管偏离原始轴的趋势,分析器械断端长度的差异便于了解每种锉发生循环疲劳时薄弱点的位置,较合适的断端长度可以更容易、更方便地取出。

综上,根管的弯曲角度、镍钛锉尖端直径的变化,以及不同加工工艺均会对镍钛锉的抗循环疲劳性能产生影响。本研究中,除25#PTG外,同种锉在根管弯曲角度较小时,有着更好的抗循环疲劳性能;30°弯曲根管中,25#WKS抗疲劳循环性能显著优于尖端同直径的HCM及PTG,但在60°的弯

曲根管中,20#HCM优于尖端同直径的其他锉,25#WKS则优于尖端同直径的HCM。该结果可指导临床治疗不同程度弯曲根管时选择相应的镍钛锉,但仍需要更多的体内研究来进一步验证。

**【Author contributions】** Wang YX designed the study, performed the experiments and wrote the article. Jiao RT, Zhao Y, Wang TQ participated in experimental design and assisted in completing the experiment. Liang GZ provided experimental guidance and revised the article. All authors read and approved the final manuscript as submitted.

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