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# An in vitro assessment of the physical properties of novel Hyflex nickel-titanium rotary instruments

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#### **Abstract**

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Aim To determine several properties including torsional and fatigue limits, as well as torque during canal preparation, of Hyflex, a rotary instrument manufactured from so-called controlled memory nickel-titanium alloy. **Methodology** The instruments were tested in vitro using a special torque bench that permits both stationary torque tests according to ISO3630-1 and fatigue limit determination, as well as measurement of torque (in Ncm) and apical force (in N) during canal preparation. Fatigue limit (in numbers of cycles to failure) was determined in a 90°, 5 mm radius blockand-rod assembly. Simulated canals in plastic blocks were prepared using both a manufacturer-recommended single-length technique as well as a generic crown-down approach. ANOVA with Bonferroni post hoc procedures was used for statistical analysis.

**Results** Torque at failure ranged from 0.47 to 1.38 Ncm, with significant differences between instrument sizes (P < 0.0001). Fatigue life ranged from 260 to 2565, with the shortest and longest lifespan for instruments size 20, .04 taper and size 25, .08 taper, respectively. Torque during canal preparation was significantly higher for small instruments used in the single-length technique but lower for the size 40, .04 taper, compared to a crown-down approach. No instrument fractured; 82% of the instruments used were plastically deformed; however, only 37% of these remained deformed after a sterilization cycle.

**Conclusions** Hyflex rotary instruments are bendable and flexible and have similar torsional resistance compared to instruments made of conventional NiTi. Fatigue resistance is much higher, and torque during preparation is less, compared to other rotary instruments tested previously under similar conditions.

**Keywords:** fatigue, force, Hyflex, torque.

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#### Introduction

Rotary canal preparation with various nickel–titanium (NiTi) instruments has been shown to be effective and generally safe (Peters 2004). However, there are reports of an increased rate of instrument fractures, more specifically fatigue failure (Cheung et al. 2005).

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It is believed that fatigue resistance of NiTi is because of the so-called pseudoelasticity associated with a stress-induced phase transformation from austenitic to a martensitic lattice. This transformation is reversed when stress subsides and the material springs back to its original shape (shape memory) (Duerig *et al.* 1996, Otsuka & Ren 2005).

The fabrication process from raw wires to the production of a finished NiTi rotary instrument involves several steps, such as cold working (e.g. wire pulling and grinding) (Thompson 2000) and a series of annealing (heating) steps to desirable acceptable material properties (Ebihara *et al.* 2011). Indeed, it has been

demonstrated that without adequate heat treatment, cold working conditions will result in a loss of pseudoelasticity (Zinelis *et al.* 2010). On the other hand, certain proprietary heat treatment sequences may enhance fatigue resistance of NiTi alloy (Alapati *et al.* 2009) and the finished instrument (Gao *et al.* 2011).

Another recent development is the fabrication of instruments with shape memory (e.g. Coltene Hyflex CM; Coltene Whaledent, Cuyahoga Falls, OH, USA). The manufacturer claims that these instruments are up to 300% more fatigue-resistant have no rebound and regain their shape after sterilization (ColteneEndo 2012c).

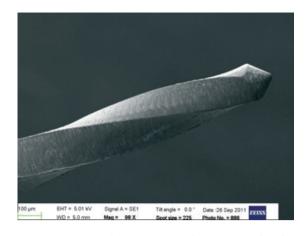
Other manufacturers market similar rotary instruments (e.g. Typhoon; Clinician's Choice Dental Products, Milford, CT, USA), and preliminary data are available for those instruments (Shen et al. 2011a,b, 2012). Specifically, Typhoon rotary instruments were characterized by an austenitic finish temperature of approximately 55 °C, indicating that at body temperature, the instrument would contain a significant proportion of martensitic alloy (Shen et al. 2011b). Instruments in the martensitic phase can be easily deformed and will recover their shape when heated beyond the transformation temperature. This is the metallurgical basis for the shape recovery during sterilization; therefore, it can be inferred that Hyflex instruments have similar metallurgical characteristics compared to Typhoon counterparts.

However, little is known about the optimal working conditions and physical properties of Hyflex rotary instruments (Fig. 1). Recently, Hyflex size 26, .06 taper instruments were found to be significantly more flexible compared to ProFile (Dentsply Tulsa Dental, Tulsa, OK, USA), Hero (MicroMega, Besançon, France) and Endo-Sequence (Brasseler, Savannah, GA, USA) (Testarelli et al. 2011).

Several important physical properties and shaping behaviour of Hyflex instruments have not been tested independently. Therefore, the aims of this study are to determine the physical parameters (torque, force, fatigue limit) of these new NiTi rotary files using a custom torque-testing platform (Peters & Barbakow 2002).

#### **Materials and methods**

A torque-testing device that has been described in detail previously (Peters & Barbakow 2002, Hübscher *et al.* 2003, Ullmann & Peters 2005) was used for the



**Figure 1** Scanning electron micrograph of an unused Hyflex rotary instrument (EVO-50; Zeiss, Jena, Germany). Note the rounded tip and the striations indicating a conventional grinding production process.

experiments. In brief, tests according to ISO 3630-1A were performed by securing the shank of Hyflex rotary instruments size 25, .08 taper, size 20, .06 taper as well as size 20, .04 taper to size 40, .04 taper into a holder and clamping the tip at D3 into a soft brass chuck. Rotating the file at 2 rpm, torque and angle of rotation at failure were determined. The torque bench was then reconfigured to perform cyclic fatigue tests. Rotating at 500 rpm around a curve with 90° and 5 mm radius in a tempered steel rod-and-block assembly, time to fracture was determined to the nearest second. The length of the smaller file fragment was determined with a calliper.

The bench was then reconfigured to determine torque and force during canal preparation. For this, plastic blocks with simulated root canals (A 0177; Dentsply Maillefer, Ballaigues, Switzerland) were secured into a rigid holder that was attached to a strain gauge, which was connected to a pre-amplifier (A&D 30; Orientec, Tokyo, Japan). The holder was constructed in a way to allow lateral movement to adjust for various canal orifice positions. A torque sensor (MTTRA 2; with amplifier Microtest, both Microtec Systems, Villingen, Germany) and a motor (Type ZSS; Phytron, Gröbenzell, Germany) were mounted on a stable metal platform, which moved along a lowfriction guide rail for a width of approximately 5 cm. The movement of this platform was manually controlled. A linear potentiometer (Lp-100; Midori, Osaka, Japan) was attached to the sliding platform to record linear movements. Two operators were specifically trained in the use of the torque platform and with the

Hyflex instruments and the experiment supervised by an experienced endodontist.

For simulated clinical use, the plastic blocks with a standardized 16.5-mm-long curved canal were initially instrumented by one operator with a K-file size 10 to confirm a glide path and to define Working Length (WL) (set at 16 mm). Canals (n = 10 each) were then prepared with two different sequences of Hyflex in the torque bench at 500 rpm, with the axial feed set to hand mode. In group I, the sequence originally recommended by the manufacturer was followed. In detail, a glide path was prepared with K-files to an apical size 20. Then, HyFlex size 25, .08 taper (just short of the curve), size 20, .04 taper (to WL as all following), size 25, .04 taper, size 20, .06 taper, size 30, .04 taper and size 40, .04 taper were used. In group II, the instrumentation sequence incorporated a crowndown approach and was as follows: size 25, .08 (to just short of the curve), K-file size 15 to WL to prepare a glide path, size 40, .04 taper to WL -3 mm, size 30, .04 taper to WL -2 mm, size 25, .04 taper to WL -1 mm, size 20, .04 taper to WL and then size 25, .04 taper and size 30, .04 taper to WL. The size 20, .06 taper was not used in technique II because pilot trials had determined that this size did not improve the shaping results. Moreover, apical enlargement was limited in technique II to a size 30, .04 taper for the same reason.

Each rotary instrument in both techniques was used to instrument two simulated canals in plastic blocks; canals were initially lubricated with liquid soap and irrigated with tap water after each rotary.

Prior to each use and upon completion of simulated shaping procedures, Hyflex instruments were inspected for plastic deformation, as recommended in the directions for use (ColteneEndo 2012b). After the experiment, all instruments were autoclaved at  $121^{\circ}$  and again inspected.

Data for torque, force and insertion depth were acquired from the sensors via three analogue channels using a 12-bit interface (PCI-MIO-16XE; National Instruments, Austin, TX, USA) using the custom-made Endotest software package (Peters & Barbakow 2002). Data were digitized at 100 Hz; variables recorded during each measurement were registered as Ncm, N and mm, respectively, for torque, force and distance of canal preparation and were stored for subsequent offline analyses. Fatigue life was expressed as number of cycles to failure (NCF). The incidence of instrument breakage or plastic deformation was tabulated. Presence of deformation was assessed visually using the criteria given by the manufacturer (ColteneEndo 2012b).

All data were found to be compatible with normal distributions, and standard deviations of subgroups were similar; therefore, data were expressed as means  $\pm$  standard deviation (SD). Analysis of variance with Bonferroni Dunn's *post hoc* comparisons was used to contrast mean maximum torque and forces during simulated canal shaping as well as canal shaping data. Proportions were statistically analysed using chi-square tests, and a level of P < 0.05 was set to denote significant findings.

#### **Results**

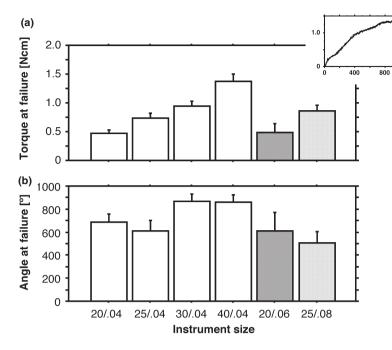
Figure 2 illustrates the data generated according to the relevant norm, ISO 3630-1/ADA No. 28. Torque at failure for Hyflex ranged between  $0.47 \pm 0.05$  and  $1.38 \pm 0.12$  Ncm. Torque at failure increased linearly with tip diameter for the .04 taper, and there were significant differences between each of those sizes (P < 0.0001, Fig. 2a). In addition, torque values at a twist angle of  $45^\circ$  were determined and are shown in Table 1. These torque values ranged between 0.09 and 0.25 Ncm.

Angles of rotation at failure are depicted in Fig. 2b, with a range of 860–505°. The highest values were found for size 30, .04 taper and size 40, .04 taper and the lowest value for size 25, .08 taper. There was no obvious correlation between instrument size and angle of rotation at failure (Fig. 2b).

Fatigue lifespans were determined as numbers of rotations until fracture, around a 90°, 5 mm radius curve, and are summarized in Table 2, along with the length of the small fragments. They ranged from 260 to 2565 for instruments size 25, .08 taper and size 20, .04 taper, respectively. The size 20, .04 taper rotary instruments had significantly greater fatigue life compared to all larger sizes (P < 0.0001). Fragment lengths were longest for size 25, .04 taper (7.41  $\pm$  0.43 mm) and shortest for size 25, .08 (4.08  $\pm$  0.36 mm). There was a significant (P < 0.0001) positive correlation between fragment length and fatigue lifespan ( $r^2 = 0.76$ ).

Torque and force values obtained during simulated canal preparation varied between the instrumentation sequences and amongst the rotary sizes (Fig. 3). Torque overall was somewhat higher for the technique recommended by the manufacturer, compared to a crowndown approach (Fig. 3a). However, this difference was not statistically significant.

Force was significantly (P < 0.001) higher for the smaller instruments used in the recommended technique but significantly lower (P < 0.0001) for the size



**Figure 2** Bar diagrams of means ( $\pm$ SD) for torque (a) and angle at failure (b), determined according to ISO3630-1 (n=10 each). All torque means were significantly different from each other (P < 0.001), except size 20, .04 taper vs. size 20, .06 taper and size 30, .04 taper and size 25, .08 taper. Inset in (a) shows a typical original record for a size 40, .04 taper Hyflex instrument.

Table 1 Mean torque (±SD) values for Hyflex rotary instruments in a device similar to ISO3630-1 at a twist angle of 45° (n = 10)

Instrument	20, .04	25, .04	30, .04	40, .04	20, .06	25, .08
Torque (Ncm)	0.09 ± 0.04	0.17 ± 0.05	0.18 ± 0.04	0.25 ± 0.05	0.17 ± 0.06	0.23 ± 0.5
Significance*	abcde	af	b	cfg	dg	е

<sup>\*</sup>Significantly different values are indicated by the same letter (P < 0.003).

**Table 2** Mean fatigue life ( $\pm$ SD), expressed as numbers of cycle to failure (NCF), for Hyflex rotary instruments of various sizes rotating around a 90° curvature with 5-mm radius (n=10)

Instrument	20, .04	25, .04	30, .04	40, .04	20, .06	25, .08
Fatigue life (NCF)	2565 ± 1069	1572 ± 330	882 ± 161	676 ± 351	1187 ± 478	260 ± 108
Significance*	abcde	af	b	cfg	dg	е
Fragment length (mm)	$7.54 \pm 0.26$	$7.41 \pm 0.43$	$5.84 \pm 0.80$	5.26 ± 1.33	$5.89 \pm 1.05$	$4.08 \pm 0.36$
Significance*	abcd	efgh	aei	bfj	cgk	dhijk

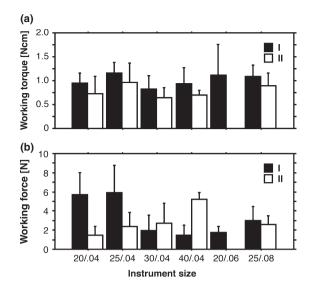
<sup>\*</sup>Significantly different values are indicated by the same letter (P < 0.003).

40, .04 taper (Fig. 3b). Torque values for the latter were not different, as were values for torque and force regarding the size 25, .08 taper. There was no difference in either torque or force when new instruments were compared with those that had been used in one plastic block before.

There were no instrument fractures; however, there were 49 plastically deformed instruments out of a total of 60 used under these experimental conditions. Table 3 provides the incidences for individual instrument sizes; autoclaving removed visible deformation in 63% of the cases.

#### **Discussion**

The aim of this study was to provide *in vitro* data that could guide the clinical use of Hyflex rotary instruments manufactured from a novel controlled memory alloy. Specifically, standard parameter such as torque at failure and fatigue limit was measured in parallel to simulated clinical conditions. There is, at this moment, only limited information available for this particular instrument (Testarelli *et al.* 2011); however, other prototype instruments manufactured from similar alloy have also been investigated recently (Shen *et al.* 



**Figure 3** Bar diagrams for mean ( $\pm$ SD) torque (a) and force (b) during preparation of simulated root canals in plastic blocks (n=10). Preparation was done in the manufacturer-recommended sequence (I, filled bars) and in a crown-down sequence (II, open bars). Note that the instrument size 20, .06 taper was not used in sequence II.

**Table 3** Incidence of plastic deformation and response to autoclaving

Instrument	20, .04	25, .04	30, .04	40, .04	20, .06	25, .08
Deformed during use	7	9	10	10	5	8
Remained deformed	5	5	4	2	0	2

2011a,b, 2012). The instruments investigated were made from a specific nickel–titanium (NiTi) alloy that has been claimed to have a lower per cent in weight of nickel (52%) (Testarelli *et al.* 2011). Earlier data from Zinelis *et al.* (2010) referred to K-files with the same name and perhaps the same manufacturing process. Reportedly, a specific sequence of heat treatments is involved in this manufacturing process leading to a significantly more flexible instrument, measured in a standard ISO 3630-1 bending test (Testarelli *et al.* 2011).

The basis for nickel–titanium pseudoelasticity, also known as superelasticity, lies in the transition between austenitic and martensitic crystal lattices (Kuhn *et al.* 2001). This transition is stress- and temperature-dependent and mainly characterized by the so-called austenitic finishing temperature or  $A_f$  (Duerig *et al.* 1996, Duerig 2006). This temperature should be just

below the working conditions to allow for the utilization of the pseudoelasticity; indeed, Miyai  $\it et al.$  (2006) showed  $A_f$  close to body temperature for several NiTi rotary instruments, namely Endowave (FKG Dentaire, La-Chaux-de-Fonds, Switzerland), as well as ProFile and ProTaper (Dentsply Maillefer). The exact temperature associated with  $A_f$  is defined by the temperature history, in other words, dependent on annealing sequences (Miyai  $\it et al.$  2006, Hou  $\it et al.$  2011).

For further and more detailed information on NiTi metallurgy and production processes, the reader is referred to reviews (Thompson 2000, Otsuka & Ren 2005, Gutmann & Gao 2012).

#### Static fracture loads

In the present study, torque at failure was determined according to ISO3630-1, specifically those torque values that were sufficient to break the instrument at D3 when rotated with 2 rpm. An attachment for a universal torque bench was used that has been described earlier for tests of conventional NiTi rotary files (Peters & Barbakow 2002). The values at failure for Hyflex ranged from 0.47 Ncm (for a size 20, .04 taper) to 1.38 Ncm (for size 40, .04 taper); using the same equipment, lower torque values were found for ProFile (Peters & Barbakow 2002) (0.37 Ncm, size 20, .04 taper). Instruments of somewhat different geometry, again tested with the same device, yielded higher values at failure, for example GTX/GT rotary instruments (0.94 Ncm; size 20, .06 taper; Dentsply Tulsa Dental) (Kell et al. 2009), ProTaper F1 (1.38 Ncm; tip size 20, .07 taper; Dentsply Maillefer) (Ullmann & Peters 2005) and Revo-S (0.65 Ncm; size 25, .06 taper; MicroMega) (Basrani et al. 2011). Moreover, the second parameter in stationary fracture tests, angle at failure indicated overall similar values compared to all previously tested instruments of similar geometry. At this point, there are no other published studies describing torsional resistance of Hyflex instruments; however, the tested Hyflex instruments all exceeded the norms for .02 taper hand files given by the governing ISO norm 3630-1.

As an additional parameter, the torque at a rotational angle of 45° was calculated. The rationale behind this was the previously observed biphasic torque increase for conventional NiTi instruments (compare Fig. 5 in Peters & Barbakow 2002). The initial steep phase is believed to be the representative of austenitic elastic behaviour, whilst a second, less steep portion represents the pseudoelastic portion of the stress–strain

curve (Thompson 2000). Hyflex does not show the typical 'spring-back' associated with NiTi wire in the austenitic conformation and may have a significant percentage of martensitic alloy, similar to M-wire (Sportswire, Langley, OK, USA) described earlier (Alapati et al. 2009). Consequently, it was hypothesized that there would be less pronounced biphasic behaviour of the stress–strain curves and perhaps lower torque values at limited deflection. However, as indicated in the insert in Fig. 2, there appears to be a triphasic increase of stress over strain; moreover, the observed torque values at 45° were similar to other instruments tested previously (data not shown).

#### Fatigue lifespan

According to the manufacturer (ColteneEndo 2012c), Hyflex may be up to 300% more fatigue-resistant, compared to other brands of rotary NiTi instruments. Under the conditions of the present study, NCF ranged from 2565 and 260 for the instruments with the smallest and largest diameter, respectively, at the point of highest surface strain in this testing set-up. This point is located under the present geometrical conditions at approximately 4 mm from the tip or D4. The surface strain at that point is in the range of 3.9-6.1%, depending on the nominal instrument size (Bahia & Buono 2005). However, the smaller instruments tested under the present conditions fractured at a significantly further distance from the tip. More research is required to understand the cause for this difference; one reason could be that heat treatment sequences have differential effects on superficial versus deep portions of the alloy.

The same geometrical conditions were present for earlier studies of ProFile .04 (Peters & Barbakow 2002) and also Flexmaster NiTi rotary instruments (VDW, Munich, Germany) (Hübscher et al. 2003). In both studies, instruments made of conventional NiTi alloy had much less fatigue resistance; indeed, similar-sized Flexmaster instruments fractured at about 1/3 of the NCF seen for Hyflex in the present study. ProFile was even less fatigue-resistant compared to Flexmaster (Peters & Barbakow 2002, Bahia & Buono 2005). More recent data on two prototypes manufactured from similar NiTi alloy showed comparable NCF numbers for size 25, .04 taper instruments when tested at comparable surface strain rates (Shen et al. 2011a). Interestingly, the triangular cross-section prototype had significantly less NCF compared to the square counterpart (Shen et al. 2011a). A pilot study for Typhoon instruments with and without proprietary heat treatment using the same experimental set-up as in the present study confirmed the NCF numbers (data not shown) of Shen *et al.* (2011a).

Of note, a fully martensitic instrument would allow only 2–3% recoverable strain, before plastic deformation occurs (Otsuka & Ren 2005). However, fatigue failure under the present experimental conditions was not associated with significant plastic deformation. One possible explanation is that Hyflex is not fully martensitic and can, under fatigue conditions, benefit from pseudoelastic recoverable deformation, which enhances fatigue resistance beyond what the inherent flexibility of the martensitic phase provides (Shen *et al.* 2011b, Testarelli *et al.* 2011).

### Torque and force during simulated canal preparation

The unique torque-testing device used in this study also permits the documentation of conditions during simulated canal preparation, as was performed earlier for conventional NiTi rotary instruments (Peters & Barbakow 2002, Hübscher *et al.* 2003). It had been noted that the amount of torque required to use a more tapered rotary instrument can be compared to fracture torque at D3, a fact also known as safety quotient (Blum *et al.* 2003). Similar to earlier data for instruments of comparable overall geometry (Hübscher *et al.* 2003), it was found that Hyflex sizes 30 and 40 had higher torsional fracture loads than working torque, whilst smaller and more tapered instruments tended to require less torque to break the tip, compared to working torques (compare Figs 2a and 3a).

As a consequence, clinical usage needs to focus on a glide path, so that the tip of a size 20 for example does not engage a relevant proportion of the canal wall. Moreover, the flaring instrument, size 25, .08 taper should not be taken deep into a root canal so as to avoid working the canal wall with the tip.

A comparison of varying tapers in a single-length technique for ProFile rotary instrument had indicated that size 35, .04 taper, in particular was experiencing high torsional load (>3 Ncm). Using intermediate instruments, for example with .06 taper, significantly reduced torsional loads (Schrader & Peters 2005). Moreover, the apical preparation with ProFile .04 to working length created more torque than the crowndown phase (Peters & Barbakow 2002). Finally, similar torsional loads during preparation of extracted teeth were found for FlexMaster used in a crown-down approach, compared to Hyflex (Hübscher *et al.* 2003).

Originally, Hyflex' manufacturer recommended a single-length technique (ColteneEndo 2012b), combined with a coronal flare. Under the conditions of the present experimental conditions, this technique resulted in overall significantly higher torque values compared to a crown-down approach, and perhaps not unexpectedly, higher axial forces for the small instruments going to working length. However, caution needs to be exercised as the crown-down sequence using the torque-testing device was stopped at size 30, .04 taper. Interestingly, the manufacturer has lately added a suggested crown-down sequence to their recommendations (ColteneEndo 2012a).

#### Regeneration of files with heat treatment

The manufacturer of Hyflex instruments states that sterilization will result in the instrument regaining its shape (ColteneEndo 2012c). During preparation of simulated canals, no sterilization was performed as only two canals each were prepared with a given set of instruments. Clinically, a multi-rooted tooth would be expected to be prepared with one set of instruments. However, after conclusion of the study, it was found that a sizeable proportion of Hyflex instruments were plastically deformed (82%). Overall, more than half of those recovered their original shape during a sterilization cycle but in particular the small instruments had often permanent deformation. Obviously, the experimental conditions lead to significant torsional loading; consequently, caution should be exercised to reuse small Hyflex rotary instruments that experience such loading.

#### **Conclusions**

Hyflex rotary instruments are fabricated from NiTi wire that is subjected to a proprietary process. This results in bendable and very flexible rotary instruments that have similar torsional resistance compared to instruments made of conventional NiTi. Fatigue resistance is much higher, and canal preparation ability appears to result in less lower working torque, compared to other rotary instruments tested under similar conditions. Future experiments should include an assessment of canal shaping capacity of Hyflex NiTi instruments.

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