Efficiency of rotary nickel–titanium FlexMaster instruments compared with stainless steel hand K-Flexofile – Part 2. Cleaning effectiveness and instrumentation results in severely curved root canals of extracted teeth

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Abstract

Aim To determine the cleaning effectiveness and the shaping ability of FlexMaster nickel–titanium rotary instruments and stainless steel hand K-Flexofiles during the preparation of curved root canals in extracted human teeth.

Methodology A total of 48 root canals with curvatures ranging between 25° and 35° were divided into two groups of 24 canals. Based on radiographs taken prior to the instrumentation with the initial instrument inserted into the canal, the groups were balanced with respect to the angle and the radius of canal curvature. Canals were prepared by FlexMaster instruments using a crown-down preparation technique or by K-Flexofiles using a reaming working motion up to size 35. After each instrument, the root canals were flushed with 5 mL of a 2.5% NaOCl solution and at the end of instrumentation with 5 mL of NaCl. Using the pre- and post-instrumentation radiographs, straightening of the canal curvatures was determined with a computer image analysis program. After splitting the roots longitudinally, the amount of debris and smear layer were quantified on the basis of a numerical evaluation scale, using a scanning electron microscope.

Results Completely cleaned root canals were not found with any of the two instruments. In general, K-Flexofiles resulted in significantly less debris (P < 0.001) and less smear layer (P < 0.05) than FlexMaster instruments, but these differences were not significant in the apical third of the canals (P > 0.05). FlexMaster instruments maintained the original canal curvature significantly better (P < 0.0001) than K-Flexofiles. No significant differences were detected between the instruments (P > 0.05) for the time taken to prepare the canals.

Conclusions Under the conditions of this study, K-Flexofiles allowed significantly better canal cleaning than FlexMaster instruments. FlexMaster instruments maintained the original curvature significantly better.

Keywords: debris, canal curvature, canal straightening, irrigation, smear layer.

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Introduction
The quality guidelines of the European Society of Endodontology (1994) state that the elimination of residual pulp tissue, the removal of debris and the maintenance of the original canal curvature during enlargement are the main objectives of root-canal instrumentation. Scanning electronic microscopy is useful in examining root-canal cleanliness after preparation with different techniques or instruments. Several studies have concluded that none of the instrumentation techniques or devices completely clean root canals, especially when

Most of these authors also indicate that the cleaning ability of manual root canal instrumentation is superior to automated devices (Mizrahi et al. 1975, Schwarze & Geurtsen 1996, Hülsmann et al. 1997). However, it was recently shown by several investigations that automated devices using rotary nickel–titanium instruments with various tapers led to good instrumentation results, even in severely curved root canals (Thompson & Dummer 1997, Kum et al. 2000). Unfortunately, little is known about the cleaning effectiveness of these systems, but most recently it has been observed that the different rotary nickel–titanium instruments showed inconsistent results (Hülsmann et al. 2000, Schäfer & Zapke 2000).

The aim of this investigation was to compare the cleaning efficacy (residual debris, quality of the smear layer) after preparation of severely curved root canals with rotary nickel–titanium FlexMaster (VDW, Antaeos, Munich, Germany) or with stainless steel hand K-Flexofile (Dentsply Maillefer, Ballaigues, Switzerland). Moreover, another purpose of this study was to assess whether instrumentation had an effect on canal curvature.

Materials and methods

Selection of teeth

A total of 48 extracted human teeth with at least one curved root and curved root canal were selected for this investigation. Coronal access was achieved using diamond burs. Only teeth whose clinical crowns were largely intact, whose root canals were freely accessible with a root-canal instrument size 10 up to the intact root tip, and whose root-canal width near the apex were approximately compatible with size 15 were included. This was checked with silver points sizes 15 and 20 (VDW, Antaeos, Munich, Germany).

Standardized radiographs were taken prior to instrumentation with the initial root-canal instrument of size 15 inserted into the curved canal. The tooth was attached to a Kodak Ultra-speed film (Kodak, Stuttgart, Germany) and was aligned so that the long axis of the root canal was parallel, and as near as possible to the surface of the film. The X-ray tube, and thus the central X-ray beam, was aligned perpendicular to the root canal. The exposure time (0.12 s; 70 kV, 7 mA) was same for all radiographs with a constant source-to-film distance of 50 cm and an object-to-film distance of 5 mm. The films were developed, fixed, and dried in an automatic processor (Dürr-Dental XR 24 Nova, Dürr, Bietigheim-Bissingen, Germany).

The degree and the radius of canal curvature were determined using a computerized digital image processing system (Schäfer et al. in press). Only, teeth whose radii of curvature ranged between 4 and 9 mm and whose angles of curvature ranged between 25° and 35° were included (Table 1). On the basis of the degree and the radius of curvature, the teeth were allocated into two identical groups of 24 teeth. The homogeneity of the two groups with respect to the degree and the radius of curvature was assessed using a t-test (Table 1). At the end of canal preparation, the canal curvatures were re-determined on the basis of a radiograph with the final root-canal instrument inserted into the canal using the same technique (Schäfer et al. in press) in order to compare the initial curvatures with those after instrumentation. Only one canal was instrumented in each tooth.

Table 1 Characteristics of curved root canals* (n = 24 teeth per group)

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Curvature (°)</th>
<th>Radius (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Min</td>
</tr>
<tr>
<td>FlexMaster</td>
<td>3.0 ± 2.87</td>
<td>25.0</td>
</tr>
<tr>
<td>K-Flexofile</td>
<td>2.6 ± 2.24</td>
<td>26.6</td>
</tr>
<tr>
<td>P-value (t-test)</td>
<td>0.854</td>
<td></td>
</tr>
</tbody>
</table>

* n = 24 canals in each group.
**Group A**

FlexMaster: these instruments were set into permanent rotation (250 rpm) with a 8:1 reduction handpiece (Type 5059, Nouvag, Goldach, Switzerland) powered by a torque-limited electric motor (TCM Endo 2, Nouvag, Konstanz, Germany) using torque setting 2, which is stated to be equivalent to a torque limitation of 1.5–1.7 Ncm by the manufacturer. Instrumentation was completed using the crown-down technique according to the manufacturer's instructions using a gentle in-and-out motion. Every instrument was withdrawn when resistance was felt and replaced by the next (smaller) instrument in the sequence. The preparation sequence was the same as described in part 1 of this two-part report (Schäfer & Lohmann 2002):

1. A 0.06 taper size 20 instrument was used to one-half of the working length.
2. A 0.04 taper size 30 instrument was used to one-half to two-thirds of the working length.
3. A 0.04 taper size 25 instrument was used to two-thirds of the working length.
4. A 0.04 taper size 20 instrument was used to the full working length.
5. A 0.02 taper size 25 instrument was used to the full working length.
6. A 0.02 taper size 30 instrument was used to the full working length.
7. A 0.02 taper size 35 instrument was used to the full working length.

Once, the instrument had negotiated to the end of the canal and had rotated freely, it was removed.

**Group B**

K-Flexofile: hand instrumentation with these stainless steel instruments with non-cutting tips was performed using a reaming motion. All canals were sequentially prepared from size 15 up to 35 without pre-bending the instruments, which were used to the full working length.

**Evaluations**

All root-canal preparations were completed by one operator, whilst the scanning electron microscope (SEM) evaluations and the assessment of the canal curvatures prior to and after instrumentation were carried out by a second examiner who was blind with respect of all to the experimental groups.

**Canal cleanliness**

After preparation, all root canals were flushed with sodium chloride and dried with adsorbent paper points. Roots were split longitudinally, prepared for SEM investigation and examined under the SEM (Philips PSEM 500 ×, Eindhoven, the Netherlands) at 20–2500 × magnification.

Separate evaluations were recorded for debris and smear layer. The cleanliness of each root canal was evaluated in three areas (apical, middle, and coronal third of the root) by means of a numerical evaluation scale (Hülsmann et al. 1997). The following scheme was used:

- **Score 1**: clean canal wall, only very few debris particles.
- **Score 2**: few small conglomerations.
- **Score 3**: many conglomerations; less than 50% of the canal wall covered.
- **Score 4**: more than 50% of the canal wall covered.
- **Score 5**: complete or nearly complete covering of the canal wall by debris.

Smear layer (dentine particles, remnants of vital or necrotic pulptissue, bacterial components, and retained irrigant):

- **Score 1**: no smear layer, orifice of dentinal tubules patent.
- **Score 2**: small amount of smear layer, some open dentinal tubules.
- **Score 3**: homogenous smear layer along almost the entire canal wall, only very few open dentinal tubules.
- **Score 4**: the entire root-canal wall covered with a homogenous smear layer, no open dentinal tubules.
- **Score 5**: a thick, homogenous smear layer covering the entire root-canal wall.

The data established for scoring the debris and the smear layer were separately recorded and analyzed statistically. Owing to the ordinal nature of the scores, the data were subjected to the Wilcoxon test ($P < 0.05$).

**Instrumentation results**

Based on the canal curvatures assessed prior to and after the instrumentation, canal strength was determined as the difference between canal curvature prior to and after the instrumentation. The t-test was used for comparison of the two groups. The level of statistical significance was set at $P < 0.05$.

The time for canal preparation was recorded, and the total active instrumentation, instrument changes within the sequence and irrigation was included. The change of working length was determined by subtracting the final length (measured to the nearest 0.5 mm) of each canal after preparation from the
The preparation time and the change of working length were analyzed statistically using the t-test (preparation time) and the Mann–Whitney U-test (change of working distance) at a significance level of $P < 0.05$. The number of fractured and permanently deformed instruments during the enlargement was also recorded.

### Results

During the preparation of the 48 canals, no instruments separated, and only one FlexMaster and one K-Flexofile permanently deformed.

#### Canal cleanliness

The scores for the debris and the smear layer are detailed in Tables 2 and 3. Completely cleaned root canals were not found with any of the two instruments. On average, more effective cleaning was observed in the coronal and the middle thirds of the canals (Fig. 1).

In general, the use of K-Flexofiltes resulted in significantly less debris ($P < 0.001$) (Fig. 2) and less smear layer ($P < 0.05$) compared to the canal preparation with FlexMaster instruments (Tables 2 and 3); these differences were not significant in the apical third.

#### Instrumentation results

The mean time taken to prepare the canals with the two types of instruments is shown in Table 4. There were no statistically significant differences between the two instruments ($P = 0.666$).

All the canals remained patent following instrumentation, thus, none of the canals were blocked with dentine. With both types of instruments, one canal showed overextension of preparation, whereas a loss of working distance was found in two canals prepared with FlexMaster and three canals enlarged with K-Flexofiltes. The mean changes of working length that occurred with the different instruments are listed in Table 4. The differences between the two instrument types were not statistically significant ($P = 0.797$).

### Table 2  Summary of scores for debris

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Coronal third scores</th>
<th>Middle third scores</th>
<th>Apical third scores</th>
<th>Total scores</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>FlexMaster</td>
<td>4 12 7 0 1</td>
<td>3 8 12 0 1</td>
<td>1 3 7 12 1 1 10 27 31 1 3 45 202 4 3 3 1 2 3 0</td>
<td></td>
</tr>
<tr>
<td>K-Flexofile</td>
<td>9 13 2 0 0</td>
<td>11 7 5 1 0 4 13 5 2 0 24 33 12 3 0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$P$-values $P < 0.05$ $P < 0.05$ $P = 0.091$ $P < 0.001$

*a*Listed are the number of canal areas evaluated as scores 1–5 ($n = 24$ teeth per group). Three canal areas (coronal, middle and apical thirds) have been evaluated per tooth, thus resulting in a total of 72 canal areas per group. Score 1 indicates the best and score 5 the worst canal cleanliness.

### Figure 1 Canal wall after preparation with FlexMaster rotary nickel–titanium instruments. (a) Clean canal wall with only very small debris particles in the middle portion of the prepared canal (score 1, original magnification $40 \times$). (b) Apical portion of the canal: Complete or nearly complete covering of the canal wall by debris after preparation (score 5, original magnification $80 \times$).

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517
The mean straightening of the curved canals is shown in Table 5. The use of FlexMaster instruments resulted in significantly less straightening during instrumentation \((P < 0.0001)\) compared to the K-Flexofiles (Fig. 3).

**Discussion**

One of the most important objectives during root-canal instrumentation is the removal of vital pulp tissue, residual necrotic material, infected dentine, and debris in order to eliminate most of the microorganisms from the root-canal system (European Society of Endodontology 1994, American Association of Endodontists 1998). The ability to achieve these objectives was examined in the present investigation on severely curved root canals, involving FlexMaster rotary nickel–titanium instruments and stainless steel hand K-Flexofiles.

The debris were defined as dentine chips, and residual vital or necrotic pulp tissue attached to the root-canal...
wall, which in most cases, is infected (Hülsmann et al. 1997). Thus, the debris might prevent the efficient removal of microorganisms from the root-canal system. The smear layer is a surface film of a thickness of approximately 1–2 μm which remains on the root-canal wall after instrumentation (American Association of Endodontists 1998). No smear layer is found on areas which are not instrumented (West et al. 1994). The smear layer contains dentine particles, residual vital or necrotic pulp tissue, bacterial components as well as retained irritants, and it blocks the openings of the dentinal tubules (West et al. 1994). In this way, a thick and heterogeneous smear layer can prevent the efficient elimination of intracanal microorganisms, and compromise the complete sealing of the root canal (Petschelt et al. 1987, West et al. 1994).

Although it is recommended to use antibacterial irrigants in combination with chelating agents in order to remove debris as well as the inorganic/organic smear layer (West et al. 1994, Hülsmann et al. 1997, Gambarini 1999), sodium hypochlorite alone was used as an irritant, in the present study. Certainly, this solution is still the best available canal irrigant owing to its antibacterial and organic tissue-dissolving properties (Spångberg et al. 1973, Turkun & Çengiz 1997), but it is not possible to remove the smear layer with NaOCl (Yamada et al. 1983). Nevertheless, considering the major objective of the present investigation (to solely to compare the cleaning effectiveness of the two instrumentation techniques under identical conditions), a simple irrigation technique was used, avoiding any associations of different irrigation solutions. Thus, it has to be taken into consideration that the cleaning efficiency of the two instrumentation techniques might be further improved using a combination of NaOCl and EDTA solutions.

In the present study, the cleaning efficacy of two instrumentation methods was examined on the basis of a separate numerical evaluation scheme for debris and smear layer, by means of an SEM evaluation of the coronal, the middle, and the apical portions of the canals (Mizrahi et al. 1975, Bolanos & Jensen 1980, Haikel & Allemann 1988, Hülsmann et al. 1997). In both instrumentation techniques, partially uninstrumented areas with remaining debris were found in all canal sections. Similar finding has also been described by other authors (Bolanos & Jensen 1980, Schwarze & Geurtsen 1996, Hülsmann et al. 1997). Moreover, the present results indicate that on average the apical third of the canals was less clean than the middle and coronal thirds regardless of the instrument used. This observation is also in agreement with other studies (Wu & Wesselink 1995, Hülsmann et al. 1997, Schäfer & Zapke 2000).

In general, the use of stainless steel K-Flexofil files resulted in significantly less remaining debris (Table 2) and a thinner and more homogenous smear layer (Table 3) compared to canal shaping with rotary nickel–titanium FlexMaster instruments. Whilst, these results corroborate a previous report, in which stainless steel hand instruments proved to be superior to Profile rotary nickel–titanium instruments as far as cleaning efficacy is concerned (Schäfer & Zapke 2000), in other studies, no significant differences between the cleaning efficacy of stainless steel hand and rotary nickel–titanium instruments were observed (Bechelli et al. 1999, Hülsmann 2000).

Nevertheless, examination of the scores for remaining debris and smear layer after instrumentation with the two instruments revealed no statistically significant differences between the instruments in the apical third of the canals (Tables 2 and 3). Clinically, this finding may be more important than the significant differences between the two instruments in the amount of debris remaining in the coronal and middle portions of the canals, because the microorganisms which remain in the apical portion of the root canal have been considered the main cause of failure (Nair et al. 1990). Moreover, compared with the results obtained in a previous study under nearly identical conditions, FlexMaster instruments displayed a clearly better debris removal efficiency than the rotary ProFile instruments (Schäfer & Zapke 2000). Obviously, even different rotary nickel–titanium instruments vary in their debris removal efficiency, possibly owing to their flute design (Gambarini 1999, Hülsmann et al. 2000). ProFile instruments have radial lands in contrast to the FlexMaster instruments and may be unable to cut dentine so effectively. This might explain the differences in the cleaning efficiency of these two rotary nickel–titanium instruments. Summarizing these aspects, it is therefore, open to question, whether the differences in the cleaning effectiveness of FlexMaster instruments and K-Flexofile observed in the present study has any clinical significance in terms of successful canal debridement, particularly as the ability of FlexMaster instruments to maintain the original canal curvature was significantly superior compared with that of K-Flexofil files.

The teeth in all experimental groups were balanced with respect to the apical diameter of the root canal. Furthermore, based on the initial radiograph the teeth were also balanced with respect to the angle and the radius of canal curvature. To achieve this a computerized
digital image processing system was used to determine both the angle and the radius of curvature (Schäfer et al. in press). The homogeneity of the two groups with respect to the defined constraints was examined using a t-test. According to the P-values obtained (Table 1), the groups were well-balanced. The curvatures of all root canals ranged between 25° and 35° and the radii ranged between 4.3 mm and 8.5 mm (Table 1). Thus, the curvatures of the human root canals were comparable to those of the simulated canals in resin blocks used in the first part of this two-part report (curvatures: 28° and 35°; radii: 6.5 and 7.5 mm), allowing a comparison of the results obtained in simulated and in human root canals (Schäfer & Lohmann, 2002).

The results of the present study using extracted human teeth confirm the findings obtained in the part 1 of this two-part report after preparation of simulated canals, in which the use of FlexMaster instruments resulted in significantly less canal transportation than K-Flexo¢les. In simulated canals, FlexMaster instruments were significantly faster than K-Flexo¢les. Certainly, FlexMaster instruments needed less time to prepare the root canals of real teeth than K-Flexo¢les, but this difference was not significant, in contrast to the results obtained in simulated canals.

Conclusions

Within the parameters of this study, manual instrumentation using K-Flexo¢les resulted in better canal cleaning than with rotary nickel–titanium FlexMaster instruments. FlexMaster instruments maintained the original curvature significantly better.

References


