

A Prospective Clinical Study of the Efficacy of Hyflex CM Rotary Instruments in an Endodontics Undergraduate Program

SUMMARY

Background/Aim: To investigate the incidence of procedural errors with the use of a novel nickel-titanium rotary system (Hyflex CM, Coltene/Whaledent, Altstätten Switzerland), evaluate the technical quality of root canal treatments and assess a questionnaire completed by the participants themselves in an undergraduate dental clinic between 2014 and 2017 (Department of Endodontology, School of Dentistry, Aristotle University of Thessaloniki). **Material and Methods:** 118 undergraduate students in their first year of clinical practice performed a root canal treatment on a patient's molar (maxillary/mandibular). None of the participants had previous experience in rotary instrumentation. The periapical radiographs were taken with the use of the paralleling technique for standardization and were collected and evaluated by the investigator. After the root canal treatment was performed the students completed a questionnaire in order to evaluate their training on rotary instrumentation. **Results:** The overall incidence of instrument separation, apical perforation, root perforation, straightening and ledges was 0.8%, 4.4%, 2.3%, 5.5% and 29% respectively on root canal level. Ledges were detected more often in mandibular mesiobuccal canals. The frequency of root canals with an 'acceptable' filling was 68.4%, while overfilled and underfilled canals were found to be 8.6% and 16.2% respectively. The response rate was high (94.9%), 35% of the participants encountered no difficulty in the use of rotary instrumentation and 98.2% would use it again. **Conclusions:** The incidence of procedural errors was considerably low and the technical quality of the filled root canals was superior to that of similar studies. The responses of the questionnaire demonstrated a positive attitude toward rotary instrumentation.

Key words: Hyflex CM, Procedural Errors, Technical Quality, Undergraduate Dental Clinic, Questionnaire

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Introduction

The advent of Ni-Ti rotary instrumentation has improved the quality and speed of cleaning and shaping procedures; simultaneously procedural errors such as transportation, ledging, zipping and perforations are decreased^{1,2}. Despite their indisputable advantages, Ni-Ti instruments are still susceptible to separation³. Their widespread use among clinicians and the need to reduce

procedural errors for more predictable results, have led to a rapid development of new endodontic rotary systems while formers are updated at an exponential rate.

Hyflex CM rotary files (Coltene/Whaledent, Altstätten, Switzerland) are manufactured from a novel type of Ni-Ti wire, namely Controlled Memory (CM) wire, which has undergone a unique proprietary thermomechanical processing⁴, that is not disclosed by the manufacturer. These instruments, as stated by the manufacturer, possess a lower percentage in weight of

nickel (52.1 Ni% wt) in comparison to the vast majority of commercially available Ni-Ti rotary instruments (54.2-56.2 Ni% wt)⁵. Due to their special manufacturing process, Hyflex CM files are highly flexible⁶, more resistant to cyclic fatigue^{6,7}, they do not rebound to their original shape⁷ and partially or fully regain their original shape after sterilization^{6,8}. Rotary instrumentation is an integral adjunct to endodontic practice, thus undergraduate programs have gradually included it in their curricula⁹⁻¹¹.

The purpose of this prospective study that was conducted in the Undergraduate Clinic of the Department of Endodontology at the Aristotle University of Thessaloniki, Greece was two-fold. The primary objective was to investigate the frequency of root and apical perforations, ledges, straightening, separated instruments and the quality of root fillings when rotary instrumentation was used for the first time by undergraduate students. The second objective was to gain an insight on the undergraduates' self-assessment concerning the root canal treatment and the evaluation of the rotary experience based on a questionnaire. To the best of our knowledge, there is no published data evaluating the efficacy of Hyflex CM rotary instruments clinically. Specifically, this is the first prospective clinical study to assess the efficacy of Hyflex CM rotary instruments in an endodontics undergraduate program and the first to use a questionnaire completed by the participants themselves to evaluate their training on rotary instrumentation.

Material and Methods

Selection of cases

During three academic years (2014-15, 2015-16, 2016-17), a total of one hundred and eighteen undergraduate students on their first year of clinical practice participated in the study. None of the participants had a previous experience in rotary instrumentation; however all of them had performed two or more root canal treatments on patients with hand instruments. The participants performed a root canal treatment on one molar (maxillary/ mandibular).

Instrumentation technique

The single-length instrumentation sequence of Hyflex CM system (Coltene/Whaledent, Altstätten, Switzerland) was demonstrated to each student on resin blocks by the investigator (ZDT), according to the manufacturer's recommendations. After the access cavity was prepared, the working length was determined with a radiograph and in a few cases with the combination of an electronic apex locator (CanalPro Apex Locator, Coltene/Whaledent, Altstätten, Switzerland) and a radiograph. The canals were negotiated to the working length with stainless steel

K-files up to size 20. The enlargement of the root canals was accomplished with the following order of Hyflex instruments, 25.08, 20.04, 25.04, 20.06 and 30.04. File size 40.04 taper was used only at the distal canals of mandibular molars and at the palatal canals of maxillary molars. All files were used in a slow speed handpiece (CanalPro CL Endodontic Handpiece, Coltene/Whaledent, Altstätten, Switzerland), at a setting and speed recommended by the manufacturer (2.5 Ncm, 500 rpm). As an irrigant between the files and after instrumentation 3% sodium hypochlorite (CanalPro, Coltene/Whaledent, Altstätten, Switzerland) was used. To remove smear layer 17% EDTA solution (CanalPro, Coltene/Whaledent, Altstätten, Switzerland) was applied. The canals were obturated with tapered master cone (0.04) and accessory points, combined with Roeko Seal sealer (Coltene/Whaledent, Altstätten, Switzerland) using the lateral condensation technique. Each file was used at a maximum of three times and was discarded either when it did not regain its form after sterilization or when a distortion or deformation were detected under magnifying loupes 3x. The incidence of each procedural error was calculated on root canal level.

Radiographic evaluation

The periapical radiographs were taken with the use of digital imaging technology (DIGORA® Optime digital imaging plate system, Soredex Tuusula, Finland). In order for the projections to be standardized the paralleling technique was used. Superimposed canals and canal fillings, working length radiographs with incorrect estimation of the working length, missed canals, calcified canals, and cases of radiographs without depiction of the apices were excluded. The data were collected and observed by the investigator.

Detection of procedural errors and evaluation of the technical quality of the root fillings

The criteria for the detection of procedural errors were as follows:

- Separated instruments were diagnosed during the time of the incidence and their location was determined radiographically,
- Ledge formation was diagnosed when the root filling was at least 1mm shorter than the working length and/or deviated from the original canal curvature¹²,
- Apical perforation was diagnosed when the filling material extruded through the apical foramen¹³,
- Root perforation was diagnosed when the filling material extruded in the lateral walls of the root¹⁴,
- Straightening was diagnosed when a deviation from the original canal curvature was evident between the working length and the cone-fit radiograph¹⁵.

The radiographic evaluation of the quality of the root fillings was based on the length and the density of the root filling and its adaptation to the canal walls. The categorization of the criteria was as follows:

- A length of ≤ 2 mm from the apex with no voids ('Acceptable' filling)
- A length of ≤ 2 mm from the apex with voids
- Overfilling with no voids
- Overfilling with voids
- A length of >2 mm from the apex with no voids
- A length of >2 mm from the apex with voids.¹⁶

Questionnaire survey

A hand-delivered questionnaire was designed including 15 closed-ended questions concerning hand instrumentation experience, degree and reason of difficulty with rotary instrumentation, familiarity with terms of rotary instrumentation, preparation's and obturation's quality, identification of procedural errors and predisposition to rotary instrumentation. An external pilot survey was conducted amongst 20 undergraduate students to evaluate the questionnaire's reliability. The questionnaire was administered to the participants after the root canal treatment was performed and only those with all questions completed were included in the data analysis.

Ethical consideration

The study was approved by the Ethical Committee of the School of Dentistry of Aristotle University of Thessaloniki, Greece (protocol no.44/24-06-2016).

Statistical analysis

Cohen's kappa coefficient was used to calculate interobserver and intraexaminer reliability regarding ledge formation and root filling's quality. Interobserver agreement was determined by the scores of the radiographs of 30 randomly selected cases, while intraexaminer agreement was obtained by rescoring the radiographs of 40 randomly selected cases one month after the first evaluation. The reliability of the questionnaire was measured with the test-retest model. Twenty randomly selected undergraduate students were delivered the questionnaire for a second time approximately one month after their first response and the scores between the two time intervals were compared using the k-coefficient. The responses of the examiners and participants were calculated using the Statistical Package for Social Sciences (IBM SPSS v.24, Armonk, NY, USA). Qualitative data analysis was carried out using descriptive statistics for observed values and frequencies, Chi Square test and Fisher's Exact test.

Results

Reliability

The k-values for interobserver reliability were 0.87, 0.88 and 0.87 for root filling's length, presence of voids

and ledges respectively. The k-values for intraexaminer reliability were 0.88 and 0.89 for root filling's length and presence of voids and 0.95 for ledges. Because of the near perfect agreement, the scores of one author (ZDT) were used for the radiographic evaluation of the study. Similarly, the k-values obtained from the test-retest reliability were 0.89.

Procedural errors

Separated Instruments

The overall incidence of rotary instrument separation on root canal level was 0.8%. Of the 3 separated instruments one was located in a distal canal while the remaining two in mesiobuccal canals of maxillary and mandibular molars. Canal location did not have an effect on instrument separation ($p>0.05$) (Figure 1).



Figure 1. Example of instrument separation located in the apical third of the distal canal on tooth #36: A) Preoperative radiograph, B) Working length radiograph, C) Cone-fit radiograph, D) Postoperative radiograph.

Ledges

Ledges were found in 29% of the root canals (96/330). 4.5% of the ledged canals was accompanied by straightening and/or root perforation. A statistical significant correlation was found between canal type and the incidence of ledges ($p< 0.05$). Statistical significant differences were found between distobuccal and mandibular mesiobuccal, distal and mandibular mesiobuccal, maxillary mesiobuccal and mandibular mesiobuccal and between palatal and mandibular mesiobuccal root canals.

Perforations

Root perforations and apical foramen damage were found to be 2.3% and 4.4% respectively. Root canal type did not affect the incidence of root perforation ($p>0.05$).

Canal Straightening

Canal straightening was detected in 5.5% of the root canals. No statistical significance was found between the type of the root canal and the incidence of canal straightening ($p>0.05$) (Figure 2, Table 1).

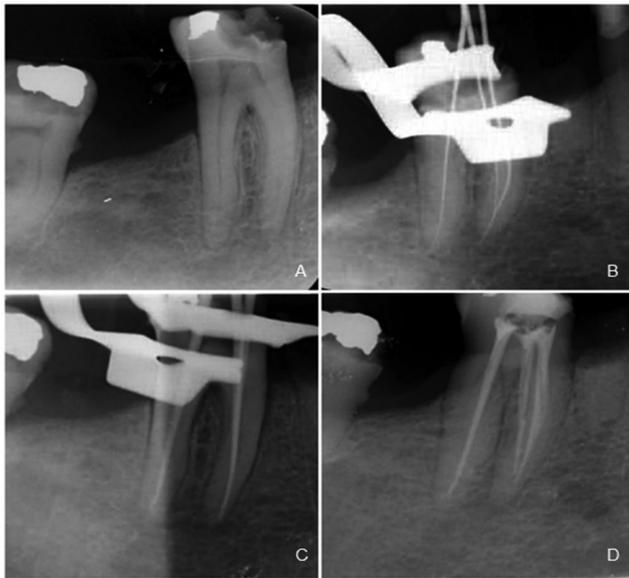


Figure 2. Case of canal straightening at the mesiobuccal canal on tooth #46: A) Preoperative radiograph, B) Working length radiograph, C) Cone-fit radiograph, D) Postoperative radiograph.

Table 1. Incidence (%) of procedural errors

Type of procedural error	Percentage	Number of root canals
Instrument separation	0.8	3
Ledge formation	29.0	96
Root perforation	2.3	8
Apical perforation	4.4	15
Canal straightening	5.5	18

Quality of the root filling

Root filling classified as “acceptable” was observed in 68.4% of the filled root canals, while 87.6% exhibited no voids and 75.2% were filled adequately. The frequency of overfilled and underfilled canals was found to be 8.6% and 16.2% respectively. Root canal type did not have an effect on the quality of the root filling ($p>0.05$) (Table 2).

Table 2. Percentages (%) of filled root canals according to classification's criteria

Classification	Number of root canals	Percentage
0.2 mm with no voids	232	68.4
0.2 mm with voids	23	6.8
Overfilling with no voids	27	8.0
Overfilling with voids	2	0.6
>2mm with no voids	38	11.2
>2mm with voids	17	5.0
Total	339	100.0

Questionnaire survey

Table 3. Response details by percentage (%) and number (N) of the respondents

Type of question	Responses	%	(N)
Most used preparation technique	Step-back	70.5	(79)
	Step-down	9.8	(11)
	Crown-down	19.6	(22)
	Other	(0)	
Degree of difficulty	Very easy	50.9	(57)
	Easy	41.1	(46)
	Moderate	7.1	(8)
	Hard	0.9	(1)
Cause of difficulty	Very hard	0.0	(0)
	Inexperience	58.0	(65)
	Protocol's complexity	2.7	(3)
	Insufficient instruction	0.9	(1)
Preparation's quality	All of the above	0.9	(1)
	None of the above	2.7	(3)
	No difficulty	34.8	(39)
	Excellent	12.5	(14)
Major advantage of rotary instrumentation	Very good	56.3	(63)
	Good	25.9	(29)
	Fair	4.5	(5)
	Poor	0.9	(1)
Use of rotary instrumentation in the future	Speed-less treatment time	70.5	(79)
	Less procedural errors	4.5	(5)
	Preparation's quality	25.0	(28)
Superiority of rotary to hand instrumentation	Other	0.0	(0)
	Yes	98.2	(110)
Use of rotary instrumentation in the future	No	1.8	(2)
	Yes	74.1	(83)
Superiority of rotary to hand instrumentation	No	25.9	(29)

The response rate was 94.9%. The respondents were mostly familiar with the step-back instrumentation technique (70.5%). Most participants (92%) reported that the use of rotary instrumentation varied from easy to very easy while only 0.9% described the experience as “hard”. As the reason for the encountered difficulty-if any, the majority identified their inexperience, while more than 1/3 of the participants experienced no difficulty. More than

half of them characterized the quality of their preparation as “very good”, while 0.9% as poor. Additionally, 70.5% considered “speed” as the major advantage of rotary instrumentation followed by “quality of the preparation”. The vast majority (98.2%) was positively predisposed to using rotary instrumentation in the future, while 74.1% considered rotary instrumentation superior to hand instrumentation (Table 3).

Discussion

This prospective clinical study evaluated the frequency of iatrogenic errors during rotary instrumentation and obturation by undergraduate students in a 3-year period. Our results indicate that the overall incidence of separated rotary instruments is lower than those of similar clinical and case-control studies. Previous studies reported instrument separation by undergraduate students that ranged between 1.0 and 2.09%^{17,18}. However those results derive from data consisting of all tooth types and the incidence of separation refers to hand and not rotary instruments. Studies referring to rotary instrument separation report results between 1.33-4.44%^{10,19,20}. The incidence reaches 2.5% when only molars are concerned¹⁰. Nevertheless, the root canal treatments in the latter studies were performed by postgraduate students and specialists with greater experience in rotary instrumentation. Mesio Buccal canals of maxillary and mandibular first molars exhibited the highest incidence of separation (0.56%). Those canals are narrow with great primary and apical curvatures^{21,22}, thus susceptible to instrument separation. The low separation rate in our study may be attributed to the establishment of a manual glide path with a No 20 K-file. A direct comparison of those results is difficult to achieve since clinical studies investigating instrument fracture use different study designs and instruments.

Regarding the presence of ledges our results are lower than those of other investigators^{12,13,16,23} who detected ledges in 33-51.5% of molar cases. Dentinal chips or residual debris which result in apical canal blockage can also affect the obturation length¹⁶, thus an overestimation of ledges might have occurred. It is also speculated that ledging was a result of inappropriate usage of hand files, overusage or loss of the determined working length. However, due to the highly controlled conditions and the fact that the canals were rotary instrumented, a lower percentage was expected.

Similarly low is the frequency of this study regarding root perforation compared to those of similar studies that range between 2.7% and 18.8%^{14,16,24}. When only molars are considered our observations are similar

to those of Balto *et al.* (2.2%)¹³. To a certain extent root perforations might have derived from the misuse of K-files when inserted in severely curved canals, followed by rotary instrumentation of the newly-created path. The incidence of apical perforation in other studies by Balto *et al.*¹³ and Khabbaz *et al.*¹⁴ is 10.6% and 25.7% respectively, which is higher compared to ours. A loss of the working length during instrumentation or canal transportation could be responsible for the incidence of apical perforations.

The percentage of canals maintaining their original shape and curvature was 94.5%. It is accepted that canal deviations are minimized when rotary Ni-Ti instruments are used^{25,26}. *In vitro* results indicate that Hyflex CM instruments produce less canal deviations compared to other Ni-Ti rotary instruments^{15,27}. In our study the results are relatively low, but it must be considered that the use of two-dimensional radiographs to evaluate the straightening of a three-dimensional structure may be inaccurate.

The radiographic evaluation of the technical quality of root fillings showed that 68.4% of the root canals fulfilled the criteria of an “acceptable” filling. Previous studies that assessed the technical quality of root fillings performed by undergraduate students exhibited a lower percentage (13-55.3%)^{13,16,28-30}. When only molars were considered, the latter studies indicated results ranging between 6.1% and 54.6%. When each root canal was considered as one unit those results reached 37.6% and 46.7%^{16,28}. Despite the superiority of our results, it is difficult to compare these studies due to the differences in the categorization criteria, the tooth type selection and the evaluation of each tooth as a unit or of each root canal individually. Moreover, the length of the root canal filling was estimated more precisely in our study, since the radiographs were taken with the paralleling technique and the distance of the root filling from the radiographic apex was calculated with digital measuring technology.

The response rate on the questionnaire was high (94.9%), thus the results can be considered representative of the population³¹. This survey could be considered innovative since it is the first to evaluate the performance of Hyflex CM rotary instruments after clinical use. Rotary instrumentation was found to be superior to hand instrumentation by the majority of the participants, which can be attributed to the fact that “speed” was suggested to be the greatest advantage of the former. The positive perception of the students about rotary techniques could be related with the very low degree of difficulty. Rotary training is not included in the preclinical courses of the undergraduate students and this justifies not only the lack of acquaintance with the geometrical traits and terms of rotary instruments but also the fact that the encountered

difficulty was mainly related to the students' inexperience. Presumably due to their inexperience, most students were not able to identify the procedural errors of their cases. Instrument separation and ledge formation were the most easily recognizable errors. Those findings demonstrate the positive attitude of the undergraduate students toward rotary instrumentation and the necessity for rotary education in preclinical training.

On the basis of the results of the present study, the incidence of procedural errors by undergraduate students was considerably low, despite their inexperience in rotary instrumentation. The quality of the filled root canals was maintained to the highest standards. Rotary instrumentation was followed easily and received a positive feedback according to the participants' responses.

Conclusions

The incidence of procedural errors was considerably low and the technical quality of the filled root canals was superior to that of similar studies. The responses of the questionnaire demonstrated a positive attitude toward rotary instrumentation.

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