

An Evidence-Based Report Comparing Stainless Steel Hand Files and Automated Rotary Nickel-Titanium Files

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Abstract

This paper, a systematic review of the published literature, investigates the evidence for the use of automated nickel-titanium endodontic filing systems versus traditional stainless steel hand files. The search conducted used the keywords hand files, rotary files and endodontics in three databases- PubMed, Ovid/Medline, and Cochrane Library, as well as the Journal of Endodontics and International Endodontic Journal. This search resulted in 161 articles of which 3 were selected based on our inclusion criteria. Schaefer et al. (2004) produced the only in vivo study comparing Flexmaster rotary files with an unspecified brand of hand files, in which they found a significant difference ($p < 0.0001$) regarding the maintenance of canal curvature and working time. Schafer et al. (2000) concluded that no significant difference ($p > 0.05$) exists between Kavo Endo Flash rotary files and hand files when examining smear layer and debris removal, whereas a significant difference was found between Profile rotary files and hand files. Finally, Bechelli et al. (1999) found a significant difference ($p < 0.05$) between rotary files and hand files, with rotary instruments resulting in a larger smear layer and superficial debris. All three studies measured intermediate outcome variables but failed to evaluate the clinical success of endodontic treatment. A recommendation for the replacement of hand files with rotary files cannot be advocated based on the current evidence. Rather, further research is indicated examining clinically relevant outcomes such as reduction of tooth pain, recurrent periapical disease or longevity of the tooth.

Introduction

The American Association of Endodontics defines endodontics as “the branch of dentistry concerned with the morphology, physiology, and pathology of the human dental pulp and the peri-radicular tissues.”¹ The phases of endodontic treatment include proper diagnosis, access preparation, working length determination, biomechanical cleansing and shaping, and obturation of the root canal system. Adequate cleansing and shaping of the root canals has been said to define the success of endodontic treatment.¹ According to the European Society of Endotology, the major goals of cleansing and shaping include: elimination of pulp tissue, the removal of debris and the maintenance of original canal curvature.² There has been development from traditional stainless steel hand files such as K-Flexofiles and Hedstroem files towards nickel-titanium rotary instruments such as K3 and Flexmaster as instruments used in the cleaning and shaping of root canals. Knowles *et al.*³ suggests that automated rotary files appear to be more fracture resistant and exhibit up to three times the elastic flexibility of traditional stainless steel hand files. Although questioned by other researchers, additional postulated advantages include reduced working time⁴ and cleaning efficacy.¹

Numerous studies have compared the effectiveness of hand instruments to automated rotary instruments by measuring a variety of outcomes. This paper is a systematic review of the literature to determine the evidence for the use of rotary nickel-titanium endodontic filing systems over conventional stainless steel hand filing systems.

Methods

To find articles pertaining to the research question, a thorough systematic search of all literature dating from 1985 to 2005 was conducted in 5 databases, namely PubMed, Ovid/Medline, Cochrane Library, Journal of Endodontics, and International Endodontic Journal. The keywords used in the search were hand files, rotary files and endodontics. The combined search using these keywords yielded 54, 1, 0, 0, 106 in the five databases, respectively, for a total of 161 papers.

Only those articles that compared stainless steel hand instruments and nickel-titanium rotary instruments were kept and 20 articles remained. Of the 20 articles, only studies performed by dentists (not students) on human teeth (not resin or other sps) were kept and 9 articles remained whose references were reviewed,, all of which were eliminated at the title stage based on the aforementioned criteria. Each of the 9 articles was reviewed by three authors and was subject to a University of Toronto Community Dentistry Checklist to Assess Evidence of Efficacy or Therapy or Prevention from Leake's ⁵ Community Dentistry, Year 2 Clinical Epidemiology Manual (see Appendix 1). In cases of discrepancies, a discussion was held until a consensus was reached. The tallied scores were compared and an additional inclusion criterion that only articles with RCT designs would be included was applied yielding the final 3 articles in the evidence table.

Next, a score based on the *Canadian Task Force on the Periodic Health Examination*⁶ was assigned to each article (see Appendix 2). Only one in vivo study conforming to the inclusion criteria surfaced written by Dr. Edgar Schafer of the University School of Dentistry, Munster, Germany. He was consulted via e-mail in an

attempt to obtain additional in vivo studies. Similarly, Dr. Basrani from the University Of Toronto Faculty Of Dentistry, Toronto, Canada was contacted. Neither was aware of such literature.

Results

A systematic review of the literature yielded three articles which met all inclusion criteria, had strong study designs, and scored highly on the checklist for efficacy. That is, the studies were randomized control trials comparing various outcomes of canal instrumentation by Ni-Ti rotary files with stainless steel hand files prepared by dentists on human teeth.

The three articles listed used as evidence are: A Comparison of Hand Stainless Steel and Nickel Titanium Rotary Instrumentation: A Clinical Study⁷; A Comparative Scanning Electron Microscopic Investigation of the Efficacy of Manual and Automated Instrumentation of Root Canals⁸; Scanning Electron Microscope Study on the Efficacy of Root Canal Wall Debridement of Hand Versus Lightspeed Instrumentation⁹.

Schaefer *et al.*⁷ produced the only *in vivo* study, in which 110 canals were treated with Flexmaster Rotary Files (NiTi) of a sample size of 194 root canals of maxillary and mandibular premolars and molars of a German population. As a control, 84 canals were instrumented with an unspecified brand of hand files. This study found a significant difference with respect to maintenance of curvature and working time. The automated Flexmaster system resulted in significantly ($p < 0.0001$) less straightening and a shorter preparation time than hand files.

Schafer *et al.*⁸ examined 120 extracted human teeth, 60 with straight canals, 60 with canals with 1 or more curve. Interventions included 24 canals that were instrumented with rotary Kavo Endo Flash (stainless steel), and 24 canals that were instrumented with ProFile System (NiTi). As a control, 48 canals were instrumented with K-Flexofile (stainless steel) hand files and 24 canals with Hedstroem (stainless steel)

files. The authors concluded that no significant difference ($p>0.05$) exists between Kavo Endo Flash and hand files. Manual instrumentation with the Hedstroem files resulted in the best cleaning, followed by K-flexofiles used both in manual and automated systems.

Finally, Bechelli *et al.*⁹ compared 10 canals instrumented with rotary Lightspeed™ (NiTi) files with 10 canals instrumented with Hedstroem (stainless steel) hand files all of which were from recently extracted single rooted teeth. There was a significant difference ($p<0.05$) in that rotary instruments resulted in more smear layer and superficial debris in the middle third of the canal whereas, there was no significant difference found in the apical and coronal thirds.

Discussion

In the study by Schafer *et al.*⁷, an ANOVA test was performed which demonstrated that no differences were due to the dentist, type of tooth or master apical file (MAF) size, thus eliminating those as confounding variables which could have skewed the observed results. The paper was assigned Level A evidence on the Canadian Task Force For Preventive Health Care (CTF) scale, indicating good evidence to recommend the use of rotary instruments since working time and undesired canal curvature alteration were significantly minimized. With respect to research design, this study received a grade of I since it was a randomized control trial (RCT).

Despite the high rating, a some weaknesses were noted. First, the researchers excluded curved canals of less than 10° and any canals with s-shaped curves, which limits the generalizability of the findings especially since there is wide variation within the population. Second, two-dimensional radiographs were used to evaluate the straightening of a three-dimensional canal which can result in inaccuracy. Third, the 8 dentists in this study did not perform an equal number of root canals treatments, which introduces potential bias. Lastly, and potentially, the largest weakness was the lack of a follow-up session to assess the success of the two treatments. However, ample time has not elapsed since publication to allow for follow up.

In Schaefer *et al.*⁸ the Profile rotary system resulted in fewer instrument grooves on the canal walls; however, the clinical relevance of these grooves has not been established. With respect to CTF, the evidence was given a level C rating suggesting conflicting evidence which does not allow for making a recommendation for or against the use of rotary instruments. Further, the study design was assigned a grade of I since it

was a RCT. There were a number of weaknesses encountered in this study. For example, this study was done *in vitro* which does not account for a large number of biological and mechanical factors found in clinical situations. Also, procedures such as sectioning the tooth may cause loss of information. Furthermore, a relatively small sample size per group (12 teeth per group) was used decreasing the power of the study design. Although a standard in endodontics, hand filing was performed without pre-bending the file which does not mimic clinical situations.

The third study, by Bechelli *et al.*⁹ was assigned an evidence grade of I according to the CTF research design rating, as well as an evidence level of C, suggesting conflicting evidence, and a recommendation cannot be made for or against the use of rotary instruments. This study had some weaknesses which may have contributed to its inconclusive results. First, regarding apical debris, debris in the apical 3rd (vs. coronal or middle) has the most clinical significance. However, in this study, the findings of clinical significance were only found in the middle third. Second, the research was conducted *in vitro*. Procedures such as the storage of teeth in solution, preservation, and mounting in resin can introduce artifacts. For example, the authors sputter-coated the teeth with 10% gold-palladium as required for scanning electron microscopy, potentially introducing artifacts. Third, this study also used a small sample size (10 teeth per treatment group).

None of the study designs available can be considered absolutely strong. First, all teeth selected for the various studies met specific criteria, which diminishes the generalizability of the results. Second, several authors have concluded that neither hand files nor automated rotary instruments can achieve perfect cleanliness, especially in curved canals. In fact, Pathways of the Pulp¹⁰ has also questioned whether canals can be

completely cleaned at all. This raises the question of whether increased cleanliness beyond what can be already achieved by hand files significantly contributes to the clinical success of the treatment.

Third, not all automatic instruments are made equal. Often, significant differences in cleaning ability are found between different hand files and different rotary files. Thus a specific rotary instrument used in one study may not exhibit the same findings with respect to statistical significance as a different rotary instrument, limiting the generalizability of the results. Similarly, not all hand instruments are made equal.

Fourth, an ideal study design would be double blinded, in which both the dentist and examiner are unaware of the treatment provided, eliminating risk of any potential bias. However, due to the nature of the experiment, only a single blind design is possible, since the dentist is always aware of the instruments in use.

Interestingly, the majority of studies have not measured the true success of endodontic treatment. Most research has only studied intermediate outcomes (smear layer reduction, straightening of curved root canals, zipping, ledging and apical transformation), which are all of inferior clinical relevance. There is an assumption that intermediate variables correlate with clinical success but only longitudinal in vivo studies can determine their clinical importance. Ideally, the success of endodontic treatment is measured by clinical outcomes including but not limited to patients' tooth pain, recurrent periapical disease or longevity of the tooth). Furthermore, there is no standard in measuring these intermediate outcomes. For example, each study provided a distinct definition of smear layer in evaluating canal cleanliness.

Characteristics of an ideal study comparing the effectiveness of stainless steel hand files and nickel titanium rotary instruments should randomly examine natural teeth in vivo using one type of operator (either a general dentist or an endodontist). Furthermore, long term follow-up sessions with patients should be arranged to assess the clinical success of endodontic treatment.

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Appendices

Appendix 1. CHECKLIST TO ASSESS EVIDENCE OF EFFICACY OF THERAPY AND PREVENTION⁵

- Was the study ethical?
- Was a strong design used to assess efficacy?
- Were outcomes (benefits and harms) validly and reliably measured?
- Were interventions validly and reliably measured?
- What were the results?
- Was the treatment effect large enough to be clinically important?
- Was the estimate of the treatment effect beyond chance and relatively precise?
- If the findings were “no difference” was the power of the study 80% or better?
- Are the results of the study valid?
- Was the assignment of patients to treatments randomized?
- Were all patients who entered the trial properly accounted for and attributed at its conclusion?
- Was loss to follow-up less than 20% and balance between test and controls?
- Were patients analyzed in the groups to which they were randomized?
- Was the study of sufficient duration?
- Were patients, health workers, and study personnel “blind” to treatment?
- Were the groups similar at the start of the trial?

- Aside from the experimental intervention, were the groups treated equally?
- Was care received outside the study identified and controlled for?
- Will the results help in caring for your patients?
- Were all clinically important outcomes considered?
- Are the likely benefits of treatment worth the potential harms and costs?

Appendix 2: CANADIAN TASK FORCE ON THE PERIODIC HEALTH EXAMINATION⁷

a. Recommendations Grades for Specific Clinical Preventive Actions

Level of Evidence	
A	The CTF concludes that there is good evidence to recommend the clinical preventive action.
B	The CTF concludes that there is fair evidence to recommend the clinical preventive action.
C	The CTF concludes that the existing evidence is conflicting and does not allow making a recommendation for or against use of the clinical preventive action, however other factors may influence decision-making.
D	The CTF concludes that there is fair evidence to recommend against the clinical preventive action.
E	The CTF concludes that there is good evidence to recommend against the clinical preventive action.
I	The CTF concludes that there is insufficient evidence (in quantity and/or quality) to make a recommendation, however other factors may influence decision-making.

b. Levels of Evidence- Research Design Rating

Grades	
I	Evidence from randomized controlled trial(s).
II-1	Evidence from controlled trial(s) without randomization.
II-2	Evidence from cohort or case-controlled analytic studies, preferably from more than one center or research group.
II-3	Evidence from comparisons between times or places with or without the intervention; dramatic results in uncontrolled experiments could be included here.
III	Opinions of respected authorities, based on clinical experience; descriptive studies or reports of expert committees.

Appendix 3: EXCLUDED ARTICLES

Articles	Reason for exclusion
Betti LV, Bramante CM. Quantec SC rotary instrument versus hand files for gutta-percha removal in root canal retreatment. Intl Endo J 2001;34:514-519.	<ul style="list-style-type: none"> - Irrelevant study on retreatment - weak design and unreliable outcomes - blindness and operator not specified
<p>Schafer e, Florek H. Efficiency of rotary nickel-titanium K3 instruments compared with stainless steel hand K-Flexofile. Part 1. Shaping ability in simulated curved canals. Intl Endo J 2003;36</p> <p>Hulsmann M, Gambal A, Bahr R. An evaluation of root canal preparation with the automated Excalibur endodontic handpiece. Clin Oral Invest 1999; 3:70-78.</p> <p>Schafer E, Lohmann D. 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. Intl Endo J 2002; 35:514-521.</p>	<ul style="list-style-type: none"> - Study not randomized - operator not specified
Chen JL, Messer HH. A comparison of stainless steel hand and rotary Nickel-titanium instrumentation using a silicone impression technique. Aust Dent J 2002; 47:12-20.	<ul style="list-style-type: none"> - weak design and unreliable outcomes - results not statistically significant - blindness not specified
Bolanos O, Sinai I, Gonsky M, Srinivasan R. A comparison of engine and air-driven instrumentation methods with hand instrumentation. J of Endo 1988; 14:392-396.	<ul style="list-style-type: none"> - weak design, subjective evaluations, and unreliable outcomes - outdated paper (1988)