

# The Impact of Instrument Fracture on Outcome of Endodontic Treatment

*Peter Spili, BSc, BDS, Peter Parashos, MDS, PhD, and Harold H. Messer, MDS, PhD*

## Abstract

Adoption of rotary nickel-titanium instruments has renewed concerns regarding instrument fracture and its consequences. The frequency of instrument fracture and its impact on treatment outcome were determined from an analysis of specialist endodontic practice records involving 8460 cases. A case-control study of treatment outcomes was conducted on a subset of 146 teeth with a retained instrument fragment (plus 146 matched controls), for which clinical and radiographic follow-up of at least 1 year was available. Masked radiographs were assessed by two calibrated examiners. Overall prevalence of retained fractured instruments was 3.3% of treated teeth. In the case-control study, overall healing rates were 91.8% for cases with a fractured instrument and 94.5% for matched controls ( $p > 0.05$ , Fisher's exact test). Healing in both groups was lower in teeth with a preoperative periapical radiolucency (86.7% versus 92.9%,  $p > 0.05$ ). In the hands of skilled endodontists prognosis was not significantly affected by the presence of a retained fractured instrument.

## Key Words

Treatment outcome, prognosis, fractured instruments, fractured instrument prevalence, case-control study

From the School of Dental Science, University of Melbourne, Melbourne, Victoria, Australia.

Address requests for reprint to Professor Harold H. Messer, School of Dental Science, University of Melbourne, 711 Elizabeth Street, Melbourne, Victoria 3000, Australia. E-mail address: hhm@unimelb.edu.au.

Copyright © 2005 by the American Association of Endodontists

Only a few small studies have evaluated the effect of a retained fractured endodontic instrument on the outcome of endodontic treatment (summarized in Table 1). Those that have been regularly cited include two early studies, which reported that the retained fragment reduced healing, particularly in the presence of a preexisting periapical radiolucency (1, 2), and others, which stated that it had no influence on healing (3, 4). Some of these studies further suggested that in most cases the retained fractured instrument can be incorporated into the final root canal filling (4, 5), although recently developed techniques have made removal more predictable (6–8). The conflict of opinion regarding the clinical significance of retained fractured instruments makes it imperative that clinicians be offered more definitive, evidence-based information for predicting the potential consequences of this procedural complication.

A brief summary of the generally recognized hierarchy in levels of evidence in clinical studies is, in descending order, randomized controlled trials, cohort studies, case-control studies, case series, and case reports (9, 10). To date, the available evidence regarding prognosis of retained fractured instruments has come from studies that have been mostly case series, which offer a low level of evidence, and only one true case-control investigation (4). Retrospective case-control studies realistically provide the highest level of evidence possible in such investigations. An important finding from many of the studies that evaluated the prognostic impact of a retained instrument fragment was that the presence of a preoperative periapical lesion served as the main prognostic factor for the successful treatment of such cases (1, 2, 5, 11, 12).

Fractured root canal instruments may include endodontic files, lateral or finger spreaders, spiral fillers, or Gates-Glidden burs, and can be nickel-titanium (NiTi), stainless steel (SS), or carbon steel. The prevalence of retained fractured endodontic hand instruments (mostly SS files) has been reported to range from 1 to 6% (1, 4, 11, 13–17). The fracture incidence of rotary NiTi files, based on only a small number of very recent investigations, has been shown to lie in the range 0.4 to 5% (17–19); the higher figure represented fractures only in molar teeth (18). In most circumstances fracture results from incorrect use or overuse of an endodontic instrument, and occurs most commonly in the apical third of a root canal (20). Although there is a perception that rotary NiTi instruments may fracture without warning, recent work indicates that fracture involves many factors the most important of which seems to be the clinician's skill (21).

Since the introduction of NiTi instrumentation over 10 yr ago, no published clinical outcome study has reported the influence of fractured rotary NiTi instruments on the prognosis of endodontic treatment and retreatment. Therefore, the purposes of this study were: (a) to determine the frequency of fractured endodontic instruments left in the root canal following treatment, and (b) to assess the influence of endodontic instrument fracture, in particular rotary NiTi, on the outcome of nonsurgical root canal treatment and retreatment, in specialist endodontic practice. The null hypothesis tested in the second part of the study was that a retained instrument fragment does not influence postoperative healing.

## Materials and Methods

### Study Design

This study was divided into two parts: 1) a retrospective survey of all cases treated nonsurgically (including retreatment) over some 13.5 yr in two endodontic practices involving seven endodontists. The main objective was to determine the prevalence of retained fractured instruments following treatment; 2) the second part was based on all

# Clinical Research

**TABLE 1.** Studies reporting the effect of a retained fractured instrument<sup>a</sup> on the outcome of endodontic treatment

Study	Observation period (yr)	Control group	Preoperative periapical status		Outcome	Stated effect of fractured instrument on healing
			Lesion	No lesion	Success (%)	
Strindberg (1)	4–10	Yes, but not case-control	2/4 <sup>b</sup>	9/11	11/15 (73%) <sup>c</sup>	Overall 19% reduction <sup>c</sup>
Grahnén & Hansson (25)	4–5	No	NR	NR	NS	No effect
Ingle & Glick (3)	0.5–5	No	NR	NR	NS	No effect
Engström et al (13)	4–5	No <sup>d</sup>	NR	NR	6/9 (67%)	No effect
Engström & Lundberg (14)	3.5–4	No <sup>d</sup>	0/0 <sup>e</sup>	5/5	5/5 (100%)	No effect
Grossman (2)	0.5–6 (average 2)	No <sup>f</sup>	9/19	42/47 <sup>g</sup>	51/66 (77%) <sup>g</sup>	Reduced only when lesion present
Crump & Natkin (4)	≥2	Yes, case-control	27/29	21/24	48/53 (91%)	No effect <sup>h</sup>
Fox et al (5)	2–14 (average 2–3)	No	NR	NR	93/100 (93%) <sup>i</sup>	Reduced only when lesion present
Bergenholtz et al (11) <sup>j</sup>	2	No	NR	NR	NS	Reduced only when lesion present
Kerekes & Tronstad (15)	3–5	No	NR	NR	9/11 (82%) <sup>k</sup>	Reduced only in teeth with necrotic pulps
Cvek et al (31)	4	No	3/4 <sup>l</sup>	NA <sup>l</sup>	3/4 (75%)	Not stated specifically for fractured files
Sjögren et al (16)	8–10	No	NR	NR	9/11 (82%) <sup>k</sup>	NS
Molyvdas et al (12)	0.5–5 (average 3)	No	8/11 <sup>m</sup>	32/35 <sup>m</sup>	40/46 (87%) <sup>m</sup>	Reduced only when lesion present
<b>Total (%)</b>			<b>49/67 (73%)</b>	<b>109/122 (89%)</b>	<b>275/320 (86%)</b>	

NR = Not reported, NS = Not stated.

<sup>a</sup> All instruments were either carbon steel or stainless steel hand files.

<sup>b</sup> Number of cases judged to be successful over total number of cases.

<sup>c</sup> At final observation. Also, this author did not classify 'incomplete healing' as success.

<sup>d</sup> Comparison between cases based only on presence or absence of positive bacterial culture before obturation.

<sup>e</sup> All cases in this study were treated only with pulpectomy, hence no cases with lesions.

<sup>f</sup> Group of 'normal' cases, not clearly defined as a control group, were used for comparison.

<sup>g</sup> If 'doubtful' cases are considered failures.

<sup>h</sup> No statistically significant difference between cases and controls.

<sup>i</sup> Only the cases with 'accidentally' fractured files are considered in this table.

<sup>j</sup> Retreatment cases only.

<sup>k</sup> Roots, as opposed to teeth in other studies.

<sup>l</sup> All cases in this study had posttraumatically reduced pulpal lumens and preoperative periapical lesions.

<sup>m</sup> If 'compromised' cases are considered failures.

cases from part 1 for which clinical and radiographic follow-up for at least 1 yr was available. Specifically, it entailed a retrospective, case-control treatment outcome analysis of equivalently matched cases, taken from the pool of cases of part 1, differing only by the presence or absence of a retained fractured endodontic instrument.

Ethics approval for the project was obtained from the University of Melbourne Human Research Ethics Committee. All patient records included for analysis were de-identified through a suitable code that maintained their anonymity throughout the study.

## Part 1: Frequency of Instrument Fracture

The overall prevalence of all fractured instruments retained in the root canal was determined from scrutiny of the records and radiographs of 8460 cases treated by seven endodontists in two private practices in Melbourne, Australia, during the period January 1990 to May 2003. Because rotary NiTi instrumentation was adopted as the primary technique for canal preparation in the two practices in 1996 to 1997, data from 1997 onwards were analyzed separately, for five endodontists, to determine the incidence only of retained rotary NiTi and SS hand files (used only as pathfinders) from 5103 cases out of the total pool of 8460 cases. The major rotary NiTi instruments used during that period included: Quantec Series 2000 (NT Co., Chattanooga, TN); Quantec LX & SC (Analytic Endodontics, Glendora, CA); GT Rotary (Dentsply-Tulsa

Dental Products, Tulsa, OK); ProFile 0.04 and 0.06 taper and ProTaper (Dentsply Maillefer, Ballaigues, Switzerland); and K3 (SybronEndo, Orange, CA). All instruments were used according to the manufacturers' recommendations. In general, multivisit endodontics was performed with calcium hydroxide paste (Pulpdent Corp, Watertown, MA) and/or Ledermix paste (Lederle Pharmaceuticals, Wolfratshausen, Germany) used as the interappointment medicament(s). Obturation in most cases involved cold lateral compaction using gutta-percha and AH26 sealer cement (Dentsply De Trey GmbH, Konstanz, Germany).

## Part 2: Case-Control Study

During the initial screening of patient records, all 8460 cases treated with orthograde endodontic treatment or retreatment during the 13.5 yr period were coded for the following potential outcome-influencing variables:

- Patient age
- Patient gender
- Tooth type
- Presence or absence of periradicular/periapical lesion
- Nonsurgical primary treatment or retreatment
- Recall period, coded as: 1 to 2 yr, 2 to 4 yr, or >4 yr

- Month and year of root filling
- Operator

Additional variables coded for the fractured instrument cases included:

- Type of instrument: rotary NiTi, SS hand file, paste filler
- Root or canal in which the fracture occurred
- Level in the root canal where the fracture occurred: coronal third, middle third, apical third, apical + beyond apex
- If the fractured instrument was bypassed or not

From this large pool of screened records, all fractured instrument cases and nonfractured instrument controls for which a minimum of 1-yr clinical and radiographic follow-up was available were identified. Each fractured instrument case was then matched as closely as possible with an equivalent nonfractured instrument control for the factors listed above. The appropriately matching control for each case was randomly selected from the pool of potential control teeth that comprised 812 primary treatment and 153 retreatment. All relevant clinical and radiographic data were coded and entered in Excel spreadsheets (Microsoft Corporation, Redmond, WA).

### Exclusion Criteria for Both Fractured Instrument and Control Cases

- Any previously root-filled tooth already containing a fractured instrument
- Any nonsurgically treated or retreated tooth with a clearly defective coronal restoration or obvious coronal leakage that was visible on the radiograph or noted in the record
- Any case with unsatisfactory or missing radiographs and/or one that was poorly documented

### Radiographic Examination

For each fractured instrument case and its matched control, a preoperative, postobturation, and appropriate recall radiograph, were sequentially mounted on gray cardboard radiographic film mounts (Rinn, Dentsply, Surrey, UK). Each film mount was first covered with a clear transparency plastic sheet (Dataline plain transparency film, Essette, EU). Then, on this sheet, every root containing a fractured instrument was masked with a dense black permanent marker that completely concealed any underlying root filling material and fractured instrument, but making sure all periapical structures of the masked root, including all other roots for multi-rooted teeth, were still visible for assessment. All equivalent roots of control cases were masked in exactly the same manner. Each radiographic series was given a numerical code and randomly distributed in preparation for rating.

Two independent endodontists were calibrated (see below) and subsequently blindly evaluated all coded radiographs. Viewing was performed in a darkened room using a well-illuminated 38 cm × 16 cm viewbox, with complete masking of peripheral light, and a magnifier viewer with 2× magnification (X-Produkt, Malmö, Sweden). The unit of radiographic evaluation was (a) the whole tooth, and (b) the individual root. The unit of clinical evaluation was the whole tooth.

### Calibration of Examiners

Each examiner was individually calibrated, for the presence or absence of a periapical lesion, by rating the preoperative and final radiographs of a random sample of 60 cases. Cases were also rated for the following four radiographic categories of healing:

- Complete healing (C), total resolution or no development of lesion on recall radiograph;
- Incomplete healing (I), radiographic

signs of obvious, but incomplete, bone repair, including repair around excess root filling material; c) *Uncertain* (U), unclear whether there had been any change in the lesion on the recall radiograph, but the clinical record did not indicate any clinical signs or symptoms; d) *No healing* (F), lesion on recall radiograph was clearly either enlarged or definitely unchanged, or a new lesion had developed. For multirouted teeth, the overall healing category assigned to the tooth was based on the root exhibiting the worst outcome.

After a 2-wk interval, the two examiners re-rated the same set of radiographs. Cohen's Kappa values for inter- and intraobserver reliability were then calculated. When they evaluated each of the 292 cases (146 case teeth and 146 control teeth) for the main part of the study, any disagreement on the final rating was resolved by reaching a consensus between the two examiners. If they still disagreed on a particular case, the opinion of the principal author (PS), who was also blinded to the case being evaluated, was accepted as final. The two examiners' interpretations of presence or absence of a preoperative lesion differed slightly from the principal author's interpretation during his initial screening of cases and selection of matched pairs. Therefore, this accounted for the small discrepancy of one case each in the number of teeth with or without a lesion between the matched pairs in Table 3 of the Results.

### Outcome Assessment

Both radiographic and clinical criteria were used to assess outcome. *Success* was defined in terms of "healing" and encompassed: (a) radiographic categories of complete healing and incomplete healing, and (b) absence of clinical signs and symptoms. *Failure* encompassed: (a) radiographic categories of uncertain and no healing, and/or (b) presence of clinical signs and symptoms.

### Recall Period

Cases were allocated to one of the following three categories: a) 1 to 2 yr, b) 2 to 4 yr, or c) greater than 4 yr.

### Statistical Analysis

All statistical analyses were performed in Minitab version 14.11 (Minitab Inc., State College, PA). Comparison of treatment outcome, and the effect of preoperative periapical status on outcome, between fractured instrument cases and controls was determined using Fisher's exact test. The same comparisons were made between fractured rotary NiTi files and SS hand files also using Fisher's exact test. The dependent variable for all analyses was outcome, which was collapsed into two categories: a) *Success* = complete or incomplete healing, and b) *Failure* = uncertain or no healing/failure. Stepwise logistic regression analysis was performed to evaluate associations among various potential outcome-influencing variables and treatment outcome. The level of significance was set at 0.05 for all analyses.

## Results

### Cohen's Kappa Values

The Kappa value for the interobserver agreement was  $\kappa = 0.73$ . The intraobserver Kappa values for the two raters were  $\kappa = 0.68$  and 0.78. All three Kappa values were in the "substantial agreement" category (22).

### Fracture Prevalence

Overall, 277 teeth from 8460 teeth were identified as containing one or more instrument fragments (total = 301 fragments), yielding a prevalence of all types of retained fractured endodontic instruments of 3.3%, from two specialist practices screened for the period January 1990 to May 2003 (Table 2). Of the instrument types, rotary NiTi in-

## Clinical Research

struments accounted for 78.1% of the total, SS 15.9%, paste filler 4.0%, and lateral spreader 2.0%. The 277 teeth with fractured instruments were identified from 263 patients (118 males and 145 females). Of these 263 patients, 143 (average age range 40–60 yr) with 146 teeth, had presented for recall of  $\geq 1$  yr.

During the period January 1997 to May 2003 ( $n = 5,103$  cases) the overall prevalence of retained fractured instruments (rotary NiTi,  $n = 226$ ; SS hand file,  $n = 35$ ), for the five endodontists was 5.1% (range: 3.5–5.3%). There was no statistically significant difference in fracture prevalence, and no significant change in fracture rate over time; specifically, there was no consistent pattern of declining fracture rate with increasing years of experience among the five endodontists. Of the overall fracture prevalence of 5.1%, 4.4% were NiTi and 0.7% were SS.

### Case-Control Study of Impact on Treatment Outcome

Of the 146 teeth with  $\geq 1$ -yr recall, 158 roots were found to contain fractured instruments. The main unit of analysis chosen for this study was “teeth” rather than “roots.” When outcomes were determined on an individual root basis, they differed from the data for whole teeth by no more than  $\pm 1.5\%$ . The overall success rate (C+I) of cases and controls was 93.7% (Table 3), specifically, 91.8% for cases and 94.5% for controls. This 2.7% difference was not statistically significant ( $p = 0.49$ , Fisher’s exact test). Overall, teeth without a preoperative periapical lesion showed a higher success rate than teeth with a lesion present. In the absence of a periapical lesion, the presence of a fractured instrument had no effect on outcome (98.4% versus 96.8% [control],  $p = 0.62$ , Fisher’s exact test). When the tooth had an associated periapical lesion, healing was lower when a fractured instrument was present (86.7% versus 92.9% [control]), but this 6.2% difference was not statistically significant (95% confidence interval:  $-3.0\%$  to  $15.3\%$ ;  $p = 0.21$ , Fisher’s exact test).

**TABLE 2.** Descriptive data for all fractured instrument cases involving 301 retained fragments in 277 teeth (January 1990-May 2003)

		Total (%)
Tooth type	Mx anterior	11 (4.0%)
	Md anterior	2 (0.7%)
	Mx premolar	19 (6.9%)
	Md premolar	9 (3.2%)
	Mx molar	110 (39.7%)
	Md molar	126 (45.5%)
	<i>n</i>	277
Treatment	Primary	254 (91.7%)
	Retreatment	23 (8.3%)
	<i>n</i>	277
Periapical status	Lesion	153 (55.2%)
	No lesion	124 (44.8%)
	<i>n</i>	277
Instrument type	Rotary NiTi*	235 (78.1%)
	SS hand file	48 (15.9%)
	Paste filler	12 (4.0%)
	Lateral spreader†	6 (2.0%)
	<i>n</i> **	301
Location of fragment	Coronal 1/3	1 (0.3%)
	Middle 1/3	57 (18.9%)
	Apical 1/3	232 (77.1%)
	Beyond apex	11 (3.7%)
	<i>n</i>	301

\*Rotary NiTi became the primary canal preparation technique from 1997 onwards.

\*\*Some of the 277 teeth with fractured instruments contained more than one fractured instrument, hence the higher number of instruments than teeth.

†The fractured lateral spreader tips were not included in the case-control study because they were not considered to affect outcome at the stage when they were fractured.

**TABLE 3.** Outcome of case-control study according to preoperative periapical status (teeth)

	No. of teeth (n)	C	I	U	F	% healed (C+I)
Fractured instrument						
No lesion	63	62	0	0	1	98.4
Lesion	83	50	22	1	10	86.7
Case-control						
No lesion	62	60	0	0	2	96.8
Lesion	84	45	33	0	6	92.9
Total	292	217	55	1	19	93.7

C = complete healing, I = incomplete healing, U = uncertain, F = no healing.

The stepwise logistic regression analysis revealed that only the presence of a preoperative periapical lesion was significantly associated with a reduced chance of healing, after adjustment for the other variables ( $p = 0.015$ ). The odds of a successful outcome were estimated to be 4.8 times greater in the absence than in the presence of a lesion. Other variables such as gender, age, tooth type, primary or retreatment, recall period, level of instrument fracture in the root canal, and whether or not the fractured instrument was bypassed did not significantly affect outcome (data not shown).

A comparison of the effect of fractured rotary NiTi files versus SS hand files on overall outcome (Table 4) revealed 113 of 119 (95.0%) rotary NiTi cases were successes, and 30 of 33 (90.9%) SS hand file cases were successes. This difference was not statistically significant ( $p = 0.41$ , Fisher’s exact test). There was no statistically significant influence on these data by the presence or absence of a preoperative periapical lesion (Table 4). When looking at the time-course of healing after treatment, the number of incomplete healing cases decreased markedly with increasing recall period (Table 5), and this was significant for both fractured instrument cases and controls. However, percent healed (as defined by C+I) was not affected by the recall period for the control cases.

## Discussion

The prospective, randomized controlled clinical trial is the gold standard by which all clinical research is judged because it represents the highest grade of evidence that can be used for the provision of evidence-based health care (9). However, the best level of evidence that can be realistically achieved for an evaluation of the impact of a procedural complication such as a fractured instrument on endodontic treatment outcome, is a case-control study; although, some would argue that a well-designed observational study (such as one with a case-control design) can produce results similar to that of a randomized controlled trial (10). Retrospective case-control studies are difficult to perform because it is challenging to identify a large number of cases and then to identify appropriate controls based on multiple selection criteria. Our sample of 146 pairs was a large sample size for a study of this kind, and was comparable with all previous studies combined (Table 1).

**TABLE 4.** Relationship between fractured instrument type and preoperative periapical status on healing (roots)

	No lesion		Lesion		Total success (%)
	Success (%)	Success (%)	Success (%)	Success (%)	
NiTi	62/63* (98.4)	51/56 (91.1)	113/119 (95.0)		
SS	16/16 (100)	14/17 (82.4)	30/33 (90.9)		
Paste filler	2/2 (100)	3/4 (75.0)	5/6 (83.3)		
Total	80/81 (99.0)	68/77 (88.3)	148/158 (93.7)		

\*Number of instruments judged to be successful over total number of instruments.



**TABLE 5.** Healing according to recall period (yr) for teeth

	No. of teeth (n)	C	I	U	F	% healed (C+I)
<b>Fractured instrument, (yrs)</b>						
1–2	83	56	18	1	8	89.2
2–4	42	36	3	0	3	92.9
>4	21	20	1	0	0	100
	146	112	22	1	11	91.8
<b>Control, (yrs)</b>						
1–2	83	53	26	0	4	95.2
2–4	45	38	6	0	1	97.8
>4	18	14	1	0	3	83.4
	146	105	33	0	8	94.5

C = complete healing, I = incomplete healing, U = uncertain, F = no healing.

This retrospective, clinical and radiographic evaluation of fractured-instrument cases versus matched controls revealed that the overall success rate of endodontic treatment and retreatment when a fractured instrument was left within a root canal (91.8%) was not significantly different from that of the controls (94.5%). When the data were analyzed according to the absence or presence of a preoperative periapical lesion (Table 3), again no statistically significant effect of a fractured instrument was found. Overall, our success rates were very high, but within the range of previously reported studies for overall success and failure of endodontic treatment (23). Our findings support those of Crump and Natkin (4) who performed the only comparable case-control study, but which involved mainly silver cone obturation. From their sample of 53 matched pairs, they also showed that there was no statistically significant difference in failure rate between broken instrument cases and controls. Additionally, based on the period when their cases were completed (1955–1965), instruments were either carbon steel or ss hand instruments. One other frequently cited controlled (but not case-controlled) study that also looked at this issue was described by Strindberg (1). He reported a significantly lower (19%) rate of healing compared to a much larger “control” group; however, this finding was based on only 15 fractured-instrument cases of which four had periapical lesions, and the author considered incomplete healing as “failure.” In contrast to all previous reports, our study included predominantly rotary NiTi instruments, and showed that retained rotary NiTi fragments do not adversely affect outcome any more than do steel hand files. Although we found only a small effect on outcome for a retained fractured instrument, it is likely that the ultimate prognosis may depend on the stage and degree of canal preparation when instrument breakage occurs and, therefore, the extent to which microbial control is compromised (1, 4, 12, 24). This information was not available from our study sample.

When endodontic treatment is performed to a high technical standard, the influence of a periapical lesion appears to be slight, but if the technical standard is compromised, the presence of a lesion can reduce the success rate considerably (1, 13, 16, 25). Hence it might be predicted that a fractured instrument would reduce the prognosis of teeth with a periapical lesion, based on the fact that the technical standard is likely to be compromised when the fractured instrument is present. Within the fractured instrument cases (Table 3), those with lesions were 11.7% less likely to heal than those without a lesion, which was statistically significant. However, the presence of a fractured instrument in itself did not compromise the outcome. This was confirmed statistically using logistic regression analysis, which accounts simultaneously for several explanatory variables—in this case, outcome-influencing variables pertaining to endodontic treatment. Of all variables examined, only presence of a periapical lesion had a statistically significant influ-

ence on healing. In teeth with a periapical lesion, a 6.2% lower rate of healing was found when a fractured instrument was present, which was not statistically significant. The wide confidence interval of this difference (–3.0 to 15.3%) makes it difficult to assign any clinical significance to this result.

This study found an overall fracture prevalence of 3.3% for all types of retained fractured instruments in the root canals of the total study sample. During the period when rotary NiTi was the primary technique for canal preparation (1997 onwards), the percentage of teeth with retained fractured rotary NiTi files was 4.4%. This falls within the range of 0.4 to 5% reported in previous clinical studies for rotary NiTi files (17, 18), and exceeds that of fractured SS hand files (0.7%). In direct contrast, Pettiette et al. (17) reported a fracture incidence of 0.4% for rotary NiTi and 1.1% for SS files. However, their sample was much smaller and the operators were undergraduate students who probably treated much simpler cases. In our study, as with the study by Pettiette et al. (17), the SS files were generally used only to establish patency and provide a glide path for the rotary instruments. Further, only the very small sizes (#06–15) were generally used and they were almost exclusively new instruments for each case. The rotary NiTi files, on the other hand, were used up to five times and considerably more were used per case than the SS hand files.

The yearly fracture rates for all endodontists did not show any consistent pattern of decline with increasing time or operator experience. A possible explanation for this finding is that between 1997 and 2003 several new designs of rotary NiTi instruments were introduced onto the market, which meant that each had its own associated learning curve. Consequently, the clinicians had to adapt to the new characteristics of the new instruments. Operator-related factors have a significant influence on fracture incidence of rotary NiTi instruments (21).

As with other retrospective outcome studies, a number of limitations must be recognized because not all outcome-influencing variables can necessarily be controlled. One of these is the recall period. In this study, 56.8% of all cases had an observation period of 1 to 2 yr, with 21.7% of these being incomplete healing, which are likely to lead to complete healing (1, 15, 26–28, 32). Additionally, mainly nonstandardized radiographs were available, but were acceptable for this study because it was a retrospective field study, and reliability of scorers was assessed. The “substantial agreement” kappa values reflect favorably on the results of this study and the means of calibration. Because most radiographs were nonstandardized, the PAI scoring system (29, 30) could not be used.

It appears from our study that a fractured rotary NiTi instrument retained in a root canal does not impact adversely on prognosis, possibly because treatment was performed to a high technical standard, including strict aseptic techniques, by experienced endodontic operators. Whether these findings can be extrapolated to general practice conditions remains to be determined.

## Conclusions

a) The overall frequency of fractured endodontic instruments left in the root canal after treatment was found to be 3.3% of treated teeth and comprised 78.1% rotary NiTi files, 15.9% SS hand files, 4.0% paste fillers, and 2.0% lateral spreaders. The frequency of rotary NiTi instrument breakage was comparable to that previously reported for hand files.

b) In the hands of experienced operators, endodontic instrument fracture, in particular rotary NiTi, had no adverse influence on the outcome of nonsurgical root canal treatment and retreatment when the instrument remained in the root canal. The presence of a preoperative

periapical radiolucency, rather than the fractured instrument per se, was a more clinically significant prognostic indicator.

### Acknowledgments

*The authors would like to thank the following for their valuable assistance in the research project: Associate Professor Ian Gordon of the Statistical Consulting Centre, University of Melbourne, Drs. Vivian Jeng and Pairoj Linsuanont of the School of Dental Science, University of Melbourne, and all the endodontists—in particular, the practice principals Drs. Garry Nervo and Peter Parashos—of the participating endodontic practices for their cooperation, patience, and contribution of cases to the project.*

### References

1. Strindberg LZ. The dependence of the results of pulp therapy on certain factors: an analytical study based on radiographic and clinical follow-up examinations. *Acta Odontol Scand* 1956;14(Suppl 21):1–175.
2. Grossman LI. Guidelines for the prevention of fracture of root canal instruments. *Oral Surg Oral Med Oral Pathol* 1969;28:746–52.
3. Ingle JI, Glick D. The Washington study. In: Ingle JI, ed. *Endodontics*, 1st ed. Philadelphia: Lea & Febiger, 1965:54–77.
4. Crump MC, Natkin E. Relationship of broken root canal instruments to endodontic case prognosis: a clinical investigation. *J Am Dent Assoc* 1970;80:1341–7.
5. Fox J, Moodnik RM, Greenfield E, Atkinson JS. Filling root canals with files. Radiographic evaluation of 304 cases. *NY State Dent J* 1972;38:154–7.
6. Ward JR, Parashos P, Messer HH. Evaluation of an ultrasonic technique to remove fractured rotary nickel-titanium endodontic instruments from root canals: an experimental study. *J Endod* 2003;29:756–63.
7. Ward JR, Parashos P, Messer HH. Evaluation of an ultrasonic technique to remove fractured rotary nickel-titanium endodontic instruments from root canals: clinical cases. *J Endod* 2003;29:764–7.
8. Ruddle CJ. Nonsurgical retreatment. *J Endod* 2004;30:827–45.
9. Sackett D, Richardson W, Rosenberg W, Haynes R. *Evidence-based medicine: how to practice and teach EBM*. London: Churchill Livingstone, 1997.
10. Concato J, Shah N, Horwitz RJ. Randomized, controlled trials, observational studies, and the hierarchy of research designs. *New Engl J Med* 2000;342:1887–92.
11. Bergenholtz G, Lekholm U, Milthorpe R, Heden G, Ödesjö B, Engström B. Retreatment of endodontic fillings. *Scand J Dent Res* 1979;87:217–24.
12. Molyvdas I, Lambrianidis T, Zervas P, Veis A. Clinical study on the prognosis of endodontic treatment of teeth with broken endodontic instruments. *Stoma* 1992;20:63 (In Greek). Data cited in: Risk management of root canal treatment. Lambrianidis I, ed. Thessaloniki: University Studio Press, 2001: 199–247.
13. Engström B, Hård L, Segerstad AF, Ramström G, Frostell G. Correlation of positive cultures with the prognosis for root canal treatment. *Odontol Revy* 1964;15:257–70.
14. Engström B, Lundberg M. The correlation between positive culture and the prognosis of root canal therapy after pulpectomy. *Odontol Revy* 1965;16:193–203.
15. Kerekes K, Tronstad L. Long-term results of endodontic treatment performed with a standardized technique. *J Endod* 1979;5:83–90.
16. Sjögren U, Hägglund B, Sundqvist G, Wing K. Factors affecting the long-term results of endodontic treatment. *J Endod* 1990;16:498–504.
17. Pettiette MT, Conner D, Trope M. Procedural errors with the use of nickel-titanium rotary instruments in undergraduate endodontics. *J Endod* 2002;28: 259 [abstract PR 24].
18. Al-Fouzan KS. Incidence of rotary ProFile instrument fracture and potential for bypassing *in vivo*. *Int Endod J* 2003;36:864–7.
19. Schäfer E, Schulz-Bongert U, Tulus G. Comparison of hand stainless steel and nickel titanium rotary instrumentation: a clinical study. *J Endod* 2004;30:432–5.
20. Parashos P, Messer HH. Questionnaire survey on the use of rotary nickel-titanium endodontic instruments by Australian dentists. *Int Endod J* 2004;37:249–59.
21. Parashos P, Gordon I, Messer HH. Factors influencing defects of rotary nickel-titanium endodontic instruments after clinical use. *J Endod* 2004;30:722–5.
22. Landis RJ, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33:159–74.
23. Friedman S. Treatment outcome and prognosis of endodontic therapy. In: Ørstavik D, Pitt Ford TR, eds. *Essential endodontology: prevention and treatment of apical periodontitis*. Oxford: Blackwell Science, 1998:367–91.
24. Torabinejad M, Lemon RR. Procedural accidents. In: Walton RE, Torabinejad M, eds. *Principles and practice of endodontics*, 3rd ed. Philadelphia: W.B. Saunders Company, 2002:310–30.
25. Grahnén H, Hansson L. The prognosis of pulp and root canal therapy. *Odontol Revy* 1961;12:146–65.
26. Byström A, Happonen R-P, Sjögren U, Sundqvist G. Healing of periapical lesions of pulpless teeth after endodontic treatment with controlled asepsis. *Endod Dent Traumatol* 1987;3:58–63.
27. Ørstavik D. Time-course and risk analyses of the development and healing of chronic apical periodontitis in man. *Int Endod J* 1996;29:150–5.
28. Molven O, Halse A, MacDonald-Jankowski D. Periapical changes following root-canal treatment observed 20–27 years postoperatively. *Int Endod J* 2002;35:784–90.
29. Ørstavik D, Kerekes K, Eriksen HM. The periapical index: a scoring system for radiographic assessment of apical periodontitis. *Endod Dent Traumatol* 1986;2:20–34.
30. Trope M, Delano O, Ørstavik D. Endodontic treatment of teeth with apical periodontitis: single vs. multivisit treatment. *J Endod* 1999;25:345–50.
31. Cvek M, Granath L, Lundberg M. Failures and healing in endodontically treated non-vital anterior teeth with posttraumatically reduced pulpal lumen. *Acta Odontol Scand* 1982;40:223–8.
32. Weiger R, Rosendahl R, Löst C. Influence of calcium hydroxide intracanal dressings on the prognosis of teeth with endodontically induced periapical lesions. *Int Endod J* 2000;33:219–26.