Impact of a Retained Instrument on Treatment Outcome: A Systematic Review and Meta-analysis

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Abstract

Introduction: Fracture of root canal instruments is one of the most troublesome incidents in endodontic therapy. This systematic review and meta-analysis aim to determine the outcome difference between retained fractured instrument cases and matched conventional treated cases. **Methods:** The MEDLINE database, EMBASE, Web of Science, and the Cochrane Database were searched. Reference lists were scanned. A forward search was undertaken on identified articles. Papers citing these articles were identified through Science Citation Index to identify potentially relevant subsequent primary research. A systematic data extraction sheet was constructed. Data in these studies were independently extracted. Risk differences of included studies were combined by using the generic inverse variance data and fixed effects method. A 2-stage analysis was conducted. The first was limited to case-control studies, and the second included case series in which data were available for teeth with and without periradicular lesions. **Results:** Two case-control studies were identified and included, covering 199 cases. Weighted mean healing for teeth with a retained instrument fragment was 91%. The 2 studies were homogeneous. Risk difference of the combined data was 0.01, indicating that a retained fragment did not significantly influence healing. Overall, 80.7% of lesions healed when a periapical lesion was present, compared with 92.4% remaining healthy when no lesion was present initially ($P < .02$). **Conclusions:** On the basis of the current best available evidence, the prognosis for endodontic treatment when a fractured instrument fragment is left within a root canal is not significantly reduced. *(J Endod 2010;36:775–780)*

Key Words

Broken instrument, outcome, prognosis, separated instrument, success

During cleaning and shaping of the root canal system, procedural accidents can occur that might affect the prognosis. Examples of procedural accidents include ledge formation, artificial canal creation, root perforation, and extrusion of irrigating solution periapically (1). Not all procedural problems lead to a reduced prognosis, but any error that compromises microbial control is likely to increase the risk of a poor outcome. Fracture of root canal instruments is one of the most troublesome incidents in endodontic therapy, especially if the fragment cannot be removed.

Fractured root canal instruments might include endodontic files, lateral or finger spreaders, spiral fillers, or Gates-Glidden burs, whether manufactured from 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 0.5%–7.4%, but it has been variably reported on a per tooth or per canal basis (2–9). With the advent of rotary NiTi files, there has also been a perceived increase in the occurrence of broken instruments (10). This perception is probably unwarranted, particularly when retained fragments in the root canal space are considered; the frequency of retained fractured NiTi instruments might be lower than that for SS files (11). The fracture incidence among discarded rotary NiTi files after clinical use has been shown to lie in the range of 0.4%–3.7% (5, 7, 12–14). In most circumstances fracture results from incorrect use or overuse of an endodontic instrument. Although there is a perception that rotary NiTi instruments might fracture without warning, recent work indicates that fracture involves many factors, the most important of which seems to be the clinician's conscious decision to use instruments a specified number of times or until defects (unwinding, torsional fracture, or flexural fracture) were evident (15).

A number of treatment protocols for removing obstructions have been described in the literature. Earlier authors have suggested that the object, regardless of the primary endodontic diagnosis, should be left in the canal, and that the canal coronal to the object should be treated according to standard endodontic procedures (3, 16). Others have suggested that the object should be bypassed and incorporated into the root filling material (17). Surgical techniques for removal of either the object itself or the entire portion of the root encompassing the object have been recommended (18, 19). In addition, several authors have introduced special instruments and techniques for intradental retrieval of the obstructing object (10, 20–23). However, the removal procedure might result in loss of considerable tooth structure and clinical complications such as root perforation (24, 25). Thus it is important to assess the impact on prognosis of a retained fractured instrument so that it can be compared with the risk of damage during attempted removal.

This systematic review and meta-analysis were undertaken to determine the influence of a retained instrument fragment on the prognosis of root canal treatment. The clinical question to be answered in this systematic review (a problem, intervention,

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TABLE 1. MEDLINE Search Strategy Developed to Find Articles Related to Retained Instrument Fragments

Search strategy	Results
broken instrument OR fractured instrument OR separated instrument AND ("Endodontics" [MeSH] OR "Root Canal Filling Materials" [MeSH] OR "Dental Pulp Test" [MeSH] OR "Dental Pulp Diseases" [MeSH] OR "Periapical Abscess" [MeSH] OR endodontics [Text Word] OR root canal filling materials [Text Word] OR dental pulp test [Text Word] OR dental pulp diseases [Text Word] OR periapical abscess [Text Word] OR apicoectomy [Text Word] OR pulpectomy [Text Word] OR pulpotomy [Text Word] OR root canal therapy [Text Word] OR dental pulp devitalization [Text Word] OR root canal obturation [Text Word] OR root canal preparation [Text Word] OR retrograde obturation [Text Word] NOT (("Dental Implantation, Endosseous, Endodontic" [MeSH] OR "Dental Pulp Capping" [MeSH] OR "Tooth Replantation" [MeSH]) NOT ("Apicoectomy" [MeSH] OR "Pulpectomy" [MeSH] OR "Pulpotomy" [MeSH] OR "Root Canal Therapy" [MeSH])) NOT ("animals" [MeSH:noexp] NOT humans [MESH])	125

comparison and outcome [PICO] question) can be framed as follows: in adult patients who have had nonsurgical root canal treatment, does the retention of a separated instrument, compared with no retained separated instrument, result in a poorer clinical outcome?

Materials and Methods

Literature Search

An exhaustive search was undertaken to identify all clinical studies that reported postoperative healing after endodontic instrument separation. The MEDLINE database was searched via the EviDents search engine (http://medinformatic.uthscsa.edu/EviDents/, last accessed September 3, 2009) by using "broken instrument OR fractured instrument OR separated instrument" as key words, which automatically created a complex search strategy (Table 1). This complex search strategy was similar to the one recommended by the Cochrane Collaboration as outlined in the Cochrane Reviewers' Handbook (26). The search of the MEDLINE database included all years from 1966–July 2009. A similar search strategy was also applied by using EMBASE, Web of Science, and the Cochrane Database and manual searches, including journals, conference proceedings, reference lists, other reviews, and unpublished studies. No language restriction was applied to the search. One hundred twenty-five studies were subjected to preliminary analysis. Titles and abstracts, where available, were scanned, and the relevance of each study to the endodontic outcome of fractured instrument was determined. Where information from the title and abstract was not adequate in determining the article's relevance, the article was automatically included in subsequent analysis. One hundred eight were excluded from the list, and the 17 remaining articles were subjected to stricter exclusion criteria.

Inclusion and Exclusion

The full texts of the remaining articles were then obtained and reviewed, and the inclusion criteria (Table 2) were applied. Reference lists from identified articles were scanned to identify other potentially relevant preceding articles (a backward search), from which 1 more article was identified (27).

TABLE 2. Inclusion and Exclusion Criteria Used in the Analysis

Inclusion criteria	
1	Subjects had a noncontributory medical history.
2	Subjects presented with mature teeth and radiographic evidence of a fractured instrument fragment such as a file (carbon steel, SS, or rotary NiTi), Gates-Glidden drill, lentulo spiral, spreader, or paste filler retained in the root canal.
3	Follow-up of at least 1 year.
4	Both clinical and radiographic examinations were completed for all patients, and the outcome was based on clearly defined criteria.
5	Case-control studies (the highest feasible level of evidence).
6	Data are accessible.
Exclusion criteria	
1	No result in terms of healing.
2	No specified observation period, or
3	Follow-up less than 1 year.
4	No specified criteria for evaluating outcome.
5	Not a case-control study.

Data Extraction

A systematic data extraction sheet was constructed. All aspects of treatment that could potentially affect the study outcomes were identified and included in the data sheet. The data in all included studies were extracted in the same fashion. The appraisal step was performed in a standardized manner by using quality assessment checklists (CASP, Public Health Resource Unit, England, 2006) that included items such as the study's design and analysis and identified the deficiencies that might arise from bias. This step was performed by 2 independent reviewers for better reliability of the results. Any disagreements were resolved by discussion.

Meta-analysis

Between-study heterogeneity was assessed by using the standard χ^2 test or Q statistic. The principal measure of treatment effect (healing) was risk difference, which for the purpose of this study is given as the difference in outcome (healing) between fractured instrument cases and control cases. Risk difference is a measure of the association between treatment (a risk of fractured instrument cases) and outcome. Risk differences of included studies were combined as generic inverse variance data type (RevMan 4.2.10; The Cochrane Collaboration's Information Management System, http://www.cc-ims.net, last accessed August 7, 2009), taking into account the separate tracking of healing and failure (developing or persistent periapical disease). The fixed effects model for combining study estimates was used, and an overall estimate was produced (28). The level of statistical significance was set at .05.

Results

Impact on Prognosis

Included and Excluded Studies. Two case-control studies met our inclusion criteria (Table 3: Crump and Natkin, 1970 and Spili et al, 2005). Fifteen studies that investigated some aspect of fractured instrument cases were excluded for various reasons (Table 3).

TABLE 3. Inclusion and Exclusion Criteria Used in the Analysis

Excluded studies	Exclusion criteria	Included studies
Nicholls 1967 (38)	2, 3, 4, 5	Crump and Natkin 1970 (3)
Sommer 1966(19)	2, 3, 4, 5	Spili et al 2005 (7)
Siskin 1967 (39)	2, 3, 4, 5	
Strindberg l956 (8)	5	
Grahnén and Hansson 1961 (40)	5	
Ingle and Glick 1965 (18)	5	
Engström et al 1964 (41)	5	
Engström and Lundberg 1965 (42)	5	
Grossman 1969 (43)	5	
Fox et al 1972 (16)	3, 5	
Bergenholtz et al 1979 (2)	5	
Kerekes and Tronstad 1979 (4)	5	
Cvek et al 1982 (9)	5	
Sjögren et al 1990 (6)	5	
Molyvdas et al 2001 (27)	5	

Data Summary of Included Studies. Sample size was 53 (3) and 146 (7) teeth. Neither of the articles reported the rationale for selecting the sample size or the details of endodontic treatment such as type of instrumentation technique, type and concentration of irrigant, and type of medicament. The 2 studies used both radiographic and clinical criteria to assess outcome. The differences in criteria for healing might affect the outcome. Crump and Natkin (3) classified the outcomes into 3 categories: success, uncertain, and failure. Spili et al (7) divided the outcome into 4 categories including complete healing, incomplete healing, uncertain, and no healing. For the purposes of this analysis, "healing" included both "success" and "uncertain" (3) and "complete healing" and "incomplete healing" (7), because teeth in the uncertain and incomplete categories showed signs of healing. If the lesion size is reduced (not completely healed) at 1-year review, the chance of complete healing at 4 years or later is high. The reverse course of event is rare (29).

For the 2 studies, weighted mean frequency of healing for teeth with a retained instrument fragment was 91%, compared with 92% for the controls. For teeth without a preoperative lesion present, a favorable outcome was recorded in 95% of both groups. When a lesion was present at the time of treatment, a positive outcome was found in 88% versus 89% for the controls (Table 4).

Assessment of Healing. One year is the earliest possible follow-up time to determine whether the lesion has healed (29). Follow-up time of both studies was adequate, ranging from 1–4 years. Crump and Natkin (3) used a 2-year minimum follow-up time. Spili et al (7) followed cases for at least 1 year, during which some cases with an apical lesion might not be completely healed. Only the study of Spili et al used Cohen kappa values for interobserver and intraobserver reliability. Masking is another technique to minimize systematic bias, which both studies clearly stated.

The 2 studies presented a somewhat low recall rate of all cases identified as having a retained fragment (33%–57%). However, recall rate is irrelevant in a case-control study because all cases (in both case and control groups) must have at least 1-year recall to be included in the study.

Meta-analysis. Outcomes of individual studies and a summary of meta-analysis results are shown in Table 5 and Fig. 1. Neither included study demonstrated a statistically significant difference in healing between the fractured instrument group versus control group. Meta-analysis was performed on the combined data. The outcome measure (healing frequency) was based on binary data, ie, healed/not healed. Study heterogeneity was assessed by using the standard χ^2 test or Q statistic. The 2 studies were homogeneous [Test of Homogeneity Cochrane Q (ChiSq) = 1.73, $df = 1$, $P = .22$]. A graphical informal test (Forest plot) also confirmed the homogeneity (Fig. 1). Thus, fixed effect methods for combining study estimates were used, and overall estimate was produced. Risk differences of included studies were combined by using the inverse variance-weighted method (RD_{fixed} = 0.01; 95% confidence interval, –0.05 to 0.06). Overall, risk difference of the combined data was 0.01, with a lower frequency of healing from the study by Crump and Natkin (3) (RD = –0.06) than that of Spili et al (7) (RD = +0.03). On the basis of the 95% confidence interval of the RD, the highest possible impact of a fractured instrument on prognosis is only 6% difference. From an epidemiologic perspective, a difference smaller than 10% is usually considered clinically unimportant (30). It is, therefore, highly unlikely that a larger trial would find a larger and/or significant difference.

Influence of a Preoperative Periapical Radiolucency

Seven studies among those listed in Table 3, including 5 excluded from the above analysis, directly compared the outcome for teeth with or without a periapical radiolucency at the time of treatment, when an instrument fragment was present (Table 6). Overall, 80.7% of lesions healed when a periapical lesion was present, compared with 92.4% remaining healthy when no lesion was present at the time of treatment ($P < .02$, Fisher exact test).

TABLE 4. Outcomes of 2 Case-Control Studies of the Influence of a Retained Instrument Fragment on Healing

Authors	No lesion	Lesion present	Overall
Crump and Nalkin 1970			
Fractured instrument cases	21/24 (88%)*	27/29 (93%)	48/53 (91%)
Control cases	22/24 (92%)	23/29 (79%)	45/53 (85%)
Spill et al 2005			
Fractured instrument cases	62/63 (98%)	72/83 (87%)	134/146 (92%)
Control cases	60/62 (97%)	78/84 (93%)	138/146 (95%)
Two studies combined			
Fractured instrument cases	83/87 (95%)	99/112 (88%)	182/199 (91%)
Control cases	82/86 (95%)	101/113 (89%)	183/199 (92%)

Data are divided into teeth either without or with a periapical lesion present at the time of treatment, and with the 2 groups combined.

*Number of cases showing healing over total number of cases (expressed as a percentage).

TABLE 5. Meta-analysis Data Summary of the Included Studies

Citation	Sample size	Risk difference (%)	95% Confidence interval		*P* value
			Lower	Upper	
Crump and Natkin 1970	53	–0.06	–0.18	0.07	.31
Spili et al 2005	146	0.03	–0.03	0.09	.62
Combined 2 studies	199	0.01	–0.05	0.06	.85

Discussion

Level of Evidence

The highest 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, because the event occurs unpredictably. Some authors argue that a well-designed observational study (such as one with a case-control design) can produce results similar in value to those of a randomized controlled trial (31). Case-control studies are observational studies in which cases with a particular feature and controls that are very similar but do not have the same feature are first selected, and assessment is done retrospectively. These studies are quick, relatively inexpensive, and appropriate in studying rare conditions or situations (32).

To date, the available evidence regarding prognosis of retained fractured instruments has come mostly from case series studies, which offer a low level of evidence, and only 2 true case-control investigations were identified (3, 7). The 2 studies, Crump and Natkin 1970 and Spili et al 2005, reported 35 years apart, in which wide variation in clinical technique would be assumed. Treatment outcomes, however, have not changed significantly during the past several decades (33). Therefore, from biologic point of view, meta-analysis of these 2 studies seems justified. Case-control studies realistically and ethically provide the highest level of evidence possible in such investigations. An important finding from many of the studies that evaluated only cases with a retained instrument fragment (no controls) was that the presence of a preoperative periapical lesion served as the main prognostic factor for the successful management of such cases (Table 6).

Data pertaining to factors influencing the prognosis of apical periodontitis after endodontic therapy are inconsistent and highly variable. In a Bayesian decision support model for predicting endodontic treatment outcome (34), 19 variables potentially affected the treatment outcome. Each variable individually might not have a strong impact on the prognosis, as was shown in this study. The narrow range of the 95% confidence interval of the risk difference (approximately ±5% differences in healing) suggests that further studies would not change the conclusion.

Clinical Recommendations Based on Results

Whether these findings (data derived from specialist practices and well-controlled university setting) can be directly extrapolated to general practice conditions remains to be determined. When endodontic treatment is performed to a high technical standard, the influence of a periapical lesion on the prognosis appears to be slight (6), but if the technical standard is compromised, the presence of a lesion can reduce the success rate considerably (8, 30). The outcome of endodontic treatment is related to effective disinfection of the root canal system and prevention of recontamination. An instrument fragment in itself is rarely the direct cause of the problem; it does, however, limit access to the apical part of the canal, compromising disinfection and obturation. The clinical situation (existence of periapical lesion), stage of canal preparation when instrument fracture occurred (canal infection), canal anatomy, fragment position, and type of fractured instrument can significantly influence prognosis and the approach to management (11).

The highest proportion of instrument fragments occurs in the apical third. In this location, an attempt to bypass a fractured instrument should always be initially considered because it can often be successful (12). Recently developed techniques and the operating microscope have made fractured instrument removal more predictable (10, 25, 35, 36). However, removal of an instrument fragment might actually make the situation worse. Because attempts to remove fractured instruments might lead to ledge formation, overenlargement and transportation of the prepared root canal, or perforation, the risks of removal should be balanced against modest benefit. The limited success of fragment removal, increased risk of perforation, and reduced root strength suggest that file removal beyond the curve should not be routinely attempted (24).

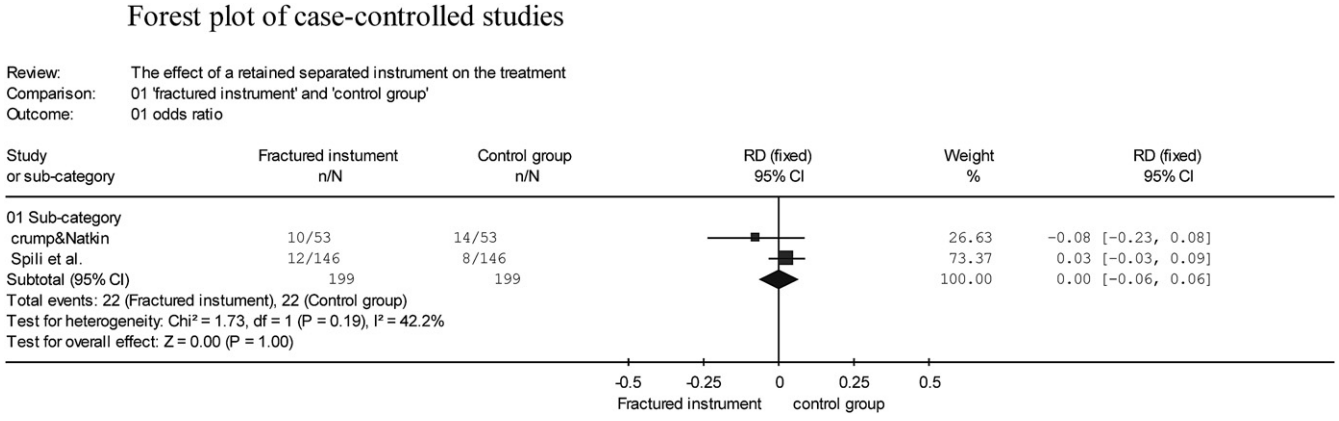

Figure 1. Forest plot of case-controlled studies.

TABLE 6. Influence of a Periapical Lesion on Healing of Teeth with a Fractured Instrument Fragment

	Lesion present		No lesion		Overall	
	Healed	Nonhealed	Healed	Nonhealed	Healed	Nonhealed
Strindberg (8)	2	2	9	2	11	4
Engström(41)	0	0	5	0	5	0
Grossman (43)	9	10	42	5	51	15
Crump (3)	27	2	21	3	48	5
Cvek (9)	3	1	0	0	3	1
Molyvdas (27)	8	3	32	3	40	6
Spili (7)	72	11	62	1	134	12
Total	121	29	171	14	292	43
Healed %		80.7		92.4		87.2

Lesion vs no lesion: $P = .002$ (χ^2 test).

All studies that compared lesion vs no lesion were included. They are case-control studies plus case series of fractured instrument cases only.

Finally, it is necessary to organize appropriate follow-up of the patient in the event of any clinical complication. This allows periodic review and radiographic assessment. If deterioration of periapical health is detected, apical surgery or extraction should be considered (37). Regular follow-ups to anticipate and deal with any potential problems are advocated. In this way, many difficult situations can be avoided and patient satisfaction maintained.

Conclusion

On the basis of the current best available evidence, the prognosis for endodontic treatment when a fractured instrument fragment is left within a root canal is not significantly reduced. The prognosis is lower if periapical pathology is present at the time of treatment, but only to the extent that effective canal disinfection is compromised. This conclusion, however, might not be fully applicable in general practice conditions because data in this review were derived from specialist practices and well-controlled university clinic.

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