

Representative survey on the reprocessing of endodontic instruments in Germany

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IN BRIEF

- This empirical study reports the results of a representative survey to the implementation of hygiene guidelines for the reprocessing of endodontic files.
- Suggests that endodontic files are not reliably decontaminated in general dental practice in Germany.

Aim The aim of the study was to review the implementation of hygiene guidelines for the reprocessing of endodontic files in a representative survey and to determine the time needed for the procedure. **Methods** A questionnaire with nine items was sent to 4,000 German dentists. In addition to obtaining personal information, it asked for the total time required for the reprocessing of instruments and contained specific questions about the cleaning procedure in order to assess whether the requirements of the German Federal Ministry of Health, as defined by the Robert Koch Institute, were complied with. Approval by the Ethics Committee was obtained. The data were analysed statistically using the Chi-square test and Cramer's V as a measurement of effect size. **Results** The response rate was 29.4% (n = 1,177/4,000). On 59 questionnaires, answers to several questions were missing; 1,118 questionnaires (28.0%) could be included in the evaluation. With effect sizes between 0.12 and 0.21, the survey could be classified as statistically representative of German dentists in terms of age and gender. The guidelines were adhered to by 31.7% (n = 354/1118) of respondents, while 68.3% (n = 764/1118) adhered to them either not fully, or not at all (P < 0.001). There were no significant differences in adherence to guidelines between younger (up to 44 years) and older (45 years and above) dentists (P = 0.31) or between women and men (P = 0.194). The reported time for cleaning a patient-related instrument set was more than nine minutes for 68.1% of respondents, not including the time needed for sterilisation; 5% of respondents treated files as single-use instruments. **Conclusions** The guidelines of the German Federal Ministry of Health for cleaning, disinfecting and sterilising endodontic files are widely disregarded in Germany. The designation and use of endodontic files as single-use instruments should be considered.

INTRODUCTION

The cleaning, disinfection and sterilisation of medical instruments has been repeatedly questioned and re-examined over the decades. While the risk of transmitting bacteria, viruses and fungi via dental instruments can be safely reduced through professional reprocessing and sterilisation in the autoclave,¹ prions are frequently still the focus of attention due to their thermal resistance to conventional decontamination methods.² Globally, there have been four cases of proven iatrogenic Creutzfeldt-Jakob disease after a surgical intervention. All affected patients had undergone neurosurgery, and

none of the cases had occurred in the last 30 years.³ Since the transmission of prions via dental instruments has only been observed in animal studies, interest in this problem has subsided in recent years.⁴⁻⁶ Nevertheless, the discussion concerning prions resulted in an increase in single-use of instruments,⁷ and manufacturers now recommend to treat endodontic files as single-use instruments.⁸

If the single-use of instruments is not feasible, national and international guidelines for re-use in medicine and dentistry must be followed. If no reprocessing instructions exist or if existing instructions are not complied with before re-use on a patient, this invariably constitutes a health risk.^{9,10}

In the past, the cleanliness of endodontic files has been evaluated and found to be insufficient in numerous studies. Smith *et al.* published a study in Scotland in 2002 which examined instruments from private dental surgeries and from dental clinics by electron microscopy and found that 76%

of instruments in dental surgeries and 14% (n = 5/37) of instruments in dental clinics were significantly contaminated.¹¹ In another study, published in 2005, instruments were inspected visually and examined for blood residue. Again, many instruments exhibited visible residual contamination (75%); 7% of instruments tested positive for blood.¹² A survey in Glasgow showed in 2006 that 98% of dentists surveyed (n = 179) cleaned manually, with 92% using ultrasonic baths, and that none of the practices surveyed had a washer-disinfector.¹³

In the UK there had been increased awareness of the difficulties in cleaning endodontic files due to the increased incidence of Creutzfeldt-Jakob disease. Therefore, in April 2007, the UK Department of Health classified reamers and files as single-use instruments.¹⁴

In Germany, only barbed broaches have been defined as single-use instruments in the field of endodontics. However, all other endodontic files have been classified as critical medical devices due to the risk of

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Table 1 Gender and age distribution. Distribution of dentists in Germany, in North Rhine–Westphalia¹⁷ and in our survey. For the purposes of the statistical analysis, dentists were assigned to two groups (up to 44 years of age, 45 years and up)

Age (years)	Germany (%)			North Rhine–Westphalia (%)			Survey (%)		
	Total	Men	Women	Total	Men	Women	Total	Men	Women
Up to 45	37	17	20	39.2	18.7	20.5	26.9	14.6	12.3
45 and up	63	40.8	22.2	60.8	43.7	17.1	73.1	53.6	19.5
Total	100	57.8	42.2	100	62.4	37.6	100	68.2	31.8

Table 2 Representative questionnaire on the reprocessing of endodontic files in Germany

Questionnaire	
Please provide your gender.	female
	male
How old are you?	under 35 years of age
	35 to 39 years of age
	40 to 44 years of age
	45 to 49 years of age
	50 to 54 years of age
	55 to 59 years of age
	60 to 64 years of age
	over 64 years of age
How frequently do you perform root canal treatments in your practice?	less than once per week
	about 1 to 3 per week
	about 4 to 6 per week
	about 7 to 9 per week
	more than 9 per week
How is the root canal procedure carried out?	manually
	mechanically
	manually and mechanically
On average endodontic files are used on how many patients?	1 patient
	2 to 4 patients
	5 to 7 patients
	more than 7 patients
Who carries out the cleaning, disinfection and sterilisation of endodontic files?	dental assistant
	dental assistant in training
	trained auxiliary personnel
Are the silicon stoppers removed before the cleaning?	always
	sometimes
	never
How is the disinfection carried out?	manually (with bath, with/without ultra sound)
	mechanically (cleaning and thermal disinfection in washers-disinfectors)
Estimate the amount of time per patient required for reprocessing endodontic files after the treatment (preparation of the instruments, packaging and labelling, unpacking and packing away of ultrasonic bath/washer-disinfectant and steriliser, excluding the preprocess and run time of washer-disinfectant and steriliser).	under 5 minutes
	5 to 9 minutes
	10 to 14 minutes
	15 to 19 minutes
	20 to 29 minutes
	over 29 minutes

disease. Critical medical devices are ‘devices for the use of blood, blood products or other sterile medicinal products/sterile medical devices, and medical devices that are intended to penetrate the skin or mucous membranes and thus come into contact with blood, internal tissues or organs, including wounds.’¹⁵ Moreover, instruments for root canal treatment are further divided into ‘Group B’, needing stricter requirements for reprocessing, because of their delicate and complex geometry.¹⁵

Since 2012, mechanical cleaning and thermal disinfection in washer-disinfectors before sterilisation in an autoclave has been mandatory for medical devices classified as critical B.¹⁵

The objective of our survey was to review the implementation of these provisions of the German Federal Ministry of Health, as defined by the Robert Koch Institute (RKI), by different groups of practitioners in Germany and to determine the time needed for the procedure.

MATERIALS AND METHODS

Number of surveyed dentists

Using the G*Power 3.1 software, a statistical power analysis software programme,¹⁶ an a-priori statistical power analysis was performed. To obtain a power of at least 80%, a comparison of means between two independent groups with an assumed small effect ($d = 0.20$) and an alpha error/significance level of 5% requires a total sample size of at least 788 participants. The number of 4,000 dentists to be surveyed was based on the assumption that, for a postal survey, response rates tend to be about 20–25%. For the survey, the most populous German state of North Rhine–Westphalia was selected because it approximately mirrors the national distribution of dentists in terms of age and gender (Table 1).¹⁷

Selection of surveyed dentists

The 2012/2013 Statistical Yearbook of the German Dental Association shows that 10,488 dentists are active in North Rhine–Westphalia.¹⁷ The group of dentists from North Rhine–Westphalia reflects the

Table 3 Steps of instrument processing, the times listed represent the minimum times for the cleaning and reprocessing of instruments as obtained by us during a pilot study

Steps of instrument processing	Duration (min)
Preparation of instruments (removing silicone stop, sorting of instruments in a washer-safe instrument box)	2
Loading/unloading the instruments into/out of the washer-disinfector	1
Optical inspection of instruments for cleanliness and integrity	2
Preparation of instruments for sterilisation (packaging and labelling of the instruments)	2
Loading/unloading the instruments into/out of the steriliser	1
Documentation	1
Total time	9

Table 4 Procedure of cleaning, disinfection and sterilisation. Percentage and absolute distribution of responses. Absolute figures may diverge somewhat due to occasional missing answers

Implementation by dental assistant (%)	Removal of the silicone stops (%)	Mechanical cleaning/disinfection in the washer-disinfector (%)	Single-use instruments (%)
97.7	43.3	60.4	5.5
(n = 1,051/1,076)	(n = 462/1,067)	(n = 643/1,065)	(n = 61/1,118)

national average in terms of age and gender (Table 1).¹⁷ Age and gender were chosen as the only available data to create a representative survey. For the postal survey, the municipalities of North Rhine-Westphalia were determined first based on data by the German Federal Statistical Office to ensure that rural and urban areas were equally considered.¹⁸ Using an electronic directory of professionals, the number of dentists in the various cities and municipalities were identified and entered in an Excel spreadsheet (n = 10,226). Dentists were randomly selected based on the calculated number of 4,000 dentists in relation to the number of dentists per city or municipality. Orthodontic surgeries were excluded because they perform no root-canal treatments.

Testing procedure

A questionnaire was used to elicit information on dentists' age and gender and the procedure used for reprocessing endodontic files in their surgeries (Table 2). Details about the procedure were elicited by inquiring about the person carrying out the reprocessing, about removal of the silicone stop, about performing the cleaning and disinfection process itself and the time required for that procedure (Table 3). The questionnaires were sent out to the selected dentists by postal mail together with a cover letter describing the project and a stamped return envelope. Dentists were assured of the anonymity of their responses. The study was approved by the Ethics Committee of Heinrich Heine

University Düsseldorf on 16 December 2013 (study no. 4,509).

The responses from the questionnaires were entered into the IBM SPSS Statistics software, version 22. The data were analysed statistically using the Chi-square test and Cramer's V as a measurement of effect size. The level of significance was set at $P < 0.05$.

RESULTS

Of the 4,000 questionnaires sent out, 1,177 were returned, corresponding to a response rate of 29.4%. Of these, 59 questionnaires were not included in the analysis because they contained more than two unanswered questions. Thus, 1,118 questionnaires (28%) with indications of age and gender were available for statistical analysis. Of the evaluable questionnaires containing gender information, 68.2% were returned by men (n = 763/1,118), 31.8% by women (n = 355/1,118).

To check whether the return rate was representative in terms of the dentists' age and gender, the data from the survey were compared to figures from the 2012/2013 Statistical Yearbook of the German Dental Association (Table 1).¹⁷

The results of the Chi-square test showed that statistically significant deviations within respondents from the distribution in North Rhine-Westphalia ($P < 0.001$) and in Germany as a whole ($P < 0.001$) are present. To determine whether these significant differences are meaningful, the Cramer's V was calculated as a measurement of effect size.

The effect sizes for the comparisons of the survey with the numbers for North Rhine-Westphalia and Germany were between 0.12 and 0.21. These results show that these are small differences, so that the survey can be considered representative.

To check whether cleaning, disinfection and sterilisation were implemented in accordance with the guidelines of the RKI, the individual data on the reprocessing procedure were considered first.

The cleaning, disinfection and sterilisation of the instruments was performed by a dental assistant or a dental assistant in training in 97.7% (n = 1,051/1,076) of cases. In 43.3% of cases (n = 462/1,067), the silicone stop used to indicate the working length was removed before cleaning, disinfection and sterilisation. Cleaning and disinfection were performed in a washer-disinfector in 60.4% of cases (n = 648/1,073), while in 39.6% of cases (n = 422/1,065), cleaning and disinfection were performed exclusively manually by submersion with or without ultrasound (Table 4).

The analysis of how many dentists comply with the guidelines of the German Federal Ministry of Health, as defined by the RKI, on all three counts revealed that 31.7% (n = 354/1,118) complied with the guidelines, while 68.3% (n = 764/1,118) did not.

The investigation of the effect the dentist's gender has on the implementation of the RKI guidelines found that 32.9% of men (n = 251/763) and 29.0% of women (n = 103/355) complied with the guidelines. The results of the Chi-square test showed that gender had no significant effect on the implementation of the RKI guidelines ($\chi^2(1) = 1.69$, $P = 0.194$). The result was confirmed by a Cramer's V of 0.04. Male dentists, however, perform significantly more root-canal treatments per week than female dentists ($\chi^2(4) = 23.14$, $P < 0.001$).

The analysis of the effect the dentist's age has on the implementation of the RKI guidelines showed that 29.3% of dentists up to 44 years (n = 88/300) and 32.5% of dentists 45 years and up (n = 266/818) complied with the guidelines. The results of the Chi-square test showed that age had no significant effect on the implementation of the RKI guidelines ($\chi^2(1) = 1.03$, $P = 0.31$). A Cramer's V of 0.03 confirmed this result. However, younger dentists (up to 44 years) perform significantly more endodontic treatments than older dentists (45 years and up) ($\chi^2(4) = 12.39$, $P = 0.015$).

Finally, the total time needed to prepare the instruments for re-use was analysed. Evaluation of the questionnaires showed that 33.3% (n = 358/1,075) of dentists assume that a maximum of nine minutes is required

for cleaning, disinfection and sterilisation. The result of the Chi-square test showed that the assumed total time spent as assumed by the dentists is significantly longer than nine min ($\chi^2(1) = 4\,781\,267.49$, $P < 0.001$). A Cramer's V of 66.69 indicated that this difference is large.

DISCUSSION

The questionnaire was printed only on one side to maximise the response rate. Nine questions addressed the elementary steps of instrument reprocessing which was important to examine compliance with the guidelines.

The actual response rate of 29.4% was better than the response rate assumed before the study. Nevertheless, compared to other empirical studies published within the field of dentistry, it was relatively low. Barnes *et al.*, in a postal survey, sent reminder letters to dental surgeries who had not responded after three weeks, which resulted in a response rate of 81%.¹⁹ Other comparable studies, too, achieved response rates of 73%²⁰ to 88%²¹ using this method. Other studies on hygiene and infection control employed survey visits in order to verify the effective implementation of the hygiene guidelines.²² On-site checks yield more accurate results, but the number of sites that can be included is smaller, and the required consent to hygiene monitoring may result in a positive selection for good hygiene practices. To assure the dentists of the anonymity of their responses, it was decided against registering participants and against on-site visits. This also excluded the possibility of identifying and reminding non-respondents. Keeter *et al.* found that forced follow-up, while increasing response rates, does not affect the composition of the group or the result of the survey.²³ The statistical analysis confirmed the representativeness of the study for Germany in terms of age and gender due to the high number of participants (1,118 dentists).

Only 43.3% of respondents reported removing the silicone stop before cleaning, so that the disinfection and sterilisation of this instrument range must be described as inadequate. Hence, there is still a risk of iatrogenic disease transmission despite reprocessing. Only completely exposed instrument surfaces can be cleaned and thus made accessible for subsequent sterilisation.²⁴

More than a third of respondents conducted the cleaning and disinfection not by washer-disinfector, as per the recommendations of the washer-disinfector, but manually. The cleanliness of endodontic files after different cleaning procedures was examined in different studies. Cleaning in

the washer-disinfector with its reproducible results is significantly more effective than non-validated manual cleaning.^{1,25-27}

Although cleaning with the washer-disinfector is more effective, this method cannot guarantee the absence of residual contamination.^{1,25,26,28}

The results of the survey have shown that compliance with the guidelines is completely independent of the age and gender of the person responsible. Cheng *et al.* were unable to find any gender-specific differences with regard to compliance with sterilisation policies, but they did find significant differences in infection-control behaviour as a function of the age of the treatment provider.²⁹ Other authors, by contrast, found that women implement hygiene directives significantly better than men.³⁰

Less than a third of respondents said nine minutes were sufficient for cleaning the instruments from one patient, while all others estimated the time required to be more than nine minutes. The total time of nine minutes was obtained by us during a pilot study. These nine minutes only include steps performed by dental assistants (Table 3). We ascertained the total time needed for reprocessing because it allows us to make conclusions about the cleaning procedure. When analysing the questionnaires, it was noted that some respondents carried out the cleaning and disinfection in an ultrasonic bath and in a washer-disinfector. While this does not adversely affect the quality of the process, it adds to the time requirement, which in turn drives up the operating and personnel costs. The result of the survey shows that the willingness exists to dedicate a significant amount of time to instrument hygiene. However, this time commitment also encompasses redundant procedures, whereas other, necessary steps such as the removal of the silicone stoppers are omitted. Due to this incomplete knowledge, or deficiencies in implementation, nearly 70% of respondents are not in compliance with the RKI guidelines¹⁵ acting for the Germany Ministry of Health.

Concluding remarks

The guidelines issued by the manufacturers and by the German Federal Ministry of Health for cleaning, disinfecting and sterilising endodontic files are widely disregarded. Based on this result, which is representative of the situation in Germany, the designation and use of endodontic instruments as single-use instruments should be considered.³¹

1. Van Eldik D A, Zilm P S, Rogers A H, Marin P D. Microbiological evaluation of endodontic files after cleaning and steam sterilization procedures. *Aust Dent J* 2004; **49**: 122-127.

2. Walker J T, Dickinson J, Sutton J M, Marsh P D, Raven N D. Implications for Creutzfeldt-Jakob disease (CJD) in dentistry: a review of current knowledge. *J Dent Res* 2008; **87**: 511-519.
3. Thomas J G, Chenoweth C E, Sullivan S E. Iatrogenic Creutzfeldt-Jakob disease via surgical instruments. *J Clin Neurosci* 2013; **20**: 1207-1212.
4. Kirby E, Dickinson J, Vassef M *et al.* Bioassay studies support the potential for iatrogenic transmission of variant Creutzfeldt Jakob Disease through dental procedures. *PLoS one* 2012; **7**: e49850.
5. Molesworth A M, Smith A J, Everington D *et al.* Risk factors for variant Creutzfeldt-Jakob disease in dental practice: a case-control study. *Br Dent J* 2012; **213**: E19.
6. Ingrassio L, Pisani F, Pocchiari M. Transmission of the 263K scrapie strain by the dental route. *J Gen Virol* 1999; **80**: 3043-3047.
7. Sonntag D, Peters O A. Effect of prion decontamination protocols on nickel-titanium rotary surfaces. *J Endo* 2007; **33**: 442-446.
8. VDW GmbH. Infection Control Made Simple: Sterile Endo Instruments by VDW. Information and Product Overview VW000289 Rev.0/13.03.11.
9. Thiede B, Kramer A. Evaluation of reprocessing medical devices in 14 German regional hospitals and at 27 medical practitioners' offices within the European context- consequences for European harmonization. *GMS Hyg Infect Control* 2013; **8**: DOI:10.3205/dgkh000220.
10. Roebuck E M, Strang R, Green I, Smith A, Walker J. The availability and content of dental instrument manufacturers' decontamination information. *Br Dent J* 2008; **204**: E14; discussion 444-445.
11. Smith A, Dickson M, Aitken J, Bagg J. Contaminated dental instruments. *J Hosp Infect* 2002; **51**: 233-235.
12. Letters S, Smith A J, McHugh S, Bagg J. A study of visual and blood contamination on reprocessed endodontic files from general dental practice. *Br Dent J* 2005; **199**: 522-525; discussion 13.
13. Bagg J, Smith A J, Hurrell D, McHugh S, Irvine G. Pre-sterilisation cleaning of re-usable instruments in general dental practice. *Br Dent J* 2007; **202**: E22; discussion 550-551.
14. Department of Health (DH). Advice for dentists on re-use of endodontic instruments and variant Creutzfeldt-Jakob Disease (vCJD). 2007.
15. Commission for Hospital H, Infection P, Federal Institute for D, Medical D. Hygiene requirements for the reprocessing of medical devices. Recommendation of the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM). *Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz* 2012; **55**: 1244-1310.
16. Faul F, Erdfelder E, Buchner A, Lang A G. Statistical power analyses using G*Power 3.1: tests for correlation and regression analyses. *Behav Res Methods* 2009; **41**: 1149-1160.
17. German-Dental-Association. *Statistisches Jahrbuch 2012/2013*. Berlin: Bundeszahnärztekammer, 2013.
18. Statistisches Bundesamt. Alle politisch selbständigen Gemeinden in Deutschland nach Bevölkerung am 31.12.2011 auf Grundlage des Zensus 2011 und früherer Zählungen. 2013.
19. Barnes J J, Patel S, Mannocci F. Why do general dental practitioners refer to a specific specialist endodontist in practice? *Int Endo J* 2011; **44**: 21-32.
20. Orafi I, Rushton VE. A questionnaire study to derive information on the working environment, clinical training, use of ancillary staff and optimization of patient radiation dose within UK dental practice. *Int Endo J* 2012; **45**: 763-772.
21. Gupta R, Rai R. The adoption of new endodontic technology by Indian dental practitioners: a questionnaire survey. *J Clin Diagn Res* 2013; **7**: 2610-2614.

22. Smith G W, Smith A J, Creanor S, Hurrell D, Bagg J, Lappin D F. Survey of the decontamination and maintenance of dental handpieces in general dental practice. *Br Dent J* 2009; **207**: E7; discussion 160–161.
23. Keeter S, Miller C, Kohut A, Groves R M, Presser S. Consequences of reducing nonresponse in a national telephone survey. *Pub Opin Quart* 2000; **64**: 125–148.
24. Linsuwanont P, Parashos P, Messer H H. Cleaning of rotary nickel-titanium endodontic instruments. *Int Endod J* 2004; **37**: 19–28.
25. Van Eldik D A, Zilm P S, Rogers A H, Marin PD. A SEM evaluation of debris removal from endodontic files after cleaning and steam sterilization procedures. *Aust Dent J* 2004; **49**: 128–135.
26. Assaf M, Mellor A C, Qualtrough A J. Cleaning endodontic files in a washer disinfectant. *Br Dent J* 2008; **204**: E17; discussion 562–563.
27. Robert Koch-Institut. Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten. Empfehlung der Kommission für Krankenhaushygiene und Infektionsprävention (KRINKO) beim Robert Koch-Institut (RKI) und des Bundesinstitutes für Arzneimittel und Medizinprodukte (BfArM). *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2012; **55**: 1244–1310.
28. Perakaki K, Mellor A C, Qualtrough A J. Comparison of an ultrasonic cleaner and a washer disinfectant in the cleaning of endodontic files. *J Hosp Infect* 2007; **67**: 355–359.
29. Cheng H C, Su C Y, Huang C F, Chuang C Y. Changes in compliance with recommended infection control practices and affecting factors among dentists in Taiwan. *J Dent Educ* 2012; **76**: 1684–1690.
30. McCarthy G M, Koval J J, John M A, MacDonald J K. Infection control practices across Canada: do dentists follow the recommendations? *J Can Dent Assoc* 1999; **65**: 506–511.
31. Shay B, Moshonov J. [Single file endodontic treatment: a new era?]. *Refu'at Ha-peh Veba-shinayim (1993)* 2013; **30**: 6–9, 76.