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A cleaning protocol for rotary nickel-titanium endodontic instruments

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Abstract

***Background*:** The cleaning of endodontic and all dental instruments prior to sterilization is a prerequisite for their processing for re-use. This study aimed to develop a clinically practical cleaning protocol for rotary nickel-titanium (NiTi) endodontic files prior to sterilization.

***Methods*:** Cleaning experiments were conducted on six different types of files that had been used on human teeth. The experiments involved three components of mechanical and chemical removal of root canal debris from the files: the use of sponges soaked with chlorhexidine to remove gross debris, pre-soaking, and ultrasonication. After cleaning, the files were immersed in Van Gieson's solution and examined under magnification for stained debris. New unused files were also examined.

***Results*:** Macroscopically, there were no instances of visible debris and all files appeared clean after all cleaning sequences. Microscopically, new files showed both stained and unstained debris, and several experimental cleaning regimens produced files that were free of stained debris. Combining elements of the most effective cleaning sequences resulted in a cleaning protocol that predictably produced clean files.

***Conclusions*:** The results do not support the recommendation for the single use of endodontic files based on inability to clean files between uses. Under experimental conditions the cleaning protocol developed rendered rotary NiTi files 100 per cent free of stained debris. The protocol comprises 10 vigorous strokes in a scouring sponge soaked in 0.2 per cent chlorhexidine solution, a 30 minute pre-soak in an enzymatic cleaning solution, 15 minutes ultrasonication in the same solution, and a 20 second rinse in running tap water. The protocol can be applied to all endodontic files.

Key words: Cleaning endodontic files, cross-infection.

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INTRODUCTION

Infection control guidelines indicate that cleaning of instruments to remove organic residue is a required step in order to achieve sterility of instruments.[1-4] Endodontic instruments must be cleaned and sterilized before their first use.[5] However, currently there is no one method recognized to test the cleanliness (i.e., lack of soil and bioburden) of an item.[6] The Australian/New Zealand Standard AS/NZS 4187:2003[2] stipulates that instruments should be 'clean to the naked eye (macroscopic) and free from any protein residues'. It does not stipulate how protein residues are to be assessed. Recommendations concerning cleaning and sterilization processes should be based on scientifically obtained and clinically relevant data,[7] and be justifiable, achievable, and consistent with known risks.[2] Unfortunately, there is little research information available on which to base infection control procedures.[8] Cleaning and sterilization recommendations made by various groups may in fact be too stringent and not reflect clinical practice.[7]

Most endodontic instruments as supplied from the manufacturer are not sterile and have been found to have metallic spurs and debris on their surfaces.[9-13] In some cases even epithelial cells have been found on new unused files.[9,11] Furthermore, the manufacturing process produces milling marks and metal debris,[14] and dentine fragments appear to adhere to deposits of carbon and sulphur resulting from the decomposition and oxidation of the lubricating oil used during machining.[5]

Although there is considerable evidence that endodontic files can be predictably sterilized even in the presence of biologic debris,[12,15-18] the cleaning of instruments to remove micro-organisms and biological debris (bioburden) effectively eliminates the majority of micro-organisms.[7,19,20] Very little information is available in the literature with reference to efficient cleaning protocols for dental instruments in general and endodontic instruments in particular. Similarly, the medical literature relating to the cleaning of instruments is sparse but the findings of the few available papers can be extrapolated to the dental scenario with reference to general dental instruments.

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Principally, it is difficult to clean instruments where their design does not allow access to all surfaces with complex designs[21] but most other instruments are not a challenge to clean and sterilize.[7,19]

As endodontic files have no internal surfaces that cannot be reached, it would be expected that a cleaning protocol could be developed that results in files free of bioburden. One such cleaning protocol for rotary nickel-titanium (NiTi) endodontic files has recently been developed, which involved a sequential combined mechanical and chemical cleaning procedure.[13] That laboratory protocol depended on carefully controlled conditions, and in the private practice setting all files were rendered macroscopically clean but only 87 per cent of files were rendered microscopically clean. The procedure involved brushing used files in an endodontic stand, followed by a 10 minute immersion in 1 per cent sodium hypochlorite (NaOCl) and then ultrasonication in the same solution for five minutes. The purpose of the present study was to test alternative combinations of mechanical and chemical cleaning methods to derive a simple, more effective protocol for the cleaning of rotary NiTi files.

MATERIALS AND METHODS

Overview

Cleaning experiments were conducted on six different types of rotary NiTi files, which differed in their cross-sectional shape and design. The files examined were ProTaper, ProFile and GT (Dentsply/Maillefer, Ballaigues, Switzerland); FlexMaster (VDW GmbH, Munich, Germany); Quantec (Analytic Endodontics, California, USA) and K3 (SybronEndo, Sybron Dental Specialties, California, USA). For the purposes of comparison the instruments were categorized according to their cross-sectional shape as triple U (ProFile, GT), triangular (ProTaper, FlexMaster), and complex (Quantec, K3).

Assessment of new files

Thirty-six new, straight-from-the-packet files to be used in the experiments on the extracted teeth were first stained with Van Gieson's solution, a histological stain, to assist in identification of debris of biological origin. The instruments were completely submerged into a glass beaker containing Van Gieson's solution for three minutes, rinsed in running tap water for 30 seconds, and allowed to air dry in a covered file stand. Files were then first examined with the naked eye and subsequently at 15-45x magnification using a dissecting microscope (American Optical Corporation, Buffalo, New York, USA). For this process the files were placed into a hollow rectangular metal block, square in cross-section with an insert of rubber impression material to accept the instrument handle. Scoring of the files involved recording the presence of red or orange stained material, of unstained material, or of totally clean files. The entire flute surface of each file was scored. Any stained material anywhere on the file led to a rating of 'dirty'. Both totally-clean files and files with slight non-stained debris were considered 'clean'.

Experiments in extracted teeth

After scoring, these new files were individually cleaned of any debris under the microscope using a moist sponge. The files were then used to instrument the root canals of extracted human molars and premolars until debris was easily visible on the files with the naked eye. The debris-laden files were used in experiments to determine feasible cleaning protocols as assessed using the staining and scoring procedure described above. Because the objective of this project was to develop a protocol with the end result of a biologically clean endodontic file, the analysis was purely a comparison of the final results of the various protocols. The protocols involved different methods of mechanical and chemical removal of the root canal debris. Based on previous experience in this laboratory,[13] a sequence of storage in a moist sponge, mechanical removal of gross debris followed by chemical dissolution and ultrasonication served as the basis for effective cleaning protocols.

Experiments on files used clinically

Once certain favourable methods of cleaning the files were identified, their clinical practicality was assessed by applying these cleaning techniques to instruments previously used in patients. Rotary NiTi files used in a private endodontic practice were subjected to the cleaning techniques by the dental assistants after instructions were provided by the principal author. No distinction was made between new or previously used instruments. The various protocols consisted of a chairside manual process followed then in the sterilization room by a chemical process and a final ultrasonication.

Details of experiments

The various elements of the three processes of the experiments involved the materials and procedures shown in Table 1.

Chairside manual processes

Different types of sponges for chairside wet storage of instruments and initial cleaning were tested. These included scouring pads, scouring sponges, dense (i.e., relatively non-porous) sponges and porous sponges. All sponges were the most inexpensive generic brands available at any supermarket. The sponges were cut to fit small plastic containers (Fig 1). The sponges were saturated in either 0.2 per cent chlorhexidine gluconate aqueous solution (Colgate Oral Care, Sydney, NSW) or 1 per cent NaOCl solution (Milton Solution, Procter & Gamble, Parramatta, NSW). The different methods of use of the sponges tested included wiping the files with dry scouring pads, using five or 10 'in-and-out' strokes with the file in a saturated sponge and 'screwing in' the file in the saturated scouring sponges followed by five or 10 strokes.

Table 1. Order, processes and results of cleaning experiments performed on debris laden files

Group*	Chairside manual process†	Chemical process‡	Ultrasonication§	Cleaning success‖
A	Scouring sponge, chlorhexidine, five strokes	1% NaOCl, 5	1% NaOCl, beaker, 5	15/20 (75%)
B	Dense sponge, chlorhexidine, five strokes	1% NaOCl, 5	1% NaOCl, beaker, 5	7/8 (88%)
C	Scouring sponge, chlorhexidine, five strokes	EmPower, 15	1% NaOCl, beaker, 10	11/14 (79%)
D	Scouring sponge, chlorhexidine, five strokes	EmPower, 15	1% NaOCl, beaker, 5	9/12 (75%)
E	Scouring pad-dry wipe; dense sponge, chlorhexidine, five strokes	EmPower, 15	EmPower, basket, 30	6/6 (100%)
F	Dense sponge, chlorhexidine, five strokes	EmPower, 15	EmPower, basket, 30	4/6 (67%)
G	Scouring sponge, chlorhexidine, five strokes	EmPower, 15	EmPower, basket, 45	5/6 (83%)
H	Dense sponge, chlorhexidine, five strokes	EmPower, 15	EmPower, basket, 45	6/6 (100%)
I	Scouring sponge, chlorhexidine, five strokes	EmPower, 15	EmPower, stand, 45	2/6 (33%)
J	Dense sponge, chlorhexidine, five strokes	EmPower, 15	EmPower, stand, 45	5/6 (83%)
K	Scouring pad-dry wipe; dense sponge, chlorhexidine, five strokes	4% NaOCl, 15, not handle	EmPower, basket, 30	7/8 (88%)
L	Scouring sponge, chlorhexidine, 10 strokes	4% NaOCl, 15, not handle	EmPower, basket, 30	6/6 (100%)
M	Scouring pad-dry wipe; dense sponge, chlorhexidine, five strokes	4% NaOCl, 15, not handle	EmPower, basket, 15	8/9 (89%)
N	Scouring sponge, chlorhexidine, five strokes	1% NaOCl, 15, not handle	EmPower, basket, 30	19/20 (95%)
O	Dense sponge, chlorhexidine, five strokes	1% NaOCl, 15, not handle	EmPower, basket, 30	18/20 (90%)
P	Dense sponge, 1% NaOCl (15 mins), 10 strokes	Nil	EmPower, basket, 30	11/13 (85%)
Q	Scouring sponge, 1% NaOCl (15 mins), 10 strokes	Nil	EmPower, basket, 30	14/16 (88%)
R	Dense sponge, chlorhexidine, 10 strokes	1% NaOCl, 15	EmPower, basket, 30	9/12 (75%)
S	Scouring sponge, chlorhexidine, 10 strokes	1% NaOCl, 15	EmPower, basket, 30	16/18 (89%)
T	Scouring sponge, chlorhexidine, 10 strokes	EmPower 30, basket	EmPower, basket, 10	30/32 (94%)
U	Scouring sponge, chlorhexidine, 10 strokes	EmPower 30, basket	EmPower, stand, 10	16/18 (89%)
V	Dense sponge, chlorhexidine, 10 strokes	EmPower 30, basket	EmPower, basket, 10	29/32 (91%)
W	Scouring sponge, chlorhexidine, 10 strokes	EmPower 30, basket	EmPower, basket, 15	30/30 (100%)

*Each group represents a separate experiment performed sequentially from A to W. Each experiment comprised, in order, the chairside, the chemical and the ultrasonication processes.
†Details include type of sponge, solution used to soak the sponge and number of strokes of the file in the sponge.
‡Details include the pre-soaking solution and the pre-soaking time (min). Files were placed into a glass beaker containing the solution. 'Not handle' indicates only the NiTi portion of the file was treated. 'Basket' indicates that the files were supported in the mesh basket whilst in the glass beaker.
§Details include the solution used, the means of holding the files and the time period of ultrasonication.
‖The fraction represents the number of clean files over the number of files tested, and is also expressed as a percentage.

Chemical processes

Different solutions were tested for pre-soaking instruments after the chairside cleaning. These included 1 per cent NaOCl, 4 per cent NaOCl (Endosure, Dentalife P/L, Croydon, Vic); 15 per cent EDTA (EndoPrep, PDS, Bayswater, Vic); EmPower enzyme solution (Metrex Research Corporation, Romulus, Michigan, USA). The solutions were tested for five, 15, or 30 minutes of pre-soaking.

Ultrasonication

After the pre-soaking stage the files were placed into an ultrasonic bath (Biosonic UC100, Coltène, Whaledent, New Jersey, USA) to test different solutions. These solutions were 1 per cent NaOCl, 15 per cent EDTA, EmPower enzyme solution. Each solution was tested for five, 10, 15, 30 or 45 minutes. The different containers used to hold the files during the ultrasonication included a glass beaker, a fine metal mesh basket (Premier Housewares, Universal Wholesalers, Yennora, NSW) (Fig 2, 3), or a plastic file stand (Dentsply/Maillefer, Ballaigues, Switzerland).

For each protocol, new sponges and new enzyme solution were used each time. After each of the protocols, instruments were rinsed in running tap water for 20 seconds and placed into autoclave pouches to await the staining and scoring phase as detailed earlier.

The resulting data were entered into a Microsoft® Excel spreadsheet from which tables were drawn and chi-square statistical analysis performed and reported where significance was reached ($P<0.05$).

RESULTS

After the various protocols, and for new and unused instruments, there were no instances of visible debris and all files appeared 'clean' when files were first examined with the naked eye. Microscopic examination found that all 36 rotary NiTi instruments examined straight from their packets showed evidence of non-stained debris and six had slight stained debris. This included one brand of files that is pre-sterilized, individually packaged, and ready-to-use. All instruments showed evidence of the manufacturing process including machining grooves on the blades and metal debris from grinding. The instrument surfaces were usually scratched by the scouring pad and scouring sponge but these scratches were always clearly much shallower than the manufacturing milling marks and ran in the flutes along the long axis of the files.

Fig 1. Small plastic container with chlorhexidine-soaked scouring sponge used chairside to clean files and keep them moist.

The potential number of combinations of the materials and procedures tested is in the thousands, so that systematic evaluation of all procedures was impractical. The experiments were conducted in the order listed in Table 1, which represents the progressive development of the final protocol and indicates that the numbers of files examined in each protocol (for a particular file type) varied. The lower end of this range represents initial trials of particular combinations and the higher end resulted from increasing the number of files tested where the initial trials pointed to promising sequences. In this way, only relatively successful procedures and materials were tested, and problems or ineffective methods were identified and progressively modified or replaced. This included methods within each protocol that proved to be clinically impractical, risky, unrealistic, detrimental, or tedious.

The four remaining clinically acceptable variables were the type of sponge (other than porous), the number of cleaning strokes in the sponge, the length of pre-soaking time in the enzyme solution (EmPower) and the ultrasonication time. Table 2 illustrates the effect of each of these on the cleanliness of all file types. The result for each individual variable was not exclusive of the influence of the other three, nor of file type. Nevertheless, it was apparent that the number of strokes and the pre-soaking time were important relative to the sponge type and ultrasonication time.

Fig 2. Small metal mesh basket used to support the files during pre-soaking and ultrasonication.

Fig 3. Mesh basket supported in a 600ml glass beaker during pre-soaking and ultrasonication. The plastic supporting ring is provided with the basket and the glass beaker fits the ultrasonic unit supporting ring.

This finding was confirmed in Table 3 where only complex cross-sectional design files are considered. Table 2 and 3 both indicate that ultrasonication for 15 minutes was beneficial, and there was a trend for a scouring sponge to work better than a dense sponge in the case of complex file designs. When using the sponge with the coarse (scourer) top layer (Fig 1), small delicate files often needed to be 'screwed' into the sponge before initiating the in-and-out strokes to avoid bending the file. Ten in-and-out strokes produced significantly better results than five strokes. More than 10 strokes proved to be tedious, particularly chairside. Overall, the results did not statistically confirm that complex designs were more difficult to clean although there was a small trend in that direction (Table 4).

Pre-soaking in NaOCl for short periods achieved better results than pre-soaking in other solutions, and a 1 per cent solution was as effective as a 4 per cent solution. A 15-minute pre-soak was more effective than five minutes. However, to prevent corrosion the files had to be placed upright in a very small beaker such that the shanks, which are not NiTi, were not immersed in the solution. This proved to be clinically tedious and

Table 2. Summary of results of cleaning experiments with emphasis on the four main components of the cleaning procedure

Procedure*	Totals	Dirty	Clean
Scouring sponge	198	25	173 (87%)
Dense sponge	106	14	92 (87%)
Five strokes in either sponge	131	25	106 (81%)
10 strokes in either sponge	193	16	177 (92%)†
EmPower pre-soak – 15 min	62	14	48 (77%)
– 30 min	112	7	105 (94%)‡
EmPower ultrasonic – 10 min	82	7	75 (91%)
– 15 min	39	1	38 (97%)§
– 30 min	125	15	110 (88%)
– 45 min	24	6	18 (75%)

*Each procedure includes all files exposed to that particular variable irrespective of the other variables to which it was also exposed.
†Significantly more with 10 strokes (x^2=8.225; DF=1; P=0.004).
‡Significantly more after 30 mins (x^2=10.024; DF=1; P=0.002).
§Significantly more than after 45 mins (Fisher's Exact test, P=0.01).

there was a risk of spillage. In some instances where NaOCl was used to saturate the sponges, evidence of corrosion resulted on some file blades. The use of EDTA as a pre-soak solution proved to be ineffective and was abandoned. Commonly, corrosion of the files occurred when they were ultrasonicated for more than 10 minutes in a beaker of either 1 or 4 per cent NaOCl. The instrument shanks were particularly affected, but the NiTi portion appeared to be affected when it came into contact with the handle of another instrument. The areas of corrosion of the instruments were sometimes stained by the Van Gieson's solution. These defects appeared as irregular eroded cavities of various dimensions, often producing a honeycomb effect.

As an ultrasonic bath solution, the enzyme solution (EmPower) was as effective as NaOCl but was considered safer than the NaOCl because it lacked the potential for corrosion. EDTA in the ultrasonic bath was ineffective. Files were cleaned better during ultrasonication if they were placed into a supported basket (Fig 2, 3) rather than left in a beaker. There seemed to be no difference in cleanliness between using the basket or using the file stand during ultrasonication. The EmPower solution did not cause damage to the fine metal mesh basket as determined by no macroscopic evidence of deterioration after conducting the many experiments.

Table 3. Summary of results of cleaning for complex files with emphasis on the four main components of the cleaning procedure

Procedure*	Totals	Dirty	Clean
Scouring sponge	50	7	43 (86%)
Dense sponge	9	3	6 (67%)
Five strokes in sponge	25	8	17 (68%)
10 strokes in sponge	41	2	39 (95%)†
EmPower pre-soak – 15 min	21	8	13 (62%)
– 30 min	40	2	38 (95%)‡
EmPower ultrasonic – 10 min	10	2	8 (80%)
– 15 min	32	0	32 (100%)§
– 30 min	9	2	7 (78%)
– 45 min	12	5	7 (58%)

*Each procedure includes all files exposed to that particular variable irrespective of the other variables to which it was also exposed.
†Significantly more with 10 strokes (Fisher's Exact Test, P=0.005).
‡Significantly more after 30 min (Fisher's Exact Test, P=0.002)
§Significantly more than after 30 min (Fisher's Exact Test, P=0.04) or 45 min (Fisher's Exact Test, P = 0.001).

Table 4. Results of all cleaning experiments according to file type

File type*	Totals	Dirty	Clean
Triangular	93	10	83 (89%)
Triple U	165	21	144 (87%)
Complex	66	10	56 (85%)

*Refers to cross-sectional shape of the files. See text for details of file brands in each category.

The results illustrate that no one single procedure by itself predictably resulted in 'clean' endodontic files. However, sequentially adding the various factors resulted in a protocol that achieved 100 per cent cleanliness of files (Table 5). Thus, the combination of favourable factors acted synergistically to produce a predictable result. Therefore, a simple effective protocol based on the above findings is presented in Table 6.

DISCUSSION

Whilst there are no reported cases of accidental cross-infection subsequent to dental treatment, the current concern over the risk of iatrogenic transmission of prion diseases has contributed to the view that consideration should be given to treating endodontic instruments as single use.[22] However, it is extremely important to consider that the consensus of expert opinion seems to be that highly specific cross-infection control measures in dentistry are required only for patients with, or at notable risk of, prion diseases.[23,24] Hence, there seems to be no scientific justification for the single use of endodontic instruments on the basis that prion diseases may be transmitted via contaminated files. Nevertheless, concerns have been raised regarding the safety of multiple use files because of an inability to clean them.[22]

The present paper assessed the ability of different protocols to produce endodontic files that were microscopically free of biological (stained) debris, and did not assess sterility. To this end this study has developed a simple protocol that reliably produces rotary NiTi files that are 100 per cent free of stained debris at a microscopic level. Importantly, the protocol was equally effective for simple file designs and for complex designs incorporating deep and narrow flutes. Therefore, the protocol described in this study can be

Table 5. Effect on file cleanliness by progressive incorporation of best factors

Procedure	Totals	Dirty	Clean
Scouring sponge	198	25	173 (87%)
+10 strokes	120	8	112 (93%)
+30 min EmPower pre-soak	80	4	76 (95%)
+15 min EmPower ultrasonication	30	0	30 (100%)

Table 6. Recommended protocol for cleaning of endodontic files

Step	Method
1	10 vigorous strokes in a scouring sponge soaked in 0.2% chlorhexidine solution
2	30 minute pre-soaking in an enzymatic cleaning solution
3	15 minute ultrasonication in an enzymatic cleaning solution
4	20 second rinse in running tap water

applied effectively to other endodontic files as well as to new unused files prior to their first use.

In the progressive development of the final protocol, certain procedures proved to be unsuitable and were abandoned. These included: the dry-wipe with a scouring pad because of the potential for needle-stick injury; the use of porous sponges because they seemed to dry rapidly; the use of NaOCl at any stage in the procedure because of the risk of file corrosion; the use of EDTA at any stage because of its ineffectiveness; and ultrasonication for 30 minutes or more, which slowed the process too much to be clinically suitable.

Some authors have reported that endodontic instrument cleaning was extremely difficult and time consuming because of the inability of a gauze wipe or ultrasonics to remove some of the plastic manufacturing debris within the flutes.[9] However, details of the cleaning procedures were not provided in that report, and plastic does not pose a cross-infection risk. Murgel *et al.*[25] reported that files could not be totally cleaned with sponge, gauze or ultrasonics. However, these authors used only two thrusts into the sponge and the ultrasonic time was for just five minutes. The present study clearly indicates that both the mechanical and chemical aspects of the cleaning protocol must be applied for a sufficient time in order for proper cleaning to occur. It has been previously established that debris and micro-organisms can be reduced by a cleaning protocol that includes a mechanical action,[11,25,26] and ultrasonic agitation of the instruments in a solvent solution.[10,27-29] The present study has confirmed these previous findings as well as confirming that new files straight from the packet, whether pre-sterilized or not, have considerable amounts of unstained debris and, in some instances, stained debris on their flutes.

The use of nylon bristle brushes and metal bur brushes to clean endodontic instruments is a common and long-used method. However, Linsuwanont[13] found that brushing was not a very successful procedure. This may be due to the brushing of instruments, while they are in a stand, restricting the access of the bristles to all surfaces of the file blade. In the case of very small files, the bristles of the brush are larger than the width of the instrument flutes. Furthermore, the brushing action in this case is perpendicular to the long axis of the instrument and not in line with the instrument flutes. Metal bur brushes are commonly used to clean down the long axis of individual instruments whilst being held between the dental assistant's fingers. With this action, the bristles of the metal brush are not moving along the instrument flutes but rather over them, and it will be unpredictable as to whether the entire circumference of the file is being contacted. Furthermore, this procedure is usually performed dry and there is a risk of needle-stick injury. The literature supports this view of the inadequacy of hand scrubbing of instruments.[27,29]

The use of a sponge implies that all sides of the instrument are likely to be contacted by the sponge simultaneously. The use of the sponge is also safer from a needle-stick-injury point of view compared with wiping with gauze or brushing.[30] The findings of the present study indicate that a dense, relatively non-porous sponge is firm enough to exert a force against the instrument during the in-and-out strokes enabling the sponge material to expand, at least partially, into the instrument flutes. A more porous sponge has less sponge material per unit volume and so there is less material available to physically remove debris from the instrument flutes. The coarse top layer of scouring sponges consists of very fine, relatively stiff fibres that enter the file flutes, thus explaining the efficacy of these sponges particularly for complex design files. Another advantage seen in the present study was that the dense sponges and scouring sponges retained the chlorhexidine solution better than the porous sponge. The latter allowed the solution to drain downward leaving the top layer almost dry. The purpose of the sponge is not only the physical cleaning action but also to keep the files and remaining debris moist, which is an important aspect of instrument cleaning.[30] The significantly better cleaning results with the greater number of strokes indicates the importance of this mechanical component of the protocol.

Pre-soaking before ultrasonication has been shown to be an important step in the cleaning process[28,30] and should begin as close to the point of use as possible to prevent the drying of debris and fluid on the instrument.[6] Drying of debris on the instruments results in it being more difficult to remove.[6,13,30] The question posed during this investigation was which solution to use for pre-soaking? Hypochlorite effectively dissolves pulp tissue,[31,32] but the possibility of corrosion damage to the instruments is a concern. The present investigations confirmed that NiTi was resistant to corrosion, as has been shown by other studies,[33,34] but the metal shanks of the instruments often became heavily corroded after ultrasonication for 30 minutes in 1 and 4 per cent NaOCl.

Enzymatic detergents such as the one used in this study are currently widely recommended for the cleaning of medical devices because they help to remove proteins, lipids and carbohydrates from the instrument surface.[35] There are many enzymatic detergents available, all of which require a minimum contact time (2-10min) and a minimum temperature (35-45°C) for optimal effect.[35] The temperature should not exceed 55°C during ultrasonication because this may prevent

cavitation by producing large vapour-filled pockets instead of minute bubbles.[36] Pre-soaking in the enzyme solution EmPower produced favourable results and eliminated the problem of corrosion. This study indicated that the pre-soaking time in the enzyme solution was more important than the ultrasonication time. A pre-soaking time of 30 minutes produced significantly better results than 15 minutes but was also clinically feasible. Longer times tended to interrupt the natural flow of tasks in the private practice setting. Although this study did not assess the relative effectiveness of different enzyme solutions, a previous study has indicated that their cleaning abilities are comparable.[35] It is important to remember that manufacturers make recommendations on such factors as times for pre-soaking and ultrasonication, but there is no information available upon which to base these recommendations.

The present study showed that ultrasonic use is an important step in instrument cleaning, and this is consistent with other studies.[27,29,30] Ultrasonics may even have an antimicrobial effect.[37] The literature recommends 6-10 minutes in special solutions,[21,27,29,30] whilst the EmPower manufacturer's instructions recommend a minimum of two minutes ultrasonication time. In the present study better results were obtained with a long pre-soaking time (30 minutes) and a shorter ultrasonication time (15 minutes), which may be due to debris being re-deposited with extended ultrasonication time as suggested by Gardner and Peel.[36] The 15 minutes of ultrasonication was suitable from a practice flow perspective. Shorter times tended to result in dental assistants not getting back to the ultrasonic unit in time, which left the files sitting in the still solution conceivably long enough for debris to be re-deposited. Furthermore, thorough rinsing after ultrasonication is important in the removal of residual contaminated solution.[29,30]

In a busy private practice setting if too much of the cleaning procedure relied on human effort the chances of producing acceptable cleaning results would likely diminish due to hurried manual attempts at instrument cleaning.[29] Human error likely plays a major role in instrument processing failures where there are many factors that can interfere with instrument sterilization.[29] The protocol presented in this paper relies more on chemicals and equipment than human effort for a satisfactory cleaning result of endodontic instruments. The initial cleaning with a scouring sponge is important and it is simple and quick to perform for the clinician and the assistant. The subsequent pre-soaking and ultrasonication are very important stages. Because the protocol presented in this paper is simple, it can be easily learned and implemented in any private practice or institutional setting. Dental personnel need to be taught the rationale for each step in the protocol including the underlying scientific principle, in order to eliminate processing errors.[38] Importantly, the protocol has been developed using a private practice setting to ensure not only its efficacy but also its practicality. This is in line with the recommendation that studies of this nature should be consistent with actual clinical practices.[39] Furthermore, the cleaning protocol recommended in this paper costs approximately 90c-$1 for each batch of instruments, which is only approximately 10 per cent the cost of one NiTi endodontic file.

CONCLUSIONS

This present work has shown that it is possible to process instruments easily to be 'clean to the naked eye' as required by AS/NZS 4187:2003. This paper has shown that even microscopic cleanliness can be achieved, thus exceeding the requirements.

New unused endodontic files are contaminated with both manufacturing debris and biologic debris. Root canal instrumentation creates biologic debris on files. A protocol has been developed using inexpensive, easily obtained materials to simply, quickly and predictably clean endodontic files to a standard that exceeds recommended levels of cleanliness in preparation for sterilization. Under the experimental conditions of this study rotary NiTi files were 100 per cent free of biologic (stained) debris. The protocol comprises 10 vigorous strokes in a scouring sponge soaked in 0.2 per cent chlorhexidine solution, a 30 minute pre-soaking in an enzymatic cleaning solution, 15 minutes ultrasonication in the same solution, and a 20 second rinse in running tap water. The authors surmise that this protocol could be used for other endodontic files.

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