



Endodontic Instrument's Single use Policy. A Literature Review

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Introduction

Over the last quarter of the century, the place of the stainless steel endodontic instruments was taken slowly and surely by nickel-titanium files, becoming a "must have" instrument for root canal treatments, even if steel instruments are still being used, mainly at the inception of the root canal treatment. Dentists increasingly use Nickel-Titanium (Ni-Ti) files for their properties that overlap those of stainless steel instruments in cleaning and giving a proper shape to the canal and the filling subsequently. It is well known the fragility and the rigidity of the steel instruments compared with the Ni-Ti ones. These new instruments also increased the speed of the treatment. In the opinion of the majority of the dentists root canal preparation represents a very important and challenging treatment being in close relationship with the following maneuvers like irrigation and filling [1,2]. The primary reason for instrumentation in case of root canals is that the bulk material contained within it needs to be removed [2] that can be either pulp tissue, infected root dentine or necrotic debris. Hulsmann considers that these two processes, mechanical instrumentation and chemical treatment, cannot be separated and must go hand in hand, referred to as chemo-mechanical treatment [3,4]. Therefore, root canal instruments are indispensable in root canal therapy, even today in the age of implants, stem cells, biologic 3D printers and lasers. Being so useful, reliable, resistant and ultimately, not cheap, the initially single-use instruments got to be reused by a vast number of practitioners because the legislation wide world is not prohibiting it nor imposing the single-use, with very few exceptions.

Discussion

- i. Reusing the endodontic files raises many debates and questions. First of all, there is the issue of prion cross-infection. The term "prion" has been first used in 1982 defining an infectious agent which has no nucleic acid, like viruses or bacteria have [5]. The cause of the prion diseases is that the typical cell glycoprotein transforms into a modified infectious isoform, named PrP. This transformation makes PrP partially immune to detergents insolubility and proteolytic degradation [6]. The most well-known prion-caused disease is Creutzfeldt-Jakob disease (CJD). The frequency of prion diseases is reported to be approximately 1:1.000.000 individuals. Among them, iatrogenic cases, which result in less than 5% of the cases, happens due to accidental transmission of the pathogenic agent by means of [7]:
 - a. contaminated surgical equipment;
 - b. organ transplants such as cornea or dura mater;
 - c. human-derived pituitary growth hormones.

According to a surveillance made in the UK on Creutzfeldt-Jakob disease, a total of 2617 cases were recorded up to May 2010, of which 1494 deaths [8]. Iatrogenic CDJ (iCJD) cases were reported to have affected at least 400 individuals all over the world [9]. People who are most exposed to infection with iCJD are those undergoing organ transplants and neurological procedures, even so, they are considered at low risk in being affected by prions. Thus no supplementary infection-control measures are required [10]. It has been long time argued about the chances of prion cross-infection by means of dental instruments. Those who argued in favour of possible transmission based their theory on prion's alleged transmission from the neural tissues to the tissues located in the mouth, due to prion accumulation in the perioral ganglia system of patients with this disease [11]. The assumptions followed the logical conclusion that since dental pulp originates from the neural crest, theoretically, the dental pulp of people suffering from any type of CJD, could be infectious. There were reported cases of infected laboratory animals that developed a certain contagiousness in the oral tissues [12,13]. It was stressed that even if the oral tissues are of merely not detectable contagiousness and the presence of PrP in these tissues has not been confirmed in humans, we cannot rule out the nosocomial transmission of prions during dental treatments [5].

According to Lodi, Porter and Scully [14], protocols that should be followed in the dental surgery for decontamination and safety include:

- a. Instruments need to be kept in wet environment until cleaning, which should not be postponed, to reduce drying of tissue remnants or blood on them; Avoid mixing instruments used on patients with CJD with those used on healthy patients;
- b. Expensive or non-single use instruments that cannot be discarded may be reused only after they were properly decontaminated;
- c. If there are automated machines used to clean the instruments, instruments must be decontaminated first
- d. clean and disinfect surfaces thoroughly or cover them with drapes and coversheets which can be disposed and later incinerated;
- e. alternatively, suspected or confirmed CJD patients should be booked in as the last patient to give more time for decontamination procedures;
- f. no dental instrument should be reused but discarded or decontaminated immediately [15]

It was reported that classic sterilization methods, like steam sterilization or by ethylene gas are ineffective against prion

agents [14,16]. therefore instruments which we do not want to discard or are not single-use has to pass through strict decontamination protocols before cleaning and then to be subjected to steam sterilization at 134 °C for 10-18 minutes in a vacuum environment. Autoclaves having these features are classified as B+. It is also recommendable to repeat the sterilization cycle couple of times [17]. In his 2003 report about CJD infection control, the Department for Health, UK, opinioned that any dental instrument used on an individual having or being at risk of CJD, can be reused after a thorough sterilization, not mentioning how many cycles has the instrument to be subjected to [18]. However, in a later report, dentists are requested to use endodontic files as single-use instruments regardless the case [19].

ii. Then the debate on sterilization and its effect on the Ni-Ti alloy itself. Since Buehler et al. [20] discovered the equiatomic Ni-Ti alloy, and [21] first reported on the use of Ni-Ti in endodontics, a vast number of researches were made and published assessing the effect of steam or dry sterilization on Ni-Ti files. these files proved to be twice as flexible, having superior resistance to fracturing as well than any file made before of classic steel. During the time many techniques were tried to further enhance these instruments' resistance, characteristics and efficiency, resulting in developing methods like heat treatment, electro-polishing, etc. Thus the idea that sterilization might work as heat treatment, inducing a "regeneration" of the used file. Several studies were made to assess how sterilization affects the durability of Ni-Ti rotary instruments. Some of them worth mentioned in this essay, both "pro" and "contra". [22] proved in their study that five cycles of dry-heat sterilization at 180 °C can extend the life of the files. But there are also reports where the sterilization proved to affect the endodontic Ni-Ti files by decreasing the cutting efficiency, increasing the surface defects in depth and number, showing crack initiation and propagation as shown in the researches done by [23-25]. Instruments that underwent numerous cycles of sterilizations showed in-depth a different chemical structure, compared to those from a control group. Rapisarda, et al. [26] assumed in their study that these differences might be explained by an increased quantity of Ti oxide that was quantified on sterilized instruments' surfaces. they mention that the files also presented a reduced efficiency when it was to be compared with the control group. Hilfer, et al. [27] proved that the more autoclaving cycles the less resistance to cyclic fatigue the file would have when it comes to newer Ni-Ti files that were manufactured by twisting instead of machining. they even emphasized in their study on Twisted File of a specific size (25/0.06) as being a vulnerable file. Stefanescu, et al. [28] found that a Ni-Ti file having the same features is the weak chain of the Bio-Race kit, being separated after five sterilization cycles. In their study, they managed to prepare 12 roots with moderate curvature, using the same file kit sterilized five times. What is interesting is that the manufacturer provides the files with a rubber stopper which resembles with a five-petaled flower, dentists being instructed to remove one "petal" after each every sterilization and when the "petals" ended, no more sterilization should be carried out nether should the file be used again. Liu, et al. [29] stressed that although a sterilization cycle might be assumed as a thermal treatment that should enhance the endurance of Ni-Ti files, this might be valid only in case of dry sterilization to some extent, considering that thermal treatment means heating the alloy to approximately 550°C. On contrary, [30] reached the same conclusion as regards the increase of resistance to cyclic fatigue after heat was applied, confirming somehow [22] study. However, for the best decontamination and cross infection control, vacuum steam autoclaving is recommended, not dry heat, as seen above.

iii. Then, even if the instrument is sterilized and reused only on the same patient, it raises questions by the mechanical point of view. Although it was considered that once introduced, all the mishaps of the steel files will be forgotten, and it proved that no material is infallible. Authors like [31,32] stated that being a ductile material, a Ni-Ti instrument would deform plastically and when its resistance is overcome, will separate. [33] emphasized that if a fracture line grows in depth to such an extent that the cross-section of the "sound" alloy is thinned down in such a manner that it cannot sustain the functional load, the instrument will separate, thus complicating the whole treatment.

Nowadays the instruments are either made by milling a Ni-Ti alloy blank, or by twisting a raw Ni-Ti wire, the so-called CM-wires (controlled-memory wires) [34]. Most Ni-Ti files are milled, causing noticeable micro-defects on their surface, pits and chippings that can serve as possible starting points for breakage if forces are applied extensively [35]. These micro-defects may increase and multiply and even unify after clinical use, leading to instrument separation [36]. While stainless steel instruments separate due to excessive torque, in case of the Ni-Ti files, the combined stress exerted by torsional and cyclic fatigue is to be blamed for it [33,37].

Many studies concluded that instrument usage could proportionally increase the potential of file separation, meaning that new instruments have decreased chances to break

than used ones [38-40], although in their study, [28] managed to shape 24 moderately curved roots using the same file kit. Some authors tried to establish a file separation rate in used and new instruments reaching the conclusion that although fracture incidence in new files is relatively low in day to day practice, approximately 1% [41-44], the rates in reused files was found to be up to 21% [31, 32, 35, 45, 46]. 21% is a number that should make the practitioner think about using the same instrument on more than one patient. The majority of teeth's anatomy presents curved canals in more than one plane, which makes root canal treatment needing special knowledge and skills [47,48]. Any instrument is subjected to extensive forces while preparing the root canal regardless of the metals it was made of. According to Gulabivala et al. [37] the factors affecting or preventing the incidence and mode of failures are:

- a. torque control kept between 1-4 N/cm,
- b. rotation rate used ranging from 300 to 500rpm,
- c. the root curvature, the dimension of the instrument (the smaller the instrument, the lower its flexibility, the thinner the instrument, the higher its flexibility and lower the resistance to fracture),
- d. the instrumentation technique and the practitioner's experience,
- e. the straight-line access (the fewer curvatures, the longer the file' life).

These were just a few of the conclusions made in time not only by researchers but felt in its entire weight by the clinicians who misused the Ni-Ti files like they were unbreakable, excellent and fit for any purpose under any condition, being usable for unlimited times on an unlimited number of teeth. Blunting and disruption of the cutting edge was signaled to precede the file separation and thus the end of use of it, therefore it is useful for the clinician to inspect the file before reusing, by means of a magnifying device (loupes, microscope, etc.) in case the reuse is the only option [36].

iv. Debate on the corrosion on used Ni-Ti files because we must not forget that the files are used in a corrosive environment provided by the irrigants. Endodontic irrigants are substances used, both as liquids as well as gels, to eliminate microorganisms, smear layer and pulp tissue from the endodontic system, due to the anatomic complexity. For this purpose sodium hypochlorite (NaOCl), citric acid, Chlorhexidine (CHX) and Ethylenediaminetetraacetic acid (EDTA) are widely used, for its antibacterial and proteolytic effect, as well as for its chelating properties. Several studies assessed the impact of these irrigants on the Ni-Ti files. In their study Novoa, et al. [49] showed that during extended periods in NaOCl 5% solutions, corrosion might be enhanced or reduced depending on the pH of the irrigants. While in his study [50] researching on NaOCl's impact, proved that it had no influence on the efficiency or resistance of Ni-Ti instruments, [51] found that it might have negative effect on file's behavior, also emphasizing on the presence of corrosion, as was later described by [22,28]. However, Novoa [49] found that corrosion can be reduced by assuring a basic pH of the NaOCl of 10.1, but no further studies were made on the efficiency of EDTA with 10.1 pH [52,53].

Conclusion

To sum up, the transmission of prions by means of dental instruments was not proved, the results of researching the effect of sterilization on Ni-Ti files were inconclusive, the mechanical resistance of the files was proven to last many cycles of sterilization, numerous roots being shaped with the same file, while corrosion is barely having any effect on the instrument's life time. Therefore, files are widely reused after sterilization, manufacturers even emphasizing on the resistance of their products to multiple uses, even if nowadays, some manufacturers introduced methods that prevent reusing the instruments after sterilization, measure made purely for financial reasons. The single-use policy means for the manufacturer more instruments sold and bigger profits. However, reusing corroded, blunted, inefficient files means a poorer root canal treatment provided, with subsequent flare-ups and failures: ledges, perforations, transportation, cases in which retreatment is attempted to save the tooth. Reuse of any endodontic instrument, after sterilization, regardless of the method used or if it is reused on the same person, is dangerous due to the possible mishaps that could occur anytime during the maneuvers. By taking the chance of reusing an instrument, we face up to decrease our treatment's success rate.

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