Environmental Effects on Ni-Ti Rotary Files: Steam Sterilization and Corrosion

A SEM study

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Present work studied the steam sterilization' effect on a BioRace® instrument kit, working in clinical conditions and corrosive environment, compared to a control kit used in similar conditions excluding sterilization. The surface changings has been examined under electron microscopy (SEM), evaluating if there are substantial differences in fatigue resistance and corrosion of one compared to other sample group. The study followed the sterilization by autoclave' effect on a BioRace® (FKG, Le Chaux-of-Fonds, Switzerland) instrument kit, working in clinical conditions and corrosive environment, compared to a control kit used in similar conditions excluding sterilizations. The surface changings has been examined under electron microscopy (SEM).

Keywords: Ni - Ti, rotary, sterilization, BioRace

Since Buehler et al.[1] discovered the equiatomic Ni-Ti alloy and Walia et al. [2], who first reported the use of Ni-Ti in endodontics, many studies were made to assess the effect of steam or dry sterilization on endodontic rotary files made out of this alloy. These files were shown to have two to three times the elastic flexibility in bending and torsion, as well as superior resistance to torsional fracturing when compared to similar stainless-steel instruments.

This alloy, due to its one-to-one atomic ratio of nickel to titanium, it is referred to as Nitinol. Only the Ni-Ti alloys with nearly equiatomic ratio possess the unique superelasticity and shape memory effect. This type of Ni-Ti alloy can exist in two different temperature-dependent crystal structures called martensite (lower temperature or daughter phase) and austenite (higher temperature or parent phase). The crystal lattice structure can be altered by either temperature or stress.

Attempts to enhance the surface of Ni-Ti instruments, resistance to cyclic fatigue, and cutting efficiency have resulted in a variety of strategies including heat treatment (thermal processing) is one of the most fundamental approach toward improving the fatigue resistance of Ni-Ti endodontic files. Thus several studies were made to assess the effect of sterilization process on the fatigue life of Ni-Ti rotary files.

Experimental part

Materials and method

30 extracted upper first bicuspids with complete root formation and apical foramina whereby it was possible to introduce a size 15 K-file, were selected for this study. After extraction the teeth were submerged in saline solution at room temperature, then the access cavity was prepared, the canal was negotiated to the working length with stainless steel hand files up to size 15, thus controlled for apical patency. Standardized radiographs were taken prior to instrumentation with the initial root canal instrument of size 15 inserted into the curved canal. A radiographic paralleling device was attached to a Minray™(Soredex, Milwaukee, United States) 70kV, 8mA X-ray generator. Teeth were included in a silicon-based material (Zetaplus™, Zhermack, Badia Polesine, Italy) in order to maintain position. The X-ray tube was aligned perpendicular to the rooth canal, with an object to film distance distance of 3 mm. Exposure time was set to 0.2 s. Digora Optime UV™ intraoral imaging plate system (Soredex, Milwaukee, United States) was used to capture the images. The degree of the canal curvature was determined using the Digora DfW2.6™ and Scanora™ (Soredex, Milwaukee, United States) image processing softwares. Based on these radiographs, root' curvatures were computed according to Pruett's method[4], and categorized as follows: straight(less then 10°), moderately curved(10-20°), and severely curved(20-30°). Only teeth with roots having a curvature between 10-20 were accepted for the study. Exclusion criteria: teeth with open apices, developmental defects, and abnormalities in root canal shape, resorption and calcified canals. None of these teeth accepted for the study received previous restorative or endodontic therapy.

The teeth were decoronated at the cemento-enamelar junction (CEJ) with a diamond disc (Besqual, META DENTAL Corp, Glendale, USA) to avoid coronal interferences during root canal preparation. Two BioRace™ (FKG, Le Chaux-of-Fonds, Switzerland) engine-driven endodontic file kits were used to prepare the roots using the crown-down technique. The preparation was carried out according to the manufacturers indications, by an experimented operator, with an electric NSK NLXplus™ engine(NSK Europe, Maidenhead, UK) having a 20:1 reduction handpiece NSK Ti-Max X-SG20L™, at a standard rpm for the present generation of Ni-Ti instruments, between 300 and 500 as recommended (Lopes et al., 2009), at 1Ncm pre-set torque value. The sequence and rpm of the RaCe instruments used in this study are shown in table 1.

Irrigation was carried out during the preparation, after every file, with 2mL of both NaOCl 5.25%(Cerkamed, Stalowa Wola, Poland) and EDTA 15%(MetaBiomed, Chungbuk, Korea).

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Instrument	Size	Taper	Rpm	Torque(N/cm)
BR0 – Pre-flaring	25	08	394	1
BR1 - Shaping file	15	05	394	1
BR2 – Shaping file	25	04	394	1
BR3 - Shaping file	25	06	394	1
BR4 - Finishing file	35	04	394	1
BR5 - Finishing file	40	04	394	1

Table 1
BIORACE KIT FILES

Preparation sequence and sample groups:

- Sample group I is represented by a BioRaCe™ kit used as follows: after preparation both canals of a bicuspid, the files from the rotary kit were cleaned in ultrasonic bath using alcohol 96%, for 120s, and subjected to steam sterilization at 135^0C. Then another bicuspid was prepared, and another sterilization process was initiated on the rotary files, and so on till the first instrument separation.

- Sample group II is represented by a BioRace™ kit that followed the same steps as sample group I, but with no sterilization between two consecutive teeth. In this sample group the files prepared the root canals until the first instrument separation.

The canals from each of the two groups were cleaned and shaped using BioRaCe™ (FKG, Le Chaux-of-Fonds, Swizerland) engine-driven files, until instrument failure occured. Similar files from each group were examined under electron-microscopy (SEM)(Jeol Jem 1010™, Jeol USA Inc., Peabody, Massachusetts), comparing similar surfaces and parts of the files, and scoring the alterations for each of the two sample groups.

Characterization method

SEM Examination

The root preparations stopped after the first file separation. Files were subsequently cleaned in Emmi4™ (EMAG Technologies, Ann Arbor, Minnesota, United States) ultrasonic bath for 400 s, in absolute alcohol 96%, and left for drying on a cotton pellet at room temperature. Every file was submitted to SEM evaluation with a magnification between x1000 and x5000, comparing the images taken with those of a brand new file, and scoring the modifications (table 2). Scoring criteria of the surface defects [5]:

Score 1- No visible defect
Score 2 – Pitting
Score 3 - Fretting
Score 4 –Micro fractures
Score 5 – Complete fracture
Score 6—Metal flash
Score 7—Metal strips
Score 8—Blunt cutting edges
Score 9- Disruption of cutting edge
Score 10-Corrosion
Score 11-Debris

Results and discussions

BioRace endodontic files are second generation Ni-Ti instruments, having the following characteristics: electropolished, triangular shape (except Race files with 2% taper), two alternating cutting edges, no radial lands, non-cutting tip design, fixed taper, alternating cutting edges along the file length due to alternating twisted and untwisted segments to reduce screw-in effect [6], thus reducing intraoperative torque values [7,8].

In our case, the first instrument that eventually separated during this study, was the BR3 (size 0.25 , taper 6%) from sample Group I, while preparing the12th root canal, after the 5th steam sterilization cycle. The separation occurred at 3 mm distance from the tip of the file. This was expected since the BR3 has a taper of 6% compared to the previous file, BR2, with taper 4%. Even if the BR2 and BR3 have similar tip size, it may not be as important as taper is for fracture, and may imply that a more rapid increase in diameter from the tip along the shaft to the rotating source, may cause excessive torsional stress that creates a critical amount of cyclic fatigue that cannot be tolerated by the alloy without rupturing [9]. This kind of events are also explained by Satapan et al. [10] who emphasized that the torque generated during canal instrumentation with rotary instruments increased as the taper increased. Haikel et al. [11], also postulated that as the taper increased, the time to fracture decreased.

After separation all the files from both sample groups were submitted to SEM analysis assessing the modifications induced by stress, steam sterilization and corrosive environment.

File Scoring

The score of each file in the table (table 2), is the sum of all changes noticed on its surface, by scanning electron microscopy (SEM). The scores of the two sample groups are quite similar, showing that the steam sterilization has no significant effect on the surface of the files. We cannot underappreciate the fact that a file from the sample group separated after the fifth sterilization cycle, while preparing the 12th root canal. Meanwhile, the same file from the sample group 2 succeeded in preparing all scheduled 30 roots. To assess the separation cause, figure 1 is quite relevant, presenting the typical image of the shear failure, with skewed dimples that are a characteristic of ductile failure of metals due to excess monotonic shear stress[12] – near the center of the fracture surface, plastic deformation of the flutes adjacent to the fracture site, and concentric circular markings at the periphery with a fibrous appearance in the center. The fibrous region corresponds to the microscopic dimples in high power, while the circular markings are due to abrasion of the opposing surfaces on either side of the fracture (fig. 2.c). A material will fail by torsion when the ultimate shear strength is exceeded[2].

In order to correctly asses our results, we emphasize on the factors that may be involved in the longevity or separation of the Ni-Ti files, like electropolishing, sterilization, irrigants.

Electropolishing is a method commonly used for surface finishing of many metallic medical appliances[13]. This process alters the surface composition and texture of the instrument and renders a more homogeneous surface oxide layer that is a protective film, with less defects and residual surface stress. In the process, the corrosion resistance of the metal is enhanced along with improved surface characteristics [14]. Although this should enhance the cycle fatigue life of the instruments, the studies made so far are controversial. No file and manufacturing method warrants fracture proof files. Some authors like Anderson

Files	Sample group 1	Sample group 2
BR0	29	24
BR1	33	31
BR2	33	30
BR3	45	33
BR4	33	30
BR5	23	28
TOTAL	196	176

Table 2
FILE SCORING RESULTS FOR EACH SAMPLE GROUP

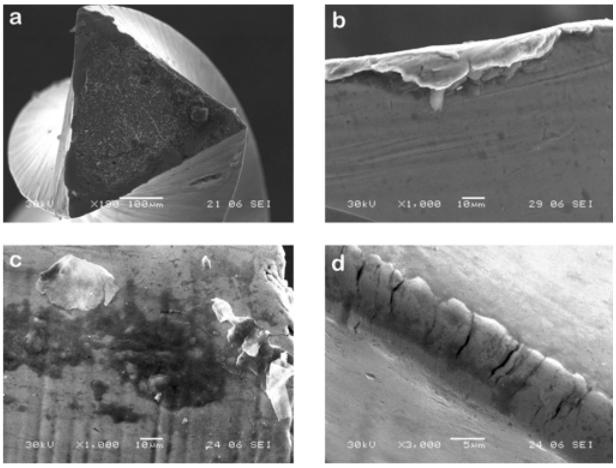

Fig. 1. a - Separation area of BR3; b-Blunt cutting edge of BR2; c. Corrosion and metal chips on BR3; d-Fractures on the cutting edge of BR4

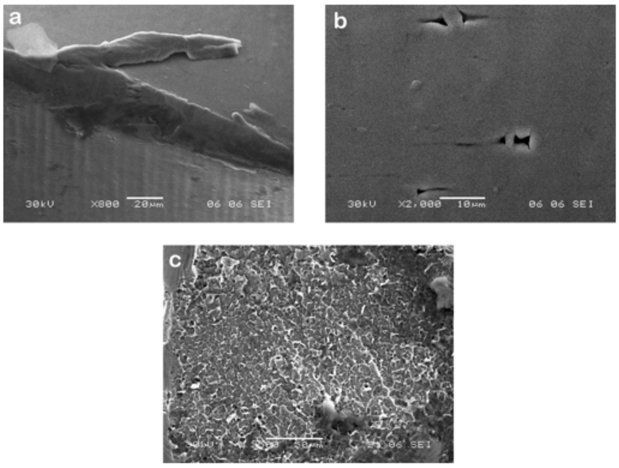

Fig. 2. a - Disruption of cutting edge of BR1; b- Pits on BRO; c - Fractographic appearance of the crack size

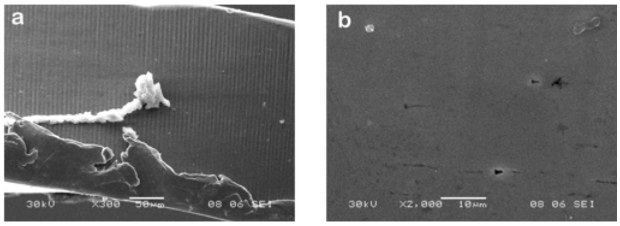

Fig.3. a - Blunt cutting edge on BR1 surface; b-Pits on BRO surface

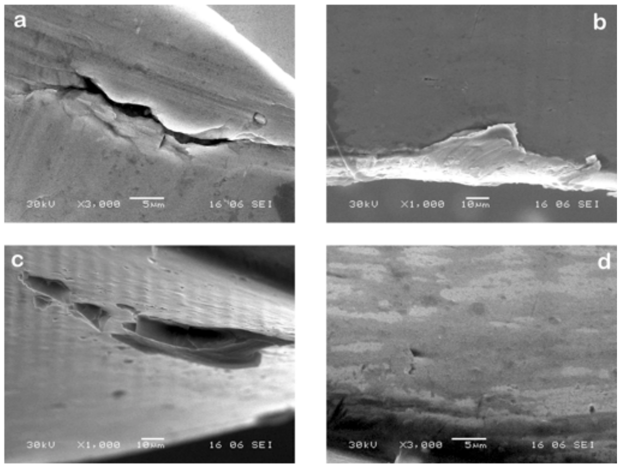

Fig. 4. a-Cutting edge disruption on BR3; b- Blunt cutting edge on BR5; c -Pitts on BR4 surface; d - Corrosion on BR2 surface

et al. [15], Boessler et al. [16] investigated the effect of electropolishing on cyclic flexural fatigue and torsional strength finding that electropolished instruments performed significantly better than non-electropolished instruments in cyclic fatigue testing. Others like Bui et al. [17], on contrary, showed through statistical analysis that electropolishing significantly reduced resistance to cyclic fatigue but did not affect torsional resistance. While most of the authors[18-21] emphasized that electro-polishing enhances only the surface properties of the Ni-Ti instruments, without protecting the file against low-cycle fatigue failure. And we could keep enumerating studies that support or not the theory of Ni-Ti instruments' life prolonging effect of electropolishing. Therefore we could conclude that, electropolishing appears to have a beneficial impact in enhancing cyclic fatigue and peak torque values for Ni-Ti instruments, the results of which may vary when the instruments are placed under significant flexion. File surfaces were smooth and improved with electropolishing, with minimal crack formation visible, thereby evidencing minimal deterioration of the instrument in the presence of NaOCl. The apparent positive effects of electropolishing, however, may vary depending on instrument type, design and, in particular, cross-sectional area [22-24].

Sterilization is indicated to affect the endodontic Ni-Ti files by decreasing the cutting efficiency, increasing in the depth of surface irregularities and surface roughness, and evidence of crack initiation and propagation [25-27]. Instruments that underwent the greatest number of sterilizations showed in-depth distributions of chemical composition that were different from those seen in the control group; this was identified as being the result of greater amounts of titanium oxide on the surfaces of the sterilized instruments. These same files also showed a decrease in cutting efficiency in comparison with those of the control group [28]. Furthermore, newer Ni-Ti files that have been twisted instead of machined showed some evidence of decreased resistance to cyclic fatigue with increased cumulative autoclaving procedures[29].

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. Thus, Condorelli et al. [30] identified the same type of increased resistance to cyclic fatigue, although the thermal applications did not alter instrument surface morphology but resulted in significant changes in the instrument bulk with the appearance of an R-phase and improved fatigue resistance. Multiple episodes of autoclave sterilization were shown to significantly decrease the cyclic fatigue resistance of the Twisted File in a specific size (25/0.06)[29], exactly the same sizes of the file from our present work.

Endodontic irrigants are used to eliminate micro-organisms, pulp tissue or tissue remnants from the pulp chamber and root canals, due to the anatomic complexity of the pulp space. It is well documented that bacterial infection of the root canal is the primary cause of apical periodontiti [31-33]. In teeth with apical periodontitis, bacteria invade and colonize the entire root canal system, and treatment is directed toward the elimination of micro-organisms from the root canal system and prevention of re-infection [33]. Therefore, chemo-mechanical preparation of the root canal through a combination of mechanical instrumentation and antibacterial irrigation is the critical stage in canal disinfection. For this purpose NaOCl and EDTA are widely used, for its antibacterial and protheolytic effect, and for its chelating properties, respectively. These irrigants are also used to suspend and rinse away debris created during instrumentation, or as a lubricant for instruments, to remove the smear layer. There are several studies that assessed the effect of these irrigants on the Ni-Ti files. During extended periods of time in sodium hypochlorite (NaOCl) solutions, corrosion may be enhanced [34] or minimized depending on the *p*H of the environment [35]. The impact of NaOCl did not show any difference in the cutting efficiency or resistance to fracture of Ni-Ti instruments [36, 37] although it did result in a reduced resistance to cyclic fatigue [38,39] and the presence of corrosion [3]. However, this latter result has been shown to be minimized by lowering the *p*H of the NaOCl to 10.1 [35]. Further studies in which the percentage of NaOCl was low (1%) showed no major impact on NiTi instruments; however, those that studied the impact of a 5% solution noted significant changes [40]. Likewise, a sterilization cycle along with immersion in NaOCl did not identify any substantial instrument changes [41].

Conclusions

Our findings support some of the previous works about instrument re-usage, concluding that instrument usage can significantly influence the potential for fracture [42-44]. This is supported by scanning electron microscopic observations proving that used instruments deteriorate and develop defects and cracks on their surfaces inducing fracture propagation [45-47], although new instruments can fracture at their first canal use, those that are used for three or more canals may have a higher susceptibility for fracture. Gambarini [42] demonstrated that the used instruments had a lower resistance to fracture than new ones. However, Gambarini [42] also reported that the used instruments that were tested had been successfully operated in up to 10 clinical cases without any failures. Yared et al. [48, 49] concluded that they could be safely used for the instrumentation of up to 10 canals in extracted molars or for the clinical treatment of four molar teeth. In a previous study [50], we succeeded in preparing 24 standardized, moderately curved root canals, until instrument failure, using files that were not submitted to sterilization. In that study the same BioRace files where used, and again, BR3 file was the first that separated. Thus, we consider that the important changes induced by the steam sterilization, are those from deep within the metal structure and the surface modifications are only signs, not reasons, for what is going on inside the alloy, leading to separation eventually. Also, we emphasize that multiple cracks larger than 10 microns, are signs of an imminent failure, and that the crack appeared on the flat surface of the flutes, are more severe than those located on the cutting edges.

This laboratory study on small size samples do not necessarily reflect the fractures rates that may occur under clinical conditions. The findings of the present study suggest that although fracture incidence is relatively low in clinical practice, the fracture rates in reused files are very high, and it can occur with any Ni-Ti rotary instrument [9]. Therefore, discarding instruments after use, wether the instrument was used on multiple canals or just a single canal in a particular session, is important for the treatment' safety and outcome. An examination with magnifying device prior use, could show noticeable structure losses of the used instrument, thus preventing a possible failure during the next usage.

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