EVALUATION OF CARDIAC ANGIOGRAPHIC CATHETERS INTEGRYTY IN THE VALIDATION OF REPROCESSED SINGLE-USE MEDICAL DEVICES

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Abstract. *Reprocessing of single-use intravascular catheters is a common practice in public health services and hospitals. The determination of safe number of reprocessing cycles before the catheter integrity becomes compromised is a priority issue. The present paper addresses the evaluating molecular and micro-structural integrity of reprocessed cardiac angiographic catheters using Fourier Transform Infrared Spectroscopy, Scanning Electron Microscopy and tensile test. It was observed that the number of hydrogen-bonded carbonyls groups and the Young's modulus increases after each reprocessing cycle. The micrographs revealed that only after the fourth reprocessing cycle an increase in the surface roughness is detectable. On the other hand, after each reprocessing cycle and as consequence of extensive aging of polyamide/polyurethane blends of the catheters surface, it was observed that the micro-fissures, micro-scratches and micro-pores increased in quantity and length.*

Keywords*: Equipment reuse, Reprocessing cycle, Molecular structure, Diagnostic techniques, Cardiovascular, Surface characterization*

1. INTRODUCTION

Reprocessing of single-use medical devices is a common practice in health services and hospitals due to the economic constraints. It means that an original device that has previously been used on a patient and has been subjected to additional processing of cleaning, disinfection, preparation, packaging, labeling and sterilization for the purpose of an additional use on another patient. Successful reprocessing cycle verification is performed by validated biological and chemical analysis and by functionality and integrity testing (FDA, 2006). The validation of the integrity is mandatory to guarantee the safeness of the devices sterilized by hydrogen peroxide plasma. The potential oxidative effects of the sterilizing agent can produce free radicals, giving rise to a wide variety of oxygen-containing molecules or functional groups. Further, auto-oxidation is the predominant reaction during the processing and aging of polymers, altering the molecular structure and the mechanical properties of the polymers. In this context, the evaluation procedures to detect scratches, micro-fissures and surface roughness are essential for the prediction of device performance after reprocessing and are useful to prevent the occurrence of adverse effects (FDA, 2006; Tessarolo et al., 2004).A minimal change in superficial properties may compromise the optimal interaction with blood and vessel wall and increase procedural risks for patients. Indeed, the increasing of roughness and variations on chemical composition in the external molecular layer can induce thrombus formation and favor bacterial adhesion. Additionally, the presence of solid particles and debris in reused catheter lumens must be eliminated to prevent the introduction of potentially hazardous solid emboli into blood stream during catheterization. Despite the fact that aging of polymers increases the risks for catheter reutilization and induces significant structural differences during its subsequent reprocessing, there are still inconsistencies related to the number of reprocessing cycles that guarantees a safe reutilization of the polymeric material. Due to the difficulty of implementation of specific validation methods that makes evident the maintenance of proper integrity, the purpose of this work is to evaluate the molecular and micro-structural integrity of the polymer chain that constitute the cardiac angiographic catheters in the different number of reprocessing cycles.

2. MATERIALS AND METHODS

In order to understand physical-chemical modification induced by reprocessing, Surface and Bulk analysis were carried out by using the Fourier Transform Infrared Spectroscopy (FTIR), Scanning Electron Microscopy (SEM), Energy Dispersive Spectroscopy (EDS) and Tensile test. Prior the integrity testing, a cycle of simulated use was

employed, which was intended to expose the catheter to mechanical and biological stresses in similar levels to those experienced in clinical use.

2.1 Materials

Catheters Judkins Left (JL), manufacturer Biotronik® (Leek, Groningen, Netherland) made of polyamide/polyurethane blends were employed. An angiographic catheter is a long tube that is inserted into the blood vessel for both diagnostic and therapeutic applications. The JL catheter has a specific design that enables a radiographic visualization of the left coronary artery after contrast injection as shown in Fig. 1.

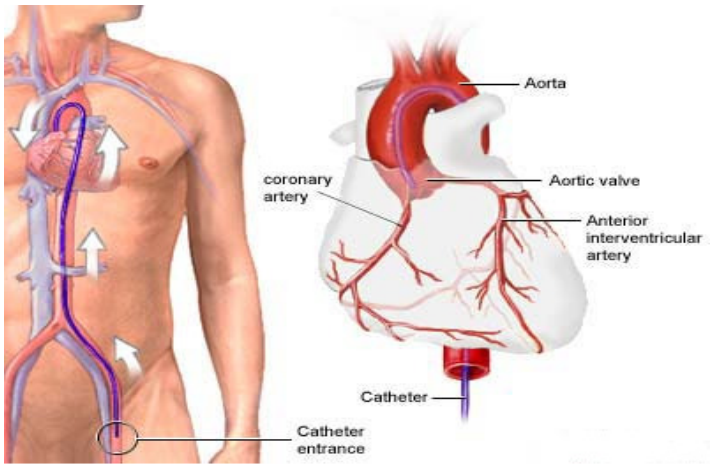


Figure 1: Angiographic catheter in a left coronary angiography.

2.2 Test bench

The use simulation of the catheter was in accordance with FDA recommendations (premarket notification). In the FDA premarket notification process, the materials pass through a series of requirements of registration, labeling, classification of risks and demonstration of quality (FDA, 2005; 2006; 2008). Such recommendations, guide the simulation of a mechanical stress in the material previously to the execution of the validation tests (FDA, 2005; 2006; 2008). Validation process should include simulation of the worst case conditions that the device is likely to encounter during clinical use. FDA recommends an evaluation of the device compared with a similar legally marketed device, using the worst case simulated static and dynamic forces to the failure point of the components. Further, it is recommended the worst case analysis of an assembly to verify that components are functioning properly and not subject to overstress during handling and use. As a result a bench testing of an arteriography of left and right coronary was built, in elastic silicone, insertion by femoral artery, following the external iliac arteries, common, abdominal and thoracic descendant aorta, aortic arch, ascendant aorta, up to the ostiums from the coronaries of an adult with about 1.75 cm of height. In order to simulate the *in vivo* physiological conditions, the bench was filled with the dirtiness challenge-test (Artificial Soil Test (AST), Healthmark Industries, St. Clair Shores, Michigan, USA). For the simulation of one use in the bench testing, the catheters were inserted by means of an introducer sheath of six French with the help of a guide wire, fifty times into the model seen in Fig. 2.

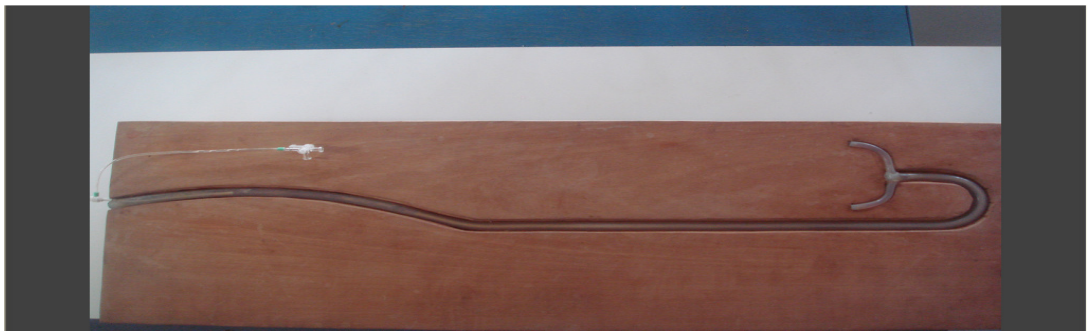


Figure 2: Test bench of the arterial angiography catheters.

For two reutilizations, the catheters were inserted fifty times into the bench, afterwards reprocessed, re-inserted fifty times more, being then reprocessed and tested, respectively. The other reutilization simulations were took place of the same way until the ninth reprocessing cycle. It is emphasized that the insertion of the catheter into the bench testing in number of fifty times, was justified by being a method used by the third party reprocessors in the USA, with premarket approval from FDA (Lester et al., 2006).

2.3 Reprocessing Protocol

The reprocessing protocol consisted basically of the following sequence: i) The catheters were rinsed in filtered running water for 10 min, in a dispositive for lumens (luer-lock termination), flow rate up to 0.01 l/min under a pressure that not exceed 1 bar. ii) Solution of enzymatic detergent (Max Zyme®) 4 ml/l (0.4%) was prepared with filtered water at 37^0C and the catheters were immersed in a plastic recipient for 5 min according to the manufacturer's orientation. iii) The catheters were rinsed for 10 min. The excess of water was drained with a compressed air jet. iv)The visual inspection of the catheters was performed, and those which presented fissures, cracks or marks of visible bends were excluded from this work. v) The catheters were individually packed on tyvek® and sterilized by hydrogen peroxide plasma (Sterrad® 100S, Advanced Sterilization Products, J&J Med.Inc.,Ascot,Berkshire,United Kingdom), duration of 51 min, in a temperature which varied from 45 to 50°C during the cycle phases.

2.4 Validation Technical Methods

It was used the FTIR in a Perkin Elmer® spectrophotometer, model Spectrum 1000 to study changes in the chemical structure of the polymers and evaluation of the following variable: alteration of the molecular structure of the polymers (modifications of functional groups and chemical bonds of polymers in the spectrum at each different cycle of reprocessing). The Attenuated Total Reflection (ATR) technique was used to collect the spectra. A total of nine samples from the curve portion of the catheter were tested, being one control and eight from the experimental group, reprocessed from two to nine times. Spectra were collected in the spectral range 400-4000 cm^{-1}, using 16 scans and 4 cm^{-1} resolution. It is important to emphasize that only the outer surface of the catheter was evaluated, since the spectrum reaches a depth of 3 to 5µm. The following variables: micro-fissures (considered the first stage of the fracture process, lead to the formation of cracks that propagate until the final fracture); roughness (group of diffuse irregularities such as hollows, saliencies and micro-protrusions; wavy and granulated asperity) and superficial imperfections (micro-scratches, micro-pores or micro-holes) were evaluated by SEM. It was used the Jeol equipment, model JSM 6360LV-15KV. A thin layer of gold was placed over the samples, to allow the electric conduction during the procedure, using a SPI Module Sputter Coater. It was used the EDS for the detection of the presence of different chemical atoms, which could be interfering in the SEM visualization. A total of six samples from the curve portion of the JL catheter was analyzed, being one control and five from the experimental group which were reprocessed four, five, six, seven, eight and nine times. The tensile test was evaluated in a universal testing machine EMIC DL 3000 with a 500 Newton load cell. A total of forty samples from the curve portion of the JL catheter was analyzed, being four control and four from each experimental group which were reprocessed one until nine times. All tests carry out with new and reprocessed catheters exceeded the acceptance criteria specified in NBR ISO 10555-1:2003(ABNT, 2003).

2.5 Data Analysis

The regions of the absorption bands of the spectra from this work were compared with different authors who identified similar vibration bands from FTIR spectroscopy measurements (Luziriaga et al., 2006; Nagle et al., 2007; Recondo et al., 2007; Simmons et al., 2006; Tsai et al., 2008; Umare and Chandure, 2008). Such authors presented

specific vibrations of each spectrum, frequencies and wavenumbers characteristic of functional groups and chemical bounds of organic molecules, originating from the oxidative degradation of polymeric materials. It was still observed modifications on the contours and peaks of the absorption bands in each spectrum, during the different cycles of reprocessing. The absorbance in the region of hydrogen-bonded carbonyls groups was measured and divided by the absorbance of the region of the C-H groups, obtaining the following ratio: $Absorbance_{C=O}/Absorbance_{C-H.}$. In order to estimate the average variation of the carbonyl group (C=O) and the Young's modulus (E) at each different number of reprocessing cycles, it was applied regression analysis linear model. Data were processed by means of the program Statistical Software for Professionals (STATA) version 9.0® and, for effects of interpretation, the type I error limit was up to 5% ($p \leq 0.05$). The significance of the model was evaluated by the F test of the variance analysis and the adjustment quality by the coefficient of determination adjusted (R^2 adjusted). The residues were evaluated according to the suppositions of normality, zero average, constant variance and independence.

3. RESULTS AND DISCUSSION

The Fig. 3 displays the spectrums difference between non-reprocessed and eight times reprocessed catheters. The bands in the regions at 1564 cm^{-1}, attributed to COO^-, 1504 cm^{-1} correspondent to NO_2 and 1243 cm^{-1} related to $CONH^+$, contributed to the modifications in the spectrum contour and were clearly observed from the fifth reprocessing.

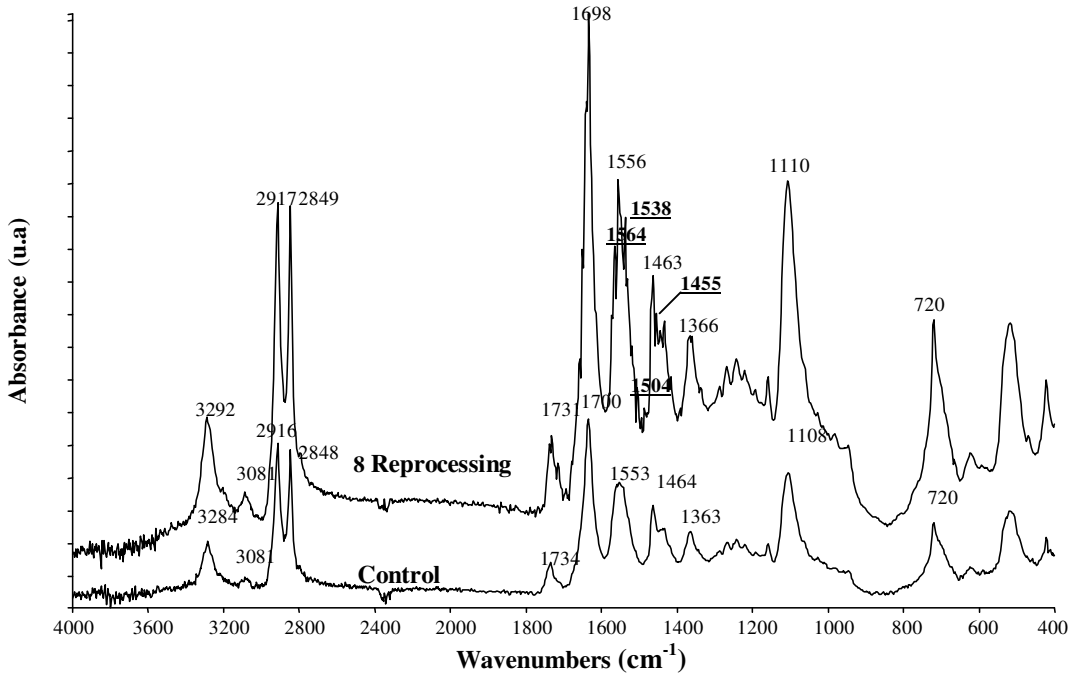


Figure 3: FTIR spectra of polyamide/polyurethane blends of the non-reprocessed (control) and eight times reprocessed catheters.

Table 1 shows the mainly absorption bands of the non-reprocessed and eight times reprocessed catheters.

Table1.Distribution of the main absorption bands identified in the FTIR spectrums of the non-reprocessed and eight times reprocessed catheters.

Wavenumbers (cm^{-1})		**Assignment**	**Type of vibration**	**Wavenumbers (cm^{-1})**
Control	**8 Reproces.**			
3284	3292	N-H + O-H	stretching vibration	3350 - 3180 (NH) 3600 - 3200 (OH)
2916	2917	C-H	stretching vibration	3000-2840
1734	1731	C=O (freeCO)	stretching vibration	1870 - 1540
1700	1698	C=O (H bonded)		
-	1564	**COO^-**	stretching vibration	1650 - 1550
-	1538	**$CONH^+$**	stretching vibration	1650 - 1515
-	1504	**NO_2**	stretching vibration	1660 - 1499
-	1455	**CH_2**	Bending vibration	1475 - 1450

It is well known that oxygenated groups like alcohol, esters and carboxylic acids are result of the oxidative degradation of polyurethane/polyamide blends. In addition in the degradation process the hydrolysis of amides leads to the formation of amines, carboxylic acids and nitrocompounds (Lerouge et al., 2000; Luziriaga et al., 2006; Nagle et al., 2007; Tsai et al., 2008). Previous study that evaluated in FTIR reprocessed electrophysiology catheters of polyurethane up to ten times by Sterrad® 100S, showed that the level of oxidation among the polymers chains was more evident and progressive after five sterilizations (Tandon et al., 2008). It is presumed that reprocessing from the five times, can not be recommended, due to the fact that oxygenated groups are one of the main factors responsible by loss of mechanical properties of the materials and emergency of micro-roughness surface (Pretsch et al., 2008 ; Tandon et al., 2008; Umare and Chandure, 2008). Absorption in the carbonyl region displayed that the different number of reprocessing cycles explained approximately 97.37% of the variability of the absorbance ratio in the hydrogen-bonded carbonyls region (R^2adjusted = 0.9733). Further, at each increase in the number of reprocessing cycles, the absorbance ratio of hydrogen bonding carbonyls increased in 0.05 u.a. (p = 0.0000) as shown in Fig. 4.

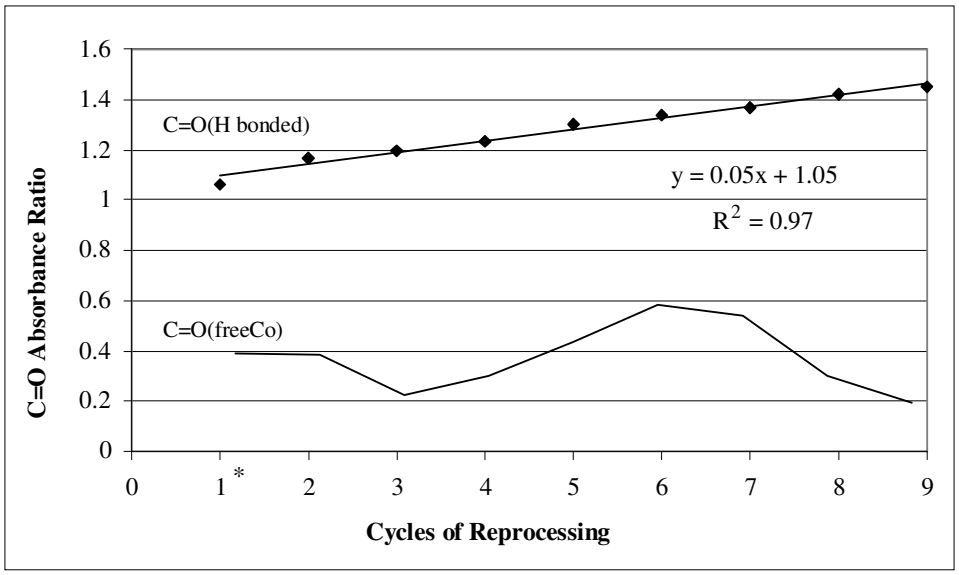


Figure 4. Relationship between hydrogen-bonded carbonyls and the different number of reprocessing cycles (Absorbance $_{C=O\ linked}$ / Absorbance $_{CH}$)
Note: 1* - refers to control catheter.

Studies of oxidative degradation of polyurethane blends have evidenced, by means of FTIR, that the absorption in the region of hydrogen-bonded carbonyls groups, tended to significantly increase ($p = 0.000$/CI=95%) when the crosslinking prevails over chain scission (Nagle et al., 2007;Tsai et al., 2008;Tandon et al., 2008). It was understood that the increase in the absorbance ratio in the region of hydrogen-bonded carbonyls is due mainly to the effect of crosslinking that approximate the polar regions of the molecules. Therefore, increase the participation of carbonyls on the formation of intermolecular hydrogen bounding. The new hydrogen bonds contribute to intensification of the device stiffness and expansion of the surface roughness (Singh and Sharma, 2008). It is important to emphasize in the degradation process the chain scission and the crosslinking formation, occurs simultaneously in a competitive way. However, in the oxidative degradation by hydrogen peroxide plasma, the formation of crosslinking prevailed over chain scission. Therefore, the crosslinking were probably responsible by increasing of the stiffness, roughness and deterioration of the polymeric materials in the different number of reprocessing cycles (Nagle et al., 2007; Umare and Chandure, 2008). Another factor that may have indicated the increase of the crosslinking on polymeric chains was the appearance of the methylene group (CH_2) from the sixth reprocessing. Such group may be considered a sub-product of the termination phase on the oxidative degradation. In this phase, unstable double bonds are formed and quickly broken, propitiating the formation of new crosslinking (Tsai et al., 2008; Umare and Chandure, 2008). Previous studies demonstrated that, on the oxidative degradation, parallel to the reticulation, occurs the oxidation and the formation of unsaturated double bonds that, in spite of being easily oxidized, the primary bonds between chains are preferably formed to oxygen-containing groups when on the splitting of double bonds (Luziriaga et al., 2006; Pretsch et al., 2009). The absorption in the free carbonyls region, showed an intense increase from third to sixth reprocessing and a tendency to fall from sixth to ninth cycle of reprocessing as illustrated in Fig. 4.

The increase of the free carbonyls can be attributed to the high oxidant action of the sterilizing agent and also polyurethane and polyamide broken chemical bonds, that leads to the production of oxygenates molecules such as ketones, carboxylic acids and esters (Nagle et al., 2007; Luziriaga et al., 2006; Lerouge et al., 2000; Pretsch et al., 2009). Furthermore, the decrease of free carbonyl can be attributed to the greater kinetics of formation of crosslinking over chain scission, as seen in the Fig. 2, the hydrogen-bonded carbonyl groups continued to increase from the sixth reprocessing. Therefore, FTIR spectra indicated that the stiffness of the material tends to be more progressive from the sixth reprocessing, due to the increase both density of crosslinking and intermolecular hydrogen bonding. Further, the increase of the density of crosslinking also leads to a decrease in permeability of atoms and molecules from the sterilizing agent, contributing to reduction of free carbonyls (Luziriaga et al., 2006). On the other hand the increase of the stiffness was evidenced in tensile test that the different number of reprocessing cycles explained approximately 84,45% of the variability of the Young' Modulus ($R^2_{adjusted} = 0.8445$). Further, at each increase in the number of reprocessing cycles, the Young' modulus increased in 0.05 u.a ($p = 0.0000$) as seen in Fig. 5. There was some suggestion that the increase of the stiffness is due to exposure by hydrogen peroxide that react with the polymer chain catalyzing crosslinking deeper and the formation of a secondary network into the material (Nagle et al., 2007; Simmons et al., 2006).

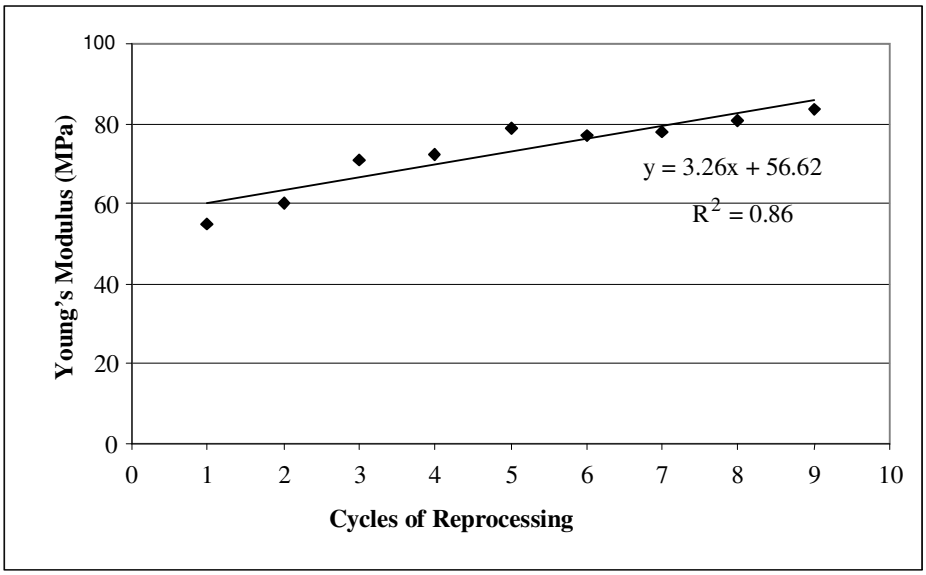


Figure 5: Relationship between Young's Modulus and the different number of reprocessing cycles

Concerning the roughness, micro-fissures and superficial imperfections, the non-reprocessed catheter had accumulated unidirectional micro-fissures in the central region of micrographs as well as superficial micro-scratches as shown in Fig.6.

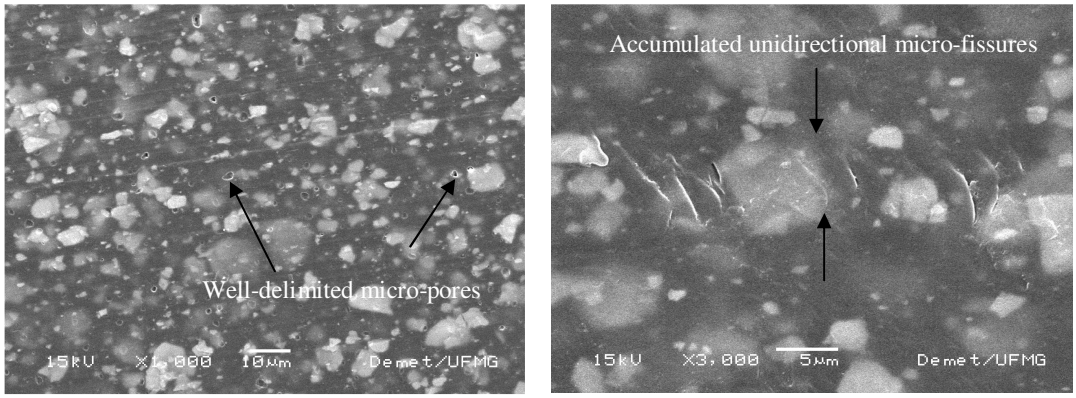
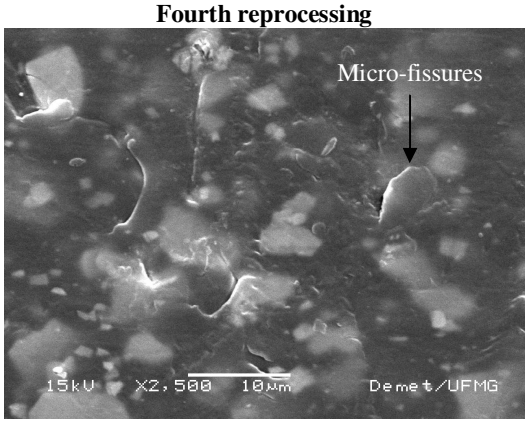


Figure 6. Scanning electron micrographs of the non-reprocessed catheters in a magnification of 1000x and 3000x

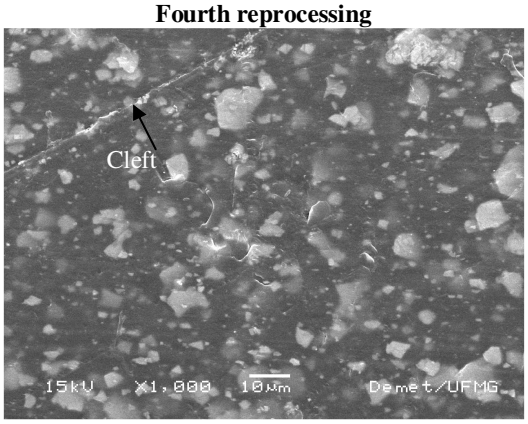
These defects, can lead to cleft formations, development of cracks and subsequent fracture of the polymeric material. Regarding the superficial imperfections, can be observed in the micrographs, the presence of well-delimited micro-pores of the non-reprocessed catheter and superficial micro-scratches. Interestingly, was that from the fourth cycle of reprocessing, the well-delimited micro-pores were replaced by diffuses saliencies, depressions and micro-protrusions. Further, the micro-scratches and micro-holes increased in quantity and length from the fifth reprocessing. When evaluated the presence surface roughness, it was verified that from the fourth reprocessing, emerging hollows, saliencies and micro-protrusions which deepen in each increase of the number of reprocessing cycles, exhibiting as entering rough from the sixth reprocessing as can be seen in Fig. 7.

Fourth reprocessing



Fifth reprocessing

Fourth reprocessing



Fifth reprocessing

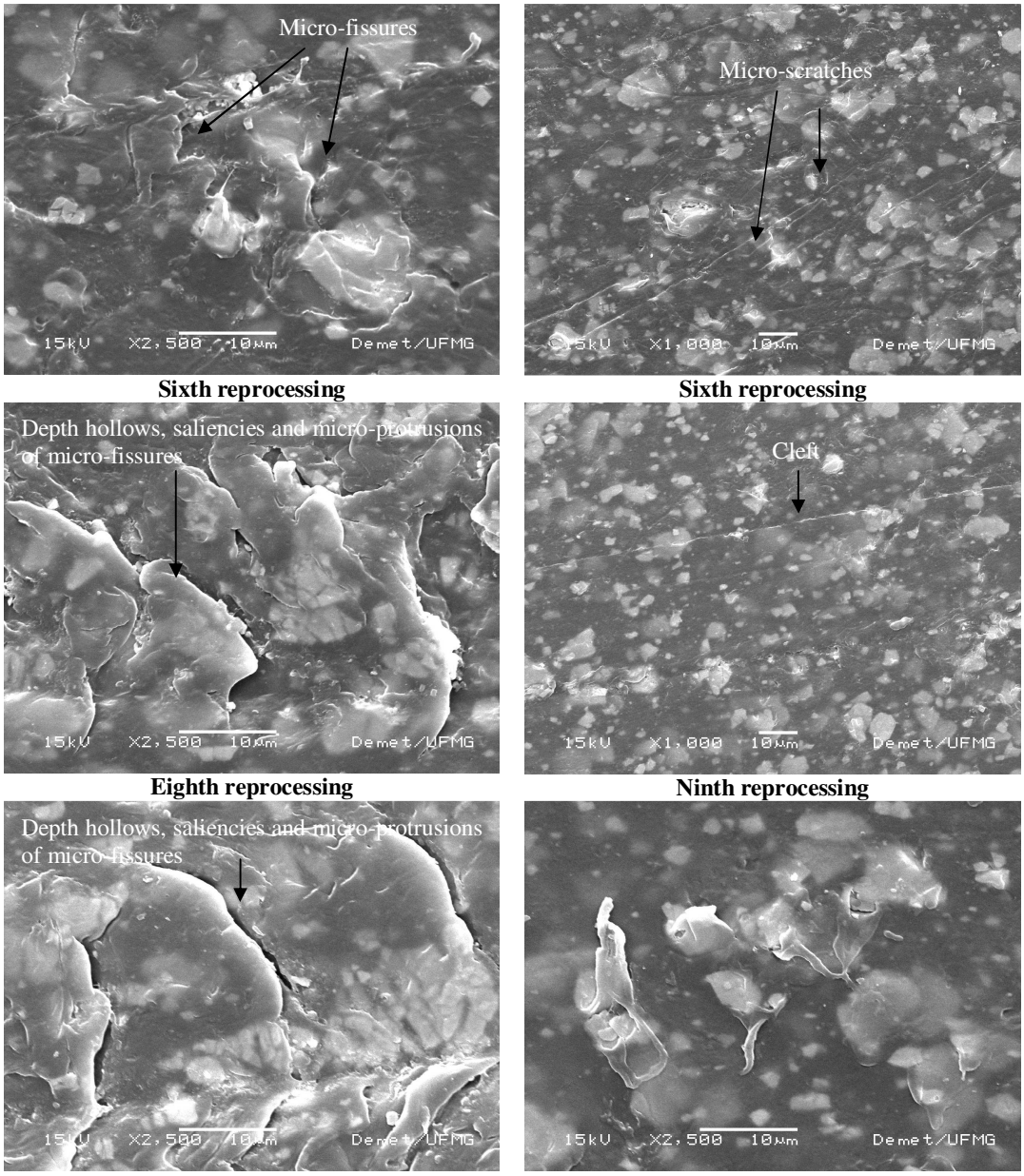


Figure 7: Scanning electron micrographs of the reprocessed catheters in a magnification of 1000x and 2500x

Previous study performed with polyurethane electrophysiology catheters, has evaluated by means of Atomic Force Microscopy, reprocessed catheters, one, four, six, seven, eight and fourteen times sterilized in Sterrad®100S (Tessarolo et al., 2004). It was checked that the changes on the surface roughness of the catheters also became more evident from the fourth reprocessing. From there, the roughness had an exponential increase until the fourteenth reprocessing (Tessarolo et al., 2004) Further, micro-scratches up to 1 mm in length were evidenced after four cycles of reprocessing (Tessarolo et al., 2004). In this work, the SEM exhibited similar results, as long as, from the fourth reprocessing the micro-scratches and the micro-fissures intensified in length and quantity up to the ninth reprocessing. Deduce that the presence of such defects on the surface of catheters may be related with efforts and mechanical requests occurred during the use, the handling during cleaning, and the own preparation of the material for sterilization. However, the presence of micro-holes and micro-fissures on polymeric materials, may also be initiated by the own process of oxidative degradation on the surface of the material (Tandon et al., 2008). A previous study, that has analyzed in SEM the oxidative degradation of a polymeric matrix of polyamide, has verified that as the material has been exposed to hydrogen peroxide plasma, micro-pores present in the surface of the polymer became increasingly enlarged, generating small micro-holes and fissures on the material (Tandon et al., 2008). A similar result was found in this work, due to the

fact that the length of the micro-fissures increased in the different number of reprocessing cycles, reaching up to 5.81 in the fourth cycle, 11.60 µm in the fifth cycle, 23.26 µm in the sixth cycle, 35.60 µm in the eight cycle and 42.20 µm in the ninth cycle of reprocessing. It is interesting to emphasize that micro-fissures is also related with the increase of the surface roughness and with the type of the polymeric material that constitute the devices. A study evaluated in SEM, the sterilization effect of two different types of polyurethane elastomers used on the production of implantable biomaterials sterilized in Sterrad® 100S one single time (Simmons et al., 2006). When comparing with the materials that were not reprocessed, it has been verified an increase of the roughness and the presence of micro-holes (Simmons et al., 2006). The micrographs of the Fig. 8, showing the presence of accumulated unidirectional micro-fissures in the catheter reprocessed six and eight times, in the curve portion, what can justify the greater probability of the formation of cracks in that region.

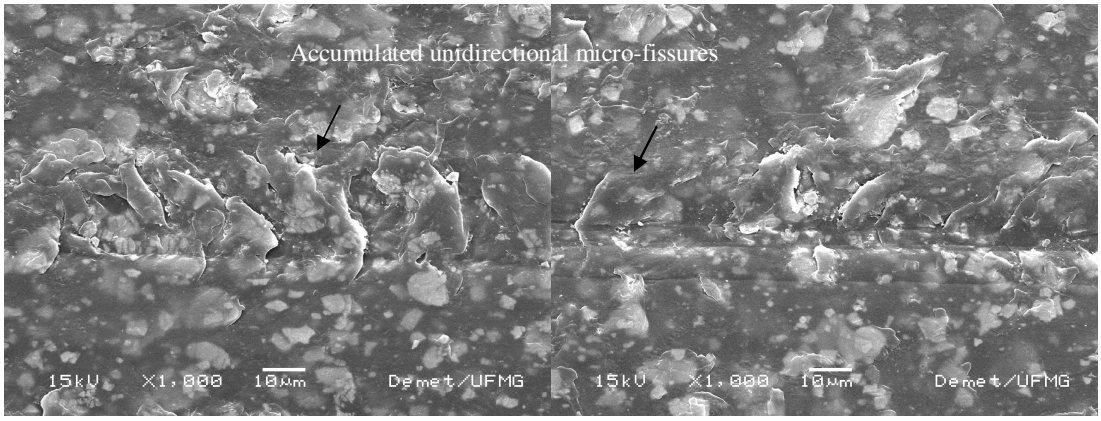


Figure 8: Scanning electron micrographs of the catheters reprocessed six and eight times in a magnification of 1000 x

In the catheter that was reprocessed five times there was a tendency for concentration of micro-fissures despite not so demarcated like in the catheters reprocessed six and eight times. Furthermore, the Fig.6 shows the presence of micro-scratches and clefts in the catheters. It is important to mention that the modification of a smooth to rough surface induces the formation of micro-fissures that increase the surface for oxidation, and generate mechanisms of initiation of collapse of the material (Tandon et al., 2008). In this work, the expansion of the depth of hollows, saliencies and micro-protrusions on the catheter surface reprocessed from six times, propitiated a greater area on sterilizing agent. As a result, the roughness can have contributed to decrease of the number of free carbonyls from this cycle and to increase of the density of crosslinking and intermolecular hydrogen bonding. Such deterioration, also, propitiated the increase of clefts and fissures on the device surface.

4. CONCLUSIONS

From the samples tested in this work, it was possible to reach some conclusions: (i) FITR evidenced that carboxylic groups, nitrocompounds and amide radicals were only seen, clearly on the spectrum, from the fifth reprocessing cycle; (ii) the hydrogen-bonded carbonyls groups and the methylene group suggested the increase of the density of crosslinking during different exposures to the hydrogen peroxide plasma; (iii) SEM revealed a tendency to the increase of the roughness of the reprocessed cardiac angiographic catheters from the fourth reprocessing. The limitations of this work included the reduced number of samples, which precluded deducing that the results found could correspond with the real specific requirements of behavior and useful life of the material. It is still important to remember that even non-reprocessed catheters presented superficial imperfections and micro-fissures that may interfere on the durability and security of the reprocessed polymeric material. However, making use of the protocol and of the catheter of this work, the reprocessing, from five times, is not recommended due to the progressive alteration on the molecular structure of the polymers from this cycle, and the increase of roughness, micro-holes, micro-scratches and micro-fissures. So, besides propitiating the accumulation of biofilms and microorganisms, also contribute for the development of cracks and fractures in the materials.

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6. RESPONSABILITY NOTICE

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