Reprocessing validation of angiographic cardiac catheters: an evaluation of the functionality and integrity*

VALIDAÇÃO DO REPROCESSAMENTO DE CATETERES CARDÍACOS ANGIOGRÁFICOS: UMA AVALIAÇÃO DA FUNCIONALIDADE E DA INTEGRIDADE

VALIDACIÓN DEL REPROCESAMIENTO DE CATÉTERES CARDÍACOS ANGIOGRÁFICOS: UNA EVALUACIÓN DE LA FUNCIONALIDAD E INTEGRIDAD

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ABSTRACT

The objective of this study was to validate the reprocessing of angiographic cardiac catheters regarding their characteristics of mechanical functionality and the molecular and micro-structural integrity of the polymeric chain. This is an experimental, applied, comparative and controlled study. A simulation set was built for a left coronary angiography in order to simulate mechanical and biological stress in the catheters. Traction tests were performed for the functionality and the integrity was tested through Infrared Spectrometry and Scanning Electronic Microscopy. The study evidenced a tendency to an increase in rigidity at every increment of the reprocessing number ($p<0.05$). The changes in the mechanical properties and molecular structures of the polymers were more evident as of the fifth reprocessing. Micrographies revealed an increase in rugosity as of the forth reprocessing. The results of this study may contribute to the elaboration of reprocessing protocols and a systematic surveillance of the reutilization of single use materials, not only due to their economical relevance, but especially from the ethical, legal, biological, functional and care point of view.

KEY WORDS

Equipment reuse.
Equipment failure analysis.
Molecular structure.
Biomedical engineering.
Nursing.

RESUMO

Objetivou-se validar o reprocessamento de cateteres cardíacos angiográficos quanto às suas características de funcionalidade mecânica e à integridade molecular e micro-estrutural da cadeia polimérica. Pesquisa experimental, aplicada, comparativa e controlada. Construiu-se uma bancada de simulação de uma arteriografia de coronária esquerda para simular um estresse mecânico e biológico em cateteres. Testou-se a funcionalidade por ensaio de tração e a integridade por Espectroscopia na Região do Infravermelho e Microscopia Eletrônica de Varredura. Evidenciou-se uma tendência ao aumento da rigidez a cada acréscimo do número de reprocessamento ($p<0,05$). As modificações das propriedades mecânicas e das estruturas moleculares dos polímeros foram mais evidentes a partir do quinto reprocessamento. As micrografias revelaram o aumento de rugosidade a partir do quarto reprocessamento. Os resultados deste estudo poderão contribuir para a elaboração de protocolos de reprocessamento e vigilância sistemática da reutilização de materiais de uso único, não apenas por sua relevância econômica, mas sobretudo do ponto de vista ético, legal, biológico, funcional e assistencial.

DESCRITORES

Reutilização de equipamento.
Análise de falha de equipamento.
Estrutura molecular.
Engenharia biomédica.
Enfermagem

RESUMEN

El objetivo del trabajo fue validar el reprocesamiento de catéteres cardíacos angiográficos en cuanto a sus características de funcionalidad mecánica e integridad molecular y microestructural de la cadena de polímeros. Investigación experimental, aplicada, comparativa y controlada. Se construyó un banco de simulación de una arteriografía de coronaria izquierda para simular un estrés mecánico y biológico en catéteres. Se testeó la funcionalidad por ensayo de tracción y la integridad por Espectroscopía Local Infrarroja y Microscopía Electrónica de Barrido. Se evidenció una tendencia al aumento de la rigidez en cada incremento del número de reprocesamientos ($p<0,05$). Las modificaciones de las propiedades mecánicas y de las estructuras moleculares de los polímeros fueron más evidentes a partir del quinto reprocesamiento. Las micrografías revelaron un aumento de rugosidad a partir del cuarto reprocesamiento. Los resultados de este estudio podrán contribuir en la elaboración de protocolos de reprocesamiento y vigilancia sistemática de la reutilización de materiales de uso único, no sólo por su relevancia económica, sino también, y sobre todo, respecto del punto de vista ético, legal, biológico, funcional y asistencial.

DESCRIPTORES

Equipo reutilizado.
Análisis de falla de equipo.
Estructura molecular.
Ingeniería biomédica.
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INTRODUCTION

Reprocessing single-use devices is the process applied to dental-medical-hospital devices in order to permit their reuse. It includes inspection, cleaning, preparation, wrapping, labeling, disinfection or sterilization, biological and chemical tests, residual analysis of the sterilizing agent, material functionality and integrity[1].

It should be highlighted that, due to the fact that this definition refers to reprocessed single-use devices, this concept includes some specific validation requisites, including functionality and integrity analysis, which are fundamental quality conditions to guarantee that the reprocessing responds to objective evidence for a given intended use.

In the United States, the Food And Drug Administration (FDA) regulates the validation of reprocessed single-use devices, so that manufacturers, outsourced reprocessors and hospital institutions have to evidence material security and efficacy through tests, demonstrating how many times the devices can be reprocessed[1].

These tests are needed to assess the potential risks the devices can cause for patients, such as: adverse tissue reaction (hemo- and biocompatibility tests), material rupture or failure (traction, torsion, flexibility tests and *in vitro* or *in vivo* tests*)* and infection (endotoxins and sterilization)[1-3].

In Brazil, Resolution No 2606 rules on the elaboration, validation and practice of reprocessing protocols, with a view to achieving effective control of the number of reuses[4]. The resolution does not specify, however, which validation methods provide objective evidence that the quality requisites for a given intended use are complied with.

With regard to proving the functionality and integrity of hemodynamic catheters after reprocessing, each catheter's range of polymers and manufacturers should be taken into account, as the degree of ramifications, crosslinking (covalent primary bonds between chains), the configuration and conformation of the polymer chains can influence modifications in mechanical (loss of resistance to traction, compression and torsion) and chemical properties (alteration of molecular weight, molecular orientations and intra and intermolecular bonds) when exposed to the sterilizing agents.

In view of these possible alterations in mechanical and chemical properties deriving from catheter reprocessing, which can imply severe consequences for the patients, institution and professional, the fact that most hospital institutions reprocess, among other single-use devices, cardiac angiographic catheters, is a source of great concern.

In most cases, this reprocessing occurs without any monitoring of specific validation methods to prove functionality (flexibility, torsional stiffness, resistance to traction and fatigue) and integrity (presence of cracks, stains, roughness, superficial imperfections, deteriorations, alteration in the molecular structure of the polymers).

Another aggravating factor is that the number of times a device can be reprocessed in order to guarantee safe reuse of the material has not been established, probably due to difficulties to put in practice specific validation methods that evidence maintained functionality and appropriate integrity for subsequent use. Reality shows that, in clinical practice, most hospital institutions empirically determine the number of reprocessing. The professionals who perform the procedure or reprocess the catheter generally do this based on simple visual inspection.

In view of these considerations on the risk of reprocessing, this study intends to assess the functionality and integrity of cardiac angiographic catheters after reprocessing, using laboratory trials to validate the following properties: a) ***Mechanical property:*** related to the catheters' mechanical functionality – resistance to *traction*; b) ***Chemical property:*** related to the molecular and micro-structural integrity of the polymer chain – *alteration in the molecular structure of the polymers, presence of microcracks, roughness and superficial imperfections.*

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Thus, the lack of validation can cause permanent injuries and/or severe clinical problems that pose threats to the patient's life, contributed to the increased risk of adverse events. Hence, the researchers hope that the validation strategies proposed for this research offer support with a view to safe clinical practice for patients as well as health professionals.

The researchers also hope to propose quality indicators in order to put in practice validated protocols and the control of cardiac angiographic catheter reprocessing, not only due to its economic relevance, but mainly from an ethical, legal, biological, functional and care perspective.

OBJECTIVE

To validate the reprocessing of cardiac angiographic catheters, considering their mechanical functionality characteristics and molecular and micro-structural integrity of the polymer chain.

METHOD

An experimental, applied, comparative and controlled research was carried out at the Bioengineering and Polymer and Composite Engineering laboratories of the Federal University of Minas Gerais (UFMG). The cardiac angiographic catheters were reprocessed at the Material and Sterilization Center (MSC) of the UFMG *Hospital das*

Clínicas. The study device was the *Judkins Left* (JL) catheter, manufactured by Biotronik®, a mixture of polyamide and polyurethane polymers, covered with a thin layer of polytetrafluorethylene inside the lumen.

Use simulation

To simulate catheter use, FDA recommendations for manufacturers and single-use dental-medical-hospital device reprocessors were followed regarding the submission of data validation in the premarket notification process, called [510 (k)]; released by this entity after the devices had gone through a series of registration, labeling, risk classification and quality and safety demonstration requirements[1,3]. These recommendations guide the simulation of the devices' submission to mechanical stress before the validation tests, guaranteeing that, in case of critical catheter use and handling in clinical conditions, due to different mechanic requests, its functionality and integrity characteristics will be preserved[1-3].

Thus, a bench was constructed, simulating a left and right coronary arteriogram in elastic silicon, insertion through the femoral artery, following the external and common iliac arteries, abdominal and thoracic descending aorta, aortic arch, ascending aorta until the coronary ostia of an adult approximately 1.75m tall.

The bench was completed with the Artificial Soil Test (AST), donated by Healthmark Industries®, St. Clair Shores, Michigan, USA, to simulate the *in vivo* physiological conditions.

To simulate one use on the bench, the catheters were inserted through a six French vinyl polychloride introducer sheath, with the help of a metal guide wire covered with polytetrafluorethylene, fifty times in the model, guaranteeing that, in a critical state of the patients' arteries at the clinic, the catheter could resist excessive efforts without any sign of rupture.

To simulate two reuses, the catheters were inserted fifty times into the silicon tube simulating the artery and, after being reprocessed, they were inserted in the same tube another fifty time, followed by reprocessing and testing. The same procedure was followed in other reuse simulations until the ninth reuse simulations.

The number of times the catheter was inserted in the artery simulation model, was justified by a method used by an outsourced reprocessor in the USA, *SterilMed,* with premarket approval by the FDA, to simulate the use of reprocessed cardiac catheters before validating the possible number of reprocessings for these devices[5].

Reprocessing protocol

After simulating the use, the catheters were rinsed for ten minutes in a device for lumens, using filtered running water. An enzymatic detergent solution (Max Zyme®) 4 ml/l (0.4%) was prepared in environmental temperature and the catheters were immersed in a plastic container for 5 minutes, according to the manufacturer's orientation. After the immersion, three manual jets of the solution were spread inside the lumen, using a ten-ml syringe. At the end of the immersion period, the catheters were rinsed for ten minutes and dried with a compressed air jet, permitting sterilization conditions. After complete drying, the catheters were submitted to visual inspection. Those with visual ruptures and marks of visible bends were considered exclusion criteria for this study, and thus discarded.

The catheters and *Cyclesure* biological indicator vials were wrapped in Tyvek and, inside each wrapping, Sterrad® chemical indicator strip was placed, guaranteeing compliance with validated parameters for the functioning of the sterilizer during the study.

A Sterrad® 100S sterilizer was used for sterilization, in which plasma is produced through hydrogen peroxide substrate bombarded with radio frequency waves.

The sterilization cycles can take 51 minutes (short cycle), or 72 minutes (long cycle), depending on the type of device to be placed in the equipment, that is, variations in lumen length and diameter of the cannulated items[6].

According to recommendations for Sterrad® sterilization, cannulated plastic items of up to one meter length and with an internal diameter of one millimeter or more should be sterilized in the short cycle, without the intensifier/adapter[6].

Hence, as the length of the catheters in this study was one meter and the internal diameter 1.45 mm, the duration of the sterilization cycle was 51 minutes and temperature during the cycle phases ranged from 45 to 50^{0}C.

Hydrogen peroxide plasma was chosen as the sterilizing agent due to its potential interaction with the polymers' polymer chain, formation of oxygenated clusters, which start chain cleavage, and the formation of crossed bonds that can contribute to the deterioration of the device and loss of mechanic properties during the different reprocessing cycles.

Among degradation types, oxidative degradation is the process most involved in devices sterilized through the hydrogen peroxide plasma method, as its decomposition produces free radicals like hydroperoxides (ROOH) and hydroxyl radicals (**.**OH) which, due to their high oxidation power, start the degradation process of the polymers constituting the catheters, thus altering the mechanical and structural performance of the thermo-sensitive devices submitted to the sterilization cycles[7-8].

The produced free radicals can give rise to polymer chain cleavage or crosslinking formation processes. In case of crosslinking, however, it should be highlighted that the established network cannot be homogeneous and generate a product with poor mechanical properties[7]. Hence, the formation of crosslinking, independently of their density, becomes non-beneficial for the materials, enhancing the decrease in their tenacity and resistance to traction.

Technical validation methods

With regard to functionality, a traction test was performed, using the EMIC® universal testing machine, model

DL 3000, in environmental temperature, with a 500N load cell at a velocity of 500 mm/minute. Test standardization followed NBR ISO 10555-1, regarding general requisites for sterile single-use intravascular catheters[9]. The sample contained four 80.0 mm long test bodies from the curved part of the catheter's distal end, the region with a greater probability of tension concentration and, hence, greater risk of cracks and fissures; for each experimental and control group, totaling forty catheters.

The following variables were related with resistance to traction: Young modulus (assessed the stiffness of the catheters), mean tension at maximum force (the maximum tension a device under traction can support and, if this tension is applied and maintained, it will break) and mean deformation at maximum force (maximum plastic deformation before the rupture of the polymer, thus behaving as a ductile material. The greater the deformation, the greater the resistance to rupture.

With regard to integrity, Fourier Transform Infrared Spectroscopy (FTIR) was used in a Spectrum 1000 Perkin Elmer® spectrophotometer to assess the following variable: alteration in the molecular structure of the polymers (modifications in the functional groups and chemical bonds of the polymers in the spectra at each different reprocessing number). In total, nine samples were tested from the curved part of the catheter, measuring 34 cm, one control and eight in the experimental group, reprocessed between two and nine times. Interval analyses were performed at intervals between 400-4000 cm^{-1}. All spectra were obtained as from 16 screenings at a 4 cm^{-1} resolution. The film spectra were obtained through the Attenuated Total Reflectance (ATR) technique, coupled to the infrared spectrometer. It is important to highlight that only the catheter's external surface was assessed, as the depth the spectrum reaches ranges from 3 to 5µm.

Micro-cracks (considered the first stage of the fracture process, lead to the formation of splits that spread until the final fracture), roughness (set of diffuse irregularities, such as wavy and granulated recesses and bulges) and superficial imperfections (micro-scratches, micro-pores or micro-holes) variables were assessed through Scanning Electron Microscopy (SEM). In total, six samples were analyzed from the curved part of the JL catheter, one control and five in the experimental group, reprocessed four, five, six, eight and nine times.

Data analysis

The analysis of variables related to the tension test was based on the Mean ± Standard Deviation (SD), calculated with Tesc software version 3.01®. To estimate the mean variation of the Young modulus at each different reprocessing number, Simple Linear Regression Analysis was used. Data were processed in Statistical Software for Professionals (STATA) version 9.0® and, for the sake of interpretation, the type I error limit was up to 5% (p = 0.05). The significance of the model was assessed through the F-test in the analysis of variance, while the adjusted determination coefficient (adjusted R^2) was used to assess the quality of the adjustment. Residues were evaluated according to the premises of normality, zero means, constant variance and independence.

With regard to the FTIR, the regions of the spectra's absorption bands in this study were compared with different authors, who identified similar absorbance regions (band intensity) in the different wave length ranges[9-14]. Those authors presented specific vibrations in each spectrum, frequencies and wave numbers characteristic of functional groups and chemical bond between organic molecules, resulting from the oxidative degradation of polymer materials. Modifications in the contours of the absorption bands were also observed in each spectrum during the different numbers of reprocessing.

To identify the degree of variation in the carbonyl group (C=O) at each different reprocessing number, absorbance was measured in the carbonyl region and divided by absorbance in the region of the C-H groups ($Absorbance_{C=O}$/ $Absorbance_{C-H}$). Next, they were analyzed through simple linear regression and processed in STATA.

RESULTS AND DISCUSSION

Mechanical functionality of the cardiac angiographic catheters

Table 1 shows the main parameters to quantify the catheters' mechanical resistance in a tension-deformation test.

Table 1 - Distribution of mechanical resistance parameters of control and experimental group catheters obtained through tension test - Belo Horizonte -2008

Groups Control and Experimental	Mean Tension at Maximum force (MPa) **Mean ± SD**	Mean Deformation at Maximum force (%) **Mean ± SD**	Young Modulus (MPa) **Mean ± SD**
Control	28.51±0.96	231.09±11.20	70.61±4.22
1st Reprocessing	29.50±0.65	311.08±23.79	55.09±3.43
2nd Reprocessing	29.74±0.14	296.09±14.22	60.19±4.02
3rd Reprocessing	30.20±0.89	307.09±25.00	70.76±2.93
4th Reprocessing	29.58±0.50	270.09±18.76	72.16±2.17
5th Reprocessing	28.75±0.16	293.03±25.38	78.64±2.05
6th Reprocessing	28.13±0.55	284.05±17.56	76.89±1.84
7th Reprocessing	28.01±0.90	278.06±28.09	78.14±1.32
8th Reprocessing	27.03±0.50	276.00±16.07	80.98±1.08
9th Reprocessing	27.03±0.92	269.05±11.10	83.56±1.02

When the catheters were submitted to the first reprocessing, decreased stiffness (from 70.61 MPa to 55.09 MPa) and increased mean deformation at maximum force were observed. As a result, it is inferred that one single reprocessing through hydrogen peroxide contributed to an improvement in catheter properties.

The modifications in the catheters' mechanical properties in one single cycle can be explained by the action of the hydrogen peroxide plasma in the initial phase of the oxidative degradation process, in which the chain split and crosslinking formation reactions can occur simultaneously[8,10]. In this case, the rupture of bonds may have prevailed, as the greater mobility and orientation of the chains produced optimal stiffness for the catheters, making them more ductile and flexible.

Moreover, the free radicals from the hydrogen peroxide plasma can permit the creation of a series of chemical groups, which contribute to improve the devices' mechanical properties[7]. This benefic effect can also have contributed to modify the resistance to traction properties during the first sterilization cycle.

Depending on the type of polymer and contact interface area, however, the behavior after the first reprocessing, sterilized with hydrogen peroxide, can be different and not offer great advantage for the material properties.

A study assessed the mechanical properties of two different types of polyurethane elastomers used in the production of implantable biomaterials sterilized in Sterrad® 100S one single time[8]. The comparison with materials that were not reprocessed (control), a great increase in the elasticity module was verified, accompanied by significant change in material stiffness (p=0.003/CI=95%) and an important reduction in the mean deformation at maximum force[9].

It was inferred that the negative effect on ductility and resistance after one single sterilization was due to the low thickness of the assessed material (0.50mm)[8]. The thickness of the catheters in this study (0.55mm), however, also permitted similar exposure to hydrogen peroxide plasma and its properties were modified in a positive way for the material. Hence, exposure to the chemical agent does not only depend on one single factor, but on a range of basic characteristics that can determine the variation of polymer properties when confronted with the sterilizing agents, such as the chain composition, degree of ramification or crosslinking between the polymer and molar mass.

In this study, a behavior typical of oxidative degradation was observed: increase in mean tension at maximum force in the initial phase of the process and a downward trend due to the cumulative effect of degradation[8,10-11]. The mean tension at maximum force increased until the third reprocessing and tended to decrease from that point onwards. It is inferred that the contribution to this increase is partially due to the decomposition of the hydrogen peroxides that permitted the increase in the oxidation level, chain split and formation of new intermolecular and crossed chemical bonds[8,10-11]. On the other hand, as the density of crosslinking increases, the device tends to produce a non-homogeneous network of chains, arranged irregularly, generating a negative effect for the device, decreasing its resistance to traction and, consequently, to the mean tension at maximum force[7]. Thus, the maximum tension the material supports when under traction tends to decrease and the probability of catheter rupture tends to increase.

A study evidenced that the polymers, in an oxidative degradation process induced by hydrogen peroxides, tended to a decrease in the mean tension at maximum force due to the increased density of crossed bonds in the amorphous region (polymer chains are arranged in a disorganized way) of the polymer materials[10]. It is interesting to highlight that, in general, the polyamide and polyurethane blends have an amorphous region superior to crystalline, so that the effect of the crossed bonds in the deterioration of the material prevails over the crystallization[12]. Thus, it is inferred that the effect of the increased stiffness and decreased mean tension at maximum force is more associated with the increase in covalent bonds between chains than with the orientation of the molecules.

Besides, the hydrogen peroxide plasma has the power to destruct the crystalline matrix of the polymers, disorganizing their molecular structure, replacing it by an amorphous region[11-12]. Hence, the amorphous region is more susceptible to degradation and the formation of crosslinking is the main responsible for the decrease in the material's ductility.

It should be highlighted that, during the fifth reprocessing, the modifications in the properties of the catheter polymers in this study became more evident. Catheter stiffness increased in comparison with earlier reprocessings, still maintaining a larger module than catheters reprocessed six and seven times. In this cycle, the mean tension at maximum force continued dropping, decreasing its ductility and resistance to traction.

In view of the above, hospital institutions and outsourced reprocessors should pay attention when assessing the maintenance of reprocessed angiographic catheter behavior as from five times, during its clinical use, verifying the preservation of original functionality, presence of micro-cracks, stains and surface roughness, which are negative consequences of oxidative degradation[8,10-11].

It could be observed that, from the fifth until the ninth reprocessing, the oxidative degradation increased, with a downward trend in the mean deformation at maximum force and increased stiffness at each reprocessing cycle. The linear adjustment equation indicated that, at each increase in the reprocessing number, on the average, the elasticity module tends to increase by 3.26 MPa (p = 0.0003). Besides, the different reprocessing numbers explained approximately 84.45% of variability in the Young modulus ($R^2_{adjusted}$ = 0.8445). This behavior confirmed the hypothesis

that the thermoplastic polymers can suddenly experience the transition from ductile to fragile, without any prevision of breaking[10-12].

Molecular and micro-structural integrity of the polymer chain

In this study, it was verified that the different reprocessing numbers explained approximately 97.37% of absorbance ratio variability in the bonded carbonyl region (hydrogen bonds in the carbonyl group - HCO) ($R^2_{adjusted}$ = 0.9733). The linear adjustment equation showed that, at each increase in the reprocessing number, the bonded carbonyl absorbance ration increased by 0.05 u.a (p=0.0000) .

Oxidative degradation studies of polyurethane blends evidenced, through FTIR, a significant upward trend (p = 0.000/ CI=95%) of absorption in the bonded carbonyl region as the oxidative degradation process developed, which evidenced the prevalence of crosslinking over chain splitting[11-15].

The increased absorbance ratio in the bonded carbonyl region is considered mainly due to the effect of the crosslinking that approach the polar regions of the molecules and increase the carbonyls' role in the formation of hydrogen bonds[12,14]. This effect is superior to the increase in hydrogen bonds in the splitting of polymer chains which, due to greater mobility, enhances molecular organization and favors crystallization.

With regard to oxygenated clusters, considered one of the main factors due to the devices' loss of mechanical properties, a study that assessed polyurethane electrophysiology catheters in FTIR, reprocessed up to ten times using Sterrad® 100S, concluded that the oxidation level between the polymer chains was more evident and progressive in the spectra after five sterilizations[15].

In this study, similar results were found, as functional groups (COO^-,NO_2 and $CONH^+$) were identified more clearly in the absorption bands as from the fifth reprocessing. It is inferred that such radicals derive from the degradation of polyurethanes and polyamides, leading to the production of functional groups, resulting from alcohol, esters and carboxyl acids and the hydrolysis of amides, constituting amines, carboxyl acids and nitro compounds.

Another factor that may have indicated the increase in crosslinking in the polymer chains was the appearance of the methylene group (CH_2) as from the sixth reprocessing. This group may be considered a sub-products of the reactions in the end phase of oxidative degradation, as unstable double bonds are established and rapidly broken, favoring new crosslinking and, consequently, increasing material stiffness[11]. Studies have demonstrated that, in oxidative degradation, in parallel with reticulation, oxidation occurs and unsaturated bonds are established. Although easily oxygenated, the primary bonds between chains are preferably established with oxygenated groups in the splitting of double bonds[10,12,14].

With regard to the variables: roughness, micro-cracks and superficial imperfections, the presence of roughness was verified on the catheter surfaces as from the fourth reprocessing. Bulges and deep recesses alternated with small superficial irregularities in the fourth and fifth reprocessing (regularly rough surface) and several deep rough areas (rough surface) as from the sixth reprocessing (Figure 1).

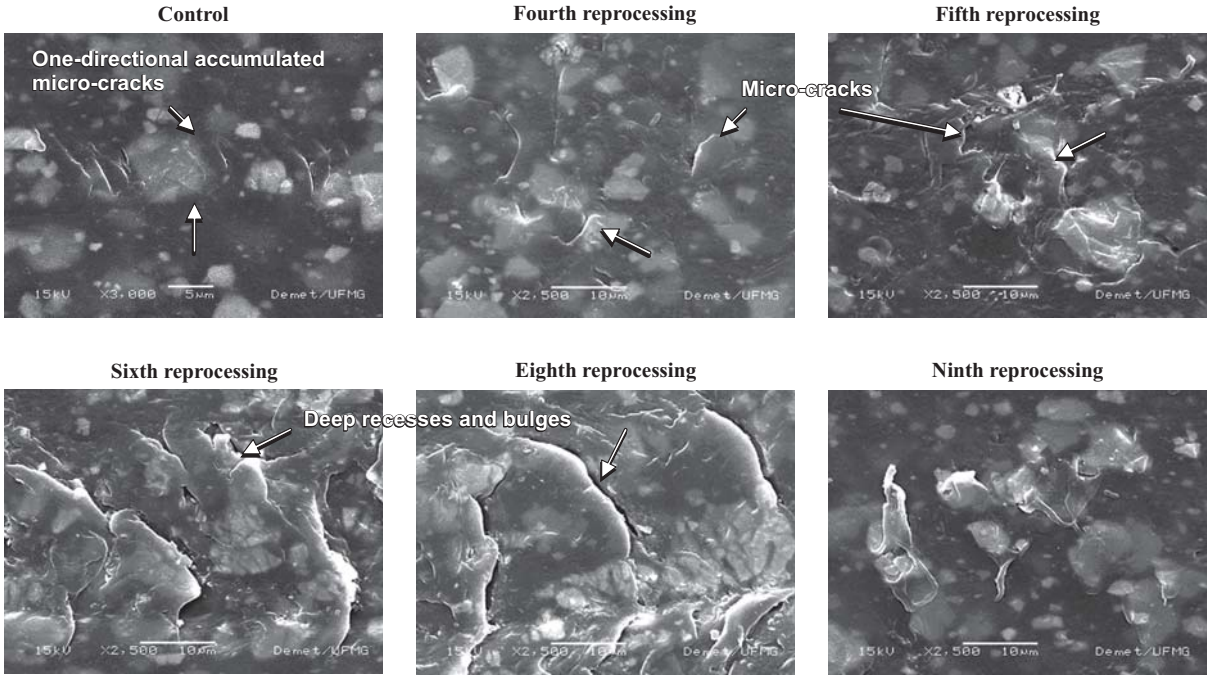

Figure 1 - Micrographs of the control catheter magnified 3000x and of reprocessed catheters magnified 2500x - Belo Horizonte - 2008

A study of polyurethane catheters for electrophysiology and ablation assessed catheters that were reprocessed one, four, six, seven, eight and fourteen times, sterilized in Sterrad® 100S, using Atomic Force Microscopy (AFM). It was verified that roughness changes in catheter surfaces also became more evident as from the fourth reprocessing. From that point onwards, roughness showed exponential growth until the fourteenth reprocessing[16].

The modification from a smooth to a rough surface favors the appearance of micro-cracks and induces openings which, in turn, increase the surface for oxidation and produce mechanisms starting material failure[17].

A study that analyzed the oxidative degradation of a polyamide polymer matrix, using scanning electron microscopy (SEM), found that, to the extent that the material was exposed to hydrogen peroxide, micro-pores on the polymer surface became increasingly wider, generating small micro-holes and cracks in the material[17].

In the present study, similar results were found, as the extent of the micro-cracks increased in the different numbers of reprocessing, reaching up to 5.81 µm in the control catheter and the device reprocessed four times, up to 11.60 µm when reprocessed five times, 23.26 µm six times, 35.60 µm eight times and up to 42.20 µm when reprocessed nine times, which suggested a decrease in the device's useful life at each reprocessing.

It is inferred that the presence of such defects on the catheter surface may be related with the efforts and mechanic requests occurred during use, handling during cleaning and material preparation for sterilization itself. The presence of micro-holes and micro-cracks in the polymer devices, however, can also be started by the oxidative degradation process itself on the material surface[8,10,16-17].

In Figure 1, it is interesting to highlight the presence of one-directional accumulated micro-cracks on the control catheter, resulting from manufacturing defects, which can lead to bursting, the development of cracks and the consequent fracture of the polymer device. Moreover, in one single use, the catheter will facilitate the accumulation of biofilms and endotoxins in the micro-crack region, which can lead to infection and blood clots in patients[18].

It should be mentioned that a study on the presence of biofilms in cardiac angiographic catheters after five reuse simulations evidenced that carbohydrate and protein residues were not totally eliminated from the catheters[19]. Although the present research did not evaluate the presence of micro-cracks or roughness, difficulties to eliminate biofilms from polymer material were verified. As these are constituted by long carbon atom chains, they show high affinity with organic residues, contributing not only to infectious reactions in patients, but also to material integrity damage.

It is highlighted that, despite the small number of samples, the results of the functionality and integrity tests offer evidence-based clinical support for test protocol acceptance criteria before the reuse of devices recommended for single use.

CONCLUSION

Based on the samples tested in this study, some conclusions could be reached:

• The tension test indicated a downward trend in mean deformation at maximum force and an upward trend in the elasticity module (stiffness) of the cardiac catheters at each increase in the number of reprocessings.

• FTIR evidenced that carboxyl clusters, nitro compounds and amide radicals were only seen clearly in the spectra as from the fifth reprocessing.

• The increased absorbance ratio of bonded carbonyls at each increase in the number of reprocessings, the appearance of the methylene group as from the sixth reprocessing, indicated increased density of crossed bonds during different exposures to hydrogen peroxide plasma.

• SEM revealed a trend towards increased roughness of reprocessed cardiac catheters as from the fourth reprocessing. The number and dimension of micro-cracks present on the catheter surfaces increased along with the number of reprocessings.

These study results will contribute to the creation of reprocessed catheter quality assessment indicators as, using the protocol and the catheter tested in this study, as from five times, reprocessing is not recommended due to the device's unforeseen mechanical behavior, progressive alteration in the polymers' molecular structure as from this cycle and increased roughness, micro-holes, micro-scratches and micro-cracks, which not only enhance the accumulation of biofilms and micro-organisms but also contribute to the development of cracks and ruptures in the devices.

Moreover, the results can raise hospital institutions and outsourced reprocessors' awareness to the creation of validated reprocessing protocols, without which careful assessment of material quality, service restructuring and standardization, detailed inspection of dental-medical-hospital devices and systematic surveillance of the reuse of devices recommended for single use are not possible.

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