

# Effects of reprocessing on chemical and morphological properties of guide wires used in angioplasty

## *Efeitos do reprocessamento nas propriedades químicas e morfológicas de fios-guia usados em angioplastia*

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DOI: 10.5935/1678-9741.20130052

RBCCV 44205-1478

### *Abstract*

**Objective:** To investigate the influence of the reprocessing technique of enzymatic bath with ultrasonic cleaning and ethylene oxide sterilization on the chemical properties and morphological structure of polymeric coatings of guide wire for regular guiding catheter.

**Methods:** These techniques simulated the routine of guide wire reprocessing in many hemodynamic services in Brazil and other countries. Samples from three different manufacturers were verified by scanning electron microscopy and X-ray photoelectron spectroscopy.

**Results:** A single or double sterilization of the catheters with ethylene oxide was not associated with morphological or chemical changes. However, scanning electron microscopy images showed that the washing method was associated with rough morphological changes, including superficial holes and bubbles, in addition to chemical changes of external atomic layers of polymeric coating surfaces, as detected by the X-ray photoelectron spectroscopy method, which is compatible with extended chemical changes on catheter surfaces.

**Conclusion:** The reprocessing of the catheters with ethylene oxide was not associated with morphological or chemical changes, and it seemed appropriate to maintain guide wire coating integrity. However, the method combining chemical cleaning with mechanical vibration resulted in rough anatomical and

chemical surface deterioration, suggesting that this reprocessing method should be discouraged.

**Descriptors:** Cardiac catheterization. Health knowledge, attitudes, practice. Diagnostic techniques, cardiovascular. Equipment reuse. Angioplasty.

### *Resumo*

**Objetivo:** Investigar a influência das técnicas de reprocessamento de banho enzimático com limpeza ultrassônica e a esterilização com óxido de etileno nas propriedades químicas e estruturas morfológicas de revestimentos poliméricos de fios-guia usados como guias em cateteres regulares.

**Métodos:** Estas técnicas simulam a rotina de processamento de fios-guia em muitos serviços de hemodinâmica do Brasil e de outros países. Amostras de três diferentes fabricantes foram verificadas por microscopia eletrônica de varredura e espectroscopia de fotoelétrons de raios-X.

**Resultados:** Uma única ou dupla esterilização dos cateteres com óxido de etileno não foi associada a mudanças químicas ou morfológicas. Contudo, imagens de microscopia eletrônica de varredura mostraram que o método de lavagem foi associado a intensas modificações morfológicas, incluindo bolhas e buracos superficiais, assim como mudanças nas ligações químicas das

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Supported by Processo Fapemig CEX, Belo Horizonte/Brazil –protocol number APQ-03992-10

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Article received on May 14<sup>th</sup>, 2013

Article accepted on July 10<sup>th</sup>, 2013

**Abbreviations, acronyms & symbols**

PTFE	polytetrafluoroethylene
SEM	Scanning electron microscopy
XPS	X-ray photoelectron spectroscopy

**camadas atômicas externas do revestimento polimérico, conforme demonstrado por resultados de espectroscopia de fotoelétrons de raios-X, compatível com extensas modificações químicas induzidas por esse processo de lavagem.**

## INTRODUCTION

The reuse of angioplasty catheters and other medical or surgical devices initially designed for single use, has been adopted in several hemodynamic services around the world, and is associated with substantial decrease in hospital costs [1]. However, this practice may be associated with malfunction of the devices related to either chemical or physical changes.

To be reused, a catheter and all its complementary parts should remain free of biological hazards, including the presence of toxins, bacteria, viruses, and fungi. Moreover, its physical properties, such as flexibility and resistance to torque, should be maintained at levels that are safe for the patient [2-6]. Several physical changes have been described in the literature, including loss of the catheter deflection property after ethylene oxide and hydrogen peroxide treatment [2], or alterations in catheter morphology after the use of enzymatic detergent and hydrogen peroxide plasma [7]. For example, micro-fissures, micro-scratches, depth hollows, saliencies and micro-protrusions in polyurethane surfaces of reused catheters were reported by Lucas et al. [7]. However, these authors did not study the guide wire used in routine catheter guiding, nor submitted their devices to some of the other common methods of sterilization used in Brazil, such as ultrasound exposition followed by ethylene oxide sterilization.

Therefore, as the guide wires used for routine catheter guiding are generally covered with surface polymers – macromolecules composed of repeated structural units, typically C-C or C-F covalent chemical bonds– aimed to be relatively inert and biocompatible, they should be checked after each reprocessing method used. We have not found studies describing morphological changes after the reuse of the guide wire catheter coated with polymeric material such as PTFE (*polytetrafluoroethylene*). Hence, in the present study, we investigated the influence of each method of

**Conclusão:** O reprocessamento dos fios-guia de cateteres com óxido de etileno não está associado a mudanças químicas e morfológicas dos mesmos e pode ser considerado adequado para manter a integridade destes materiais. Entretanto, o método que combina lavagem química com vibração mecânica resulta em intensas deteriorações anatômicas e químicas, sugerindo que esse método de processamento deve ser desencorajado.

**Descritores:** Cateterismo cardíaco. Conhecimentos, atitudes e prática em saúde. Técnicas de diagnóstico cardiovascular. Reutilização de equipamento. Angioplastia.

reprocessing in the chemical and morphological properties of the polymeric coatings of guide wire catheters.

## METHODS

Guide wire catheters from three different manufacturers (termed samples A, B and C), composed of polymer-coated stainless steel were investigated. The guide wires were coated either with PTFE (*polytetrafluoroethylene*) (samples A and B) or with an unknown polymer (sample C).

All guide wire samples were pristine and, to simulate the washing routine in hospitals, they were washed in enzymatic bath at least once (ultrasound 1X, termed AU1, BU1 or CU1) or twice (samples AU2, BU2 or CU2). This procedure simulates what would be done on any reuse of the material. In the same way, pristine guide wires were sterilized using ethylene oxide once (samples AS1, BS1 and CS1) or twice (samples AS2, BS2 and CS2).

### Cleaning with ultrasound.

An ultrasonic washer was employed for the mechanical washing of the guide wire catheters, at 37 kHz frequency and ultrasonic-power of 4400 W. Initially, the guide wire was immersed in detergent enzyme and processed in ultrasound at 40°C for 15 minutes. Then, it was rinsed with three water jets using a sterile syringe, dried with sterile gauze and compressed air. Finally, it was placed in a plastic bag for transport and subsequent analysis.

### Sterilization with ethylene oxide

The guide wire catheters were sterilized with ethylene oxide at 100% (Sterivac 5XL, 3M - sterilization equipment under low temperature). The guide wire catheters were packed in surgical papers and placed in the sterilization chamber. The sterilization cycle lasted 4 hours at a temperature of 55°C. At the end of this time, the guide wires were maintained for 18

hours in mechanical aeration in the chamber, and as a final step, at 132°C for 4 minutes.

The morphology of the guide wire surfaces was analyzed by scanning electron microscopy (SEM), using a Dual Beam FIB/SEM (Focused Ion Beam/Scanning Electron Microscopy) Model Nanolab Nova 200 (FEI Co.). All specimens (guide wire pieces of 3 cm in length) were coated with a 3-5 nm Cu film using a DC sputtering system. All images were obtained in the secondary electron mode. An electron beam of 5 kV and 0.4 nA was used.

To investigate changes in the chemical composition of the coating surfaces, XPS was used. Measurements were carried out with a VG Microtech ESCA3000 spectrometer, operating at a base pressure of  $3 \times 10^{-10}$  mbar. The Al K<sub>alpha</sub> non-monochromatic radiation was used for photoelectron generation. Binding energy corrections were made in the raw spectra using the Handbook reference of the saturated hydrocarbon C1s peak at 285 eV [8]. For these measurements, the samples (1.0 cm guide wires) were mounted protruding from the sample holder to avoid any sample holder signals in the spectra.

## RESULTS

### SEM Results

The SEM images of surfaces of the polymeric coatings of pristine guide wires A, B, and C are shown in Figure 1. Fairly uniform surfaces are revealed by the three micrographs. The small irregularities observed in the three pictures are typical of pristine guide wires and were considered normal.

The effect of ultrasonic and enzymatic detergent cleaning treatments of the three samples can be seen in the SEM images (Figure 2), which depict the surfaces of the samples after a single cleaning. Pronounced surface damage is observed in samples AU1 and CU1 while damage is less significant in sample BU1. Sample AU1 was the most affected, as seen in Figure 2.

The persistence of debris larger than 200 µm can be observed at the surface of guide wires after the washing procedure using ultrasound. Sample BU1 shows defects in the PTFE structure, including holes and bubbles, that were not observed in the pristine material. A marked roughness in the polymer coating surface is seen in the CU1 sample, with some holes in the microstructure and micrometric flakes, smaller than those observed in sample A.

At naked eye, the catheters washed only once showed slight color changes, varying from green to a yellowish-green color, a phenomenon which is markedly observed after the second washing (samples AU2 and BU2). The intense modifications are best observed through scanning electron microscopy, which allows for viewing at the micrometric level (Figure 3).

Regarding the sterilization process, the images obtained (not shown) do not reveal significant changes in the PTFE coatings (catheters type A and B) as well as in the coating of guide wire type C, even after a second sterilization process.

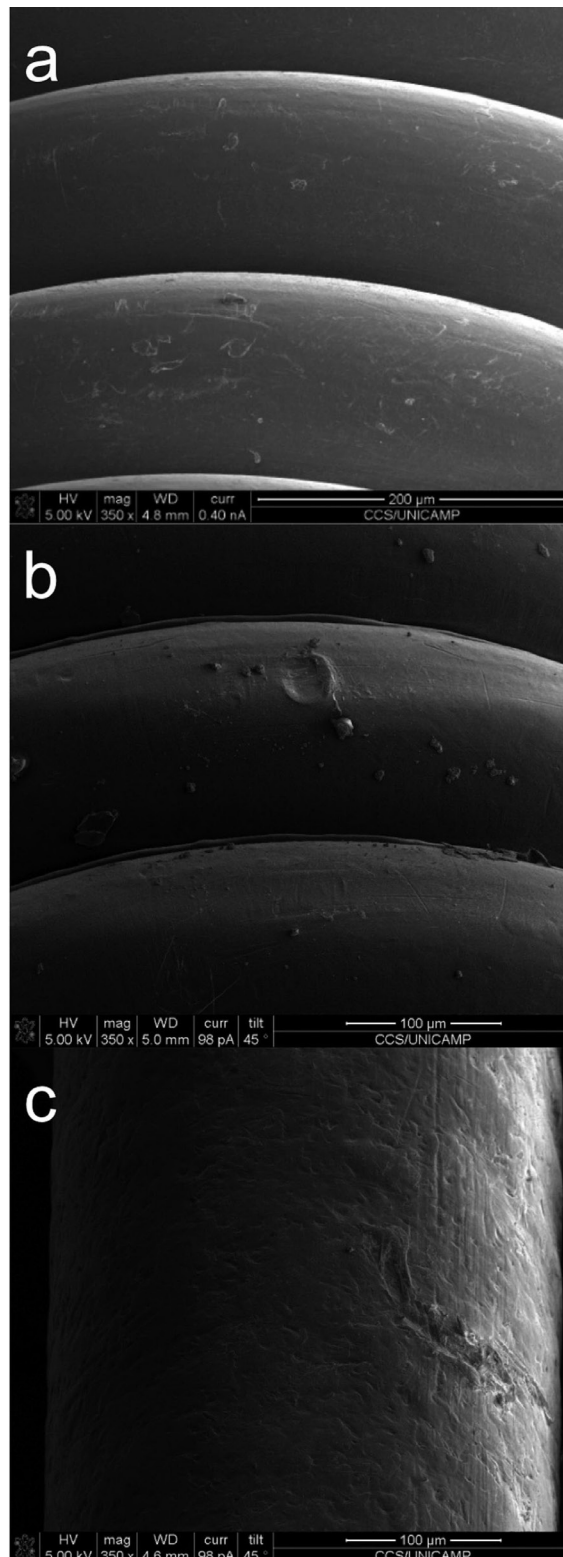


Fig. 1 – SEM pictures of guide wire catheter samples A, B and C. All surfaces with few small irregularities, considered normal for this material. Small artifacts from the manufacturing process are seen in Figure B.

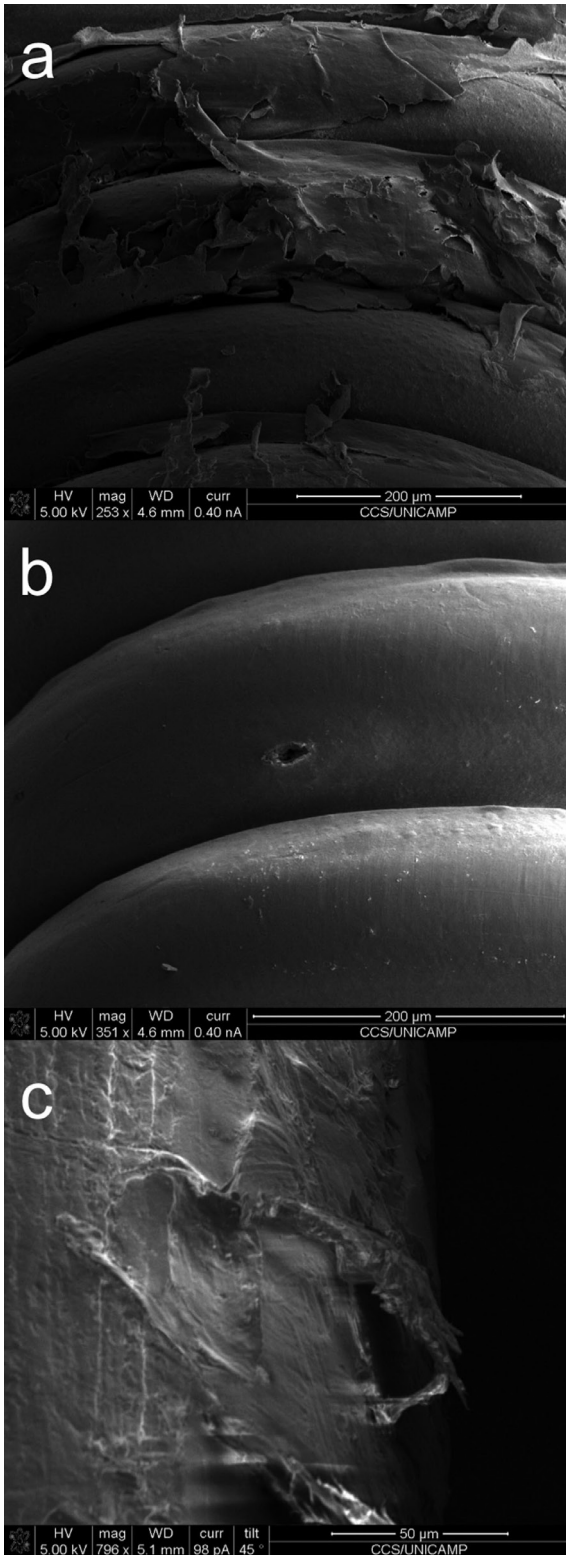


Fig. 2 – SEM images of guide wires AU1 (A), BU1 (B) and CU1 (C), washing 1X using enzymatic detergent in ultrasonic bath. Debris and holes of considerable size are observed mainly in Figures A and C, while bubbles and a non-conformal surface are observed in Figure B.

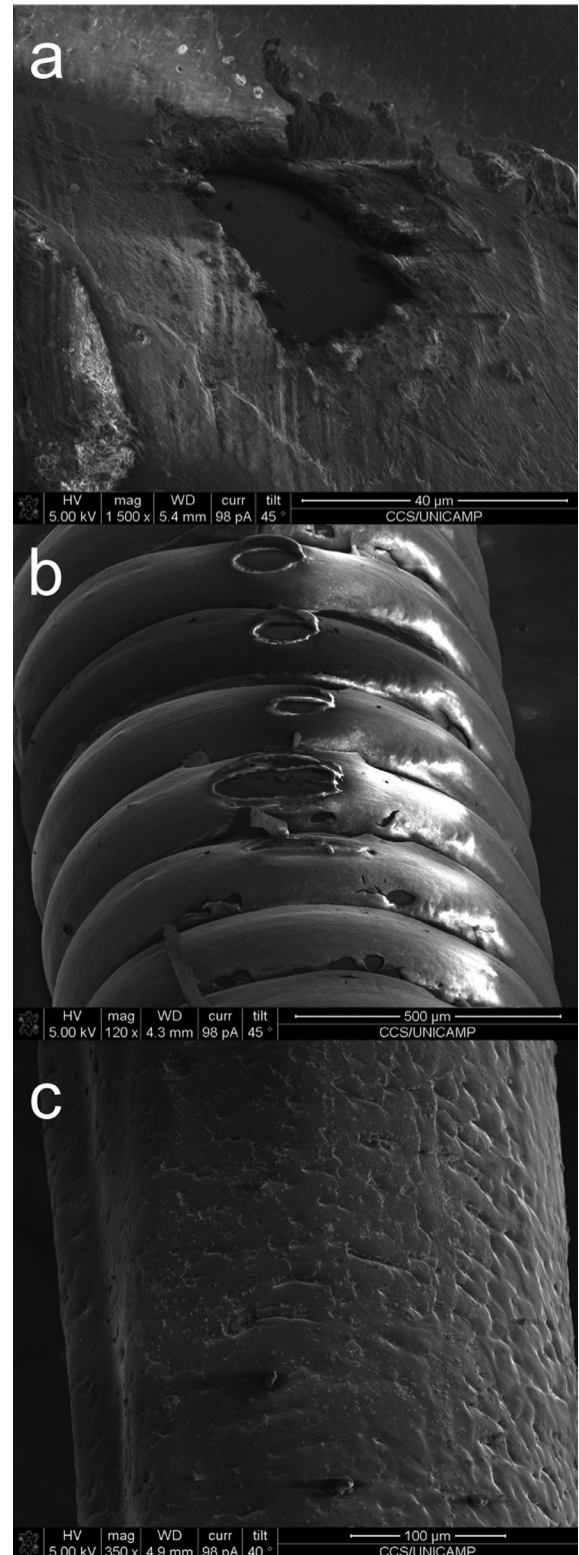


Fig. 3 – SEM images of guide wires AU2, BU2 and CU2, washing 2X using enzymatic detergent in ultrasonic bath. Persistence of debris and holes in Figures A and B and an increase in roughness is observed in Figure C.

### XPS Results

Figure 4 shows high resolution photoelectron spectra in the C1s (carbon electronic level 1s) binding energy region of three samples derived from type A guide wire (pristine - A, sterilized in ethylene oxide - AS1, and washed 1X in enzymatic ultrasonic bath - AU1). Both pristine (A) and sterilized (AS1) samples show two peaks from the C1s electronic level, i.e. (i) the C-C/C-H peak, composed of carbonaceous carbon at 285 eV; and (ii) the CF<sub>2</sub> peak, due to C bound to two F-atoms at 292 eV [9]. The higher intensity of the latter, much higher than those of the C-C/C-H peak, shows that the C atoms in the polymer coatings are predominantly in CF<sub>2</sub> groups, confirming the presence of a typical PTFE structure. The additional peak at 278 eV for the pristine sample is due to the use of non-monochromatic X-rays.

Since the spectra do not differ from those obtained with the pristine material, the XPS results suggest that the sterilization process does not induce significant changes in the chemical structure of the polymer coating, while maintaining the chemical inertness of the material. On the other hand, the washed samples displayed intense changes in the chemical structures, as verified by the complete removal of CF bonds from the material, expected at 292 eV (Figure 4), with preservation of the C-C and C-H linkages around 285 eV.

The XPS spectra of samples from guide wire type B (not shown) are similar to those of guide wire type A, indicating little or no effect of the sterilization process on the chemical structure of PTFE, but with significant changes produced by the ultrasonic bath. Again, the CF<sub>2</sub> peak strongly

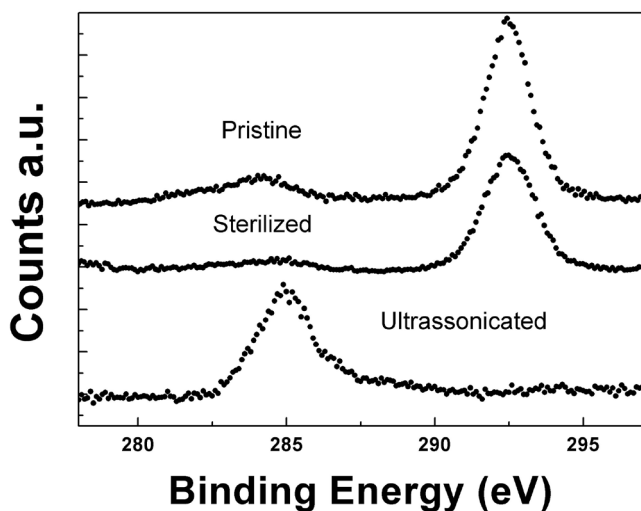


Fig. 4 – XPS spectra of samples from guide wire catheter type A.: pristine - A1, sterilized in ethylene oxide - AS1 and ultrasonically cleaned in enzymatic detergent - AU1. Suppression of CF peak related to CF bonds is observed in sample submitted to the ultrasound washing.

decreased while the intensity of the C-C/C-H feature was not significantly decreased.

With respect to the samples from guide wire type C, the XPS spectra reveals a strong predominance of the C-C and hydrocarbon bonds, as indicated by the intense and broad peak at 285 eV (Figure 5). The similarity in the two spectra indicates that sterilization did not alter the chemical structure of the polymer. A different behavior is observed in the sample subjected to ultrasonic washing: a decrease in the C-C/C-H peak and the rise of a peak at about 293 eV, suggesting the presence of C-F bonds in CF<sub>3</sub> groups. A possible explanation for such new groups would be some chemical reaction of the polymer with a component of the enzymatic detergent, or a removal of polymer surface layers with the exposure of CF<sub>3</sub> from some other polymer underneath.

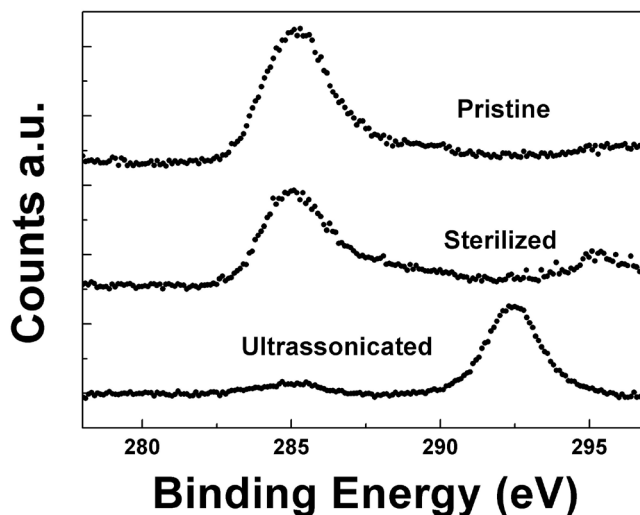


Fig. 5 – XPS spectra of samples from guide wire catheter type C: pristine - C1, sterilized in ethylene oxide - CS1 and ultrasonically cleaned with enzymatic detergent - CU1.

### DISCUSSION

A major finding in this study was that a single sterilization of the guide wire catheter with ethylene oxide was not associated with morphological or chemical changes, as indicated by SEM and XPS methodology, the same occurring after sterilizing the guide wires two times. Notwithstanding, as it can be verified by SEM images, washing the guide wires once or twice using a mix of ultrasound vibration and enzymatic detergent was associated with different degrees of structural changes. Mechanical agitation caused by ultrasound vibration results in formation of cracks in the polymer surfaces, especially on PTFE, a material known

for its low resistance to repeated cyclic loading [10]. Since the XPS method is particularly useful for the detection of chemical changes of superficial layers of polymeric coating, including in the C-F or C-C chemical groups, it is reasonable to presume the occurrence of extended chemical changes on guide wire surfaces.

To our knowledge, this is the first study that describes both morphological and chemical changes in the guide wire catheter coated with polymeric material commonly used in hemodynamic services in Brazil. Granados et al. [1], studying samples of reprocessed central venous PVC catheter sterilized with ethylene oxide verified that successive catheter recycling produced increased plasticizer loss, increased glass transition temperature, slight decrease on average molecular weight, and increased roughness and incidence of surface grooves. They concluded that the reuse could alter the original device performance, and suggested that possible adverse clinical events could include presence of toxic agents, device breakage or inflexibility, increased protein catheter retention, and increased bacterial adhesion.

Avitall et al. [2] described several changes in ablation catheters submitted to more than one process of sterilization with ethylene oxide or hydrogen peroxide treatment, including: tip electrode glue separation, loss of deflection, and electrical discontinuity between the catheter handle and electrodes. Despite the limitations of their study, performed with optical microscopy magnification of 30X, they concluded their catheters could be reprocessed a maximum of five times, without any appreciable changes in the morphological and mechanical properties.

Lucas et al. [7] studied morphological changes of angiographic catheters sterilized up to nine times with hydrogen peroxide plasma. They evaluated the molecular integrity of these catheters through Fourier Transform Infrared Spectroscopy, describing an increase in degradation products on the surface of catheters, including the presence of acids, esters, alcohols, and small amounts of products containing a carbonyl functional group. Using SEM, they found enhanced surface roughness after the fourth reprocessing cycle, and from then on, the well-delimited micro-pores were replaced by diffuse saliences, depressions and micro-protrusions.

By carefully observing the SEM images (Figure 2), it becomes apparent that blocks of PTFE 40 to 300 micrometers in length were removed from the surface of the guide wire catheters after only one washing procedure. In addition to eventual occurrence of embolization of distal coronaries or other systemic arteries with surface detached debris, accompanied or not by tissue infarction [3], changes in wettability and in the electrical charge of catheter surface are major factors in additional platelets aggregation and thrombosis formation [11]. The chronic fate of this PTFE debris in tissues is also not known, but potential

consequences include granulomatous inflammation and/or cancer development [12].

However, the significance of these findings is not easily apparent. Investigators have not been able to document additional risks, including those of transmitting infectious diseases and of adverse reactions to disinfectants when catheters are reused after careful cleansing and re-sterilization by either ethylene oxide or hydrogen peroxide [13]. A randomized, controlled double blind, single center catheter clinical trial comparing the safety and efficacy of reused or pristine catheters found no differences in clinical or angiographic success and similar rates of fever, mortality, and length of hospital stay [14].

### CONCLUSION

The treatment of the catheters with ethylene oxide was not associated with morphological or chemical changes, and it seemed appropriate to maintain guide wire coating integrity. However, the ultrasonic cleaning was not suitable for polymer-coated guide wires, and a combination of chemical reaction with mechanical vibration may have resulted in the further deterioration observed. Therefore, the reuse of these devices is not recommended.

### ACKNOWLEDGMENT

The Conselho Nacional de Desenvolvimento Científico e Tecnológico – CNPq, the Center of Semiconductor Components / Unicamp - CCS and Fundação de Ensino e Pesquisa de Uberaba – FUNEPU.

Authors' roles & responsibilities	
RVG	Study design, protocol execution, data analysis and manuscript writing
ECVS	Material processing and manuscript writing
LP	Material analysis, processing samples in ultrasonic cleaning and sterilization
CCHBO	Study design and data analysis
ALM	Study design, protocol execution, data analysis and manuscript writing
WHS	X-ray photoelectron spectroscopy and data analysis
MBM	Material processing and manuscript writing
ARV	Material processing
SAM	Material processing
DFC	Study design, protocol execution, data analysis and manuscript writing

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