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SURFACE CHARACTERIZATION OF REPROCESSED SINGLE-USE MEDICAL CATHETERS BY FRACTAL MASS DIMENSION

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Abstract

Reprocessing of single-use medical devices is an issue of concern and discussion due to infection risk and operation failure. Cleaning procedures and sterilization processes can produce structural changes and relevant topographical alteration of the biomedical device surfaces which may activate mechanisms able to cause unwanted biological response. Atomic Force Microscopy analysis (AFM) to measure Poly(vinyl chloride) (PVC) catheters surface roughness variation along successive sterilization cycles was applied. In this work, the relation between the number of reprocessing cycles and the fractal mass dimension of reprocessed catheter surface microscopic images is studied.

Keywords: Catheter Reprocessing; Fractal Mass Dimension; Surface Roughness; Image Processing.

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1. INTRODUCTION

The practice of single-use device (SUD) recycling raises public health concerns, primarily with regard to potential risks of infections and device malfunction.[1,2]

SUD's and those marketed as reusable have been recycled in-house by hospitals, third party companies and other treatment facilities for decades.

Twenty to thirty percent of American hospitals report reusing at least one type of SUD because of substantial cost saving that can be achieved by inhouse recycling.

In practice, with most diagnostic catheters, the annual saving decreases exponentially and the risk increases with the number of reuses.

Catheter-related septicemia defines a primary bloodstream infection with clinical and quantitative microbiologic evidence that implicates the catheter as a source of the infection. Awareness of risk factors is vital in developing effective strategies to reduce the frequency of this serious complication. Materials and damaged tissues are ideal sites for colonization. The number of microorganism binding sites is modified by device surface texture, manufacturing processes, trace chemicals, debris and composition of host environment.

Because of the variety of formulations available in the market and the different technological options for device manufacturing and surface modification, much research must be carried out in order to answer questions such as:

(1) How to set limits to reprocessing cycles.
(2) How to keep track of this number to ensure the item is discharged when this limit is reached.
(3) How to define the appropriate sterilization procedure for each particular polymer formulation and specific device design.

For example, it will be useful to develop a method to establish the degree of luminal or external catheter damage correlating with preferential bacterial colonization.

The absorption of proteins to the biomaterial surfaces is a selective and largely irreversible process that mediates cell adhesion.[3]

Adsorbed proteins are able to cause a cell, for which it has a receptor, to adhere to the adsorbed protein-solid interface. Biological activity of the adsorbed proteins varies on different surfaces.

"Surface roughness" can be an important variable to control because it can modify the protein retention selectivity or promote bacterial adhesion on reprocessed biomedical devices.

The fractal dimension determined from AFM images analysis can be a useful and alternative way of devices topography control taken into account that the protein adsorption mechanisms can be affected by topography variations in the range of 50 nm and the cell adhesion ones in the scale of microns.[4]

In this work, we have measured surface roughness of new and reprocessed catheters by AFM technique followed by the characterization of samples images in terms of fractal dimension. The results obtained showed the same trend where both parameters decrease with the reprocessing cycles performed.

2. MATERIALS AND METHODS

Commercial central venous PVC catheters, Stöckert-ShileyTM (Fig. 1), were selected to carry

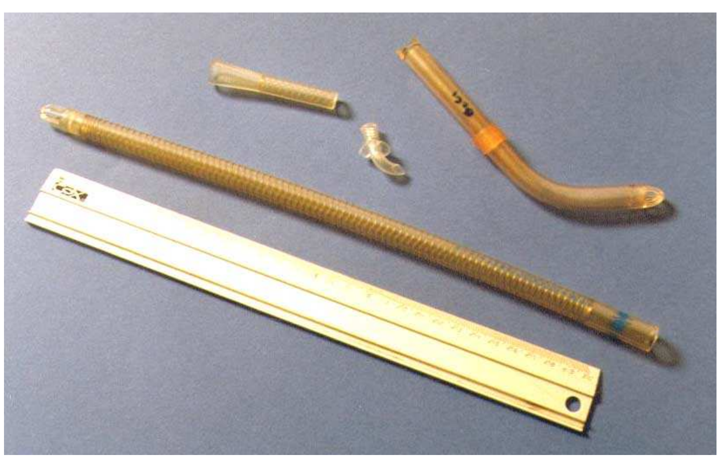


Fig. 1 Stöckert-Shiley™ central venous PVC catheters.

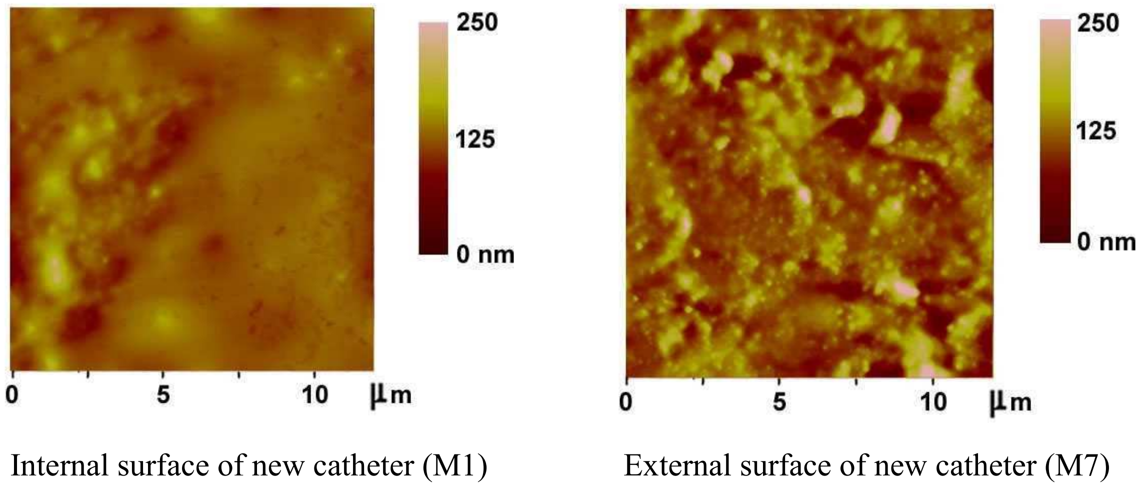


Fig. 2 AFM images.

out the study, where the samples were reprocessed 2 and 9 times and compared with new ones. The samples were ultrasonically washed in a detergent solution, rinsed and air dried before steam sterilization (120°C-1.2 bar-15 minutes). The images, (see Fig. 2), have been acquired by Atomic Force Microscopy (AFM), the surface roughness was assessed using a NanoScope III system, operated in constant force mode. The equipment was provided with a cantilever of 200 μm length, spring constant of 0.06 N/m. The images covering 12×12 μm were attained in air at room temperature.

In this work, two-image sets were used. For internal and external surfaces, see Table 1.

Table 1 **Samples.**

Surface	Code	Reprocess Cycles
Internal	M1	0 (new)
	M4	2
	M5	9
External	M7	0 (new)
	M10	2
	M11	9

3. IMAGES

A digitized image is a pattern stored as a rectangular data matrix. It is distinguished between binary images, grayscale images and color images. Binary images are matrices where pixels belonging to the pattern are stored as 1, pixels from the background are stored as 0. The storage may also be *vice versa*. On a video screen the 1-pixels are rendered as black, the 0-pixels as white or again *vice versa*. Binary images are said to have a depth of 2 values, i.e. each pixel has value 1 ("black") or 0 ("white"), or *vice versa*. Grayscale images are matrices where the matrix elements can take on values from 0 to 255. The rendering on a video screen is a presentation of the values from white (0) to black (255). Most color images are overlays of three gray scale images.[5]

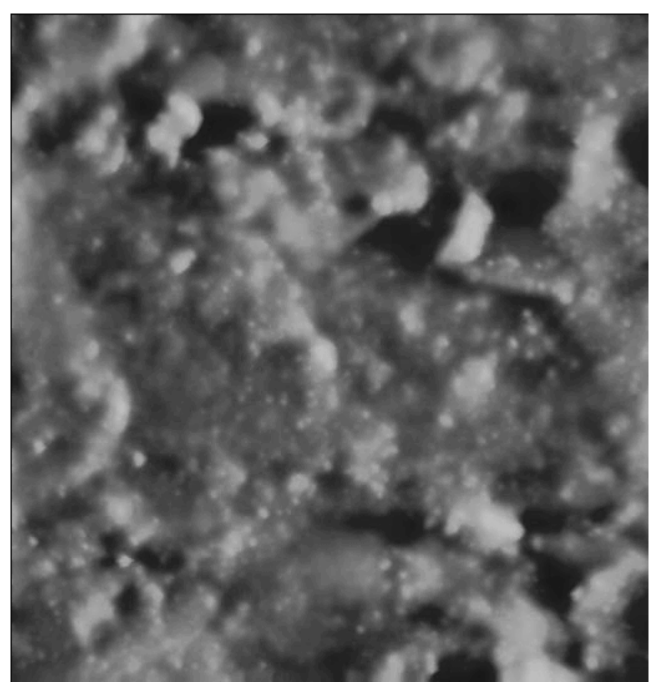


Fig. 3 Gray scale image (M7).

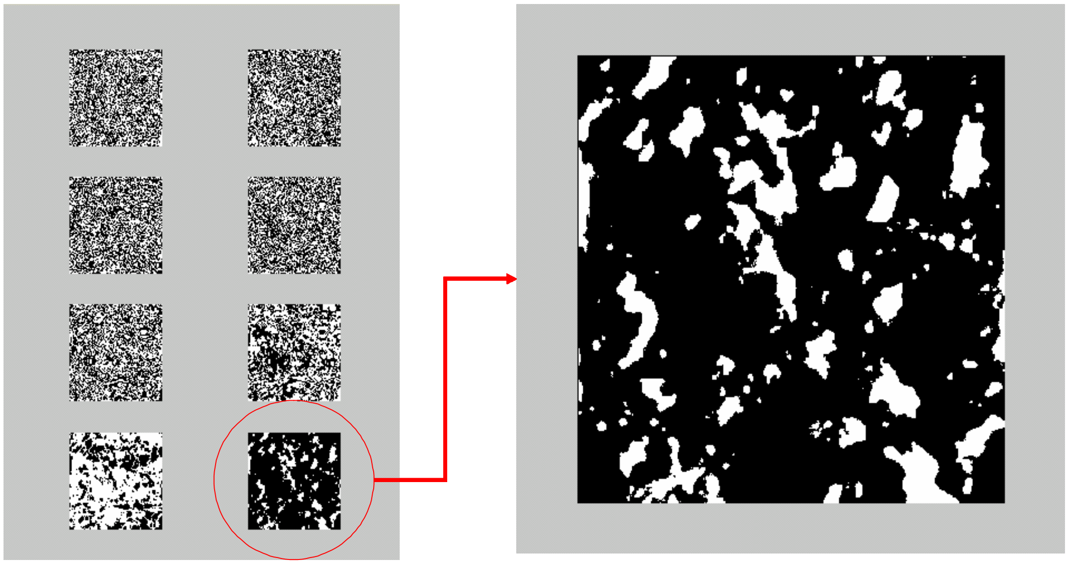


Fig. 4 Bit plane slicing, plane 7, most significant bits (M7).

In order to work, the sample images (12×12 μm size and 250 nm thickness) were converted from TIF (color) to BMP format (gray scale, see Fig. 3), 512×512 pixels size. For the gray scale object, an edge-detecting algorithm is usually applied to produce a binary image. Those images were converted by bit-plane slicing,[6] in binary images, with values 0 and 1 (see Fig. 4).

4. FRACTAL ANALYSIS

Though fractal geometry has been introduced a long time ago in image analysis, it is not yet used extensively.[7] Some authors have used the fractal dimension to perform texture classification and image segmentation, others have used correlation or lacunarity.

It was shown[8,9] that the image of a fractal surface is also a fractal. Fractal dimension remains the primary characteristic calculated from image surfaces. It is invariant to change in scale and can characterize the roughness of the surface. Fractal theory is a good choice for modeling of 3-D natural surfaces, capable of describing such surfaces qualitatively.

The mass method applied in images, involves counting of pixels contained in a sampling region (e.g. disc diameter) as a function of the sizes of the sampling regions. One centers boxes or circles (the result is the same irrespective of the shape used) of different sizes at many randomly located points on the image and counts the number of pixels contained within each box or circle. The log of the number of pixels within each box or circle is plotted against the log of the measuring element (box length, diameter). A fractal model gives a line with a positive slope. The power relationship plotted is $N_p(L) = AL^D$ where $N_p(L)$ is the number of pixels (mass) in a box of size L, A is a prefactor, and D_m is the slope of the plot of $\log[N_p]$ versus $\log(L)$ is the *fractal mass dimension.*[10]

The usual problem that appears with the application of this method to images is that the randomly chosen centers may fall on inactive or "off"

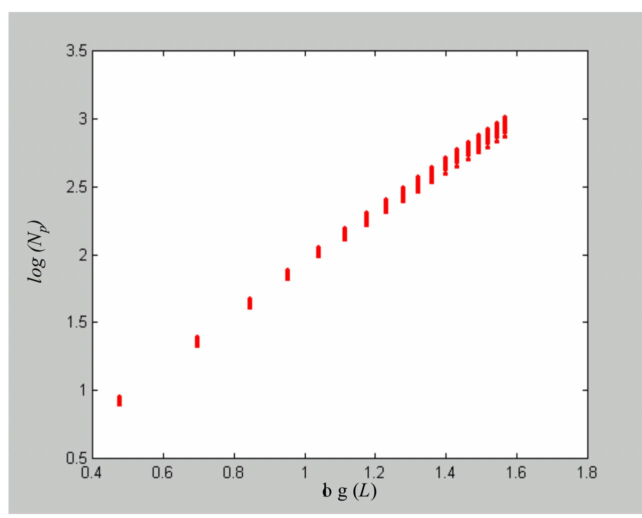
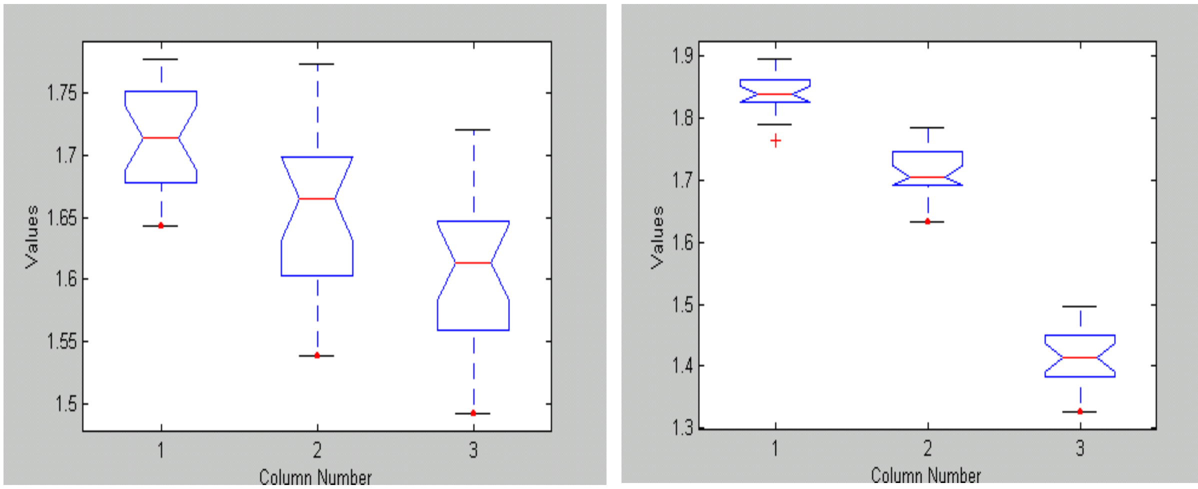


Fig. 5 Run for the internal surface image (M1).



ANOVA of the runs for external surface images — ANOVA of the runs for internal surface images

Fig. 6 ANOVA test.

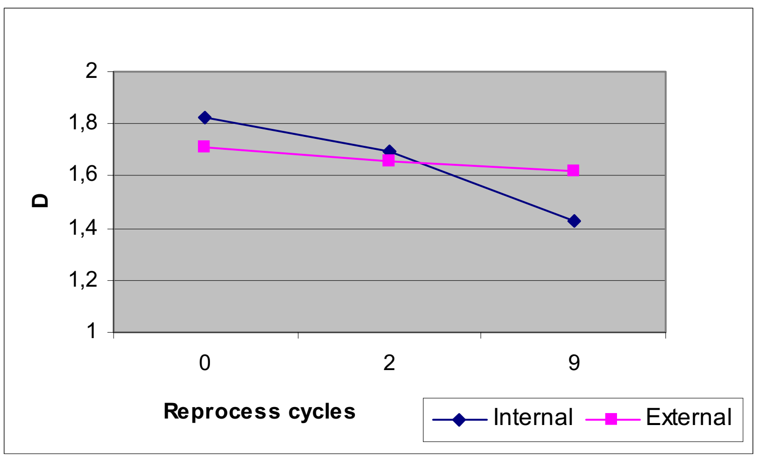


Fig. 7 Fractal mass dimension for internal and external surfaces images.

Table 2 **Results.**

Surface	Code	# Rep.	Ra [nm]	D_m	D	σ	ANOVA
Internal	M1	0	10	[1.7707, 1.8776]	1.8254	0.0337	$p < 0.0001$
	M4	2	9	[1.5921, 1.7797]	1.6930	0.0516	
	M5	9	5	[1.3115, 1.5262]	1.4285	0.0603	
External	M7	0	19	[1.6434, 1.7775]	1.7108	0.0446	$p < 0.0001$
	M10	2	10	[1.5493, 1.7389]	1.6544	0.0593	
	M11	9	14	[1.4703, 1.7350]	1.6205	0.0680	

pixels, which produces an increase in the dispersion of D_m obtained. In our application, 19 center points are chosen with a uniform random distribution, but only over the set of "on" pixels in order to minimize the dispersion of D_m. Concentric boxes of 18 different sizes are drawn around the centers with side lengths ranging from 3 to 37 pixels (only odds). The corresponding mass dimension D_m is the slope of the linear regression of the mean number of "on" pixels for each box size and center. This process is repeated 20 times getting a set of D_m values.

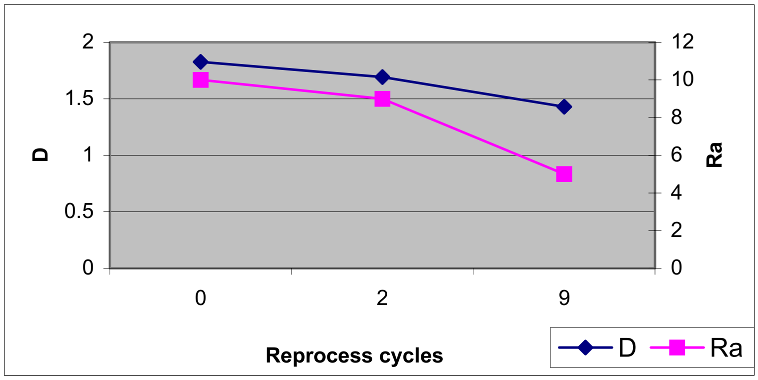


Fig. 8 Fractal mass dimension and roughness coefficients.

The reported *fractal mass dimension* D is the average over the set and the error is the dispersion of the D_m values. We call the 20 repetitions a *run*.

In order to validate the algorithm, the fractal mass dimension of a part of a Sierpinski triangle was calculated. The range of $1.552 \leq D_m \leq 1.615$ is found. The average D of 1.5753 ± 0.017 is close to the expected value of $D_{\text{analytic}} = \log 3/\log 2$ which is approximately 1.5849.

$\text{Log}[N_p]$ versus $\log(L)$ for a whole run corresponding to the external surface is shown in Fig. 5.

The main features of the D_m distributions may be seen in Fig. 6 where the ANOVA test for the runs correspond to the external and internal surfaces. Fractal mass dimension for both cases versus the number of reprocesses can be observed in Fig. 7.

In Table 2, the main results are shown:

(1) Surface roughness coefficient R_a (arithmetic mean), obtained with the AFM equipment.[11]
(2) D_m interval, range of D_m values for each run.
(3) Fractal mass dimension D, which represents the average value of all D_m ones calculated for each image.
(4) σ indicate the standard deviation of the D_m value set.
(5) Probability coefficient of the ANOVA test, p.

The Fractal mass dimension and roughness parameters value of internal surfaces versus the number of reprocessing cycles performed are shown in Fig. 8.

5. DISCUSSION

The results included in Table 2 show the decreasing trend of the fractal dimension and roughness coefficients of reprocessed devices compared with the new ones. The surface smoothing can be attributed to the successive cycles of thermal expansion and relaxation of the sterilized catheters structure.

The level of temperature reached in the steam sterilization process ($T = 121°\text{C}$) is well above the glass transition temperature ($Tg = 16°\text{C}$) of the PVC formulation constituent of the catheter body. The Tg value of PVC material previously mentioned was measured by Differential Scanning Calorimetry. Also, this technique permitted to discharge the possibility of residual reactions of PVC in the range of reprocessing temperatures.

The reprocessing technique applied does not modify the catheter bulk structure. The evaluation of material soluble content present in all samples under study, determined by Supercritical Fluid Extraction with cyclohexane as a solvent, showed a constant value indicating the formulation stability. The soluble component extracted, PVC plasticizer, was also identified by Gas Chromatography.

The average molecular weight of the PVC catheter wall, determined by Gel Permeation Chromatography, remained constant after the senes of cleaning and sterilization procedures applied.[12]

The difference in roughness measured for original and reprocessed internal and external surfaces is the result of the extrusion technique applied to produce this type of devices.

The fractal dimension is an alternative parameter capable of detecting the surface smoothing above mentioned. The D values calculated also allowed us to distinguish between internal and external surface topography.

6. CONCLUSIONS

In both cases (internal and external surface), the fractal dimension decreases as the number of reprocessing increases. This behavior agrees with the fact that steam sterilization reprocessing lowers the surface roughness.

The fractal mass dimension of AFM catheter surface images is an alternative way to express the level of accumulative damage produced by the successive reprocessing cycles performed.

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