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Technical note

A comparison of surface roughness analysis methods applied to urinary catheters

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ABSTRACT

The resolution of conventional tactile surface roughness measurement is limited by the stylus tip radius since the stylus can only make a good contact in a valley wider than tip diameter. A 3D scanning electron microscopy (SEM) technique, namely SEM stereo-imaging, was used to reconstruct the surface features of 12 different catheters to validate tactile measurement results. It is demonstrated that if the surface roughness and the stylus tip differ by one order of magnitude, the results of the tactile measurement may not be reliable.

1. Introduction

Like many medical devices, catheters are made of relatively soft materials, e.g., silicone elastomers, latex and poly(vinyl chloride); latex catheters may be coated with a hydrogel, Teflon or silicone [1]. The Foley catheter is a tube that passes through the urethra to drain urine from the bladder; the proximal end has a domed tip, to aid insertion; below the tip, an eye passes through the wall to allow urine to drain through the tube [2].

There are many reasons why the surface roughness of these catheters, and similar medical devices, may be important. For example, encrusting deposits tend to form on the catheter surface, initially on the outer surface of the proximal end (that is in the bladder), especially around the eye [3]. Imperfections in the catheter surface may then form nucleation sites for crystallization of the minerals that form the deposits [4]. Also, the inner wall of the bladder may sometimes be sucked into the eye of the catheter [5,6]; any sharp peaks may then lead to irritation or damage to the bladder.

This paper concerns measurement of the surface roughness of urinary catheters at two different scales: by scanning electron microscopy (SEM) stereo-imaging (examining a region of interest of length 100–800 μm) and by conventional tactile methods (scanning lengths of about 5 mm). The former method provides information of the surface features to validate the tactile measurement technique. Fig. 1 shows a catheter and its eyes with their dimensions.

2. Tactile measurement

In a conventional tactile measurement, a stylus is placed against the surface to be measured and its lateral and vertical movements are recorded while it scans the surface. The stylus has a typical tip radius of a few micrometers and it scans a recommended length of 5 mm. The benefit of this method is that it scans a macroscopic length within a few minutes. The scan length is important because the catheter and the bladder have a contact area of the order of square centimeters.

The resolution of the tactile measurement is limited by the tip diameter of the stylus, as it can only make effective contact, required for a reliable measurement, in a valley wider than its diameter. It is believed that if the average surface roughness (R_a) [7] is less than stylus tip radius, the surface features should be verified with a higher resolution device, e.g., Atomic Force Microscopy (AFM) or by using a smaller stylus tip for the tactile technique [8]. The disadvantage of using AFM is that the measurement area is very small, typically around $70 \times 70\,\mu\text{m}^2$, and the corresponding time for each scan is about 1–2 h. Also AFM measurements could be difficult to apply on the curved surface of catheters since AFM samples are usually flat. Using smaller (less than a micrometer) tip may also cause damage to the surface especially when soft materials are investigated [9].

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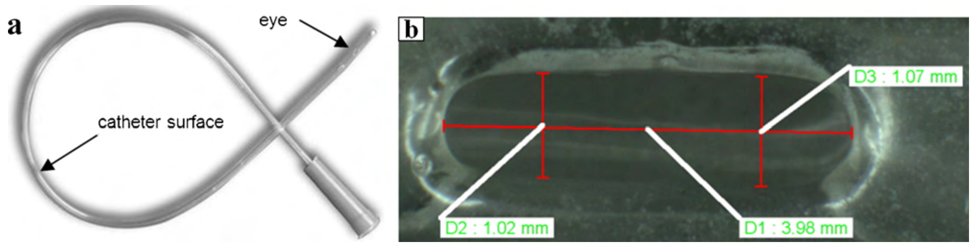

Fig. 1. (a) A 40 cm urinary catheter showing the eye and (b) an optical micrograph of the eye. The length of the eye (D1) is less than 4 mm.

3. SEM stereo-imaging

Here SEM stereo-imaging is used to validate tactile measurements. This method is based on computing 3D coordinates from the 2D coordinates of corresponding points from two separate images, one tilted with respect to the other (by 5–10°). Recently, it has been successfully employed for surface characterization of surfaces [10–12]. Fig. 2 shows the effect of tilt angle (α) on the coordinates of point P_1, projected on to the XY plane; P_2 is the corresponding point in the tilted image. In this figure, X lies in the plane of the untilted image, Y is perpendicular to X and Z lies in the direction of the electron beam.

The Z-coordinate of P_1 can be calculated from [10,11]:

$$Z = \frac{X_1 - X_2}{\sin\alpha} = \frac{X_1(1-\cos\alpha)}{\sin\alpha} \qquad (1)$$

This process can be carried out for other points, on both images, to find the shape of the surface.

In order to get reliable results from this method, the image noise should be reduced and, to obtain the maximum volume of 3D reconstruction, three further factors should be considered [13]. Firstly, the reconstructed feature should be visible and show sharp edges. Secondly, the images should be eucentrically tilted about a single axis; this means that a particular feature should be seen close to the center of both stereo-pair images. Moreover, the length of any diagonal line connecting two opposite corners of the images should not be more than 70 times larger than the height of the feature.

4. Experiments and results

Three series of experiments were performed as described below.

(i) Surface roughness measurement were made different catheters were carried out using the tactile technique with a stylus radius of 2 μm over a 5 mm sample length with a recommended cut-off length of 800 μm through a Taylor–Hobson machine (Talysurf 120 L, Leicester, UK: Taylor Hobson Ltd.). Two different stylus forces (0.5 and 1 mN) were applied to ensure that the pressure exerted by the stylus tip was not flattening surface features in the soft catheter material. Results showed that R_a changed only 5% when the applied force was doubled. Hence the effect of applied force on the surface is negligible. Table 1a shows the values obtained for R_a.

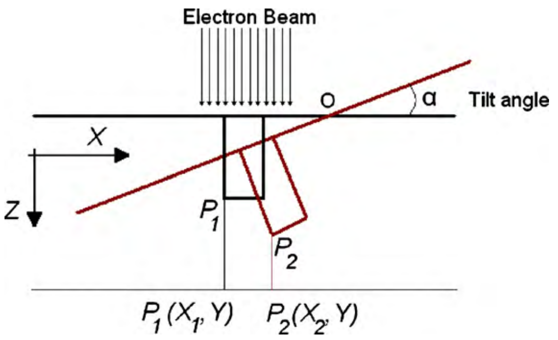

Fig. 2. Stereo images of an object before (black) and after (red) tilting. Tilting about O transforms P_1 to P_2. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.).

(ii) For those catheters with an R_a less than 1 μm (nos. 1, 2, 4, 5, 7, 8, 9, 12 in Table 1) three samples of each catheter surface were examined by SEM stereo-imaging and the surface features investigated for validation (Fig. 4a and b).

To satisfy the conditions stated in Section 3, the samples were coated with a thin layer of gold (~5 nm thick) to make the surface of the catheter conductive in order to facilitate electron imaging and to enhance the image sharpness. The centre point of the image was marked on the SEM screen, and the sample was then tilted until the marked point was positioned on the edge of the image. The position of the specimen was then adjusted so that the marked point was at the centre point of the image again. The process was repeated until the specimen was tilted to the desired angle of 8° to the horizontal (eucentric tilting). Finally, a magnification was chosen such that the length of any diagonal line connecting two opposite corners of the image would be 70 times larger than the height of the feature to be analyzed.

Fig. 3 shows a pair of SEM stereo images of the catheter surfaces taken with an SEM (JEOL-7000, Tokyo, Japan: JEOL Ltd.) at an operating voltage of 15 kV. Fig. 4a shows the reconstructed sur-

Table 1
Average roughness of catheters using both methods. (a) Catheter surface R_a values from tactile measurements; (b) eye surface R_a values from SEM stereo-imaging.

No.	R_a (μm)
a	
Cath. 1	0.29
Cath. 2	0.87
Cath. 3	5.09
Cath. 4	0.11
Cath. 5	0.21
Cath. 6	1.03
Cath. 7	0.07
Cath. 8	0.16
Cath. 9	0.08
Cath.10	1.12
Cath.11	1.34
Cath.12	0.16
b	
Cath. 1	0.37
Cath. 2	0.33
Cath. 3	0.28
Cath. 4	0.45
Cath. 5	0.53
Cath. 6	0.29
Cath. 7	0.34
Cath. 8	0.37
Cath. 9	0.48
Cath.10	0.29
Cath.11	0.41
Cath.12	0.43