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Relationship between biomedical catheter surface properties and lubricity as determined using textural analysis and multiple regression analysis

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Abstract

In this study, the surface properties of and work required to remove 12 commercially available and developmental catheters from a model biological medium (agar), a measure of catheter lubricity, were characterised and the relationships between these properties were examined using multiple regression and correlation analysis. The work required for removal of catheter sections (7 cm) from a model biological medium (1% w/w agar) were examined using tensile analysis. The water wettability of the catheters were characterised using dynamic contact angle analysis, whereas surface roughness was determined using atomic force microscopy. Significant differences in the ease of removal were observed between the various catheters, with the silicone-based materials generally exhibiting the greatest ease of removal. Similarly, the catheters exhibited a range of advancing and receding contact angles that were dependent on the chemical nature of each catheter. Finally, whilst the microrugosities of the various catheters differed, no specific relationship to the chemical nature of the biomaterial was apparent. Using multiple regression analysis, the relationship between ease of removal, receding contact angle and surface roughness was defined as: Work done (N mm) = 17.18 + 0.055 Rugosity (nm) − 0.52 Receding contact angle (°) ($r = 0.49$). Interestingly, whilst the relationship between ease of removal and surface roughness was significant ($r = 0.48$, $p = 0.0005$), in which catheter lubricity increased as the surface roughness decreased, this was not the case with the relationship between ease of removal and receding contact angle ($r = -0.18$, $p > 0.05$). This study has therefore uniquely defined the contributions of each of these surface properties to catheter lubricity. Accordingly, in the design of urethral catheters, it is recommended that due consideration should be directed towards biomaterial surface roughness to ensure maximal ease of catheter removal. Furthermore, using the method described in this study, differences in the lubricity of the various catheters were observed that may be apparent in their clinical use.

Keywords: Lubricity; Catheters; Dynamic contact angle analysis; Microrugosity; Textural analysis; Agar; Multiple regression

1. Introduction

An important property of a medical device, e.g. urethral catheters, ureteral stents, peripherally inserted central catheters, is the ease with which it can be inserted and then removed after it has performed its required function. Friction between a catheter and mucosa can damage the surrounding tissues and, therefore, care should be taken to minimise these effects [1–3]. Accordingly, an important property in the design of catheters is the slipperiness or lubricity of materials [4–6]. In the development of catheters, it is commonplace to examine their lubricity using conventional frictional tests, e.g. ASTM D 1897-90 [4]; however, the relevance of this test to the in vivo situation is unclear. Therefore, it would be advantageous to have an in vitro test that bears greater relevance to the in vivo situation and would allow the suitability of novel medical devices to be rapidly evaluated. In a study by Marmieri et al. [5], a weight was employed to pull the sample catheter materials from a stationary position in a model biological medium selected to simulate the humid, moist environment that materials encounter in vivo (agar). The time taken to remove the samples was then related to the slipperiness (lubricity) of the materials; slippery

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materials were removed quickly, whereas a longer period of time was taken to remove more frictional materials. More recently, we have described a method to examine and compare the lubricity of urethral catheters that employs a texture analyser to characterise the force required to insert catheters into and remove catheters from model substrates [1]. A modification of this method is described herein in which the texture analyser is employed in the adhesion test mode to pull catheters from an agar substrate, which allows the calculation of the work required to remove the material. Furthermore, calculation of the work required to remove the catheters from the model substrate allows for a more accurate discrimination between the lubricity of materials and, in addition, provides a more comprehensive description of the process of catheter withdrawal.

It has been suggested that the surface properties of medical devices influence their lubricity. For example, the contribution of surface roughness of hydrogel materials to the slipperiness and, hence, the ease of insertion and removal from the urinary tract has been suggested by Cox [7]. Furthermore, it has been suggested that the surface energetics (hydrophilicity/hydrophobicity) of biomaterials affect their subsequent lubricity [8]. However, there has been a paucity of studies that have statistically examined the relationship between surface rugosity, surface energetics and lubricity. One of the reasons for this deficiency relates to the unavailability of a rapid, reliable method for the in vitro evaluation of biomaterial lubricity. Therefore, a second aim of this study was to characterise the surface properties and lubricity (determined as the work required to remove the catheters from an agar substrate) of 12 commercially available and developmental catheters, and, using multiple regression analysis, to examine the relationships between these parameters. This approach has not been previously performed. The information generated within this study will therefore offer a direct comparison of the lubricity of catheter biomaterials and, in addition, will provide information concerning the contribution of surface hydrophobicity/hydrophilicity and surface roughness to the lubricity, which, in so doing will assist the development of new catheters.

2. Materials and methods

2.1. Chemicals

The biomaterials tested were all either commercially available or experimental catheters that were polyurethane-based, silicone-based or a copolymer of polyurethane and polyethylene oxide (Table 1). The commercially available catheters were purchased from Belfast City Hospital, whereas the developmental catheters were supplied by Menlo Care Ltd (CA, USA). The diameters of all catheters were identical (12 Ch).

Table 1
Urethral catheters examined in this study

Urethral catheter[a]	Material of construction
Per-Q-Cath	Silicone
V-Cath	Silicone
Silicone containing barium sulphate[b]	Silicone
Silicone containing bismuth trioxide[b]	Silicone
Silicone containing bismuth subcarbonate (low concentration)[b]	Silicone
Silicone containing bismuth subcarbonate (high concentration)[b]	Silicone
Picc Shield	Polyurethane
L-Cath	Polyurethane
Polyurethane containing barium sulphate[b]	Polyurethane
Polyurethane containing bismuth subcarbonate[b]	Polyurethane
Centermark	PU/PEO copolymer
Landmark	PU/PEO copolymer

[a] All catheters were of identical diameter (12 Ch).
[b] Experimental catheters.

Bacteriological agar was purchased from Oxoid, Basingstoke, Hampshire, England.

2.2. Evaluation of the surface lubricity of biomaterials

Prior to the commencement of the test, a dispersion of agar (1% w/w) was prepared by adding the appropriate mass of agar to the required volume of water and mixing with the aid of a mechanical stirrer. This dispersion was then heated in a water bath at 60°C until the solution was optically clear and then stored 4°C for 2 days until required for testing. Sample sections (7 cm in length) of each catheter were cut, care being taken not to handle the sections for testing, and attached to the upper grips of the texture analyser. The samples were then vertically lowered at a defined rate (5 mm s^{-1}) into agar, contained in McCartney bottles, to a depth of 3 cm and maintained in this position for 30 min to equilibrate at room temperature. The crosshead of the texture analyser was then elevated vertically at a constant speed of 5 mm s^{-1} and, from the resultant force–distance plot, the work required to remove the sample form the agar substrate was determined. In all cases, six replicate measurements were performed.

2.3. Examination of the dynamic contact angles of the catheters

The dynamic (advancing and receding) contact angles of all catheters were determined by the Wilhelmy plate technique using a CAHN Dynamic Contact Angle Analyser, DCA 312. Initially, the end sections of the