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A catheter friction tester using balance sensor: Combined evaluation of the effects of mechanical properties of tubing materials and surface coatings

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ARTICLE INFO

Acronyms:
SUMSilicone-based Urethra Model
CFT-BSCatheter Friction Tester based on Balance Sensor
PU-UnPolyurethane-Uncoated
PVC-UnPoly(vinyl chloride)-Uncoated
PU-CPolyurethane-Coated
PVC-CPoly(vinyl chloride)-Coated

Keywords:
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Friction
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ABSTRACT

In this study, we introduce a new experimental approach to characterize the forces emerging from simulated catherization. This setup allows for a linear translation of urinary catheters in vertical direction as controlled by an actuator. By employing silicone-based elastomer with a duct of comparable diameter with catheters as urethra model, sliding contacts during the translation of catheters along the duct is generated. A most unique design and operation feature of this setup is that a digital balance was employed as the sensor to detect emerging forces from simulated catherization. Moreover, the possibility to give a variation in environment (ambient air vs. water), clearance, elasticity, and curvature of silicone-based urethra model allows for the detection of forces arising from diverse simulated catherization conditions. Two types of commercially available catheters varying in tubing materials and surface coatings were tested together with their respective uncoated catheter tubing. The first set of testing on the catheter samples showed that this setup can probe the combined effect from flexural strain of bulk tubing materials and slipperiness of surface coatings, both of which are expected to affect the comfort and smooth gliding in clinical catherization. We argue that this new experimental setup can provide unique and valuable information in preclinical friction testing of urinary catheters.

1. Introduction

Since urinary tubing is generally made of polymeric materials, they are hardly wet by water, causing high friction, discomfort, and tissue trauma during clinical applications. For this reason, most of catheters are covered with hydrophilic and slippery coatings on the surface in order to assist easy gliding along urethra (Ho et al., 2003; Ikeuchi et al., 1993; Tunney and Gorman, 2002; Uyama et al., 1990, 1991), although fluidic lubricants such as silicone gels or hydrogels are also widely used (Bardsley, 2003; Cindolo et al., 2004; Gerard et al., 2003; Wilson, 2013). As with other biomedical devices or implants, preclinical testing is essential for urinary catheters too. Since frictional properties are of critical importance for urinary catheters, a number of conventional or specially designed equipment have been employed to characterize the slipperiness of catheters in laboratory (Jones et al., 2001; Røn and Lee, 2016; Stensballe et al., 2005; Tunney and Gorman, 2002). Briefly, there are two major parameters to be considered in the design or selection of friction testing equipment of catheters. The first one is the counter-surface that slides against catheters. In clinical applications, the counter-surface is biological tissues, and more specifically urethra tissue for urinary catheters. Thus, it is most reasonable to provide soft and compliant contacts against catheters, in order to emulate the tribological contacts in clinical applications. A majority of previous studies, however, employed hard materials, such as thermoplastics (Kazmierska et al., 2008) or ceramics (Graivier et al., 1993; Uyama et al., 1990; Uyama et al., 1991), presumably because of convenience and/or availability problem. In this context, we proposed an elastomer-based urethra model with a duct can be a viable approach in a recent study (Røn and Lee, 2016), although further improvement is needed. While animal or human subjects are also employed for pre-clinical testing of frictional properties of catheter (Coveney and Gröver, 2001; Khoury et al., 1991; Nickel et al., 1987; Stensballe et al., 2005), it can be hardly a practical solution due to accessibility issue. The second parameter is the equipment/sensor to probe the emerging forces during simulated catherization. Many studies employ texture analyzer setup and probe the forces emerging from sliding contacts between catheter samples and modeled urethra, and they are interpreted as friction forces (Jones et al., 2001; Røn and Lee, 2016; Stensballe et al., 2005; Tunney and Gorman, 2002). Pin-on-disk type tribometer is also a popular approach to probe the resistance of sliding between catheters and modeled friction forces (Graivier et al., 1993; Kazmierska et al., 2008), which is also interpreted as friction forces between them. Both

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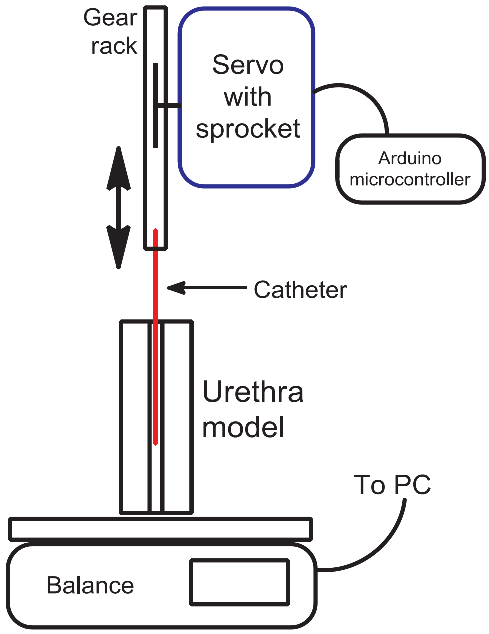

Scheme 1. Schematic illustration of testing setup for measurement of friction forces.

approaches are based on sensing the forces using strain gauge.

In this study, we introduce a new home-built instrumental approach to assess the forces emerging from simulated catherization process in laboratory. The operation principles are similar to those of texture analyzer in the sense that linear movement of catheters in vertical direction is enabled and the resistance from the sliding contacts against model urethra are to be probed. Previously developed silicone-based urethra models with a duct along the cylinder (Røn and Lee, 2016) have been employed in this study too. But, a broader range of parameters, such as environment (ambient air vs water), elasticity of urethra model, clearance and curvature of duct, was varied to investigate the force responses in different experimental conditions. A salient feature of this setup is that a laboratory digital balance is employed as a sensor to probe forces occurring from the sliding contacts between catheter and urethra models (Scheme 1).

A photograph of the entire setup is shown in Fig. S1 in Supplementary Material. As will be addressed in detail below, this simple, yet unique force sensor allows for the assessment of both mechanical properties of tubing material as well as slippery coatings on the surface.

2. Materials and methods

2.1. Buffers, chemicals, polymers and catheters

Agar and polyethylene oxide-*block*-polypropylene oxide-*block*-polyethylene oxide (PEO-*b*-PPO-*b*-PEO) triblock copolymer (the type known as “F127” (Wanka et al., 1994)) were purchased from Sigma Aldrich (Brøndby, Denmark) and used without further purification. F127 solution (10%, weight/vol) was prepared by dispersing in MilliQ water. PBS tabs purchased from VWR Prolab were dissolved in MilliQ water (resistivity ≥ 18 MΩ cm) to prepare phosphate buffered saline (PBS) at pH 7.4. Sylgard 184 and Sylgard 527 polydimethylsiloxane (PDMS) kits were purchased from Dow Corning (Midland, MI). The list of catheter samples in this study is shown in Table 1.

All tested catheters were commercially available except for polyurethane (PU)-based uncoated catheters with 4.0 mm diameter that were kindly supplied by Coloplast A/S (Denmark). Uncoated PU catheters with 4.7 mm diameter were obtained from extensive rubbing and cleaning of commercially available PU-based ‘SpeediCath®’ (Coloplast A/S, Denmark) with ethanol to remove coating of hydrophilic poly(vinylpyrolidone) (PVP) layers (SpeediCath® Product Monograph, 2010; Madsen, 2010). Hereafter uncoated SpeediCath will be denoted as ‘**PU-Un**’ and regular SpeediCath will be denoted as ‘**PU-C**’. Likewise, uncoated PVC catheters from Pennine Healthcare (UK) and PVP-coated PVC catheters (brand name ‘Curicat®’ (Report on Curicat) from Curion (The Netherlands) will be denoted as ‘**PVC-Un**’ and ‘**PVC-C**’, respectively. The diameters of the catheters were 4.0 mm (CH/FR 12) or 4.7 mm (CH/FR 14) and the length was 18–20 cm. See Table 1 for details.

Solvents were purchased from VWR (Denmark) or Sigma Aldrich (Denmark) and used as received without further purification. Fluorosilane for hydrophobic functionalization of steel rods was trichloro(1 H,1 H,2 H,2H-perfluorooctyl)-silane (Sigma Aldrich).

2.2. Pin-on-disk tribometry

The surface friction forces of the catheters were characterized by means of pin-on-disk tribometry. To this end, catheters were circularly mounted on a rotating cup and slid against a flat-ended PDMS pin under controlled speed and external load. See Fig. 1(b) below for more details on the configuration of pin and catheter in this experiment. Flat-ended, cylindrical PDMS pins were prepared with Sylgard 184 kit according to a standard manner described below (see the Section 2.3 for details), and BRAND*plates®* 96 microwells C type (VWR) was used as mould. The dimension of flat-ended PDMS pin was 6.1 mm in diameter and 11.0 mm in height. Pin-on-disk tribometry experiments were conducted on a commercial pin-on-disk tribometer (CSM Instruments, software version 4.4 M, Switzerland). The principal setup of pin-on-disk tribometer consists of a stationary pin pressing down on rotating disk surface. The pin is connected to an arm with a strain gauge enabling measurement of the friction force laterally exerted onto the pin. The load was controlled by applying dead weights on the pin. Friction coefficient (μ) is calculated according to the formula $\mu = F_{friction}/W$. The external load (W) was 1 N in all pin-on-disk experiments, if not stated otherwise. The friction signals for a minimum of 10 rotations were recorded for each measurement to provide μ average and standard deviation. The cylinder on plane contact model was applied to calculate the mean contact pressure (P) against flat PDMS pin; $P = F/A = F/(2aL)$, where L is the contact length of cylindrical catheter with flat-ended pin (6 mm), and a is the half width of the line contact and equals as $a = (4{\cdot}W{\cdot}[(1\text{-}\nu^2)/E'_{PDMS} + (1\text{-}\nu^2)/E'_{cath})]{\cdot}(\pi{\cdot}L{\cdot}[1/R_{PDMS}+1/R_{cath}])^{-1})^{½}$, where R_{cath} is radius of catheter (2 mm) and R_{PDMS} is infinite for a cylinder-plane contact (Gohar and Rahnejat, 2008; Johnson, 1985). The calculated mean contact pressures in pin-on-disk tribometry under 1 N were 182 kPa and 189 kPa for PVC and PU catheters, respectively. In this calculation, the reported Young's moduli (E') of 17.8 MPa and 44.3 MPa for PVC and polyurethane, respectively, by (Cervera et al., 1989) were used, and Poisson's ratios (ν_x) were approximated to 0.5 for PDMS, PVC, and PU. The influence of surface coating and catheters’ tubing hole on the reduced Young's modulus (E^*) was ignored.

2.3. Silicone-based urethra model (SUM)

PDMS-based urethra models were prepared using commercially available two-component silicone kits, namely Sylgard 184 and Sylgard 527. The base fluid and crosslinker were mixed at 10:1 and 1:1 wt ratios for Sylgard 184 and Sylgard 527, respectively, according to a standard procedure. After mixing, dispersed air bubbles were removed by vacuum, and the fluid mixtures (Sylgard 184, Sylgard 527, or their mixtures) were cast into a 15 mL polypropylene (PP) centrifuge tube with a vertically positioned stainless steel rod. The sample was cured in an oven (70 °C) overnight. Upon completion of curing and crosslinking of PDMS, the rod was removed and it generated a duct through the center