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Determination of urethral catheter surface lubricity

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Abstract Device for in-vitro measurement of static and kinetic friction coefficient of catheter surface was developed. Tribometer was designed and constructed to work with exchangeable counter-faces (polymers, tissue) and various types of tubes, in wet conditions in order to mimic in-vivo process. Thus seven commercially available urethral catheters, made from vinyl polymers, natural latex with silicone coating, all-silicone or hydrogel coated, and one made from polyvinylchloride with polyurethane/polyvinylpyrrolidone hydrogel coating obtained in our laboratory, were tested against three various counter faces: polymethacrylate (organic glass), inner part of porcine aorta and porcine bladder mucosa. Additionally, the hydrophility/hydrophobity of tested catheters was stated via water wetting contact angle measurement. Superhydrophilic biomaterials revealed low friction on tissue and hydrophobic counter-face; slightly hydrophobic showed higher friction in both cases, while more hydrophobic manifested low friction on tissue but high on hydrophobic polymer. The smoothest friction characteristic was achieved in all cases on tissue counter-faces. The measured values of the static coefficient of friction of catheters on bladder mucosa counter-face were as follows: the highest (0.15) for vinyl and siliconised latex catheters and 3 folds lower (0.05) for all-silicone ones. Hydrogel coated catheters exhibited the lowest static and kinetic friction factors.

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1 Introduction

Biomaterials, defined as any natural or synthetic substance interfacing with living tissue at some stage of patient's therapy, evolved through centuries from parts of the plants and ancient metal tubes to complex polymeric materials [1–3]. Any potential biomaterial (bulk or coating) has to pass rigorous tests prior to use in humans. In case of urethral catheters one of the main factors involved with a biocompatibility issue is friction between given material and a tissue, catheter lubricity [4, 5], often determined using convectional frictional tests based on ASTM standards [6]. However, these tests do not simulate wet conditions in the body. It is worth to notice that in the presence of a liquid film the measured value of the friction coefficient is different from measured for the same dry surfaces, and, in case of rubber, wet friction at low velocities is typically 20–30% smaller [7, 8]. Nevertheless, the existing ASTM standards with respect to the physical and mechanical properties of catheters are very loosely defined and open to interpretation [2]. As the example can serve a lack of standard specification for Foley catheters with enhanced by chemical treatment surface lubricity [9].

Thus, tabularization and comparison of frictional properties of biomaterials is still problematic, although many attempts have been made.

When our laboratory team started to work with modification of the urethral catheters, to make their surface highly lubricious and hydrophilic, one of the first difficulties we encountered was the determination of lubricity. At the beginning tubes with variable composition of coatings were organoleptically tested in the group of students (by hands), stating if the sample is "more" slippery or "less". This approach has obvious drawbacks: necessity of testing all probes at the same time, lack of small changes

detection, subjectivity. Nevertheless, some research still base on similar questionnaire for patients [10].

Some studies have reported on in-vivo determination of the lubricity in the animal model, but also in the urethra of human volunteers [4, 5, 11, 12]. However, this approach seems not to be appropriate as a standard catheter lubricity tests.

Many researchers have developed their own methods of laboratory evaluation of friction factor. Ramesh [13] measured the apparent coefficient of friction from the slope of the force versus normal load graph. Graiver [14] run his test using a water environment, determining coefficient of friction between hydrated catheter surface and hydrogel surface. Marimieri [15], after Tunney and Gorman [16], proposed a method based on time measurement: the longer time is needed to pull the biomaterial section out of agar with defined load of weight, the greater is the friction. Some of the machines can even imitate a process of the suprapubic catheterization, like a simulator of the abdominal wall constructed by Conveney and Grover [17, 18]. Jones [19, 20] described a method that simulates insertion of a catheter into the urethra. His method employs the texture analyzer and agar or mucin-coated silicone tubing; the tests are performed in one diameter of the urethra-mimicking tube, which means a problem with testing different catheter sizes. The numerical results are presented there in force (or work done) units, hence are strongly dependent on experimental conditions. Consequently these results are difficult to compare in reliable way with results obtained in other laboratories. An interesting method of the friction coefficient evaluation was patented by Biehl [21], but its reliability bases on a choice of an appropriate tissue-like synthetic viscoelastic substance, with known material properties letting evaluate normal force from applied pressure. All these methods have disadvantages, they are hard to perform without special equipment or need long preparation before each experiment (gel casting, thermostating).

Finally, we solved the problem by designing and building our own device able to measure, with high time resolution, wet friction coefficient between polymeric tube, irrespective its size, and a small fragment of tissue or other polymer, in repetitive conditions, and collect and process data by personal computer.

2 Materials and methods

Porcine tissue (bladder and aorta), from local slaughterhouse, was participated into fragments (about 3 × 2 cm each), frozen immediately after animal's death and defrozen in distilled water 1 h before friction measurement. For every single test a new fragment was used.

Table 1 Catheters tested in this study

No.	Details
1	PVC, Nelaton, 14Ch (Galmed, Poland)
2	All-silicone (100%), Foley, 14Ch, Bardia Aquafil (Bard, UK)
3	Silicone coated latex, Foley, 16Ch, Curity (Kendall)
4	Siliconised latex, Foley, 18Ch (Unomedical)
5	Tiemann, 12Ch (Maersk Medical A/S)
6	Tiemann, 18Ch (Unomedical A/S)
7	Nelaton, 12Ch, EasiCath (Coloplast A/S)
8	Hydrogel (PUR/PVP) coated PVC (no. 1)

As a forcemeter TF100 (range 1 N, power input 10 VDC, response 1.5 mV/V; Megatron. Germany) was employed.

PVC catheters, Nelaton type, were a gift of firm Galmed (Bydgoszcz, Poland) and a part of them was subjected to hydrogel coating performed in our laboratory. The rest of tested urethral catheters was purchased from local pharmacy. The details of each catheter (signed related number) are listed in the Table 1.

Prepared hydrogel coating based on polyurethane, PUR (ESTANE 5715P), a high molecular PVP (Polyvinylpyrrolidone K90, Fluka), urea (Ph Eur, Fluka) and anhydrous glycerol p. a. (Chempur) as a plasticizer. All used organic solvents (purchased from Chempur), namely isopropyl alcohol (iPA), 2-butanone (MEK), dichloromethane and cyclohexanone were of analytical grade, and were used without preliminary purification.

2.1 Hydrogel coating preparation

PVC catheters (no. 1 in Table 1) were coated with hydrogel in two steps, through deep-coating technique described by Micklus et al. [22]. The obtained PUR/PVP interpolymer coating is super-hydrophilic, but insoluble in water, the layer is durable and becomes extremely lubricious when wetted. Additionally high osmomolarity, to prevent "sticking" effect between hydrogel and tissue [10, 23, 24], was ensured by urea or sodium chloride addition to the top layer.

2.2 Tribomertric device

A scheme of the device is shown in Fig. 1; Fig. 2 details the forces having an effect on tested catheter and the principle of friction factor measurement.

The DC engine coils a strand moving catheter (connected by the catch) in parallel plane with constant speed of 1 cm s^{-1}. At the same time the catheter is pressed down

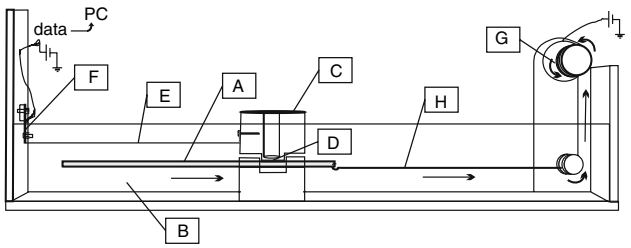

Fig. 1 Scheme of the device. A—tested catheter; B—a vessel filled with distilled water; C—polymer element pressing down the catheter, rigidly connected, via rod E, with forcemeter F; D—an exchangeable counterface; G—DC engine coiling the strand H

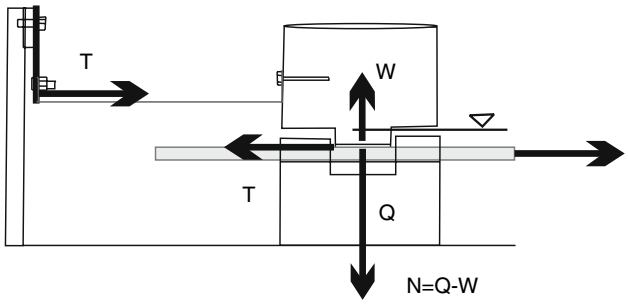

Fig. 2 Forces having an effect on friction factor measurement: $\mu = N/T$; T—friction force, N—normal force, being a difference of a force of gravity Q and a buoyancy W

with an element with known weight and the exchangeable counter surface (the normal pressure force N), fixed with a rubber-band. The contact surface remains immersed in distilled water.

Relative motion of tested catheter and a counter surface causes a displacement of the pressing element due to a friction force phenomenon (T), which can be registered by the forcemeter and aquisited in PC using A/D converter made by National Instruments. For measurement data processing original computer application was prepared. It was done in LabView 8 environment. This simple application allows the user to choose sampling rate (default 1 ms) and to observe friction force changes in real time on the graph.

All the measurements were performed at room temperature, although the device was designed to mimic in-body conditions; we assumed, according to d'Angelo [25], that the friction of the tissue is not affected by temperature in the range 19–39 °C, sliding velocity (up to 3 cm s^{-1}), prolonged sliding, normal load, and nominal contact area, consistent with boundary lubrication.

2.3 Contact wetting angle analysis

Hydrophility or hydrophobity of the tested catheters was determined with use of the sessile drop optical method. A small drop of deionized water (1 μl) was placed at the top of the horizontally fixed catheter and photographed in the normal plane (Fig. 3).

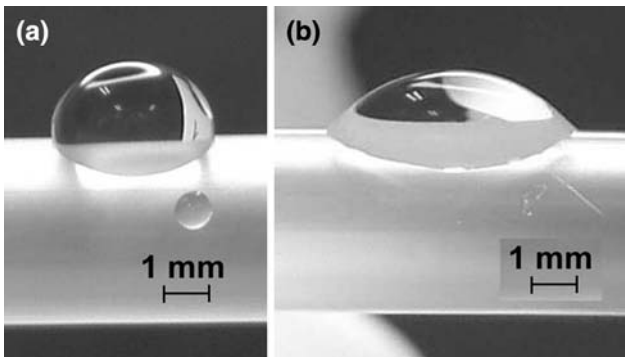

Fig. 3 Behavior of a drop of water on: (**a**) hydrophobic PVC catheter no. 1 and (**b**) hydrophilic no. 8—PCV with hydrogel PUR/PVP coating (numbers are referred to Table 1)

During digital image analysis an angle between the baseline of the drop and the tangent at the drop boundary was measured (θ).

The catheters were tested in the dry state and, consequently, measured wetting angles for hydrogel coated catheters were higher than observed in hydrated state ($\theta \sim 0°$).

3 Results and discussion

Tribometric device allows for measurement of wet friction forces between different types of elastomeric tubes (independent on their Young's modulus) and various counterfaces (polymer, tissue). A simple force balance, according to the Amonton/Coulomb friction law, let us evaluate from collected data the friction coefficient. Additionally we have reduced the noise from data signal by low pass filter (7 Hz).

Friction characteristics of catheters 1–8 on three types of surfaces: hydrophobic rigid polymer (p—light grey line), smooth and dense aortal tissue (a—grey line) and a soft bladder mucosa tissue (m—black line) are shown in the Fig. 4. Graphs introduce data collected 5 s before start of the driving engine, the moment of a start, and subsequent 5 s of running. A peak observed at the beginning of the catheter motion relates to the maximum value of friction coefficient, which is called static. When the catheter continues its movement the registered value is lower, describing the kinetic friction coefficient.

Table 2 gathers tested samples into material groups with determined hydrophility ($\theta < 90°$; Fig. 3b)/hydrophobity ($\theta \geq 90°$; Fig. 3a) showing mean values of friction coefficient from four measurements in each case.

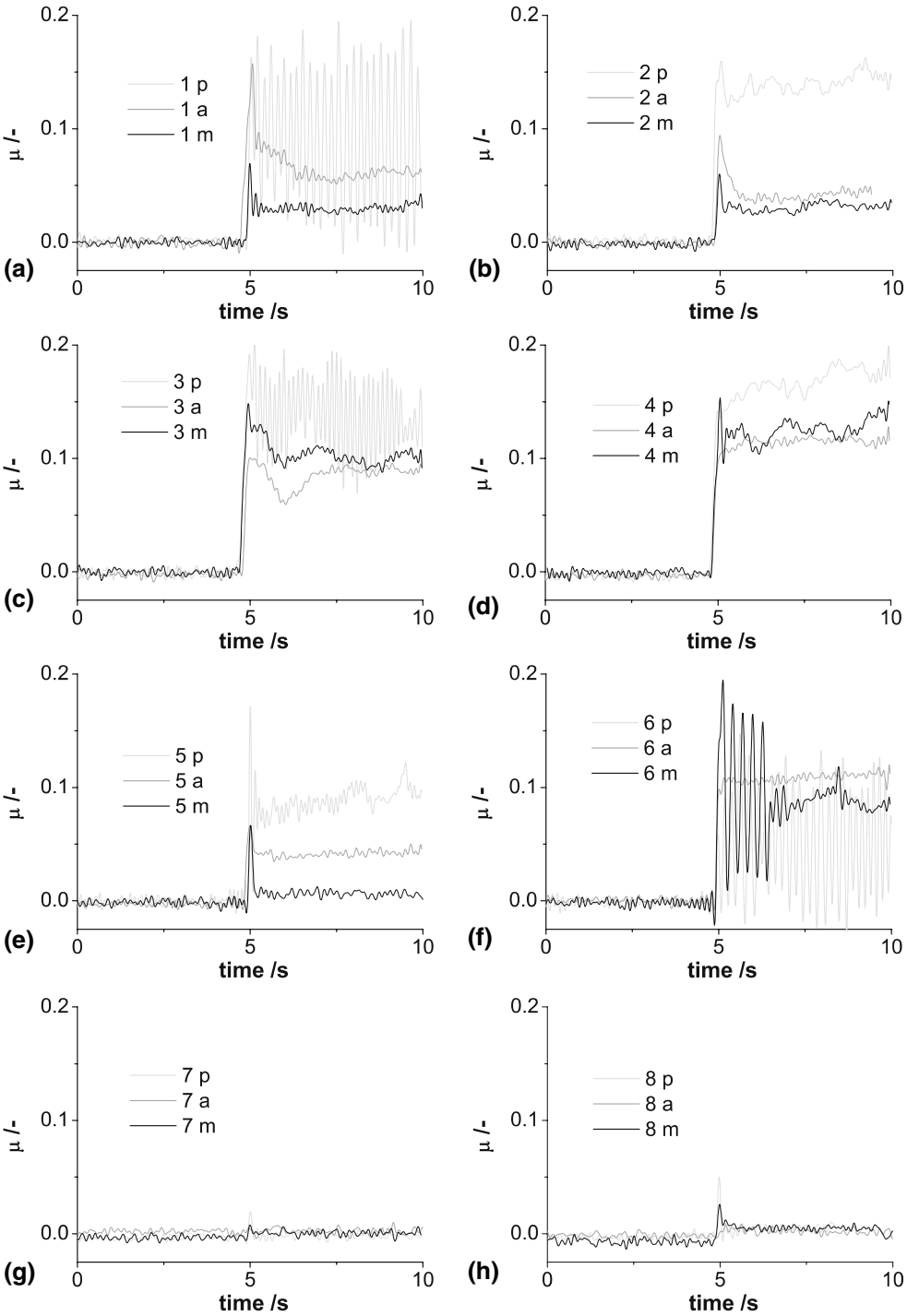

Fig. 4 Each graph (**a**–**h**) shows examples of friction characteristics of single catheter (1–8; details in Table 1) on different counterfaces (p—polyacrylate, a—aorta, m—porcine bladder mucosa); the peak at 5th second. (movement start) refers to the static coefficient of friction

3.1 The effect of the biomaterial on friction coefficient

In some cases (catheters 1, 3 and 6 in Fig. 4a, c, f) the adhesive force was too high to allow a tested sample to move smoothly, the pushing element jumped and only the value of static friction coefficient could be measured. This phenomenon can cause additional patient discomfort during catheterization.

The connection of the friction characteristic shape with lubricity and hydrophobic or hydrophilic interactions between contacted surfaces is clearly visible (Table 2, Figs. 4 and 5).

The example can be slightly hydrophobic silicone catheter 2 exhibiting the same level of the friction factor on polyacrylic surface, as siliconised 3 and 4, but much smaller friction on tissue (Fig. 4b, c and d), or

Table 2 Water-wettability (determined by a contact wetting angle, θ, between a drop of water and a surface) of urethral catheters and static (μ_s) or kinetic (μ_k) friction coefficients against polyacrylate (p), porcine aorta (a) or porcine bladder mucosa (m); mean values ± SD

Material	Catheter no.	θ	Counterface	μ_s	μ_k
Polyvinyl	1	104° ± 11°	p	0.21 ± 0.05	f
			a	0.08 ± 0.02	0.06 ± 0.03
			m	0.08 ± 0.01	0.03 ± 0.01
	5	84° ± 9°	p	0.14 ± 0.07	f
			a	0.08 ± 0.03	0.01 ± 0.01
			m	0.08 ± 0.03	0.01 ± 0.01
	6	87° ± 6°	p	0.14 ± 0.03	f
			a	0.11 ± 0.03	0.11 ± 0.02
			m	0.15 ± 0.02	f
Silicone	2	89° ± 14°	p	0.20 ± 0.08	f
			a	0.10 ± 0.02	0.05 ± 0.01
			m	0.05 ± 0.02	0.02 ± 0.01
Siliconised latex	3	56° ± 8°	p	0.19 ± 0.06	f
			a	0.13 ± 0.03	0.09 ± 0.01
			m	0.13 ± 0.02	0.11 ± 0.01
	4	79° ± 11°	p	0.14 ± 0.01	f
			a	0.11 ± 0.02	0.11 ± 0.01
			m	0.16 ± 0.01	f
Hydrogel	7	47° ± 22°	p	0.04 ± 0.01	0.01 ± 0.01
			a	0.02 ± 0.02	0.01 ± 0.01
			m	0.01 ± 0.01	0.01 ± 0.01
	8	49° ± 10°	p	0.07 ± 0.01	0.02 ± 0.01
			a	0.01 ± 0.01	0.01 ± 0.01
			m	0.03 ± 0.03	0.01 ± 0.01

f—friction force was to high to allow smooth motion of catheter

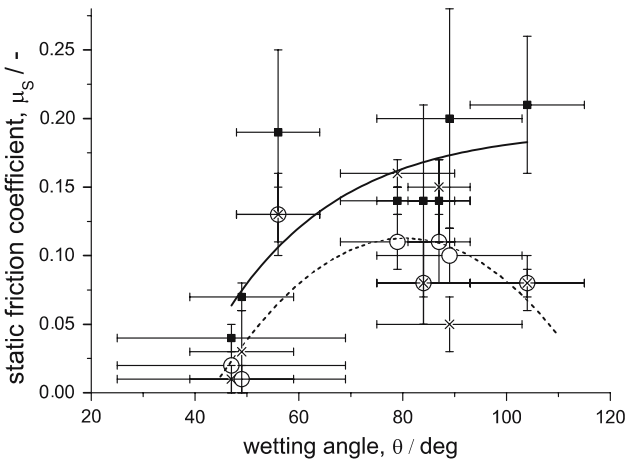

Fig. 5 Correlation between contact wetting angles of tested biomaterials and their static friction coefficients measured on hydrophobic polymer (solid line; ■—polyacrylate) or on the tissue (dashed line; ○—aorta; ×—bladder mucosa)

differences in friction characteristics in vinyl catheters group due to varying composition of hydrophobic 1 and 6 or more hydrophilic 5, despite similarities in their outer look and other mechanical properties (Fig. 4a, e and f).

To summarize, on the bladder mucosa the highest static friction coefficient had Unomedical Tiemann vinyl catheter and both siliconised latex catheters; from group of the uncoated catheters the lowest had all-silcone Bardia Aquafil. Negligible kinetic coefficient had Maersk Medical Tiemann vinyl catheter and both hydrogel coated ones (in range of measuring error). Hydrogel coated catheters exhibited the lowest static and kinetic friction factors and the lowest wetting angles.

3.2 The effect of the counter-face on friction coefficient

Satisfactory results on rigid polyacrylate counter-face were mostly the hardest to obtain (Fig. 4a–f). In these cases the friction force had the highest values. The best comparative information about urethral catheter frictional behavior brought tests with porcine bladder mucosa. The results for

aorta tissue counter-face were slightly different than for a bladder mucosa.

An interesting fact is the connection between measured wetting angle and the static friction coefficient, μ_S, on different counter-faces (Fig. 5): on hydrophobic polyacrylate μ_S increases with increasing wetting angle and thus biomaterial hydrophobity, while on tissue this function has a maximum, due to the physiological hydrophilic–lipophilic balance. One can conclude that lubricious superhydrophilic biomaterials (hydrogel coated), as well as the super-hydrophobic ones, seems to be applicable to lower the friction in contact with tissue.

3.3 The effect of the hydrogel coating on friction coefficient

Tests carried out on the hydrogel coated catheters, 7 and 8, revealed reduction of friction to the negligible value on all counter-faces (compare uncoated PVC 1 and the same PVC, but PUR/PVP hydrogel coated 8 in Fig. 4), mostly in the range of a measuring error. Here especially important is the decrease in static friction coefficient value.

4 Conclusion

The presented device allows for an in-vitro comparison of the lubricity or tribometric characteristics of the number of tubes (catheters, intubation or feeding tubes; irrespectively to their elastic properties) having a contact with patient's body (urethra, arteries, trachea etc.), in convenient, fast, repetitive and objective way. Proposed set-up mimic in-vivo conditions during catheterization due to presence of water (body fluids) and a tissue as a counter-face.

Results obtained for different counter-faces can vary in dramatic way. Hydrophobic biomaterial can have high friction coefficient on hydrophobic polymer counter-face but much lower on tissue, so the choice of the appropriate surface with respect to clinical application place is of great value. Thus for venous catheters porcine aorta can be chosen and for urethral catheters: porcine urethra or bladder.

This method of surface analysis can contribute to faster development of more biocompatible materials with care of patient comfort.

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