JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE **17** (2006) 147 – 152

Kink, flow and retention properties of urinary catheters part 1: Conventional foley catheters

E. L. LAWRENCE, I. G. TURNER*
Department of Mechanical Engineering, University of Bath, Bath BA2 7AY, UK
E-mail: I.G.Turner@bath.ac.uk

The treatment for urinary incontinence, a common condition affecting a considerable number of older and disabled members of society, involves the use of a Foley catheter for drainage of the bladder. The basic design of the catheter has remained the same for over seventy years. Despite modifications to the materials used there has been very little research directly comparing the physical properties of the different types of catheter. This study developed a range of tests to enable comparison of the resistance to kinking, flow rate properties and the retention forces of both latex-based and all-silicone catheters. The results indicated that the all-silicone device had superior resistance to kinking and better flow properties when compared to the latex-based catheters. However, greater retention forces were recorded for the all-silicone device, in both the inflated and deflated condition, indicating that much more force would be required to remove the this type of catheter.

1. Introduction

Historically the Foley catheter, introduced in the 1930's for the management of urinary incontinence (UI), was manufactured from natural latex rubber [1, 2]. The commercially available range of devices now extends to include latex coated with materials such as PTFE or hydrogel, together with the alternative of all-silicone catheters [2]. The 'in-service' requirements of a urinary catheter include the need for a smooth surface for ease of insertion and removal without compromising patient comfort, the ability to conform readily to the contorted anatomical route dictated, the ability to drain the bladder effectively and to continue to perform these functions for extended time periods in what can be an aggressive environment. Following insertion, the catheter can remain *in situ* for periods of up to three months, during which time it is exposed to a wet environment where the pH values can vary from pH5–pH9 [3, 4].

Despite the fact the UI is a common condition affecting approximately three million people in the UK alone [3], there has been very little research directly comparing the properties of the different types of catheter. The basic design of the devices has remained the same for over seventy years but there have been modifications to the materials used. Research to date has focussed primarily on the biological problems associated with the infection and encrustation of catheters [4–10]. The aim of this research project was to develop a range of *in vitro* tests to enable comparison of some of the physical properties of different commercially available catheters. The ability of the devices to resist kinking was studied, along with their flow rate characteristics. In addition, the forces required to remove the devices was evaluated using an *in vitro* model.

2. Materials and methods

Three different types of commercially available, clinically used Foley catheters were obtained for testing from the suppliers 3S Healthcare, London N14 6JH. Details of these are listed below in Table I. All were of the same overall diameter, 14Fr, the equivalent of 4.62 mm in diameter. The catheter types were selected as a representative range of different materials currently used to manufacture catheters. Samples were studied in their 'as-received' state, and following treatment in buffered distilled water at pH 5, pH 7 and pH 9. Samples were stored in these solutions, at body temperature, 37 °C, for periods of 30 to 90 days, as detailed in Table II.

2.1. Kinkability

A kinkability test was designed based on a British Standard for rubber tubing (BS EN 3212:1991) [11]. A

*Author to whom all correspondence should be addressed.

TABLE I Details of foley catheters

Catheter type	Description	Manufacturer
'Biocath' Hydrogel coated latex Foley	Latex substrate coated with a hydrogel	Bard*
PTFE coated latex Foley	Latex substrate dipped in suspension of PTFE particles dispersed within carrier polymer (e.g. polyurethane)	Bard*
All-silicone Foley	Extruded silicone rubber	Ideal**

*Bard Ltd, Crawley TH11 9BP, supplied by 3S Healthcare.
**Originally manufactured by Maersk Medical; now sold as the UHS Silicone Foley supplied by 3S Healthcare.

TABLE II Details of buffer solutions

Buffer agent	Chemical formula	g/litre of H_2O	Amount/ml for indicative pH		
			pH5	pH7	pH9
di-sodium hydrogen phosphate	$Na_2HPO_4{\cdot}2H_2O$	9.465	2.5	60.0	95.0
mono-potassium phosphate	KH_2PO_4	9.07	97.5	40.0	5.0
Submersion Period/days			30	30, 60 & 90	30

manometer was constructed and linked to an argon gas supply, as shown in Fig. 1. The sample to be tested was attached to the manometer, through which the flow of argon gas could be controlled. With the sample lying flat on the table, the manometer was adjusted to ensure that a constant flow of argon gas at 28 mbar pressure was maintained. The sample was then gently gripped at two points 28 cm apart. These two points were brought closer together, in four centimetre steps, whilst the sample remained flat on the table. The sample was held in each position for 30 s, after which any change in the height of the manometer water level was noted. The pressure change due to sample bending could then be measured, giving an indication of the resistance to kinking, i.e., kinkability of each sample type. This process was repeated three times on every sample, of which there were three for each different catheter. The average pressure change due to bending was then calculated.

2.2. Flow rates

A glass funnel, as shown in Fig. 2, was used to assess the flow characteristics of the catheter samples (all size 14Fr and ~45 cm long). For each device, flow rates were measured with the balloon seal both inflated and deflated. Each sample was positioned inside the funnel, and a rubber valve used to ensure the system was sealed without causing sample deformation. The entire system was suspended using a clamp stand, the position of which was adjusted to ensure the open end of each sample was at the same fixed height for every test. A plug was placed in the bottom of the sample, and the funnel filled with distilled water. The plug was removed, and the time for flow of 50 ml of distilled water recorded using a stopwatch. This process was repeated three times on every sample, of which there were three for each different catheter type. An average flow rate, in ml/s, was calculated.

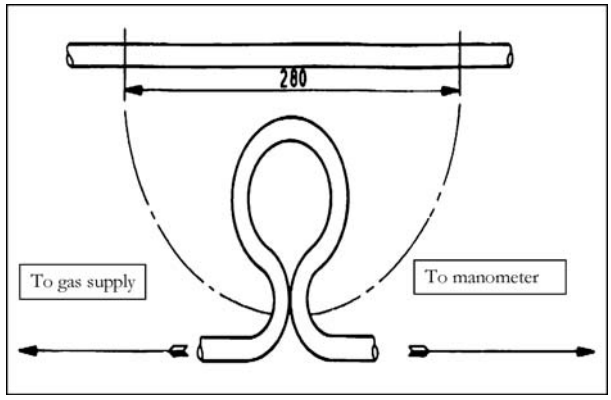


Figure 1 Kinkability measurement.

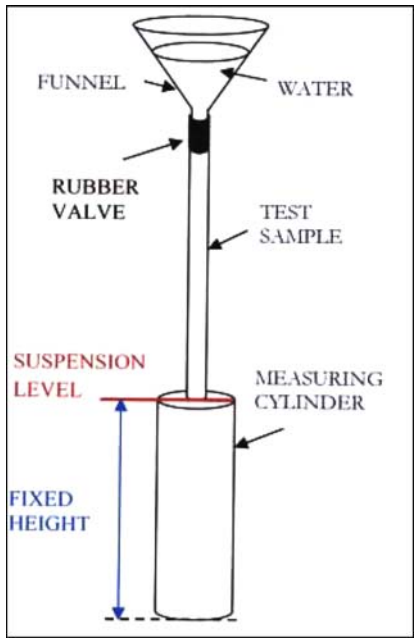


Figure 2 Flow rate apparatus.

2.3. Retention forces

Using known pressures of urethral sphincter muscles, a retention rig, designed by Ranier Technology Limited, Greenhouse Park Innovation Centre, Newmarket Road, Cambridge CB1 5AS, was used to evaluate the force required to remove a catheter *in situ*. As shown in Fig. 3, the rig consists of an inflatable polyurethane balloon cuff, which simulates the sphincter muscle, and

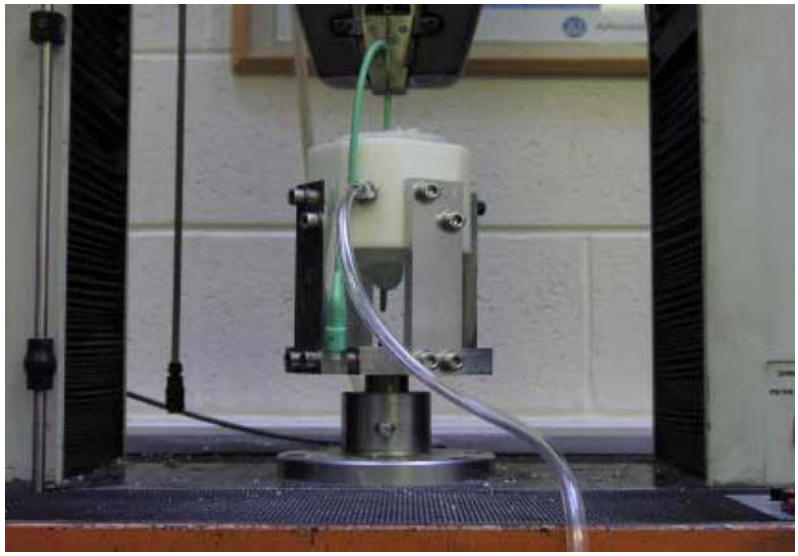


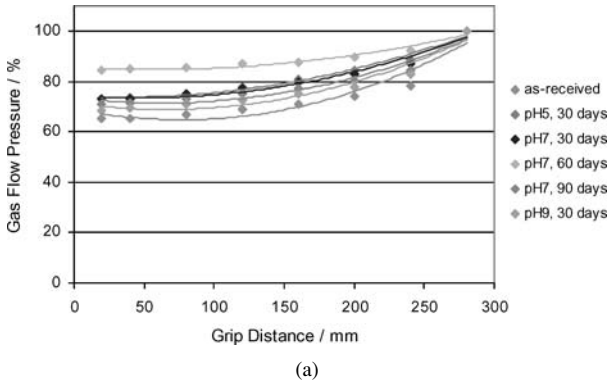
Figure 3 Retention rig.

which is secured to the base of a standard Instron 1122 testing machine. After positioning the sample, the cuff was inflated to the desired pressure of 68.65 mbars. The exposed section of the catheter was gripped in the Instron. Based on the British Standard BS EN 1618 [12], a crosshead speed of 200 mm/min was used to apply a load to the sample until it was pulled clear of the retention rig. The maximum force required to do this (i.e. the retention force) was recorded. This process was repeated three times on every sample, of which there were three for each different catheter, and an average retention force calculated. This force was measured both when the balloon seal was deflated and inflated.

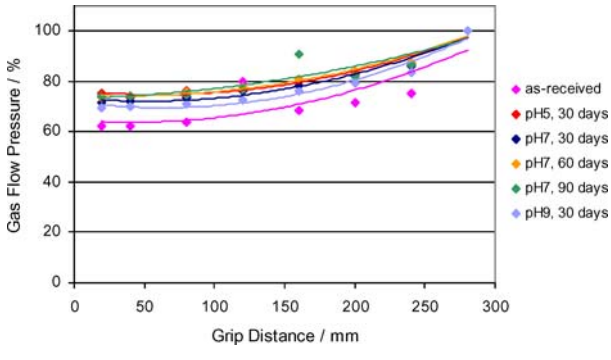
3. Results and discussion

3.1. Kinkability

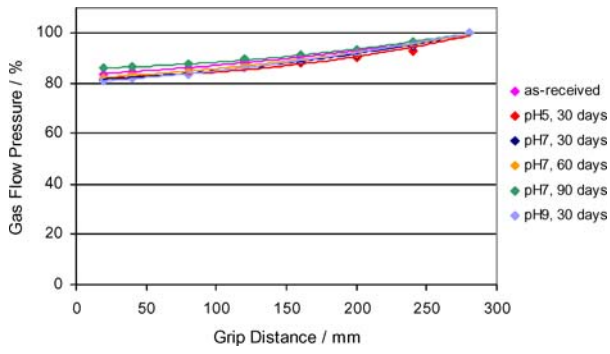
Figs. 4(a)–(c) show the average reduction in gas flow pressure due to kinking for the hydrogel- and PTFE-coated latex catheters and the all-silicone device. The term 'Gas Flow Pressure/%' is used to label the y-axis on the graphs. 100% gas flow pressure refers to the original pressure (28 mbar) of gas flowing through a flat sample when a test was initially set up. Any drop in the gas flow pressure due to kinking/bending was noted, and the subsequent average gas flow values calculated as a percentage of the original 28 mbar.



(a)

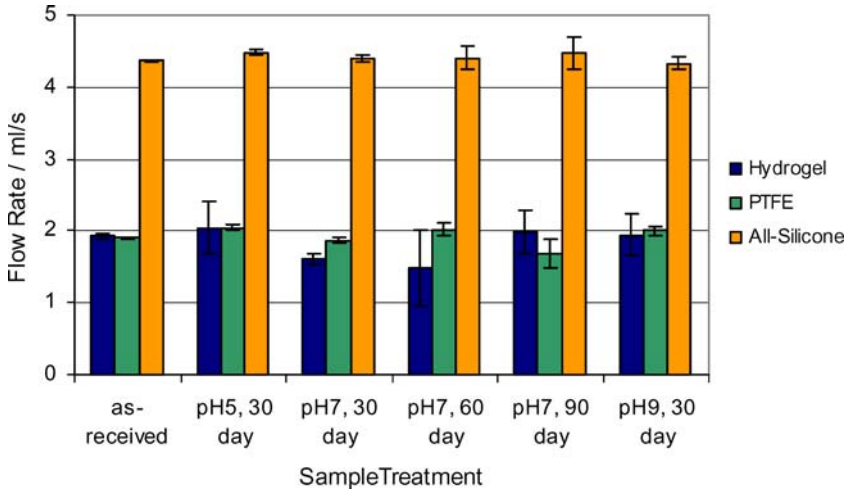


(b)

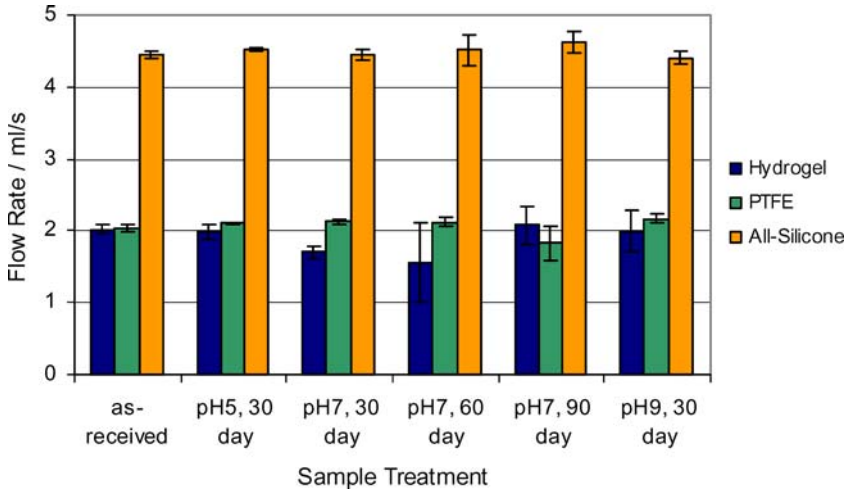


(c)

Figure 4 (a) Pressure reduction on kinking, hydrogel samples, (b) Pressure reduction on kinking, PTFE samples and (c) Pressure reduction on kinking, all-silicone samples. *(Continued).*



(a)



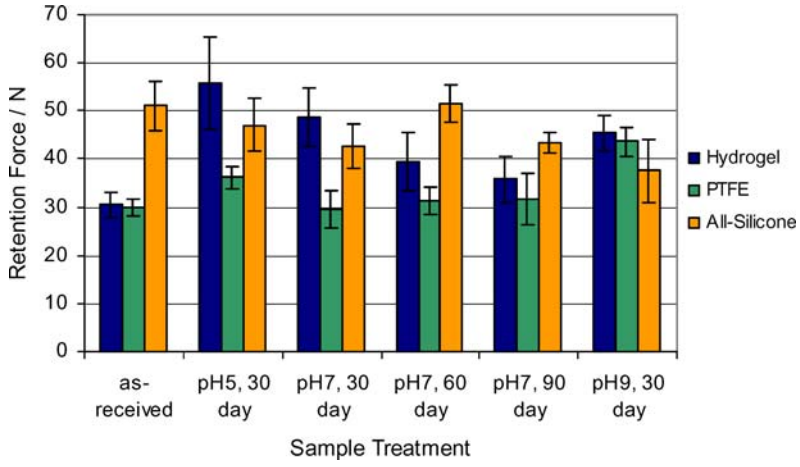
(b)

Figure 5 (a) Flow characteristics of inflated catheters and (b) Flow characteristics of deflated catheters.

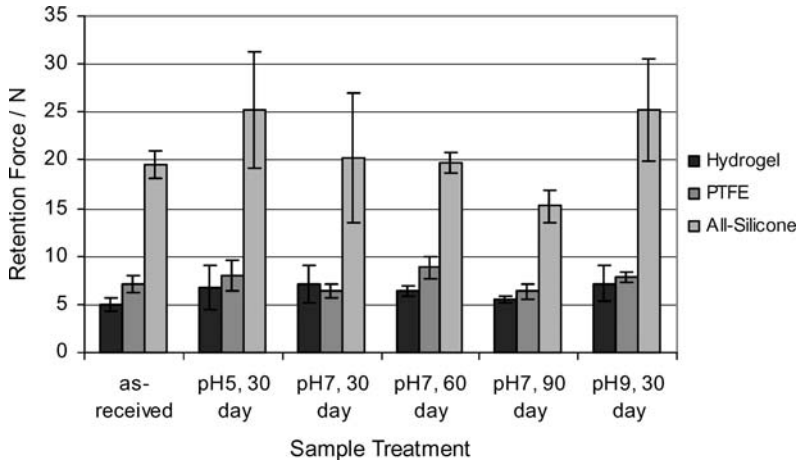
These percentages were then plotted against 'grip distance/mm', which refers to the distance between the gripped points on the samples. These two grip points were positioned 28 cm apart on a flat sample, and were progressively brought closer together by gradually introducing a loop into the sample in 4 cm steps. From Fig. 4, it can be seen that reducing the grip distance resulted in a decrease in the gas flow pressure through each sample type. This trend was more obvious in the case of the latex-based samples, which experienced a reduction in gas flow pressure to between 60 and 80% of the original. In comparison, the gas flow through the all-silicone samples reduced in pressure to between 80 and 90% of the original. This was probably because the drainage lumens of the all-silicone devices had a larger diameter than those of the latex-based catheters. As can be seen from the graphs the soaking of the catheters for different time periods had a negligible effect on the properties of the all-silicone devices, Fig. 4(c). In contrast, the two latex based devices, Figs. 4(a) and (b) were more susceptible to the ingress of moisture which resulted in a slight change in dimensions. As a consequence of this change, the diameter of the internal lumen increased in these samples. This would explain lower drop in gas pressure for these catheters relative to the 'as-received' samples, as seen in Fig. 4(a) and (b) as the testing progressed.

3.2. Flow characteristics

Figs. 5(a) and (b) compare the average flow rate characteristics of each catheter type, and represent the catheters with their securing balloon inflated and deflated respectively. The most prominent feature of both the graphs is the distinct difference between the flow rates of the latex-based catheters and the all-silicone variety. Whilst both the hydrogel coated and PTFE coated latex catheters had flow rates in the region of 1.5 ml/s



(a)



(b)

Figure 6 (a) Retention forces of inflated catheters and (b) Retention forces of deflated catheters.

to 2 ml/s, those of the all-silicone device were more than double this, at approximately 4.5 ml/s. This can be explained by the results obtained from dimensional measurements. These revealed that, whilst the external diameters of the 14Fr latex-based and all-silicone catheters are roughly equivalent, the walls of the latter were much thinner, thus giving it a far greater diameter internal drainage lumen. Consequently, the all-silicone catheters are significantly more effective at liquid drainage than the equivalent latex-based devices. Soaking for different time periods at the different pHs can be seen to have had little effect on the flow properties.

3.3. Retention properties

Figs. 6(a) and (b) compare the average retention forces of each catheter type. The graphs represent catheters with their securing balloon inflated and deflated respectively. Prior to soaking, the inflated latex-based catheters both had retention forces that were far lower than those of the all-silicone device. However, following soaking, the retention forces of all three of the inflated conventional catheters were more comparable. This could be due to the increase in the dimensions of the latex-based devices following liquid ingress. The known tendency for rapid deformation of the balloon seal on the all-silicone devices may also have been a factor in making the results more comparable [13–15].

In contrast to the inflated catheter results, the retention forces of the deflated all-silicone devices remained significantly higher (approximately three times greater) than those of the deflated latex-based catheters. The probable explanation for this is the high coefficient of friction and non-wetting characteristics associated with the all-silicone devices, which resulted in them being more ‘tacky’ in nature than the latex-based catheters. In addition, it was found that the deflated balloon material of the all-silicone samples frequently formed a ‘cuff’ during removal from the retention rig. This well documented phenomenon [13–16], which may arise as a result of creep, could have had a significant influence on the subsequent retention forces of the all-silicone

samples, and may have contributed to the relatively high retention values measured for them in their deflated state.

4. Conclusions

The successful development of experimental methods has allowed the measurement and comparison of the kink, flow and retention properties of different types of Foley catheter currently in clinical use.

The results indicated that the all-silicone catheters were slightly more resistant to kinking when compared to the latex-based devices. This could be due to a combination of factors. In terms of the material properties, the all-silicone devices were less pliable than the latex-based ones. However, in terms of design they had a larger diameter internal lumen. The properties of the all-silicone catheters did not vary significantly on exposure to different pH solutions during time periods of up to 90 days. The latex-based catheters, which are more susceptible to the ingress of moisture, showed more variability.

The flow rate through the all-silicone devices was more than double that recorded for the latex-based devices—again attributable to the larger diameter lumen of the former. The relative flow rates through all three types of catheter were similar irrespective of whether the retention balloon was inflated or deflated. As before, the soaking regimes had little measurable effect on the flow properties.

Compared to the previous two tests, the retention force results showed more variability. The forces required to remove all three catheters were comparable. Initially, in the as-received condition, the inflated latex-based devices had approximately 60% of the retention force of the all-silicone devices. Following exposure to a wet environment, this trend reversed, with the retention forces for the all-silicone devices decreasing whilst those for the latex-based devices increased. This phenomenon was attributed to the liquid absorption and swelling characteristics of the latex catheters.

In contrast, for the deflated catheters, the retention forces measured for the latex devices were significantly lower than those for the all-silicone devices. This trend remained following exposure to the wet environments. In clinical practice the formation of a 'cuff' has been observed on deflation of the retention balloon in the all-silicone catheters—this may contribute to the high retention forces recorded.

Test protocols have been successfully developed to allow comparison of a range of physical properties of urinary catheters that are of clinical relevance. The tests will prove useful, not only in terms of yielding basic comparative data on the physical properties of existing catheters, but could be used as a benchmark against which alternative designs incorporating new combinations of materials could be evaluated in the future.

Acknowledgments

The authors would like to thank the EPSRC for the provision of a studentship for EL Lawrence and Ranier Technology Limited for their financial support.

References

1. L. WINSON, *British J. Nursing* **6** (1997) 1229.
2. I. POMFRET, *Nursing Standard* **14** (2000) 46.
3. A. EVANS, D. PHEBY, *et al.*, *British J. Community Nursing* **5** (2000) 477.
4. N. S. MORRIS, D. J. STICKLER and R. J. C. MCLEAN, *World J Urol* **17** (1999) 345.
5. J. D. DENSTEDT, T. A. WOLLIN and G. REID, *J. Endourology* **12** (1998) 493.
6. L. L. SULLIVAN, B. W. STEINERT, *et al.*, *ASEE Annual Conference Proceedings* **2** (1995) 2168.
7. N. S. MORRIS and D. J. STICKLER, *Urol Res* **26** (1998) 275.
8. N. SABBUBA, G. HUGHES and D. J. STICKLER, *BJU Intl.* **89** (2002) 55.
9. D. J. STICKLER and N. MORRIS *et al. Eur. J. Clin. Microbiol. Infect. Dis.* **17** (1998) 649.
10. D. J. STICKLER and G. HUGHES, *ibid.* **18** (1999) 206.
11. British Standard 3212. Rubber Tubing. (1997). [WWW] http://bsonline.techindex.co.uk/
12. British Standard EN 1618. Catheters other than intravascular catheters—test methods for common properties. (1997). [WWW] http://bsonline.techindex.co.uk/
13. J. PARKIN, J. SCANLAN, M. WOOLLEY, *et al.*, *BJU Intl.* **90** (2002) 666.
14. J. ROBINSON, *Nursing Standard* **17** (2003) 33.
15. M. L. GONZALGO and P. C. WALSH, *Urology.* **61** (2003) 825.
16. S. DANESHMAND D. YOUSSEFZADEH and E. C. SKINNER, *Urology.* **59** (2002) 127.

Received 30 March
and accepted 28 June 2005