Kink, flow and retention properties of urinary catheters part 2: Novel design

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Research has shown that all the current designs of urinary catheters based on natural latex or silicone rubber are susceptible to the major problems associated with their use—infection, encrustation and blockage. Research, to date, has focussed on the biological aspects of these complications; little research has been directed towards the contribution of the design or materials used in the manufacture of the catheters. The aim of the current study was to evaluate a totally new concept in catheter design based on nylon braid encased in a polyurethane matrix. Novel prototypes were tested using a range of established protocols to assess their flow properties, resistance to kinking and retention properties. The results were compared to those for the conventional latex and silicone based catheters currently in clinical use. The indications were that the new designs had superior flow properties and equivalent retention properties to the all-silicone catheters. Following further modification they also had superior resistance to kinking.

1. Introduction

Catheters used for the long term treatment of urinary incontinence are manufactured from a variety of materials to a common design—that of the original Foley catheter introduced in the 1930's. The majority are based on natural latex which has either been treated with silicone or coated with PTFE or hydrogel [1, 2]. The alternative is an all-silicone device composed entirely of silicone rubber [2]. Research has shown that all the current designs available for clinical use are susceptible to the major problems associated with the use of urinary catheters—infection, encrustation and blockage. As the result of contaminating bacteria—commonly *Proteus Mirabilis*—crystalline salts can precipitate from urine, attach and accumulate on the surfaces of the catheter, eventually causing complete blockage of the device [3]. This can result in retention and by-passing of urine and can cause trauma to the urethra and bladder mucosa when the catheter is removed [4]. It has been identified that encrustation affects approximately half the patients undergoing long term catheterisation [2, 5] and it is associated with the development of serious complications such as pyelonephritis, septicaemia and shock [6, 7]. Recent research has indicated an association between surface morphology of urinary catheters and the development of such problems [8].

To date, most research in the field of urinary catheters has focussed on the biological aspects of complications associated with the use of urinary catheters [3, 4, 7, 9, 10]. Little research has been directed towards the contribution of the design or materials used in their manufacture. The aim of the current study was to evaluate a totally new concept in catheter design based on nylon braid encased in a polyurethane matrix. This innovative device was designed in such a way as to address some of the serious complications that can arise from the use of the current conventional Foley catheters. The new prototypes were tested using a range of protocols that had been developed to assess the flow properties, resistance to kinking and retention properties of the new designs relative to the conventional latex and silicone based catheters currently in clinical use [11].

2. Materials and methods

Braided prototypes, comprising a braided nylon monofilament encased in a polyurethane (PU) matrix, were supplied by Ranier Technology Limited. Braid

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Figure 1 The 48 Carrier fine wire braider[167].

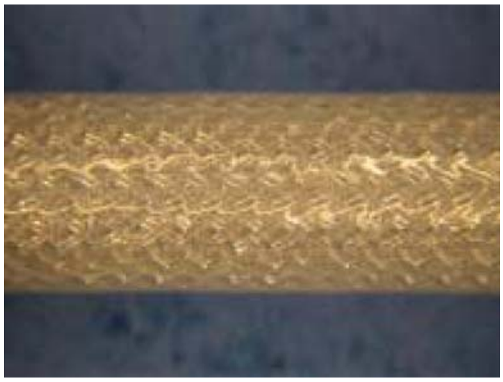


Figure 2 Example of braided sample[167].

type 1 used Pellethane 2363-80A PU, whilst braid type 2 used Tecothane TT-1074A PU. Tubular sections were produced by dipping 40 cm lengths of polytetrafluoroethylene (PTFE) rod, approximately five millimetres in diameter, into solutions of 10% Pellethane or Tecothane PU. Following initial dipping, the rods were dried overnight at room temperature to produce an undercoat approximately 50 μm in thickness. A 48 carrier fine wire braider, as shown in Fig. 1, was set at 45 picks per inch (ppi), and used to braid a 130 μm diameter nylon 6,6 monofilament over the coated rod. Over-dipping was repeated six times (with a drying step between each layer), using the same PU solution as for initial undercoating. The resultant PU encased nylon braid (as shown in Fig. 2) was then removed from the PTFE rod.

At a later stage in the project, modified braided samples were supplied by Ranier Technology Limited. These were manufactured in the same way as previously described, but involved the use of a 230 μm diameter nylon 6/6,6 monofilament and Tecothane PU solution.

Given the novel nature of the new design and materials used to manufacture the prototype braided devices, the results were compared with those from two types of latex based catheter coated with either PTFE or hydrogel (manufactured by Bard Ltd, Forest House, Crawley, W Sussex RH11 9BP) and a third, all-silicone type (manufactured by Ideal, Maersk Medical). Both the Bard and Ideal catheters were supplied by 3S Healthcare, Medical Supplies, London N14 6JH. Apart from the complete change in the materials used to manufacture the new devices, there was a major difference in the cross-sectional dimensions of the tubular section of the braided devices compared to the conventional catheters. The wall thickness of the new design was considerably less than that of the conventional designs, making the internal lumen much larger.

A series of test protocols have been developed to measure and compare the flow rates, resistance to kinking and retention forces of urinary catheters. These experimental protocols are described in detail elsewhere [11]. Samples were studied in their 'as-received' state, and following treatment in buffered distilled water at pH5, pH7 and pH9, as detailed in Table I. Samples were stored in these solutions, at body temperature, 37 °C, for periods of 30 to 90 days to represent the typical 1–3 month indwelling time of a catheter.

3. Results and discussion

3.1. Flow rates

Fig. 3 shows the flow rate characteristics of braid types 1 and 2, in as-received and treated conditions. In all cases, braid type 1 had a slightly higher flow rate than braid type 2. Both braid types displayed a reduction in flow rates following sample soaking; braid type 1 reduced from an as-received flow rate of approximately 26 ml/s to between 21 ml/s and 24 ml/s in soaked samples; braid type 2 reduced from just over 25 ml/s to between 20 ml/s and 22 ml/s. These trends can be explained in terms of the mass gain and dimensional changes recorded. Water ingress during immersion resulted in swelling of the sample walls and a consequent reduction in the diameter of the internal drainage lumen.

TABLE I Details of buffer solutions

			Amount/ml for indicative pH		
Buffer agent	Chemical formula	g/litre of H_2O	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

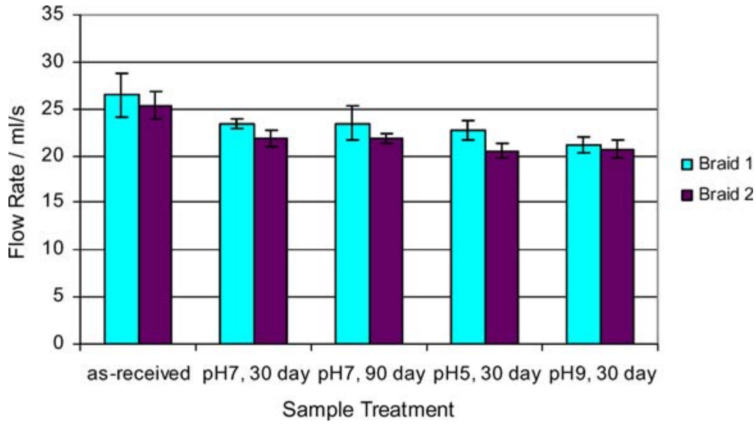


Figure 3 Flow characteristics of braided devices.

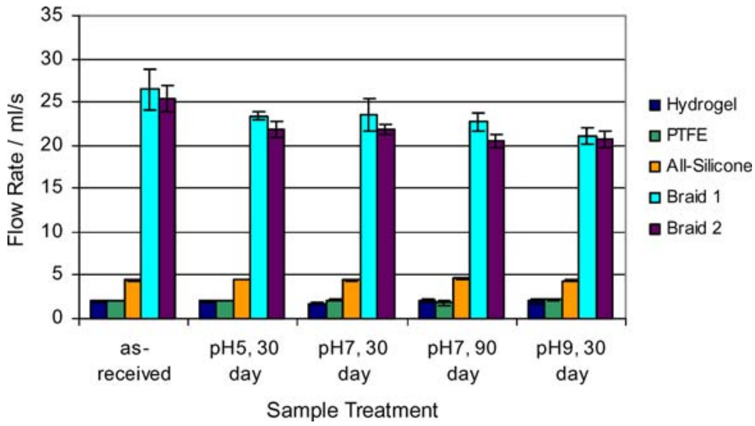


Figure 4 Comparison of conventional & braided device flow rates.

Fig. 4 compares the average flow rate results for both types of braided device tested with those for the conventional catheters. As the braided samples were supplied in tube form with no securing device, data for deflated conventional catheters is used as a comparison. The graph clearly illustrates the significant difference between the flow characteristics of the conventional catheters and braided devices, the latter being far more effective at liquid drainage.

The braided devices had flow rates that are approximately five times greater than the all-silicone catheters and ten times greater than the latex-based samples. It may be argued that the eyehole access for drainage on the conventional catheters may effectively reduce the relative flow rate but the difference in the diameters of the internal lumens will have the overridng influence. This is not surprising as the braided devices had far thinner walls and therefore larger internal diameter drainage lumens.

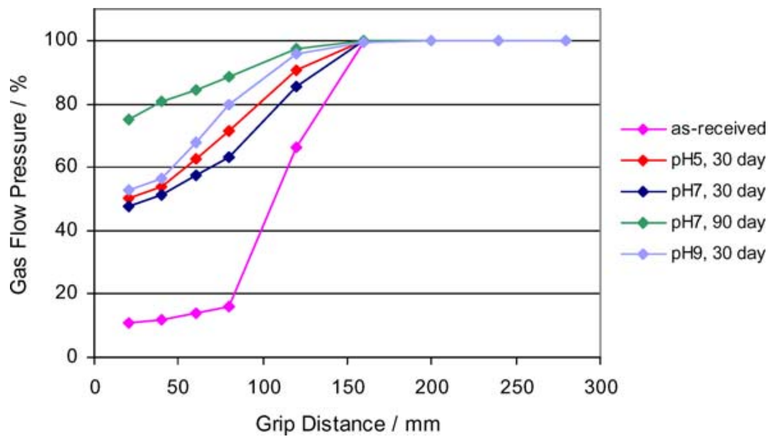
3.2. Resistance to kinking

Figs. 5(a) and (b) display graphs of the average reduction in gas flow pressure on kinking for braid type 1 and braid type 2 respectively. Reducing the grip distance resulted in a decrease in the gas flow pressure through each braid type. Unfortunately, however, both braid types experienced a sudden and abrupt drop in gas flow pressure during testing. This suggests that the braided designs were highly susceptible to kinking, a characteristic that can be linked to two factors, the first being their modulus of elasticity values. Tensile tests revealed that both braid types had relatively high modulus of elasticity values, and, consequently, were quite stiff. This lack of compliance meant that the samples could not accommodate a large amount of bending before succumbing to kinking. The second factor to consider is the contribution of hoop stress to the abrupt kinking of the braided samples. Hoop stress can be calculated using the following equation [12]:

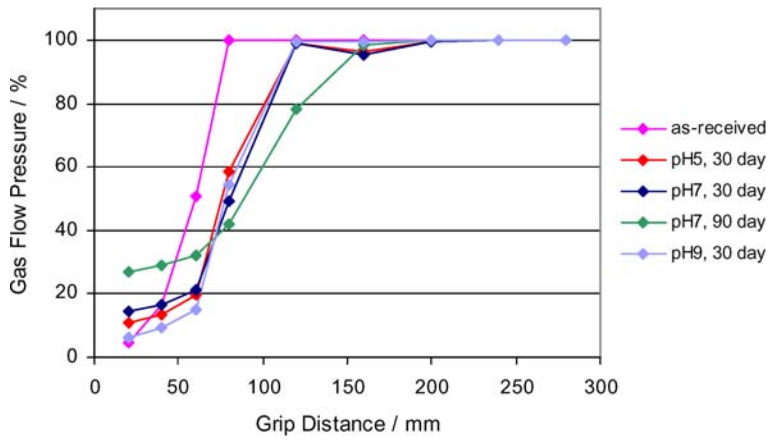
$$S = PD/2t$$

where: S is hoop stress; P is internal pressure; D is outside diameter of the pipe; t is the wall thickness.

From this it can be seen that a thin-walled tube, such as the braided samples, would experience a greater hoop



(a)



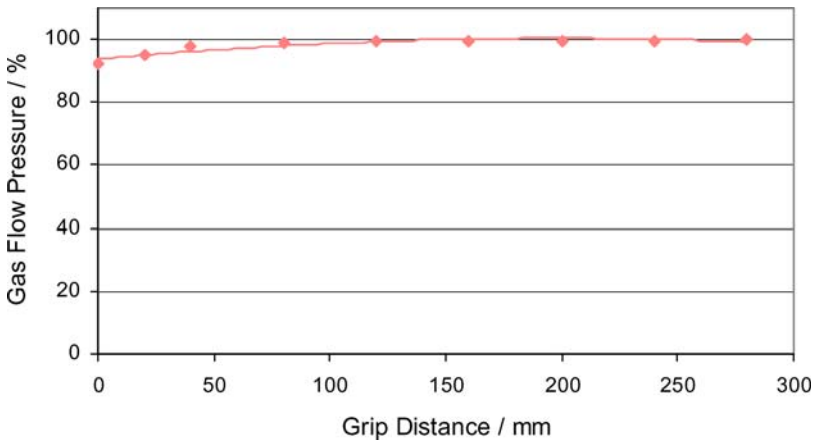
(b)

Figure 5 (a) Pressure reduction on kinking, Braid Type 1. and (b) Pressure reduction on kinking, Braid Type 2.

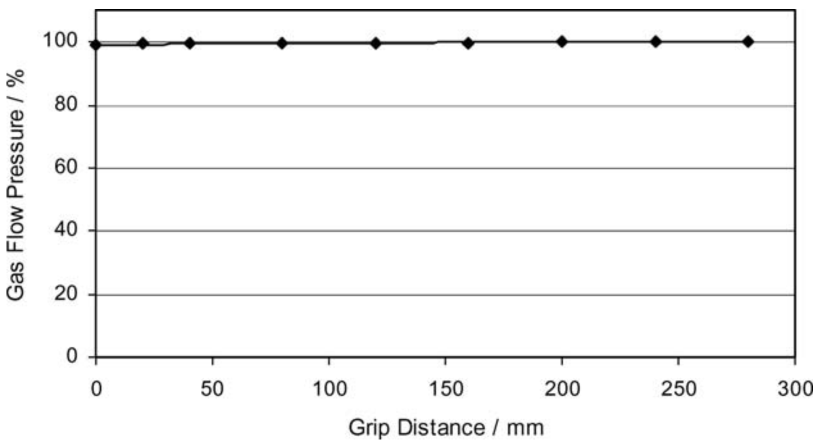
stress than a sample with thicker walls, such as the conventional catheters. When subjected to the same internal pressure, this would result in thin-walled samples being more prone to collapse than thicker-walled devices.

Both the modulus of elasticity and hoop stress theories correlate with the changes in kinking characteristics of braid type 1 following soaking. The graph shown in Fig. 5(a) shows that, for braid type 1, the drop in gas flow pressure was not as abrupt or as large in soaked samples as it was for those in as-received condition. This susceptibility to kinking can be explained by the fact that, in braid type 1 samples, the elasticity increased after soaking. In addition, the walls of this sample type were found to swell to a relatively large degree during soaking thus giving soaked samples thicker walls, with a lower susceptibility to hoop stress and kinking. Consequently the soaked samples were more compliant, and thus more able to bend, rather than kink, during testing. Another trend apparent from Fig. 5(b) is that, after soaking, braid type 2 samples appeared to kink at an earlier stage than those in as-received condition. This observation correlated with the change in modulus of elasticity results for this braid type following immersion for different time periods.

Following assessment of the kinking characteristics of braid types 1 and 2, Ranier Technology Limited addressed the problems associated with these samples by producing modified braided samples, using 230 μm diameter Nylon 6/6,6 monofilament and Tecothane polyurethane. One batch was close in size to 16Fr (equivalent to the original braided samples), whilst the other was closer in size to 14Fr, the most common size used clinically. Each had the same overall wall thickness. The results of subsequent kink tests carried out on these modified samples, in as-received condition, are shown in Figs. 6(a) and (b). It can be seen that the modifications to the braid design had a considerable and very positive effect on the kinking characteristics with both sizes of modified braids shown to be extremely resistant to kinking. The nylon 6/6,6 monofilaments used for the production of these samples had a diameter of 230 μm, as compared to the 130 μm diameter of the original monofilaments. The use of larger diameter



(a)



(b)

Figure 6 (a) Pressure reduction on kinking, modified braid, size 16Fr. and (b) Pressure reduction on kinking, modified braid, size 14Fr.

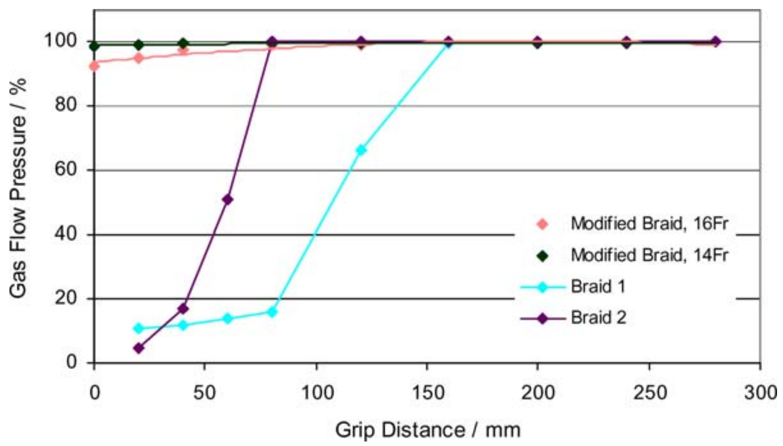


Figure 7 Kink characteristics, original and modified braided samples.

monofilaments resulted in a thicker-walled braided tube and a reduction in the hoop stress experienced by the samples. This significantly improved the kinking characteristics of both sizes of modified braid types, as shown in Fig. 7.

Fig. 8 compares the kinking results of the conventional catheters and original braided samples in as-received condition. The graph illustrates the significant differences between the kinking characteristics of the conventional and braided samples. The results illustrate

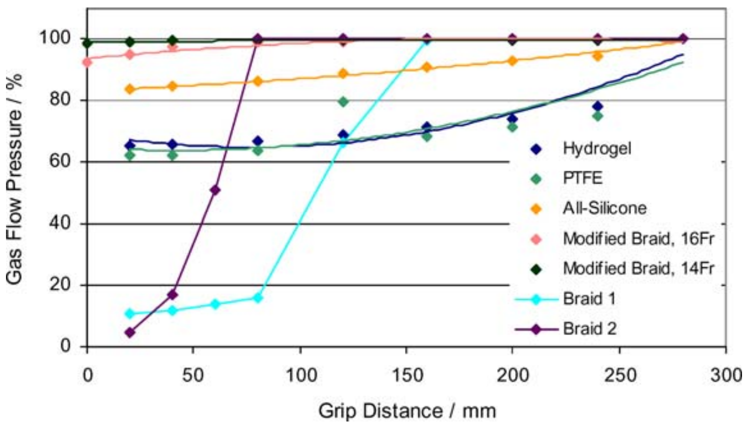


Figure 8 Kink characteristics, all braided samples and conventional catheters.

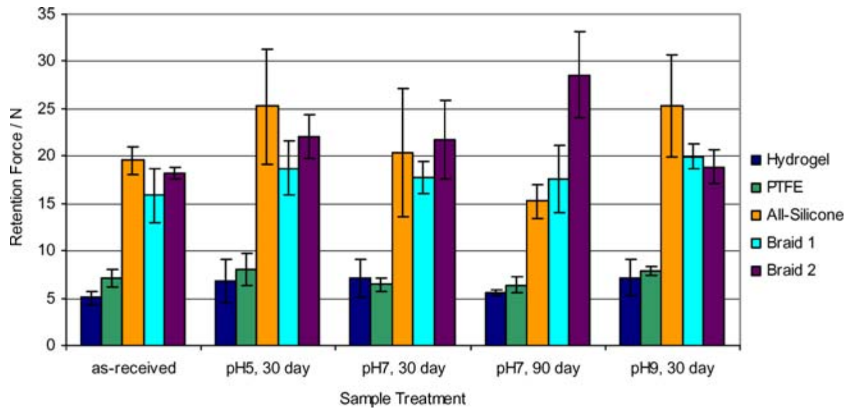


Figure 9 Comparison of conventional and braided device retention forces.

that what could potentially be a fundamental flaw in the design of the novel braided concept has been overcome with the modified braid designs that display kinking characteristics superior to those of the original braided samples.

3.3. Retention forces

Fig. 9 compares the average retention results for both the braided and conventional devices. As the braided samples were supplied in tube form with no securing device, data for deflated conventional catheters is used as a comparison. Both braid type 1 and braid type 2 had retention forces that were, in general, comparable to those of the all-silicone devices. Whilst it is difficult to identify any clear trends from the above graph, it can be seen that all the sample types tested experienced higher retention forces following soaking. In addition, both braid types had retention forces that were, in general, comparable to those of the all-silicone devices.

For all the sample types tested, it is important to consider the potential influence of the retention mechanism on the results. For conventional Foley catheters, the pressure of the inflated retention balloon is highly significant in terms of the retention properties. For the new alternative designs, the frictional characteristics of the constituent polyurethane material could have had an effect on the retention results. Studies have indicated that polyurethane based materials experience relatively high frictional forces [13, 14]. Thus, the frictional forces experienced by the catheters during the retention tests may have been magnified by the frictional properties of the polyurethane, thus resulting in somewhat exaggerated retention force results. This may be of particular significance in the case of, firstly, the braided samples, with both types consisting of a polyurethane matrix material, and secondly, the all-silicone catheters, which themselves have a high coefficient of friction, particularly when subjected to moderate applied forces. However as all the devices were tested under identical conditions, the relative values are of relevance.

4. Conclusions

The development and use of standard testing techniques allowed direct comparison of some of the physical properties of the new braided prototypes with the conventional Foley catheters. The flow rates of both braided devices were significantly greater than those of all the conventional catheters; five times those of all-silicone devices and ten times those of latex-based catheters. Both original braid types experienced a sudden and abrupt drop in gas flow pressure during testing indicating their high susceptibility to kinking. Following modifications to the materials used, the braided designs experienced a far lower and much more gradual drop in gas flow pressure than the original designs, and therefore appeared to have a far better resistance to kinking. The modified braids compared favourably, in this respect, to the latex-based conventional catheters and to an even greater extent with the all-silicone catheters. The retention forces measured were comparable to those for the all-silicone catheters with a slight increase in retention forces recorded following immersion for extended time periods which could be related to the swelling of the samples tested.

Preliminary results indicate that successful development of these alternative designs could contribute to overcoming some of the limitations currently associated with the catheters in clinical use. They also indicate the value of developing standard testing protocols to allow direct comparison of relevant properties of new and existing designs.

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