

Characterisation of the internal and external surfaces of four types of Foley catheter using SEM and profilometry

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Abstract Unfortunately the use of Foley catheters for long-term catheterisation is frequently associated with complications such as infection and encrustation. This study investigated whether a link could exist between the surface properties of the catheters and the problems that can develop. The internal and external surfaces of four different types of urinary catheter were examined. Three latex devices coated with either PTFE or hydrogel or surface treated with silicone were investigated. In addition, an all-silicone device was examined. The surfaces of the all-silicone catheters were relatively smooth and featureless. In contrast, the external surfaces of each of the latex devices were ‘paved’ in nature. The internal surfaces of latex based devices produced by different manufacturers showed distinct differences with evidence of inorganic inclusions on the internal surfaces of two of the catheter types. These findings may be significant in the context of catheter infection and encrustation.

1 Introduction

Urinary incontinence (UI) is a common condition that affects the function of the bladder. It is estimated that almost one quarter of the population of the UK will suffer from UI at some point in their lives [1]. The treatment varies according to its cause and severity. Long Term Catheterisation (LTC), used for the treatment of permanent UI, involves the insertion of a hollow, flexible tube, commonly the Foley catheter, into the bladder to allow drainage of urine [2–4]. The catheter is typically 3.96–5.94 mm in diameter and up

to 380 mm in length, with a balloon seal and drainage funnel incorporated in the design [5]. It is inserted into the bladder, via the urethra, and held in place by inflating a retention balloon, using sterilised liquid, just below the drainage eye in the catheter tip [4]. Urinary catheters can remain in patients for periods of one to three months between catheter replacements [2, 6]. It is estimated that the management and treatment of UI currently represents an estimated £1.4 billion per annum total cost to the NHS [7]. Such costs are dependent on the degree of nursing care needed [2], which can increase due to a number of serious complications that often arise as a result of long term catheterisation using Foley catheters.

Unfortunately the use of Foley catheters for long-term catheterisation is frequently associated with complications such as infection and encrustation [8]. The latter can occur as a result of contaminating bacteria, commonly *Proteus mirabilis*, causing precipitation of crystalline salts from urine. These crystals attach to the catheter surfaces and accumulate, eventually causing complete blockage of the catheter lumen [9]. This can lead to urine retention and by-passing, and, on removal of the device, can cause trauma to the urethra and bladder mucosa [6]. Encrustation affects approximately half of all patients undergoing LTC [5, 10] and can culminate in episodes of pyelonephritis, septicaemia and shock [11, 12]. It has been identified that the surface morphology of the urinary catheter may have an effect on the incidence of such problems [13].

Since its introduction in the 1930s, the Foley catheter, which was originally made of natural rubber latex, has been subject to modification by means of the application of surface coatings. As a result, there are a number of different types of catheters available commercially, including those coated with hydrogel, PTFE or silicone. New catheter alternatives based entirely on silicone are also now available.

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This research project investigated the surface characteristics of a range of commercially available Foley catheter materials by means of scanning electron microscopy (SEM) and laser profilometry. These techniques were used to analyse the internal and external surfaces of ‘as-received’ samples, together with those of specimens stored, *in vitro*, in a wet environment for specific periods of time. A quantitative study of the surface roughness of each type of Foley catheter was also conducted, by means of laser profilometry.

2 Materials and methods

Details of the four different types of Foley catheters tested are listed below in Table 1. All were of the same overall diameter—14Fr—which equates to 4.62 mm. They were selected as being representative of the range of different materials currently used to manufacture commercially available catheters, and were selected from a number of different companies in order to avoid focusing on a single manufacturer.

The catheters were tested in as-received condition and following exposure to wet environments. To investigate the effects of pH on the materials’ properties of the catheters, buffered solutions of distilled water were prepared, and samples immersed in these, at body temperature, for time periods of 30 and 90 days prior to testing. The normal pH of urine is usually approximately seven, although factors such as diet, illness and infection can cause it to vary between pH4.6 and pH9.1 [14–16]. Solutions of pH5, pH7 and pH9 were used to represent this range, with di-sodium hydrogen phosphate and mono-potassium phosphate used as buffer agents. Details of the compositions of the solutions are given in Table 2. The pH of each solution was monitored throughout the experimental time periods.

SEM was used to investigate both the external and internal surfaces of as-received and treated specimens. Two sections of each catheter tube, five millimetres in length, were prepared for each condition. Following soaking, treated samples were subjected to freeze-drying in an Edwards-Pearse Tis-

sue Dryer EPD3. All samples were gold coated using an Edwards S510B sputter coater prior to examination in a JSM 6310 SEM and a JEOL JSM T-330 SEM.

A Proscan 2000 non-contact surface profilometer was used to compare the roughness of the internal and external surfaces of the catheters. Using laser triangulation and a high accuracy optical displacement meter, this computer-controlled apparatus is able to measure fine changes in surface texture, at resolutions of up to 0.01 μm. Due to the curved nature of the samples involved, longitudinal strips, measuring 0.4 mm by 4 mm, were examined using step sizes of 5 μm. For each sample analysed, a three dimensional surface profile was obtained, to which a surface filter was applied in order to remove the general curved shape of the sample. Subsequently, eight xy-line profiles were obtained from each 3-D surface scan, and the Proscan software was used to calculate the average surface roughness, Ra, along each one. As shown in equation 1, this gives the arithmetic average deviation of the points in the x and y cross section, which is, effectively, the average distance of points from the mean value (i.e., the standard deviation). An overall average surface roughness value was then calculated for each test conducted.

$$Ra = \frac{1}{Im} \int_0^{Im} |y(x)| dx \quad (1)$$

where: Im is the total scanned area

3 Results and discussion

3.1 Scanning electron microscopy (SEM) of external surfaces

3.1.1 Silicone treated latex catheters

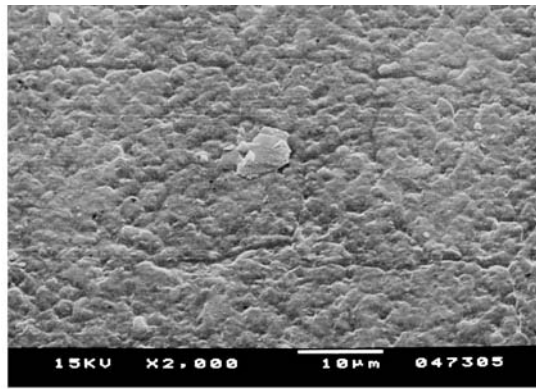
Figure 1(a)–(c) show typical examples of the external surfaces of Rusch silicone treated latex catheters, in as-received and post-immersion condition. A common characteristic appeared to be the existence of cracks and fissures on the

Table 1 Details of conventional Foley catheters

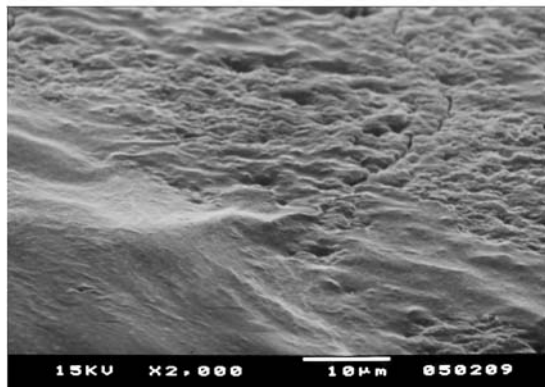
Catheter type	Description	Manufacturer
Silicone treated latex Foley	Latex substrate impregnated with silicone oil	Rusch
‘Biocath’ Hydrogel coated latex Foley	Latex substrate coated with a hydrogel	Bard
PTFE coated latex Foley	Latex substrate dipped in suspension of PTFE particles dispersed within carrier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

Table 2 Details of Buffer solutions

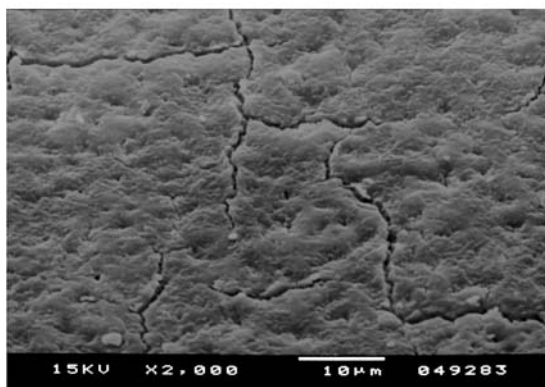
Buffer Agent	Chemical formula	g/litre of H ₂ O	Amount/ml for Indicative pH		
			pH5	pH7	pH9
Di-sodium hydrogen phosphate	Na ₂ HPO ₄ ·2H ₂ O	9.465	2.5	60.0	95.0
Mono-potassium phosphate	KH ₂ PO ₄	9.07	97.5	40.0	5.0
Submersion Period/days			30	30, 60 & 90	30



(a)



(b)



(c)

Fig. 1 Rusch, external surface (a) as-received, (b) pH7, 90 days and (c) pH9, 30 days

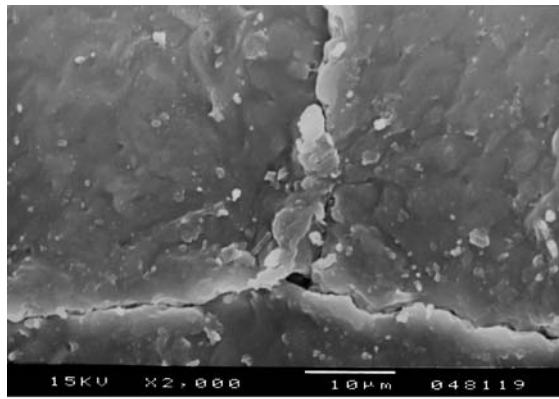
surfaces that resulted in a ‘paved’ appearance. The cracks appeared to become more exaggerated following immersion, [Fig. 1(c)]. Such features are often characteristic of latex material [17, 18], although they could result from differences in elastic modulus values of the latex substrate and silicone coating [18] or be present as a result of the freeze-drying process used to prepare the treated samples for SEM analysis [17]. SEM also revealed areas of the external surface which were smooth in nature [Fig. 1(b)], with no evidence of cracks or fissures. It is possible that these regions were areas in which a significant level of silicone coating was present.

In contrast to this, another common characteristic was the rough and ‘dimpled’ surface texture visible in some areas, which could be the result of manufacturing factors such as chemical treatment or drying rate and temperature [17]. The resulting morphology is similar to that of uncoated latex, which suggests that the technique used to produce these ‘silicone treated’ catheters may not ensure consistent and complete silicone impregnation across the entire external surface. It also suggests that, in the case of this catheter type, the cracks and ‘paved’ characteristics are most likely to be a feature of the latex substrate, as opposed to being a consequence of differences in elastic modulus values of the latex and silicone treatment substance.

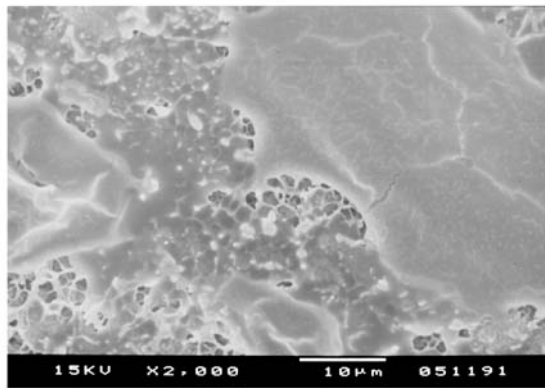
Overall, whilst soaking did appear to have a detrimental effect on the external surface characteristics of the Rusch silicone treated catheter samples, there were no distinguishable trends caused by variations in pH or soaking periods.

3.1.2 Hydrogel coated latex catheters

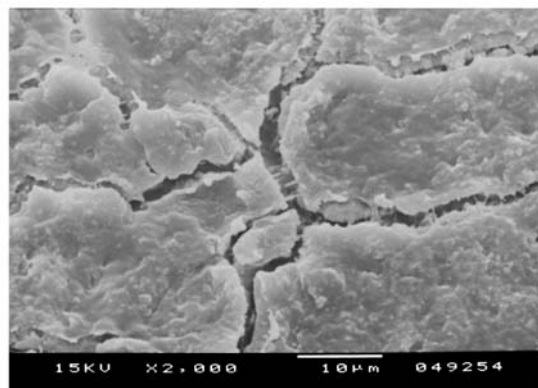
Figure 2(a)–(c) are of the external surfaces of Bard hydrogel coated latex catheters, in as-received and post-immersion condition. Once again the most apparent of the features observed was the ‘paved’ appearance of the surfaces. As before, this may be a characteristic of the latex substrate, although it could also result from differences in elastic modulus values of the latex substrate and hydrogel coating material [18]. In the case of the as-received sample, such cracks were likely to be visible despite the presence of the hydrogel coating, simply because, in this condition, the hydrogel was not hydrated. Once hydrated, it would be expected that the coating would swell and smooth out any fissures [19]. There were a number of areas on the external surfaces where there appeared to be



(a)



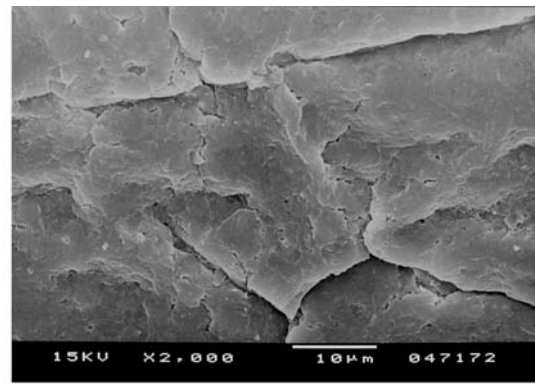
(b)



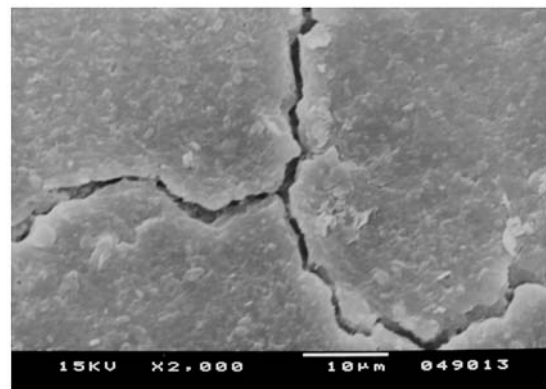
(c)

Fig. 2 Hydrogel, external surface (a) as-received, (b) pH7, 30 days and (c) pH9, 30 days

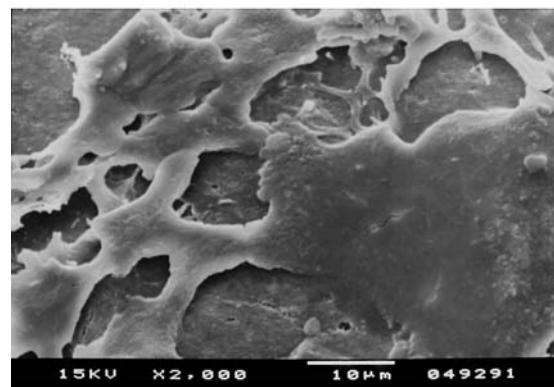
hydrogel coating material present as can be seen in Fig. 2(b). It appears that, once hydrated, the hydrogel coating smoothed the surface texture of the underlying latex substrate. There were, however, a number of areas where the paved and rough surface texture remained apparent after soaking [Fig. 2(c)]. This suggests that the coating techniques used to produce such catheters may not necessarily ensure complete and consistent coverage of the external surfaces. It could also indicate that the coating is susceptible to damage due to poor adhesion between the hydrogel and latex substrate.



(a)



(b)



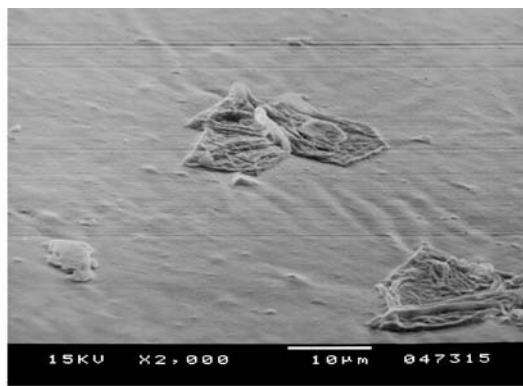
(c)

Fig. 3 PTFE, external surface (a) as-received, (b) pH5, 30 days and (c) pH9, 30 days

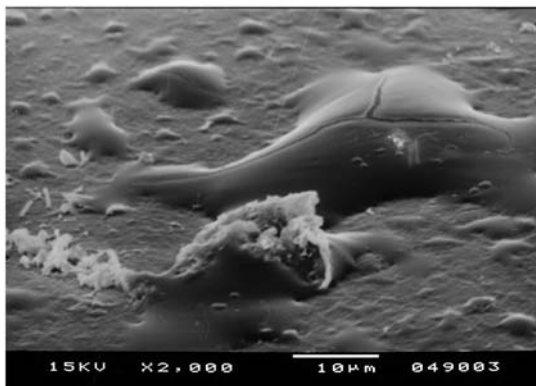
From the SEM study it was concluded that whilst soaking did appear to have a detrimental effect on the external surface characteristics of the hydrogel coated catheter samples, there were no distinguishable trends caused by variations in pH or soaking periods.

3.1.3 PTFE coated latex catheters

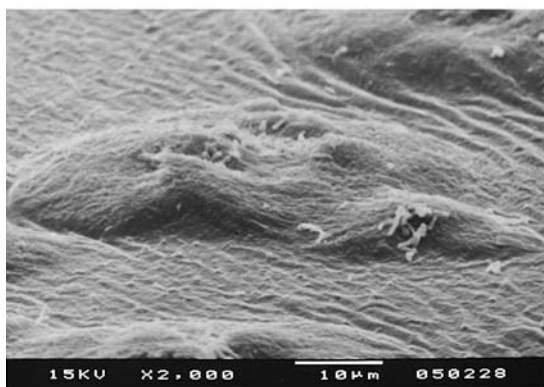
Figure 3(a)–(c) show the external surfaces of Bard PTFE coated latex catheters, in as-received and post-immersion



(a)



(b)



(c)

Fig. 4 All-silicone, external surface (a) as-received, (b) pH7, 30 days and (c) pH7, 90 days

condition. Once again, the most apparent feature of the external surfaces of the PTFE coated samples was their ‘paved’ nature. However, the ‘dimpled’ texture associated with latex was not evident on the as-received sample [Fig. 3(a)]. This suggests that, in the case of this catheter type, the coating was present, and the cracks and ‘paved’ characteristics resulted from the considerable difference in elastic modulus values [18] of latex and PTFE (which are approximately 0.9–1.3MPa and 410MPa respectively) [20–22]. In contrast

to the previous two latex-based catheters, the cracks did not appear to increase in size following soaking and sample preparation. This again suggests that the fissures seen on this sample type potentially arose from different circumstances to those seen on the silicone treated and hydrogel coated catheters.

SEM analysis of soaked samples also revealed what appeared to be damaged areas in the PTFE coating. This is illustrated clearly in Fig. 3(c) in which it seems that the coating is ‘peeling’ away from the substrate, revealing the characteristic ‘dimpled’ nature of the underlying latex.

It was seen that, whilst immersion did appear to have a detrimental effect on the external surface characteristics of the PTFE coated catheter samples, there were no distinguishable trends caused by variations in pH or soaking periods.

3.1.4 All-silicone catheters

Figure 4(a)–(c) are of the external surfaces of Ideal all-silicone catheters, in as-received and post-immersion condition. It can be clearly seen that the external surface characteristics of the all-silicone samples were distinctly different to those of the latex-based catheters. For the as-received all-silicone sample, [Fig. 4(a)], the external surface was found to be generally smooth with visible parallel ripples and striation lines most likely the result of the extrusion process used to manufacture such devices [17].

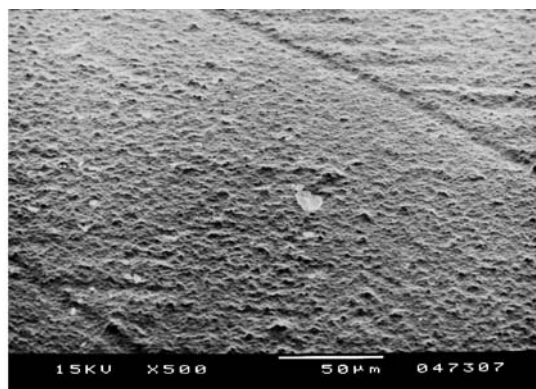
Whilst no surface cracks were seen on the surface of the as-received all-silicone sample, occasional inclusions were found. It is thought that such features may again be attributed to manufacturing processes and techniques. For example, it is possible that fillers are used [17] in the production of all-silicone catheters, and such substances could result in particulate debris as shown in Fig. 4(a). Similar inclusions were seen on the surfaces of as-received and soaked samples. In contrast, soaking often appeared to conceal or perhaps eliminate the rippled nature of many of the samples, resulting instead in the formation of surface bubbles as shown in Fig. 4(b) and (c). It is possible that such features were formed due to liquid ingress and sample swelling. It is, however, also possible that these surface bubbles or ‘blisters’ were part of a bacterial biofilm that formed on the samples during soaking. The occasional presence of a small number of rod-like projections, examples of which can be seen in Fig. 4(b) and (c), also supports this theory.

Whilst soaking did appear to have a detrimental effect on the external surface characteristics of the all-silicone catheter samples, there were no distinguishable trends caused by variations in pH or immersion periods.

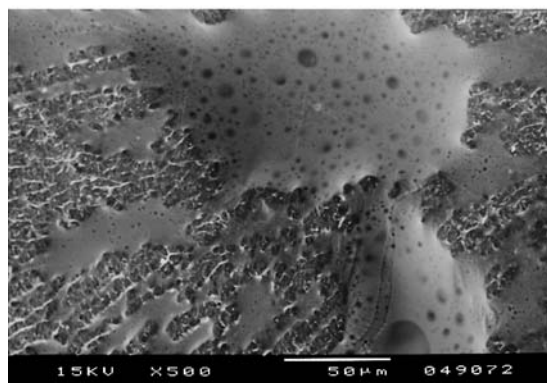
3.2 Scanning electron microscopy (SEM) of internal surfaces

3.2.1 Silicone treated latex catheters

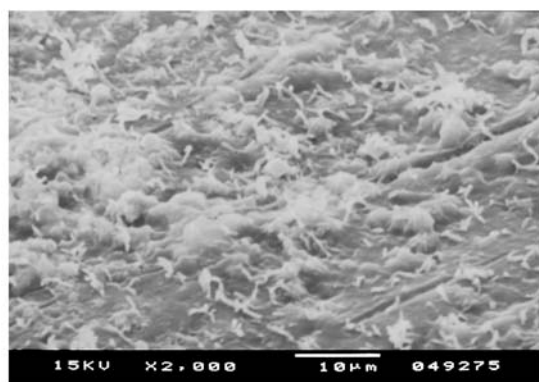
Figure 5(a)–(c) show the internal surfaces of Rusch silicone treated latex catheters, in as-received and post-immersion condition. The SEM micrograph of the as-received sample, Fig. 5(a), indicated the internal surfaces were relatively featureless, with no evidence of surface cracks or fissures,



(a)



(b)



(c)

Fig. 5 Rusch, internal surface (a) as-received, (b) pH7, 30 days and (c) pH9, 30 days

although the surface texture was relatively rough with distinctive parallel striations running along it.

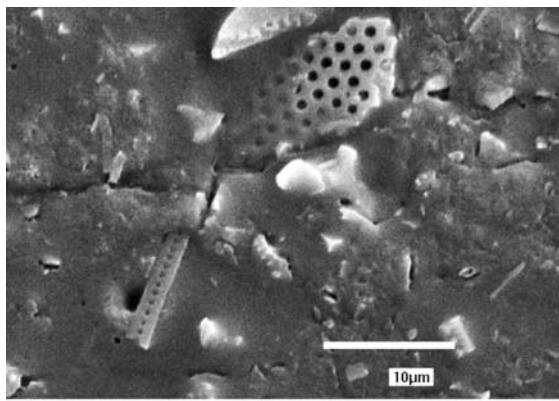
Immersion appeared to have had a detrimental effect on the surface characteristics of these catheters in that whilst some areas remained relatively unchanged, the volume of surface debris dramatically increased in others. Such extremes are visible in Fig. 5(c); both clear and debris strewn areas could be identified. SEM analysis also revealed areas of the internal surface where silicone material appeared to be present. One such region is shown in Fig. 5(b), in which patches of smooth, but seemingly swollen and damaged, material are clearly visible. Another possible explanation for the occurrence of such smooth regions is bacterial contamination, which could have resulted in the formation of a biofilm, together with an increase in the volume of rod-like particulate projections and inclusions.

Whilst soaking did appear to have a detrimental effect on the internal surface characteristics of the Rusch silicone treated catheter samples, there were no distinguishable trends caused by variations in pH or soaking periods.

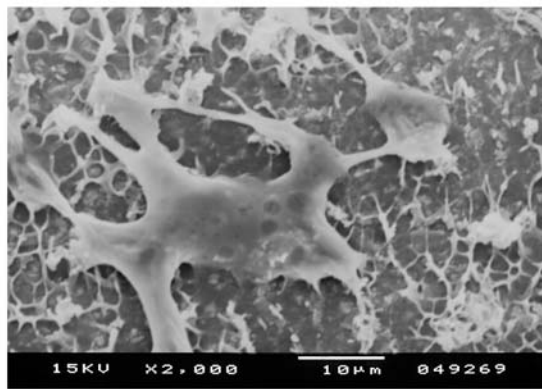
3.2.2 Hydrogel coated latex catheters

Figure 6(a)–(c) show the internal surfaces of Bard hydrogel coated latex catheters, in as-received and post-immersion condition. The most apparent features, commonly found on all of the samples, were mesh-like inclusions together with the ‘ladder-like’ projections seen in Fig. 6(a) and (c). These were identified as being diatoms, which are inorganic skeletons of microscopic unicellular algae [23], and ranged in size from approximately two to 20 microns. Diatomaceous earth, as it is known, is often used as filler in polymers. However, no diatoms were observed on the external surfaces of these catheters and SEM analysis of transverse sections revealed no evidence of diatoms of any kind through the wall thickness. This suggests that polymeric fillers were not the source of the diatoms seen on the internal surfaces. Instead, it is likely that such inclusions resulted from the processes used during device manufacture, of which little detail is available.

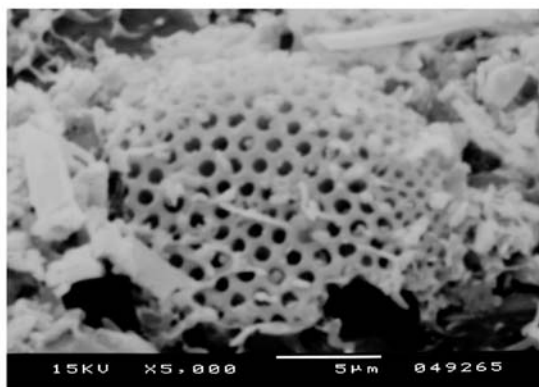
Another characteristic commonly seen on the internal surfaces of the hydrogel samples was cracking, similar in nature to that seen on the outside of this device type. However, in the as-received samples, Fig. 6(a), there was little evidence of the ‘dimpled’ texture characteristic of latex. It is possible that a hydrogel coating was present, but due to its dry state, was not sufficient to smooth the cracks or debris within the latex substrate. Another possibility is that the texture of the latex was affected by drying temperatures and times and that, in fact, there were regions of the internal surface that were not successfully coated during manufacture. However, in many samples examined after immersion there appeared to be evidence of smooth, hydrated hydrogel material. As was the case with the Rusch silicone treated catheter, if these



(a)



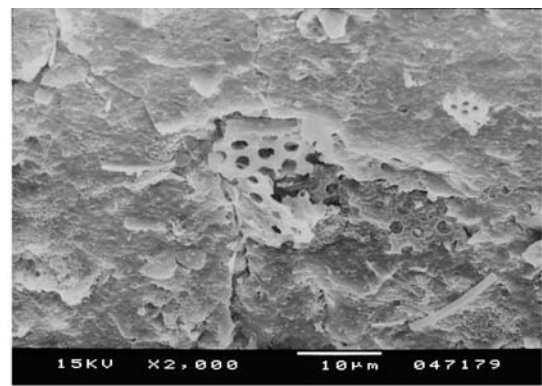
(b)



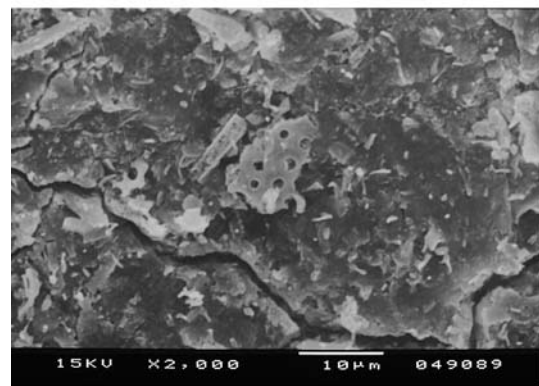
(c)

Fig. 6 Hydrogel, internal surface (a) as-received (b) pH9, 30 days and (c) pH9, 30 days

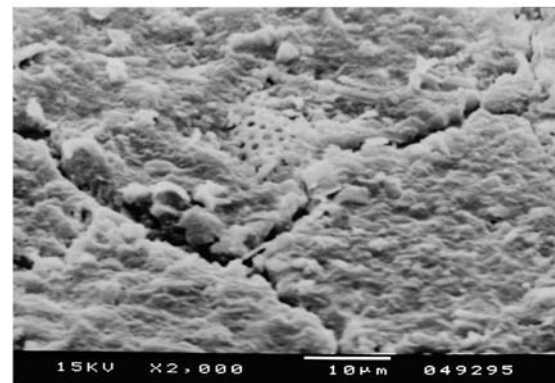
smooth patches were indeed coating material, they appeared to be damaged and peeling away from the underlying latex, a good example of which is shown in Fig. 6(b). This was possibly due to differences in the elastic modulus values of the hydrogel and latex substances (which are approximately 0.23MPa and 0.9MPa respectively)[20, 24]. It should also be noted, however, that such smooth regions could be due to bacterial contamination, which could result in the formation of a biofilm.



(a)



(b)



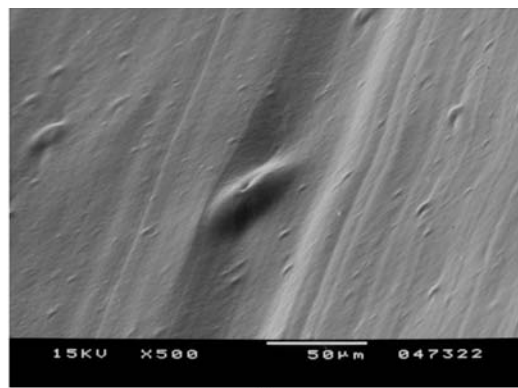
(c)

Fig. 7 PTFE, internal surface (a) as-received, (b) pH7, 30 days and (c) pH9, 30 days

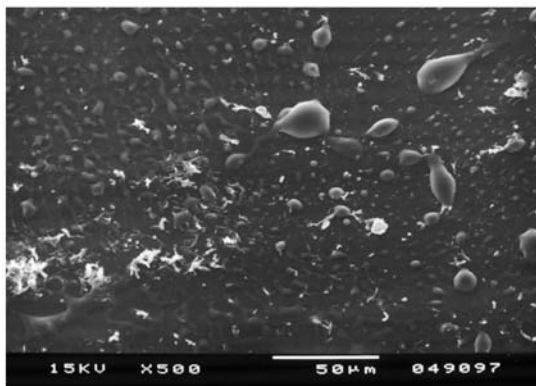
As was the case with the Rusch silicone treated samples, whilst immersion did appear to have a detrimental effect on the internal surface characteristics of the hydrogel coated catheter samples, there were no distinguishable trends caused by variations in pH or soaking periods.

3.2.3 PTFE coated latex catheter

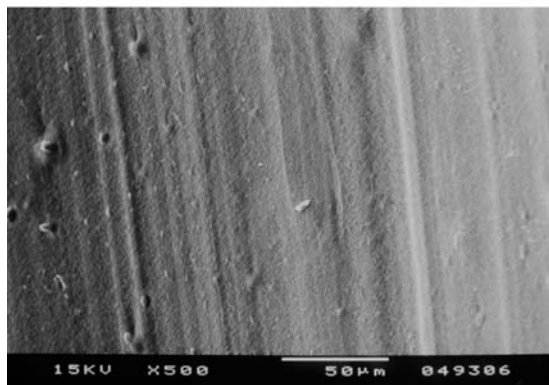
Figure 7(a)–(c) show the internal surfaces of Bard PTFE coated latex catheters, in as-received and post-immersion



(a)



(b)



(c)

Fig. 8 All-silicone, internal surface (a) as-received, (b) pH7, 30 days and (c) pH9, 30 days

condition. They are very similar to those of the hydrogel coated devices. The most apparent features were the frequently seen diatomaceous inclusions which, again, were not found within the exterior or through-wall material of this catheter type. This implies that the source of such deposits was the manufacturing process mentioned previously in the context of the hydrogel coated catheter samples.

As was the case with the hydrogel coated catheters, the internal surfaces of the PTFE samples appeared to have cracks and fissures present which were similar in nature to those

seen on the outside of this device type. Unlike the hydrogel samples, however, the PTFE samples also seemed to have the dimpled internal surface texture, associated with latex. This characteristic was not evident on the external surfaces of the PTFE coated catheters and suggests that the internal lumens of such devices are not successfully coated during manufacture. This theory is further supported by the fact that, in contrast to the external surfaces of this catheter type, there was little evidence found of any coating, be it damaged or intact, on the internal surfaces of the PTFE catheter samples. The smoother regions that were evident may have formed as part of a bacterial biofilm. This theory is supported by the fact that a large number of rod-like projections, which could be bacteria, can be seen in Fig. 7(b).

As before, whilst immersion did appear to have a detrimental effect on the internal surface characteristics of the PTFE coated catheter samples, there were no distinguishable trends caused by variations in pH or immersion periods.

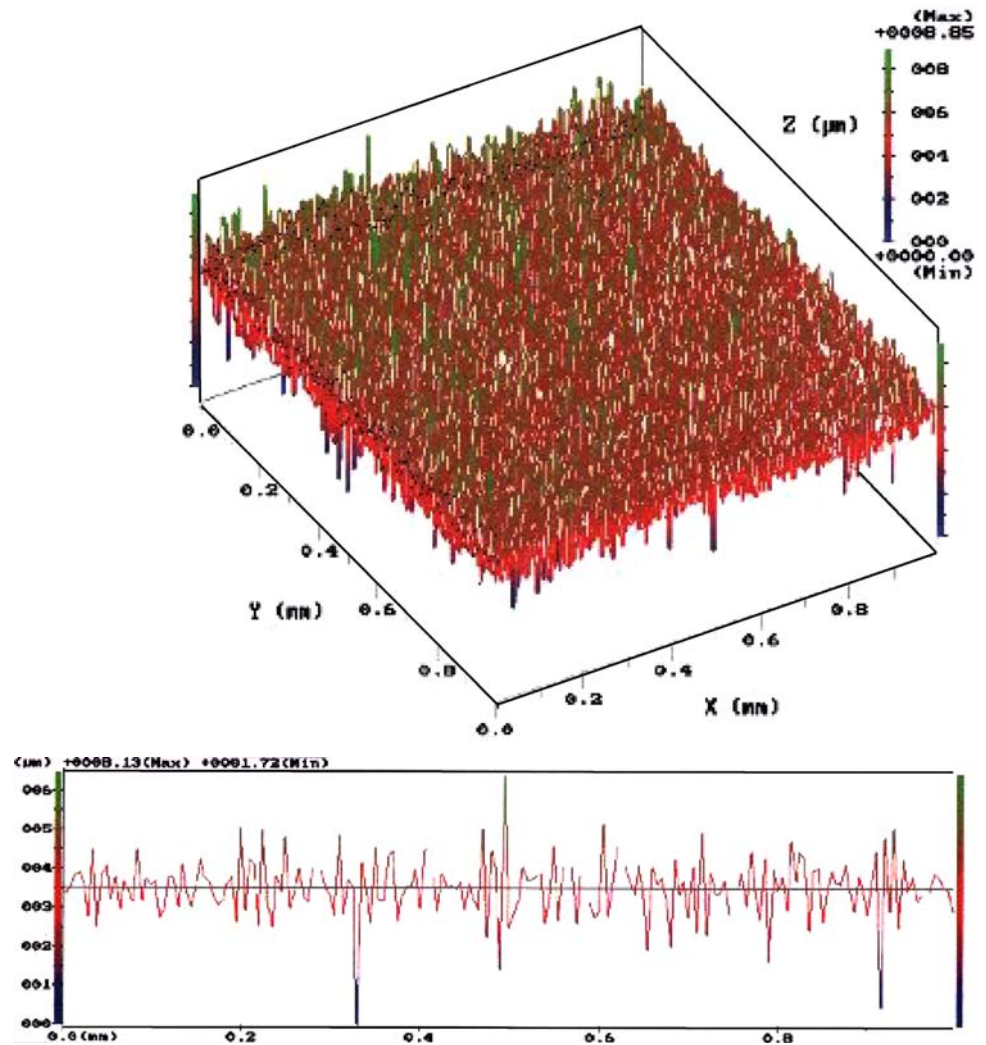
3.2.4 All-silicone catheter

Figure 8(a)–(c) show the internal surfaces of Ideal all-silicone catheters, in as-received and post-immersion condition. In contrast to the latex-based catheters analysed, the internal surfaces of the all-silicone devices were found to be relatively smooth and featureless, particularly in the case of the as-received sample. As the micrograph in Fig. 8(a) shows, there were no surface cracks or fissures, and the only feature apparent was the presence of parallel striations, running along the length of the tube. These were probably a result of the extrusion processes used to manufacture this type of catheter and were present on all the samples examined. Apart from such manufacturing artefacts, there was little evidence of any surface debris or inclusions, suggesting that stringent cleanliness standards have been adopted during the production of all-silicone device types.

Whilst the parallel extrusion lines were found on both as-received and post-immersion samples, the latter also appeared to have a large number of surface bubbles, as shown in Fig. 8(b). These were similar to those found on the external surfaces of soaked all-silicone samples, and it is possible that such features resulted from sample swelling due to liquid ingress, or were part of a bacterial biofilm that formed on the samples during soaking. The occasional presence of a small number of rod-like projections, examples of which can be seen in Fig. 8(b), support the latter theory.

As was the case with the external surfaces of the all-silicone devices, immersion appeared to have a detrimental effect on the internal surface characteristics of this catheter type. However, there were no distinguishable trends caused by variations in pH or soaking periods.

Fig. 9 Example of a 3-D (a) Surface Profile and (b) Line Profile



4 Optical surface profilometry

A *Proscan 2000* optical surface profilometer was used to produce a 3-D surface profile for each of the catheters included in the study. An example is shown in Fig. 9(a). From such images, line profiles were produced, as shown in Fig. 9(b). The surface roughness of the sample along that particular x-y plane could then be calculated. For each sample analysed, a total of eight line profiles were taken, and the values of surface roughness obtained used to calculate the average surface roughness of the entire scanned area.

Figure 10(a) and (b) show the average surface roughness values (R_a) for the internal and external surfaces of the conventional catheters, together with the standard deviations. Each bar chart shows results for as-received samples as well as those subjected to the various immersion regimes.

Both of the bar charts highlight the marked difference in the surface roughness of latex-based and all-silicone catheters, as was clearly evident during SEM analysis. The all-silicone catheters had a far superior surface quality as

compared to the latex-based devices; internally, they were approximately four times as smooth as the latex-based catheters, whilst externally they were three times smoother.

The measurements also indicate the relative differences between the three types of latex based catheter. It can be seen that the Bard PTFE and hydrogel coated catheters are consistently rougher internally and externally compared to the Rusch silicone coated latex device. This observation correlates with the SEM findings where both Bard catheters were found to have inorganic inclusions embedded in their internal surfaces.

The graphs clearly show that, in the case of all the catheters tested, the external surfaces were found to be smoother than the internal surfaces. This correlates with characteristics identified during scanning electron microscopy which showed a distinct visible difference between external and internal surfaces.

It is also apparent that soaking had little measurable effect on the surface roughness, with the exception of the PTFE coated, pH 7 for 90 days, sample. This extreme result may be

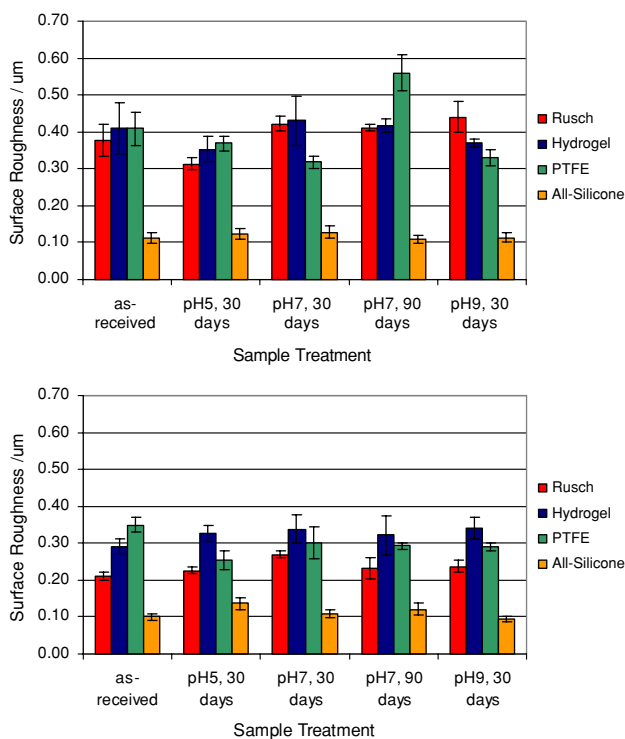


Fig. 10 (a) Internal surface roughness of catheters and (b) External surface roughness of catheters

due to profilometry being conducted on a particularly irregular section of the sample, or on an area that was damaged, or which had uncharacteristic surface features, including dust or other contaminants.

5 Conclusions

SEM revealed differences in the appearance of the internal and external surfaces of the three latex-based catheters. The Rusch silicone coated device had an evident dimpled surface texture, whereas the Bard PTFE and hydrogel devices both had a more ‘paved’ surface appearance which, in the case of the hydrogel device, was accentuated following the periods of immersion. Another major difference between the two manufacturers’ products was the presence of inorganic material identified as diatoms on the internal surfaces of both the PTFE and the hydrogel coated Bard catheters; this material was not seen on the Rusch devices. The presence of such extraneous material may have implications with respect to bacterial contamination and the nucleation and growth of crystal, which, in turn, may contribute to the associated problems of infection and blockage of urinary catheters.

For all the coated devices it was difficult to assess the thickness of the coating which appeared to vary in quality and ‘coverage’. However in some areas the coatings appeared to be peeling away from the underlying latex substrate. This

could be attributed to the mismatch in moduli between the coating and the substrate. In contrast, the internal and external surfaces of the all-silicone catheters were relatively smooth and featureless with little change over time.

The results from the laser profilometry correlated well with the SEM observations. The external surfaces of all the latex based catheters were found to be smoother than the internal surfaces; in the case of the Bard devices this may be due to the presence of the diatoms observed on the internal surfaces of these catheters. The internal surface roughness measurements for the Bard devices were also higher than the equivalent for the Rusch – this may be attributable to the same cause. For the Ideal all-silicone devices the surfaces were found to be much smoother both internally and externally compared to the latex based catheters.

In general, little difference was found between the surface roughness of ‘as-received’ and treated samples. The profilometry enabled quantitative values of surface roughness to be calculated and the results were found to correlate with the SEM analysis.

Analysis of the four different types of catheter made by three different manufacturers has shown there to be distinct differences in their surface characteristics. Given the inherent problems associated with the use of these devices, further work needs to be carried out to establish if such differences are significant in the context of the development of catheter infection and encrustation.

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