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Resistance of catheters coated with a modified hydrogel to encrustation during an in vitro test

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Summary. Mid-shaft specimens were cut from latex catheters coated with a modified hydrogel, latex catheters coated with silicone elastomer, and 100% silicone catheters. These specimens were subjected to controlled in vitro encrustation conditions. During a test period of 11 weeks, there was no significant difference in the quantities of encrusting deposits formed on the three materials.

Key words: Catheters – Encrustation – Hydrogels

Introduction

An in vitro test was used previously to show that a simple hydrogel-coated latex catheter resisted encrustation as well as 100% silicone indwelling catheters [4]; here we show that more recent catheters, coated with a modified hydrogel resist encrustation equally well. Both the inner and outer surfaces of the catheter are coated; the presence of the hydrogel coating on both these surfaces may be demonstrated by dyeing it with Congo red solution. In vitro tests provide a means of determining the tendency of the materials to encrust and so have an advantage over clinical trials; the results are not influenced by patient diet and medication or by metabolic differences between individuals [3, 4]. The modified hydrogel was introduced to further decrease friction when the catheter is inserted. In the USA the catheters coated with the simple hydrogel are referred to as "Biocath", while "Lubricath" refers to catheters coated with a modified hydrogel (C. R. Bard Inc.). In the UK "Biocath" catheters were originally coated with the simple hydrogel but now have a modified hydrogel coating (Bard Ltd.).

Indwelling urinary catheters encrust with a mixture of struvite, $NH_4MgPO_4 \cdot 6H_2O$, and calcium phosphate, in the form of poorly crystalline hydroxyapatite, $Ca_5(PO_4)_3OH$ [2, 7, 9]. The extent of encrustation can then be quantified by determining the mass of Ca and Mg deposited on a unit area of catheter surface. These surface densities (in mg cm^{-2}) were calculated from the Ca and Mg concentrations after the deposits had been dissolved in a known volume of acid; they are more reliable for assessing encrustation than simply weighing samples before and after the test, because latex absorbs water to an extent which depends on how heavily it is encrusted [4]. In the experiments reported here, the encrustation on samples cut from catheters coated with modified hydrogel was compared with that on samples cut from 100% silicone and silicone elastomer-coated catheters.

Materials and methods

Tests were performed on samples from the following types of catheter: latex coated with modified hydrogel (Biocath, Bard Ltd.), latex coated with silicone elastomer (Bard Ltd.), and 100% silicone (Bardex, C. R. Bard Inc.). All catheters of the same type were manufactured in the same batch. Sixty samples (6 cm long) were cut from the mid-shaft region of 18F catheters of each type i.e. 180 samples were tested in total. Each specimen was cut in half longitudinally to remove the inflation lumen and to expose the inner and outer surfaces equally. The surface area of each sample was measured by the method described previously [4].

Test samples were suspended from the lid of a reaction vessel, in an arrangement which ensured that samples could be removed at different times from an even distribution of positions. The samples were encrusted in artificial urine by the method described previously [4]. Further details of the composition of the artificial urine, and of the use of urease to initiate the reaction used in the process, were described elsewhere [3, 13].

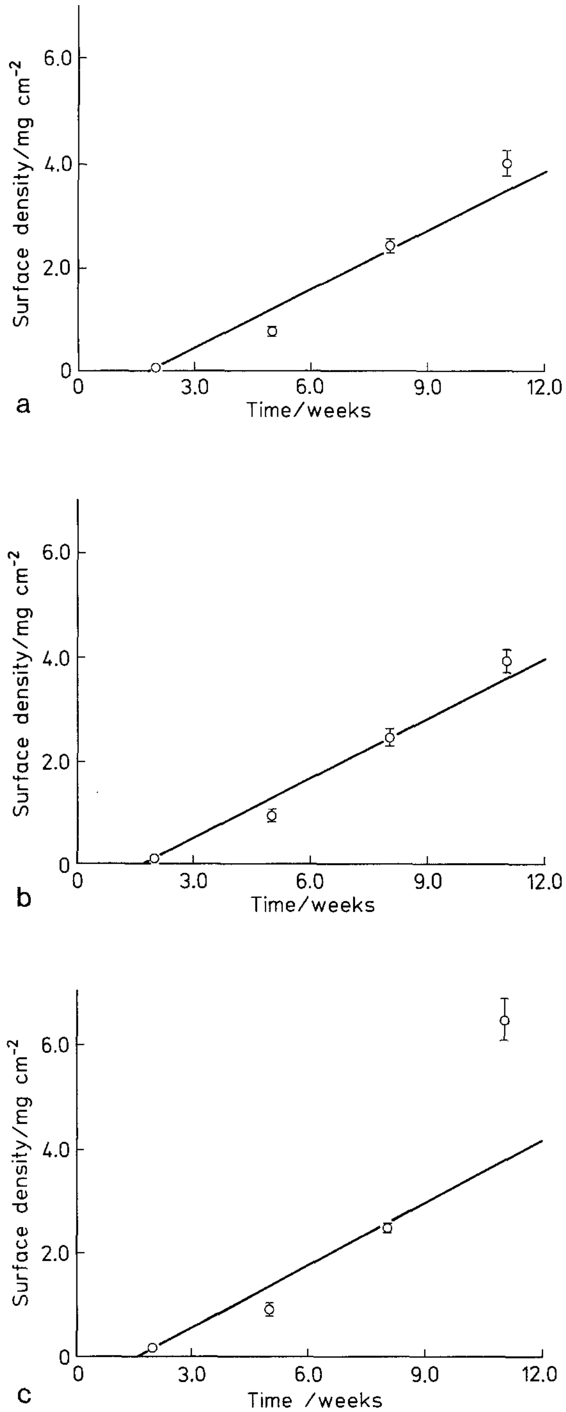

Fig. 1a–c. Ca surface density on (a) latex coated with modified hydrogel, (b) latex coated with silicone elastomer, and (c) 100% silicone. Error bars show standard errors

Ten samples of each type were removed after periods of 2, 5, 8, 11, 14 and 18 weeks. They were gently rinsed in distilled water and the deposits dissolved in acetic acid (7 cm^3; 1 M). Ca and Mg concentrations were determined by atomic absorption spectroscopy, as described previously [4], and converted to surface densities of Ca and Mg using the surface areas which had been measured at the beginning of the experiment. All statistical tests on the results were performed using the Minitab program package [15]. Chauvenet's criterion was used to provide an objective criterion for rejecting samples which yielded anomalous results, e.g. because of damage during handling as described previously [4].

Table 1. Coefficients for the regression lines of Fig. 1a–c. Regression lines have the form y = Ax + B where y is the surface density of Ca (mg cm^{-2}, and x is time (weeks). Standard errors of A and B are given in brackets

	A	B
(a)	0.38 (0.04)	−0.64 (0.09)
(b)	0.37 (0.05)	−0.64 (0.12)
(c)	0.40 (0.08)	−0.64 (0.20)

Results

The quantity of encrusting deposit at each stage of the test, up to and including 11 weeks, appeared similar on each of the three materials. However, after 11 weeks the surfaces became so heavily encrusted that the deposits were easily dislodged. Therefore, a detailed analysis of the results obtained at 14 and 18 weeks was considered invalid, in this experiment. In an experiment published previously, less deposit was formed, after the same time, so that results obtained from different materials could be compared after 18 weeks of encrustation [4]. This difference in quantity of deposit formed in different experiments appears to be a feature of in vitro encrustation techniques [5, 8]. However, comparison of the results from the material under test with those obtained from all-silicone samples, which are always included in our tests, overcame the problem of comparability between different experiments [3].

Statistical tests showed that there was no significant difference between the extent of encrustation on the three materials during the 11 weeks period of the test. Figure 1 shows the surface densitiy of Ca on each of the three materials at each of the sampling periods. The dependence of this surface density on time can be satisfactorily represented by the regression lines shown, which indicate a lag time of 1.7 weeks before there was appreciable encrustation. Similar results were obtained in a previous in vitro experiment [4], except that the encrustation rate was about half that reported here. The t-test showed that the slopes and intercepts (Table 1) of the three regression lines shown in Fig. 1 were not significantly different ($P > 0.05$). Using polynomials to represent the time dependence of the encrustation data did not give a significantly better fit than straight lines previously [4]; exactly the same

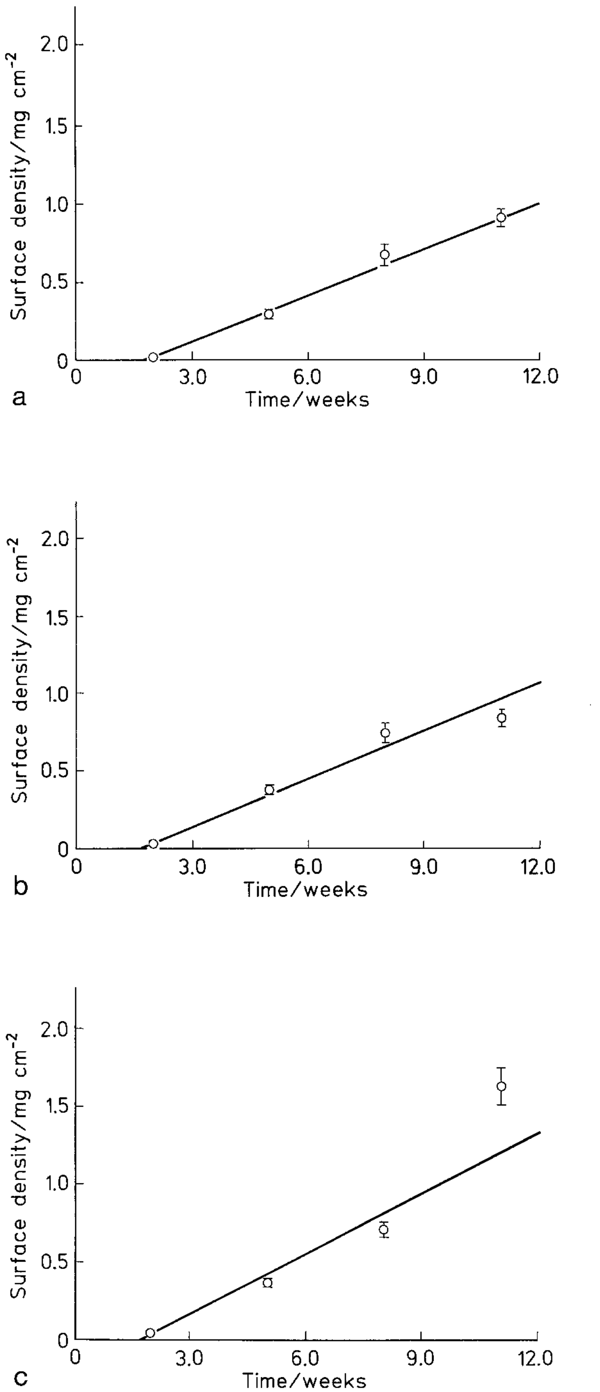

Fig. 2a–c. Mg surface density on (a) latex coated with modified hydrogel, (b) latex coated with silicone elastomer, and (c) 100% silicone. Error bars show standard errors

statistical treatment of the data was used here for consistency. Figure 2 shows that the surface density of Mg leads to the same conclusions. Once again, the time dependence of encrustation was adequately represented by straight lines whose slopes and intercepts (Table 2) were not significantly different for the three materials.

Table 2. Coefficients for the regression lines of Fig. 2a–c. Regression lines have the form $y = Ax + B$ where y is the surface density of Mg ($mg\ cm^{-2}$) and x is time (weeks). Standard errors of A and B are given in brackets

	A	B
(a)	0.101 (0.010)	−0.169 (0.032)
(b)	0.096 (0.004)	−0.167 (0.010)
(c)	0.130 (0.023)	−0.223 (0.071)

Discussion

100% silicone catheters are often preferred for long-term use because they are believed to resist encrustation better than most latex-based catheters [1]. Recently, latex-based catheters have been coated with hydrogels which are soft and slippery when wet, and so are less likely to damage the urethral mucosa [14]. A simple hydrogel coating was shown to resist encrustation equally as well as 100% silicone [4]. The reported superiority [10, 12] of hydrogel-coated surfaces in resisting encrustation was not confirmed in this series of experiments.

More recently catheters have been coated with a modified hydrogel which has a very low coefficient of friction, making the catheters easier to insert; these experiments were designed to test the susceptibility of this new material to long term encrustation in vitro. Like the hydrogel coatings tested previously, this modified hydrogel resists encrustation equally as well as 100% silicone in the tests. In vivo additional factors may be important. For example, it has been suggested that hydrogels tend to resist the colonisation of catheters by bacteria [10]. Any such resistance would be expected to delay the onset of encrustation since the formation of struvite is a consequence of bacterial infection [6]. Nevertheless, under the experimental conditions reported here, the modified hydrogel-coated latex catheters resisted encrustation as well as silicone elastomer-coated and 100% silicone catheters.

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