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Evaluation of a novel composite hydrogel polymer for use as a urinary tract biomaterial

M. M. TUNNEY AND S. P. GORMAN

School of Pharmacy, The Queen's University of Belfast, Medical Biology Centre, 97 Lisburn Road, Belfast BT9 7BL

The effective use of ureteral stents to facilitate drainage in the upper urinary tract is hindered by the fact that they are prone to bacterial biofilm formation and the development of encrustation which may lead to occlusion of the lumen with subsequent loss of urine flow (Tunney et al 1996a & b). The development of novel ureteral stent biomaterials which reduce bacterial adhesion, encrustation and intraluminal encrustation to a minimum is clearly necessary. Hydrogels that absorb and retain water within their structure possess properties which may be useful if fabricated as ureteral stents. The aims of this study were to evaluate the properties of a novel poly(ethylene oxide)/polyurethane copolymer and to determine its suitability as a ureteral stent biomaterial in comparison with silicone and polyurethane, two widely used stent biomaterials.

The inside and outside surfaces of the copolymer were examined using scanning electron microscopy (SEM), confocal laser scanning microscopy (CLSM) and atomic force microscopy (AFM). Tensile testing of the biomaterials was carried out using a Lloyd JJ tensile tester and the test data was used to calculate Young's modulus. Intraluminal encrustation (Tunney et al 1997) and adherence of ureteral stent biofilm isolates (Bonner et al 1997) were determined as described previously.

The outer surface of the copolymer appeared rougher by SEM than the lumen surface where channels varying in size from 1 to 3 μm in diameter were apparent. Examination of the hydrated copolymer by CLSM and AFM revealed that the channel sizes had increased with diameters ranging from 3 to 10 μm. The Young's modulus of the copolymer was significantly greater than that of silicone and polyurethane in their dry states. After hydration, however, the Young's modulus of the copolymer decreased significantly and was less than calculated for silicone and polyurethane (Table 1). The lumen of the copolymer remained patent for the 24 week period in which the simulated urine flow model was allowed to run. In contrast, lumen blockage required removal of silicone and polyurethane after 8 and 10 weeks, respectively. The amount of encrustation in the lumen of the copolymer after 24 weeks was significantly less ($p < 0.05$) than that in the lumen of silicone and polyurethane. Adherence of an *Escherichia coli* urinary isolate to the copolymer was similar to adherence to polyurethane but significantly less than adherence to silicone. In contrast, adherence of an *Enterococcus faecalis* urinary isolate to the copolymer was significantly less than adherence to polyurethane but similar to adherence to silicone.

Table 1. Young's modulus (MPa, mean±s.d.) of dry and hydrated biomaterials

Biomaterial	Dry	Hydrated
Silicone	14.21±0.92	18.73±1.77
Polyurethane	25.64±2.53	13.93±0.30
Copolymer	34.14±5.84	12.28±0.37

In conclusion, this novel copolymer has been shown to possess properties which would be beneficial if fabricated as a ureteral stent. It provided superior resistance to encrustation and intraluminal blockage compared to silicone and polyurethane in a simulated urine flow model. Furthermore, the fact that it is rigid when dry would enable insertion past obstructions in the ureter. Upon subsequent hydration it would become soft and flexible, thereby providing good patient tolerance.

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