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Development of a novel polymer coating for urinary medical devices: assessment of biodegradation and resistance to encrustation

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Deposition of ammonium magnesium phosphate hexahydrate (struvite) and calcium phosphate in the form of the poorly crystalline hydroxyapatite onto the surface of urological medical devices is a common problem in urological patients (Elves et al 1997). Colonisation of the biomaterial surface with urea-splitting bacteria (such as Proteus spp) causes alkalisation of the urine, thus lowering the solubility of struvite and hydroxyapatite which then become deposited on the device biomaterial (Gorman et al 1997). Such encrusted deposits can lead to blockage of the medical device, leakage of urine, bacteriuria, discomfort to patient etc. It has been suggested that coating of such urological devices with biodegradable polymers may assist in the removal of adherent microorganisms and urinary encrustation and hence, would be expected to decrease the incidence of many of the problems associated with urinary medical devices (Djokic et al 1997). One potential candidate is the biodegradable, aliphatic polyester Poly(ε−caprolactone). Poly(ε−caprolactone) is already used in controlled delivery of drugs and it is proven to be biocompatible and non-allergenic (Lin et al 1994).

The aim of this study was to examine the resistance to encrustation and biodegradation of the films of PCL alone and composites of PCL and Povidone-Iodine (PVP-I). High and low m.wt. PCL (50 000 and 4000 respectively) were used in this study and were dissolved in dichloromethane in range of m.wt. proportions. When required, PVP-I was dissolved in these polymeric solutions. Films were prepared by casting such solutions in glass petri dishes allowing dichloromethane to evaporate under controlled air flow at 25°C.

Each polymer was incubated in PBS (pH=7.4) at 37° C and biodegradation was quantified gravimetrically over a period of twenty one weeks. Scanning Electron Microscopy (SEM) was employed to assess the surface properties of these films before and during degradation.

Resistance to encrustation was evaluated as previously reported (Tunney et al 1996). The effects of PCL m.wt. ratio and % PVP-I on encrustation and biodegradation *in vitro* are shown in Table 1.

Table 1. Amount of Ca encrusted on, and the % biodegradation of each polymer following 2 and 21 weeks incubation, respectively

PCL	% PVP-I	Ca (μg/cm^2) ± sd	% weight loss ±sd
100	0	56.89±5.38	11.32±0.76
100	0.5	45.17±7.35	7.08±1.47
100	1	44.02±5.75	12.45±1.12
80/20	0	55.22±8.32	12.12±1.44
80/20	0.5	50.82±6.65	-
80/20	1	36.85±3.33	12.47±1.20
60/40	0	54.55±8.48	9.87±5.20
60/40	0.5	45.50±2.66	14.16±1.30
60/40	1	40.97±5.42	13.35±2.94
50/50	0	43.05±5.21	15.55±2.79
50/50	0.5	42.61±5.76	-
50/50	1	40.68±8.05	14.32±2.55
40/60	0	39.39±6.68	25.50±1.02
40/60	0.5	36.36±3.88	22.12±1.66
40/60	1	36.86±3.31	20.91±2.20

Increasing film content of lower m.wt. PCL significantly decreased both encrustation and the rate of biodegradation. Increasing the content of PVP-I significantly reduced encrustation, reflecting the possible effects of PVP-I on the solubility of the inorganic salts. Conversely PVP-I did not effect the rate of biodegradation.

As a result of these findings, it may be concluded that certain formulations of PCL and PVP-I, when used as a coating, may be useful for reducing the incidence of encrustation onto the surface of existing urinary medical devices.

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