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Development and testing of a novel dynamic encrustation model

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Reproducing conditions which are encountered by urinary tract prostheses *in vivo* has been investigated by many workers. Models developed include sections of biomaterials suspended in infected human urine (Gleeson et al., 1989), infected artificial urine (Schmitz et al., 1993) or in artificial urine designed to mimic infected urine (Cox et al., 1988; Tunney et al., 1996; Cox et al., 1987). As there is movement of urine in the upper ureteric portions of the urinary tract where stents reside, it would be useful to have a model to mimic these conditions. In this study a novel dynamic model has been developed to simulate urine flow in the ureteric portion of the stent.

The aims of this study were to test the novel model and compare it to a static encrustation model (Tunney et al., 1996). The model was tested using three urinary biomaterials polyurethane (PU), percuflex and silicone.

The dynamic encrustation model consisted of a glass reaction vessel and a pumping system to circulate artificial urine from a reservoir. Material sections to be tested (x3) were secured equidistant along each of 3 mandrels per vessel. The model was placed in an incubator at 37°C. The composition of the artificial urine was similar to that used by Tunney et al., 1996 but with a reduced albumin level. Validation of the dynamic model showed no statistically significant difference in calcium or magnesium encrustation between any position on any mandrel in any vessel, thus enabling its use to compare encrustation developing on biomaterials.

After two weeks in the model, encrustation on each material section was removed using ultrasonication and 1M acetic acid. Calcium and magnesium encrustation levels on each material were detected using atomic absorption spectrophotometry. One-way analysis of variance was used to compare the levels of calcium and magnesium encrusting deposits on the different materials.

Testing of encrustation using the static model was as described by Tunney et al., 1996.

	Dynamic Model	
	Ca (μg/cm²)	Mg (μg/cm²)
PU	40.79±3.18	25.47±2.14
Percuflex	42.39±3.04	28.64±3.89
Silicone	25.29±2.26	20.32±1.52

	Static Model	
	Ca (μg/cm²)	Mg (μg/cm²)
PU	86.81±10.28	41.82±6.19
Percuflex	91.28±8.47	45.12±5.14
Silicone	71.27±6.14	32.84±2.18

A clinical need exists for materials resistant to encrustation for use in the urinary tract. The dynamic model described here has proven to be a useful *in vitro* model to mimic *in vivo* conditions and so study the performance of existing biomaterials. The reaction vessel is simple, different materials can be compared concurrently and safety problems are reduced as an artificial urine is used.

A comparison was made between the level of deposits found on the 3 materials after testing in this dynamic model and in the static model. The levels of encrustation detected on silicone were significantly lower than on percuflex or PU. The tables show that the dynamic model deposited less calcium and magnesium on the materials' surfaces than on the static model. Some of the deposits are dislodged due to the constant flow of urine over the surfaces of the materials mimicing more closely the *in vivo* situation. When compared to the static model, this novel method gave the same rank order of encrustation on each of the three biomaterials, but at a much lower level as can be seen in the tables. This dynamic model is, therefore, a suitable method of assessing the encrustation of urinary tract biomaterials.

Cox, A.J.; Hukins, D.W.L.; Davies, K.E. (1987) Eng. in Med. 16: 37-41.

Cox, A.J.; Hukins, D.W.L.; Sutton, T.M. (1988) Br. J. Urol. 61: 156-161.

Gleeson, M.J.; Glueck, J.A.; Feldman, L. (1989) Trans. Am. Soc. Art. Int. Org. 35: 495-498.

Schmitz, W.; Nolde, A.; Marklein, G. (1993) Cells and Materials 3: 1-10.

Tunney, M.M.; Bonner, M.C.; Gorman, S.P.; Keane, P.F. (1996) Biomaterials 17: 1025-1029.