Minimising Urethral microtrauma: Evaluating Intermittent Catheters using an *Ex Vivo* Porcine Model

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Background

Intermittent catheterisation (IC) is a technique for patients requiring bladder drainage, with hydrophilic-coated ICs offering advantages over uncoated ICs by reducing friction and enhancing comfort. Hydrophilic coatings, typically composed of polyvinylpyrrolidone (PVP), absorb water to create a lubricious surface. However, PVP can become mucoadhesive upon drying, potentially increasing friction during catheter withdrawal (1). Now a recently introduced IC provides an alternative coating-free, **integrated amphiphilic surfactant (IAS)** technology with hydrophilic properties comparable to existing hydrophilic-coated ICs but without the problematic adhesive properties associated with **PVP** which could improve patient experience.

Existing methods for assessing IC performance often lack physiological relevance and provide no insight into the risk of urethral microtrauma.

Study aims

1. Develop a physiologically relevant *ex vivo* model for the evaluation of IC performance.
2. Investigate urethral microtrauma that occurs due to IC.
3. Compare the effect of IAS IC and hydrophilic-coated IC surfaces on urethral microtrauma.

Methods

Ex vivo porcine urethral model

An *ex vivo* porcine urethral model was designed using texture analyser apparatus (1). Urethras were placed into centrifuge tubes and secured with agar (**Figure 1**). One uncoated PVC ICs and four different PVP-coated catheters were compared with the IAS IC.

Catheterisation force

ICs were lowered (5 mms^{-1}) into the urethra, then withdrawn after 120 s (average time to self-catheterise) (1). Force required for IC insertion and withdrawal from the urethra was determined.

PVP-coating delamination

ICs were stained with trypan blue. Images of the ICs and the urethra, post-catheterisation, were taken.

Methods cont'd

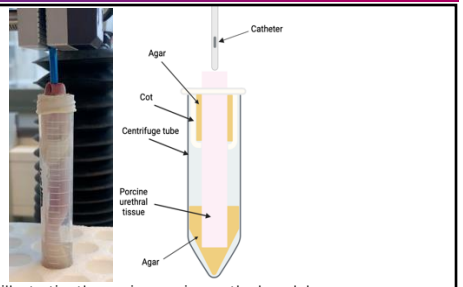


Figure 1. Diagram illustrating the *ex vivo* porcine urethral model

Urethral microtrauma

Histological samples (4 µm) were prepared, and immunohistochemistry performed (primary antibody anti-E-Cadherin rabbit 1/100 / secondary antibody Goat anti-rabbit IgG Alexa Fluor 488). Fluorescence was used to analyse potential damage to the urethra's transitional membrane after IC use.

Results

Withdrawal force

Force required to remove uncoated PVC, PVP-coated brand's 2 and 4 ICs from the porcine urethra (0.29 N ± 0.05, 0.38 N ± 0.06, 0.38 N ± 0.06 respectively) was significantly greater than the IAS IC (0.24 N + 0.06) (**Figure 2**).

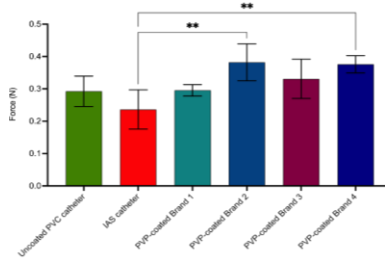


Figure 2. Force (N) required to remove intermittent catheters from porcine urethra after 120 s indwell time in an *ex vivo* porcine urethral model.

Error bars represent S.D.s of the mean values (n=5). Where ** represents a statistically significant difference ($p < 0.01$).

PVP-coating delamination

After staining, hydrophilic PVP-coatings were observed to delaminate from the catheter surface, remaining within the urethra after IC (**Figure 3**).

Results cont'd

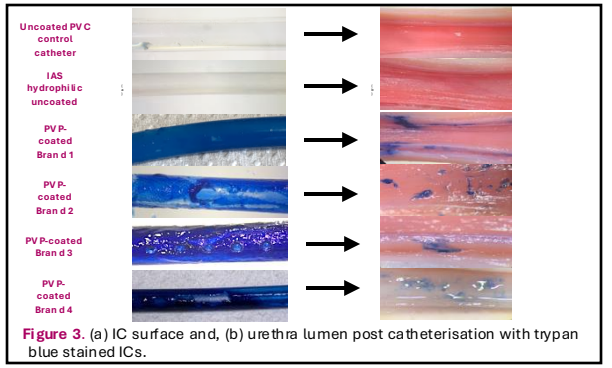
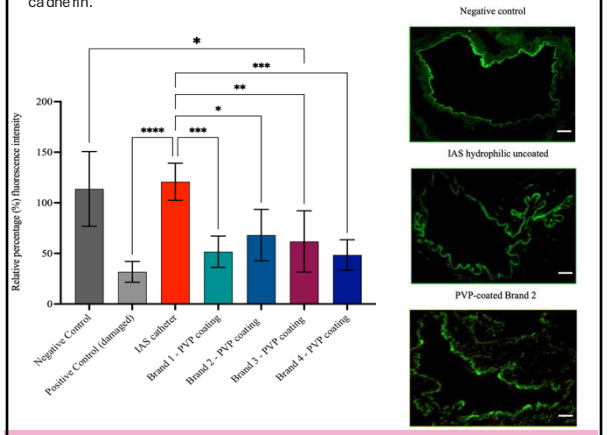


Figure 3. (a) IC surface and, (b) urethra lumen post catheterisation with trypan blue stained ICs.

Urethral microtrauma

Following 120 s contact with urethral tissue hydrophilic PVP-coated Brand 1, Brand 2, Brand 3, Brand 4 and the IAS IC displayed 51.68±15.45, 68.10±25.38, 61.85±30.264, 48.44±15.07 and 120.82±18.37 relative percentage (%) fluorescence to uncatheterised negative control respectively. As an important intercellular adhesion protein in epithelial tissues, loss of e-cadherin suggests damage to the uroepithelium (**Figure 4**).

Figure 4. Relative percentage fluorescence equivalent to e-cadherin component in the urethral transitional membrane after IC. Images depict fluorescent e-cadherin.



Error bars represent S.D.s of the mean values (n=5). Where *, **, *** and **** represents a statistically significant difference ($p < 0.05$, 0.01, 0.001 and 0.0001 respectively).

Discussion

Following 2 mins indwell time, (typical average time to self-catheterise), the hydrophilic PVP-coated catheters brand 2 and 4 required a **greater force to withdraw** from the *ex vivo* porcine urethral model in comparison to novel IAS hydrophilic catheters.

All of the **PVP-coated catheters** were observed to exert coating **delamination** and remain behind in the urethras. Moreover, the *ex vivo* model indicated the IAS hydrophilic IC caused significantly less damage to urethral transitional membrane than the hydrophilic PVP-coated ICs.

As the PVP-coated catheters dry out, the potentially adhesive surfaces may stick or increase friction between the catheter surface and the urethral tissue, requiring more force on withdrawal, and could result in coating removal and microtrauma which agrees with the data generated from our proposed *ex vivo* model.

Conclusion

1. The *ex vivo* porcine model provides a more physiologically relevant method of testing the performance of ICs.
2. PVP-coated ICs exerted coating delamination and increased damage to the urethral tissue.
3. Preliminary *ex vivo* model findings suggest that the use of IAS hydrophilic ICs could have the potential to cause less damage to urethral tissue than uncoated and hydrophilic PVP-coated ICs.

References & Acknowledgements

1. Pollard (et al.), Biotribology 2022; 32:100223.

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