# Evaluating the effects of intermittent urinary catheters on urethral microtrauma

Burns, J., Pollard, D., Ali, A., Wylie, M., & McCoy, C. (2023). Evaluating the effects of intermittent urinary catheters on urethral microtrauma. *Continence*, *7*(Supplement 1,), Article 18. https://doi.org/10.1016/j.cont.2023.100736

**Published in:**
Continence

**Document Version:**
Publisher's PDF, also known as Version of record

# EVALUATING THE EFFECTS OF INTERMITTENT URINARY CATHETERS ON URETHRAL MICROTRAUMA

Burns J[1], Pollard D[2], Ali A[2], Wylie M[1], McCoy C[1]
*1. School of Pharmacy, Queen's University, Belfast BT9 7BL, United Kingdom, 2. ConvaTec Limited, GDC First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, United Kingdom*

## HYPOTHESIS / AIMS OF STUDY

The introduction of hydrophilic-coatings in the 1980s provided a paradigm shift in care for patients with voiding dysfunction and, a significantly improved user experience compared to uncoated intermittent urinary catheters. Hydrophilic coatings absorb water, producing a hydrated catheter surface with reduced friction but such coatings often contain Polyvinylpyrrolidone (PVP), which causes the catheter surface to become adhesive as it dries out (1). Consequently, increased force and friction during catheter withdrawal may cause complications including urethral microtrauma, pain, discomfort and impact patient quality of life.

Recently, a new device with novel coating-free technology known as integrated amphiphilic surfactant (IAS) has been developed with hydrophilic surface properties comparable to existing hydrophilic coated catheters but without the problematic adhesive properties associated with PVP during catheter dry out. The aim of this study was to compare the effect of IAS catheter surfaces and hydrophilic coated catheter surfaces on urethral microtrauma by using a biomimetic model of the urethral lining to assess cell damage and removal by shearing.

It was hypothesised that the IAS catheters will cause less cellular damage than hydrophilic coated catheters.

## STUDY DESIGN, MATERIALS AND METHODS

To investigate urethral microtrauma that occurs as a consequence of intermittent catheterisation, a biomimetic model was designed from a modified coefficient of friction (CoF) assay using CoF-1000 apparatus, (Figure 1) (2). T24 human urothelial cells monolayers were cultured in-vitro on fibronectin-coated silicone sheets (50x103 cells/cm2). No ethical approval required. A range of commercially available catheters, one uncoated PVC catheter and three hydrophilic-coated catheters, were chosen and compared with the novel IAS catheter.

Urinary catheters were attached to a 15 g weight and placed onto the cell-seeded substrate. The catheters were advanced over the cell monolayer (software-programmed speed of 15 cm/min for 5 cm) immediately, or after 2 minutes to mimic real life catheterisation and assess catheter dry-out.

To examine for microtrauma, cells were stained with crystal violet and visually observed for damage by light microscopy and image analysis. Cell damage was scored according to detachment, cell lysis and debris observed. A template for grading cell damage was adapted from the morphology grading of cytotoxicity approved by ISO (3). The attachment of urethral cells to the catheter surfaces was also examined by fluorescent staining. 4% w/v paraformaldehyde was added to the catheter surface to fix potentially adhered urethral cells. Fluorescent microscopy was used to visually examine and quantify cell attachment.

Based on a one-way ANOVA, performing the biomimetic model with 12 replicate samples allowed for a 10% difference between cell damage caused by the IAS catheters and the hydrophilic coated catheters to be determined.

## RESULTS

Preliminary cell culture data (n = 6) shows minimal cell removal was observed for both the hydrophilic PVP-coated and IAS hydrophilic catheters when fully hydrated, (tested immediately after lubrication). However, a significant increase in cell removal and damage to the monolayer was observed for hydrophilic PVP-coated catheters, in comparison to novel IAS hydrophilic catheters after 2 minutes, (Figure 2). Significantly greater cell coverage ($p < 0.0001$) remained after catheterisation with the IAS hydrophilic catheters (75.1 % ± 9.9) when compared with two of the PVP-coated catheters, (25.1 % ± 6.2, 48.5 % ± 6.2 and 72.7 % ± 7.7). Moreover, the IAS hydrophilic catheters demonstrated slight to mild cell damage whereas the hydrophilic-coated catheters showed moderate damage.

## INTERPRETATION OF RESULTS

Following 2 mins of contact time with the cell monolayer, (typical average time to self-catheterise), the hydrophilic PVP-coated catheters displayed greater cell damage in comparison to novel IAS hydrophilic catheters. As the PVP coated catheters dry out, the potentially adhesive surfaces may stick or increase friction between the catheter surface and cell monolayer, exerting enough force to overcome cell adhesion to the silicone substrate. Findings from this in vitro biomimetic model demonstrate that novel IAS hydrophilic catheters may have the potential to cause less uroepithelial cell damage than hydrophilic PVP-coated catheters.

## CONCLUDING MESSAGE

The use of IAS (coating-free) hydrophilic catheters instead of hydrophilic catheters may help reduce urethral microtrauma experienced during catheter withdrawal from the bladder. This may reduce pain and catheter related complications thus improving quality of life in patients performing self-catheterisation.

## FIGURE 1

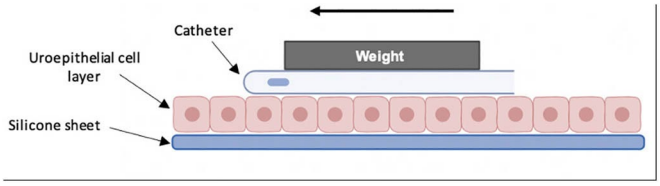


**Figure 1: Diagram illustrating the biomimetic urethral model.**

## FIGURE 2

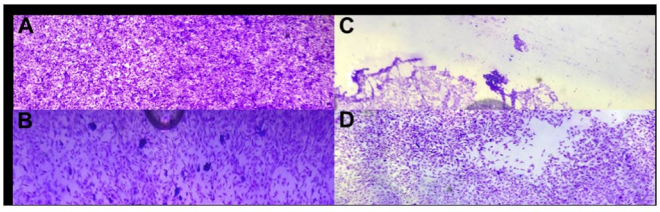


**Figure 2: T24 monolayers seeded on silicone substrates (A) pre-catheterisation and, post-catheterisation after 2 minutes contact with (B) IAS hydrophilic catheter, (C) Brand 1 PVP-coated catheter, (D) Brand 2 PVP-coated catheter. Cells were incubated at 3**

## REFERENCES

1. Teodorescu M, Bercea M. Poly(vinylpyrrolidone) - A Versatile Polymer for Biomedical and Beyond Medical Applications. Polymer-Plastics Technology and Engineering. 2015;54(9):923–43.
2. Humphreys O, Pickering M, O'Cearbhaill ED, Flanagan TC. A biomimetic urethral model to evaluate urinary catheter lubricity and epithelial micro-trauma. Journal of the Mechanical Behavior of Biomedical Materials. 2020;108:103792.
3. ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity.

**Funding** ConvaTec Limited, GDC First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU, United Kingdom **Clinical Trial** No **Subjects** None

**Continence 7S1 (2023) 100736**
**doi:** 10.1016/j.cont.2023.100736