FeelClean[™] Technology Cell Culture Study Outcomes

A comparative study conducted at Queen's University Belfast to understand the effect catheterisation has on the cells of the urethral lining



...causes less uroepithelium cell damage or microtrauma than PVP-coated hydrophilic catheters in the biomimetic urethral model¹

Study rationale

A **known issue** with traditional **PVP-coated hydrophilic** catheters is that the coating becomes **adhesive as it dries**, potentially **sticking** to patients' urethral mucosa during use.¹

FeelClean™ Technology has been designed to avoid such stickiness by removing the need for the PVP-coating and integrating the lubricious properties within the core of the catheter.

Catheters investigated

| Catheter | Technology | |
|--|---------------------------|--|
| Self-Cath | Uncoated control | |
| GentleCath™ Glide | FeelClean™ Technology | |
| Vapro Pocket™ SpeediCath® Flex LoFric® Origo | Hydrophilic PVP-coated | |



The biomimetic model

Human uroepithelial cells fixed to a silicone base mimicked the properties of the urethra. Catheters were hydrated to manufacturers' IFUs and pulled across the cell layer at a speed of 15 cm/min for 5 cm.



The tests



Insertion

Catheters were still fully hydrated after 0 min of contact with cells.



Withdrawal Hydration levels dropped after 2 mins of contact with cells. To explore the potential effect of different catheters on urethral health, two tests were conducted to mimic the catheter insertion & withdrawal at 0 mins and 2 mins. The scientists assessed three factors after the catheter was pulled across the cell layer.

| TESTS | Cell detachment | Cell adhesion | Cell health |
|------------|---|---|---|
| | Percentage area of cells | Percentage area of the | How damaged were the cells |
| | remaining on the silicone base | catheter covered in cells | left on the silicone base? |
| | All hydrophilic catheters | All hydrophilic catheters | Damage to cell health ranged |
| | performed equally well, causing | performed equally well with few | from none for LoFric® Origo to |
| | <20% cell layer disruption. | cells attached to their surface. | moderate for VaPro Pocket™. |
| MITHDRAWAL | Significant cells detachment with VaPro Pocket™ and SpeediCath® Flex vs GentleCath™ Glide and LoFric® Origo. | VaPro Pocket™ had 5x more cells attached than others. Surprisingly, SpeediCath® Flex had few cells attached. | All hydrophilic catheters caused moderate to severe damage. GentleCath™ Glide caused only mild. |
| SUMMARY | GentleCath [™] with FeelClean [™] Technology showed superior performance compared to VaPro Pocket [™] and SpeediCath® Flex at 2 minutes. | Preliminary investigations suggest that SpeediCath® Flex's coating sheds onto the cell layer while the adhesive drying properties of PVP could cause damage. | GentleCath™ with FeelClean™ Technology was the only hydrophilic catheter to not cause moderate-to-severe damage. |

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REFERENCES: 1. Humphreys O, Pickering M, O'Cearbhaill ED, Flanagan TC. A biomimetic urethral model to evaluate urinary catheter lubricity and epithelial micro-trauma. J Mech Behav Biomed Mater. 2020;108:103792. doi:10.1016/j.jmbbm.2020.103792. In vitro data on file.