New micro-hole zone catheter prevents flow-stops and bladder micro-trauma during intermittent catheterisation

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Introduction:

Urinary tract infections (UTIs) are the main complication in clean intermittent catheterization. Among others, increased post-void residual urine and bladder microtrauma represent risk factors for UTIs.
In a previously published study **[1]** we presented the results from the use of three male intermittent conventional eyelet catheters (CEC) in an *ex vivo* bladder model mimiciking the '*In vivo*' conditions of the lower urinary tract (LUT). Mucosal suction was perceived by the operator 60—100 % of the tested catheter types at first flow stop. The flow stops in the CECs result in large residual urine volumes. A reduction in the UTI-related parameters may be beneficial in lowering the number of UTI cases in users.

Methods:

We measured UTI-related parameters for innovative micro-hole zone technology catheters (MHZC) with a drainage zone of 80+ micro-holes and compared it to a SpeediCath® CEC in CH12 size. We assessed the flowrate, residual volume at first flow-stop, intra catheter pressure, and incidence of mucosal suctioning in an ex vivo porcine LUT model **[1]**. Four different micro-hole diameters were investigated. We examined the flow rates, residual volume of urine, and occurrence of mucosal suctions and flow stops for each catheter type. Furthermore, we collected cystoscopic images from inside the catheter lumen, in vivo, in pigs to expand the mechanistic understanding of the MHZC functionality. All results presented herein was conducted at a simulated abdominal pressure of 50 mmH_2O, which is the highest pressure described in the literature, and therefore considered as worst case.

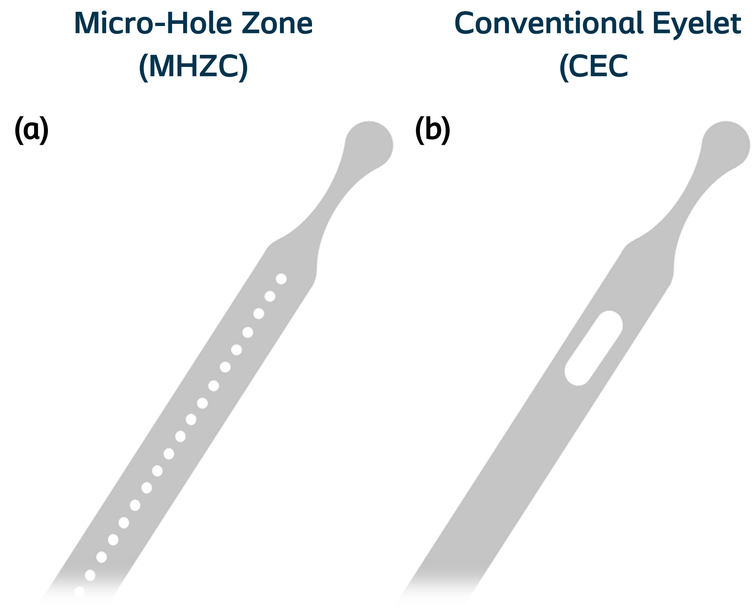

Figure 1 *- Catheter overview and mucosal suction. Conceptual schematic overview of* ***(a)****: MHZC shown with a row of many micro-holes,* ***(b)****: CEC control catheter.*

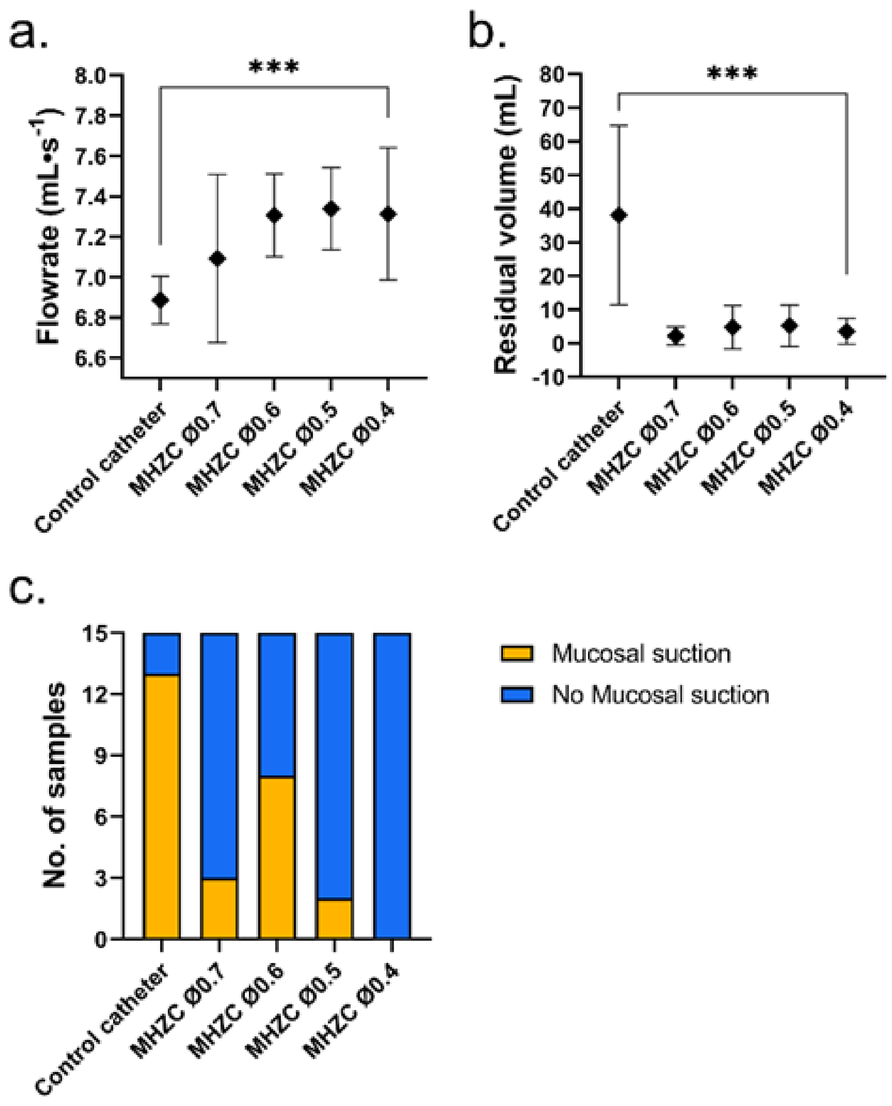

Figure 2 *- Results from measured UTI-parameters for CEC control catheter and four different MHZC configurations with decreasing micro-hole size from Ø0.7 to Ø0.4.* ***(a)****: Flow rate during the first 5 seconds of catheterization.* ***(b)****: Residual volume in the bladder at first flow stop,* ***(c)****: the occurrence of mucosal suction as perceived by the operator at first flow stop.*

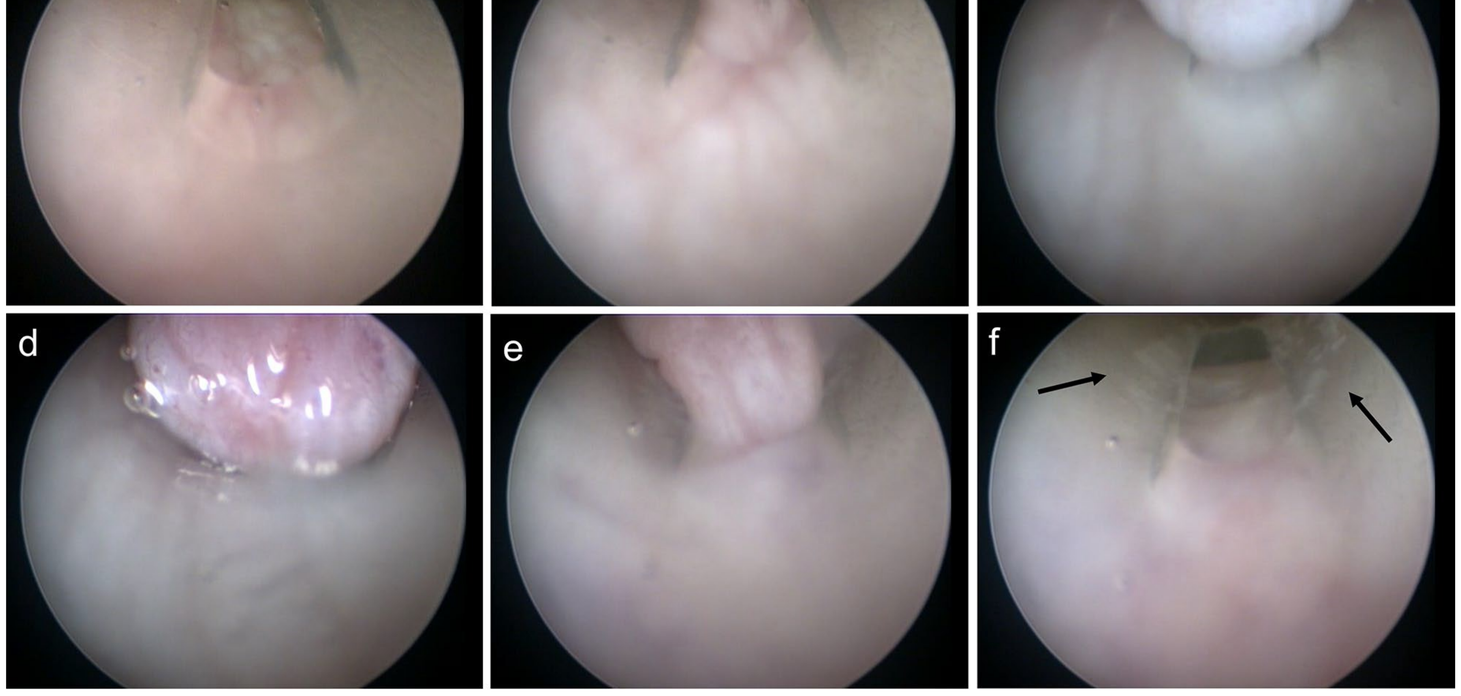

Figure 3 *- In vivo cystoscopy from pig study showing different stages of a mucosal suction in a CEC, showing large ingress of tissue into the catheter lumen, and leaving visible residue from the tissue inside the catheter* ***(f).*** *From published journal article* **[1]**.

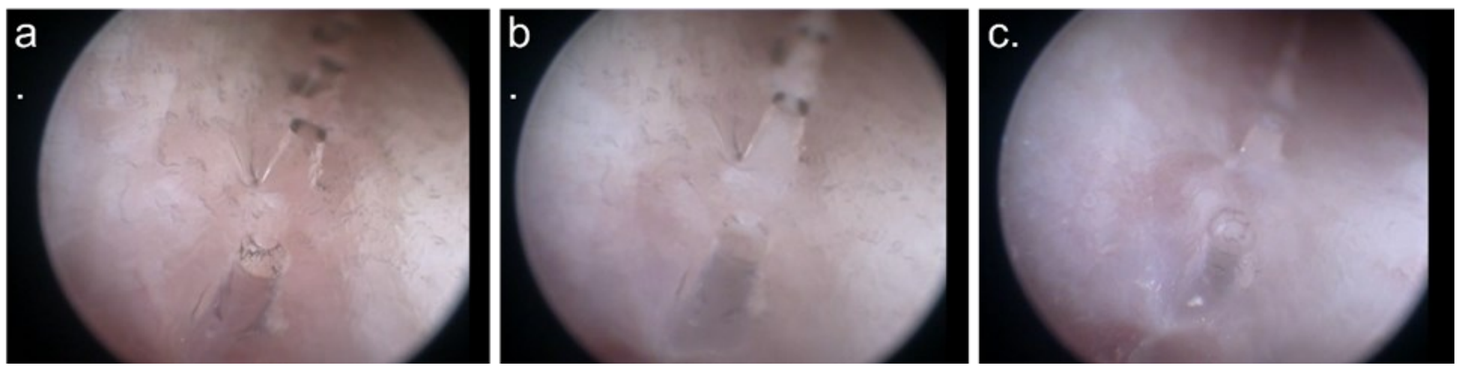

Figure 4 *- In vivo cystoscopy using three different versions of the Ø0.4 MHZC. Here, the ingress of tissue into the catheter lumen is limited to the eyelets, avoiding the scraping effect seen in* ***Figure 3.***

Results:

All MHZCs had significantly higher flowrates (**Figure 2a**) and significantly lower residual volumes than the CEC. Investigating mucosal suction, only the Ø0.4 mm MHZC showed no mucosal suctioning events in contrast to the CEC (**Figure 2c**). Cystoscopic studies showed gradual bladder folding around the MHZC during voiding, but without complete blocking of the micro-holes (**Figure 4**), or bladder tissue ingress through the holes, thus avoiding flow-stops, improper voiding, and micro-trauma.

Conclusion:

The MHZC significantly reduces residual urine and bladder mucosal suction during intermittent catheterization, practically eliminating the need for catheter repositioning and potentially decreasing the risk of UTIs.

[1]: Tentor, F., Schrøder, B. G., Nielsen, S., Schertiger, L., & Stærk, K. (2022). Development of an ex vivo porcine lower urinary tract model to evaluate the performance of urinary catheters. Scientific Reports, 1–17. https://doi.org/10.1038/s41598-022-21122-6