

# Reduction in eyelet size in intermittent urinary catheters results in less urothelial microtrauma in the bladder

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## Introduction

Microtrauma in the bladder is considered as a risk factor for development of infections in the lower urinary tract. In some catheter types, e.g., indwelling and supra-pubic catheters, microtrauma in the bladder has been associated with the phenomenon mucosal suction. However, the phenomenon is poorly described for intermittent catheters.

## What is mucosal suction?

Mucosal suction describes the suction of the mucosa of the bladder into a catheter eyelet during drainage due to localized pressure dynamics (Figure 1b). It occurs when the last catheter eyelet is closed by the bladder tissue generating a negative pressure wave and often resulting in a flow stop.

## What can we do?

By replacing the conventional eyelets (Figure 1a) with a Micro-hole drainage Zone (Figure 1c) with many holes we can lower the negative pressure peaks during a mucosal suction (Figure 1d) and lower the level of microtrauma.

## Methods

We compared a Conventional Eyelet Catheter (CEC) with a Micro-Hole Zone Catheter (MHZC) in an ex-vivo porcine mucosal suction model able to recreate the pressure conditions of the bladder. We used the model to record intra catheter pressures, and subjected tissue to mucosal suction with the different catheter technologies to be analyzed using histology. A simulated abdominal pressure of 50 mbar was used to mimic a person standing. The pressure was applied by conducting the suction in a water reservoir.

## Pressure Dynamics During Drainage

Recorded pressures (Figure 2) near the eyelet was significantly higher for the conventional eyelet catheter (CEC) than the pressures recorded for the catheter featuring the Micro-hole Zone (MHZC). Each conventional (CEC) had a single eyelet occluded with porcine bladder tissue, while closure of 8 micro holes simultaneously was done for the MHZC.

Table 1 : Summary statistics of pressure peaks. 7 catheters tested in 3 different bladders for, total of 21 runs per catheter type.

Catheter	Negative pressure peak Average (mbar)	Standard Deviation Relative (%)
CEC	-806.8	8.97 %
MHZC	-192.4	35.63 %

Figure 1: Catheter overview and mucosal suction. (a): Overview of a CEC. (b): Suction mark from mucosal suction with CEC (c): Overview of a MHZC, and (d): Small micro suction marks from the MHZC.

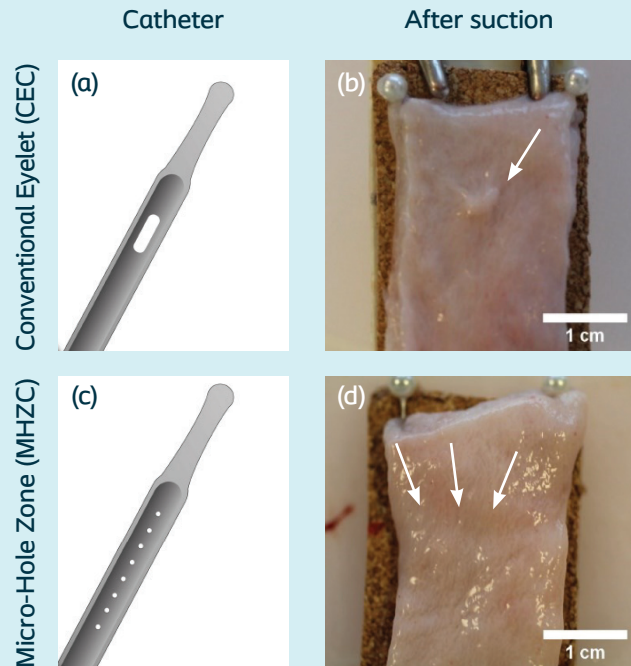
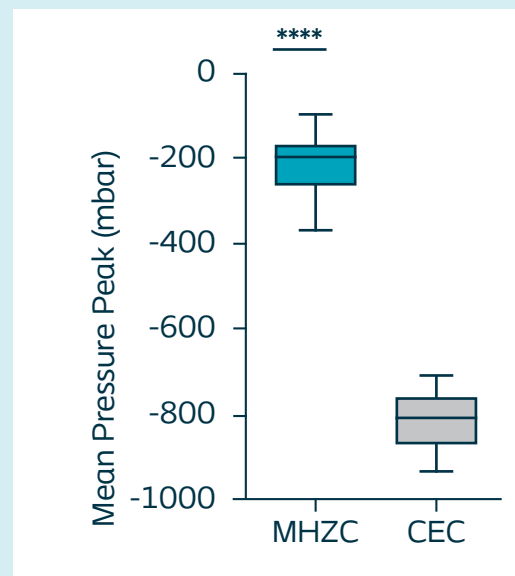


Figure 2: Pressure recordings of negative pressure peaks, or suction, during mucosal suction in CEC and MHZC. A significant difference was found between the negative pressure peaks of the catheter types ( $p < 0.0001$ ).



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### Histological analysis

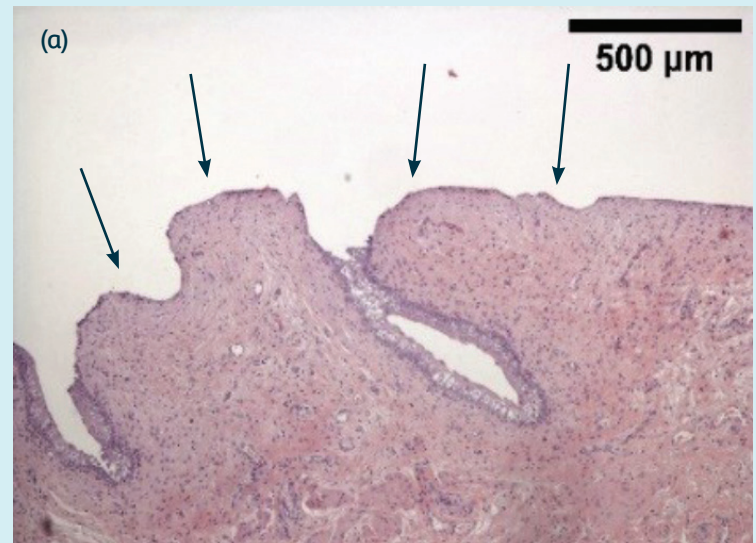
Histological analysis of the porcine tissue samples subjected to mucosal suction using CEC showed exfoliation of the bladder urothelium (arrows in **Figure 3a**). The lack of urothelium allows for easier access for bacteria and other harmful substances associated with urinary tract infections. For the MHZC the microtrauma was limited to thinning of the urothelium and tiny breaches (arrows in **Figure 3b**), preserving more of the natural defence of the bladder against urinary tract infections.

### Conclusion

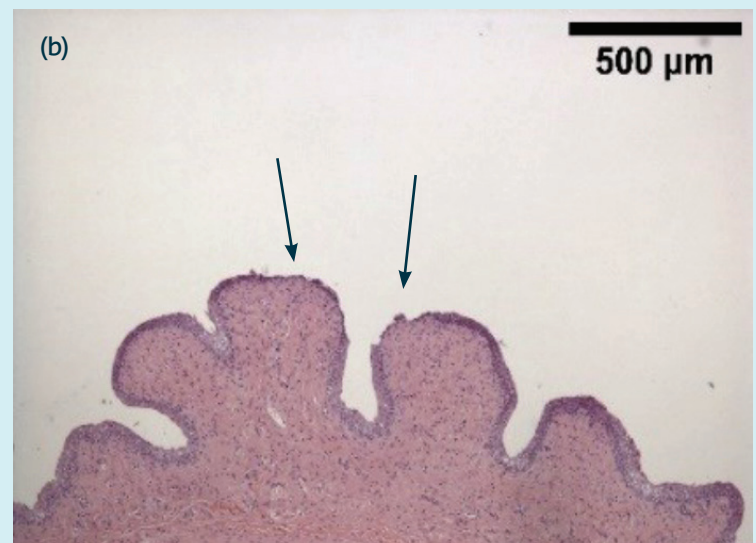
In an *ex vivo* mucosal suction model it was shown that a catheter utilizing a Micro-Hole drainage Zone (MHZC) would significantly lower the localized pressure peaks near the catheter micro-holes compared to a CEC. Therefore, less suction is available to deform the tissue and the smaller microholes completely removed the ingress of the bladder tissue into the catheter lumen. This resulted in a lower level of microtrauma incurred in the bladder compared to a CEC. The lower level of microtrauma may lead to fewer instances of urinary tract infections *in vivo*.

Figure 3: H&E stained histological sections of porcine tissue samples subjected to mucosal suction with CEC and MHZC. Arrows point to areas of interest, such as thinning and exfoliation of urothelium. (a): Microtrauma from CEC, (b) Microtrauma from MHZC, and (c): Negative control.

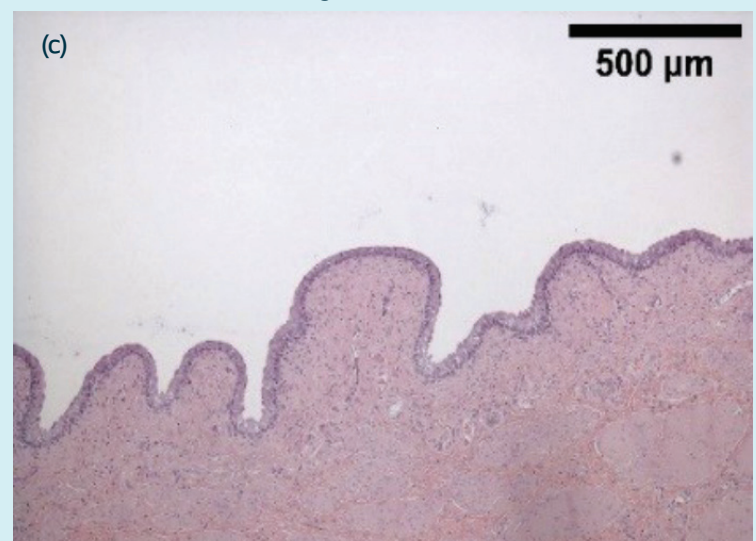
Conventional Eyelet (CEC)



Micro-Hole Zone (MHZC)



Negative Control



Prior to use, refer to product labeling for complete product instructions for use, contraindications, warnings and precautions.

