Micro-hole zone technology shows superior ability to empty the bladder: A crossover randomised controlled trial in users of intermittent catheters

M.H. Landauro[1], C. Rovsing[2] , L. Jacobsen[1], O.F. Nascimento[1], R. Vaabengaard[1] and M. Kennelly[3]
[1]Coloplast A/S, Humlebæk, Denmark, [2]SANOS Clinic, 9362 Gandrup, Denmark, [3]Department of Urology, Carolinas Medical Center, Charlotte, NC, US

Background: Residual urine is seen as an important risk factor for acquiring UTIs* and many clean intermittent catheter (CIC) users are uncertain about whether they have residual urine after performing CIC. With conventional eyelet catheters (CEC), users can experience urine flow stops during catheterisation leading to possible residual urine. This study investigated the performance of a new CIC with Micro-hole Zone Technology (MHZC) (figure 1) designed to reduce urinary flow-stops and minimise residual urine.

Figure 1. Luja with Micro-hole zone technology

Method: The investigation was a single-centre, crossover, randomised, controlled study performed at Sanos Clinic, Denmark (ClinicalTrials.gov NCT05485922). The study consisted of one inclusion visit and two single test visits (figure 2). Subjects were catheterised by a health-care professional with a MHZC (Coloplast Luja™) and a CEC (Hollister Vapro™). Primary study endpoints were number of flow-stop episodes and residual urine volume at 1st flow-stop (RV1). RV1 represents worst case of residual urine when a CEC is withdrawn without proper repositioning.

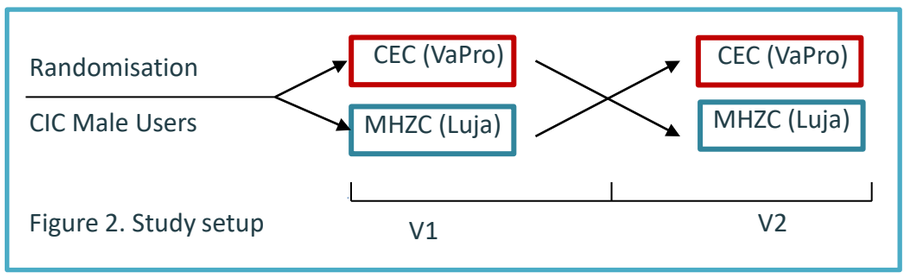

Figure 2. Study setup

Results: Forty-two male CIC users were enrolled. Mean age was 68 (range 41-87 years) with a 3:2 split between individuals with non-neurogenic and neurogenic bladder dysfunction (table 1).

Results showed that catheterisation with MHZC resulted in close to zero flow-stops (mean: 0.17; 95% CI: 0.06-0.45) compared to approximately 1 flow-stop with CEC (mean: 1.09; 95% CI: 0.75-1.6) (figure 3).
Mean [SE] residual urine at 1st flow-stop was 5.10 mL [1.14] for MHZC vs. 39.40 mL [9.65] for CEC (p<0.001) (figure 4), and 90% of the catheterisations with MHZC led to less than 10 mL urine at 1st flow-stop compared to 52% for CEC.
After repositioning, both catheters emptied the bladder to low and comparable RV post-catheterization levels (mean values for both Luja and VaPro were <8 mL).

The results also showed a 74% less likelihood for haematuria post-catheterisation with MHZC (mean: 5.71 Eryt/mL) compared to CEC (mean: 22.14 Eryt/mL; p<0.05).

Total	**N = 42**
Age (years), mean (range)	68 (41; 87)
Non-NBD, n (% total)	29 (69)
NBD, n (% total)	13 (31)
Medical history	
Benign Prostate Hyperplasia	26 (62)
Spinal Cord Injury	9 (21)
Multiple Sclerosis	4 (10)
Stenosis	2 (5)
Prostate cancer	1 (2)

Table 1: Demographics, NBD= neurogenic bladder dysfunction

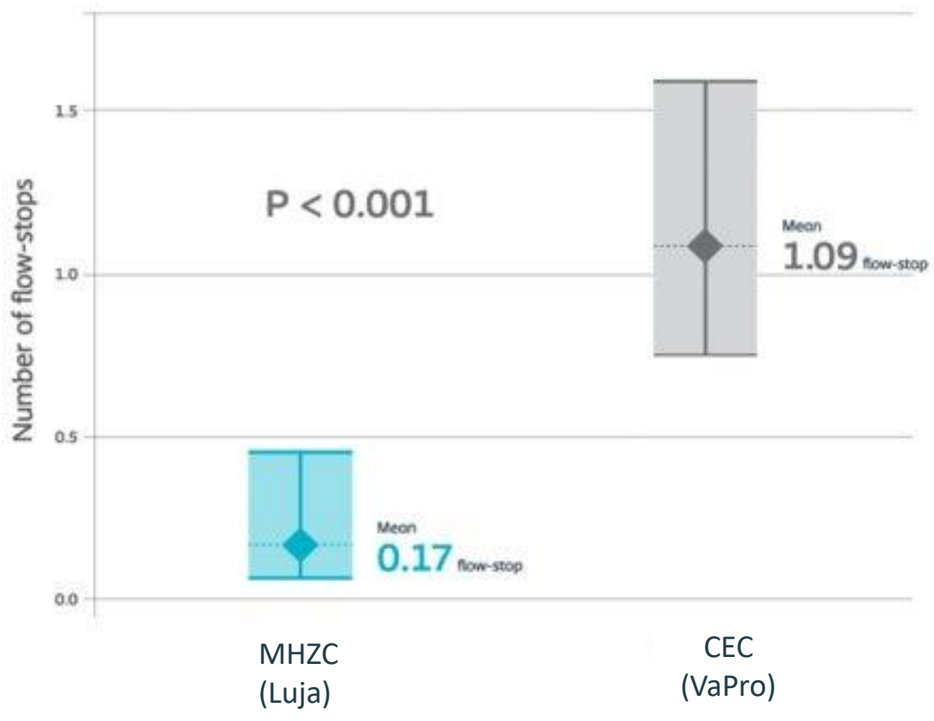

Figure 3. Number of flow-stops with the MHZC (Luja) and the CEC (Vapro) catheter

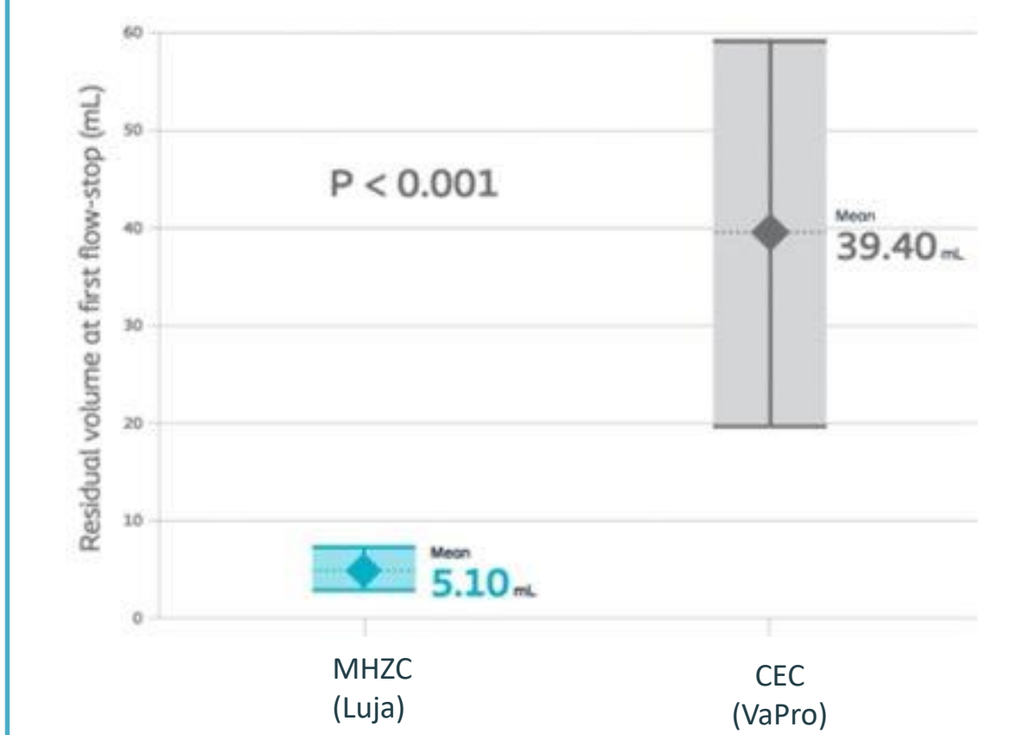

Figure 4. Residual urine (mL) at 1st flow-stop for the MHZC (Luja) and the CEC (Vapro) catheter

Conclusion: Results from this study underlines the superiority of the MHZC with significantly reduced number of flow-stops and significantly less residual urine volume at 1st flow-stop compared to a CEC. With this new micro-hole zone technology, CIC users will experience a simpler catheterisation process without flow-stops and no need to reposition the catheter to completely empty their bladder, potentially lowering the risk for future UTIs.

* Kennelly, M., et al., Adv Urol. 2019;2019:2757862.