A multi-centre randomised controlled study confirming the improved performance with a new Micro-hole zone catheter in a population of adult male intermittent catheter users

M.H. Landauro[1], L. Jacobsen[1], O.F. Nascimento[1], R. Vaabengaard[1] , N. Thiruchelvam[2] and P. Bagi[3]

[1]Coloplast A/S, Humlebaek, Denmark, [2]Department of Urology, Addenbrooke's Hospital, Cambridge, UK, [3]Department of Urology, Rigshospitalet, Copenhagen, Denmark

Background: Residual urine is seen as a risk factor for acquiring urinary tract infections (UTIs) and most users dependent on clean intermittent catheter (CIC) are uncertain if they empty their bladder completely. With conventional eyelet catheters (CEC, Figure 1a), users can experience urinary flow-stops during catheterization, caused by mucosal suction, giving a false impression that the bladder is empty. Removing the catheter prematurely may leave residual urine behind. This study investigated the performance of a new micro-hole zone catheter (MHZC, Figure 1b) designed to improve bladder emptying as a result of a free urinary flow without premature flow-stops.

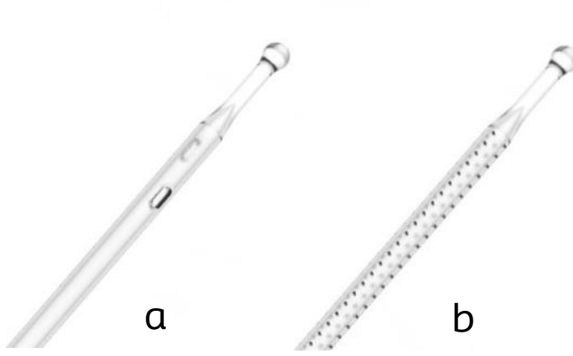

Figure 1.
a) conventional eyelet catheter (CEC)
b) Micro-hole zone technology catheter (MHZC)

Method: The investigation was a multi-centre, randomised, controlled crossover study including 73 male IC users (ClinicalTrials.gov NCT05485935). The study consisted of four study visits and two 4-week test periods at home (Figure 2). The MHZC (Luja™, Coloplast A/S) was compared to a CEC with a sleeve (SpeediCath® Flex, Coloplast A/S or Vapro™, Hollister, Inc).

Flow-stop episodes and residual volume at 1st flow-stop (RV1) after healthcare professional (HCP)-led catheterisation were included as primary endpoints, and after self-catheterisation as supportive endpoints. RV1 represents worst case of residual urine when a CEC is withdrawn without proper repositioning.

Pressure inside the catheter (at 1st flow-stop) was included as exploratory endpoint and a perception questionnaire was filled out after each of the 4-weeks test period by each IC user.

Results on flow-stop episodes, RV1 and intra-catheter pressure concern a subset of subjects who underwent flow/pressure measurements during HCP- and self-led catheterizations at hospital visits 2 and 3. Results on perception concern all subjects.

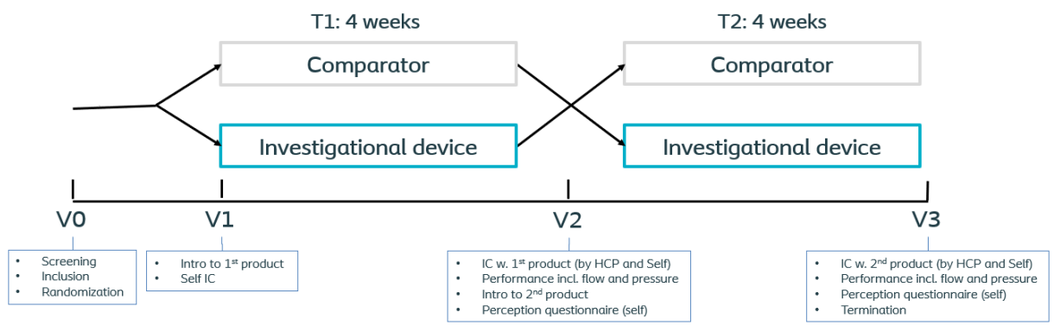

Figure 2. Study setup

Total	N = 73
Age (years), mean (range)	63.9 (28; 87)
Non-NBD, n (% total)	45 (61.6)
Benign Prostate Hyperplasia	26 (36)
Chronic urine retention	7 (10)
Atonic bladder	6 (8)
Other	6 (8)
NBD, n (% total)	28 (38.4)
Spinal Cord Injury	17 (23)
Multiple Sclerosis	7 (10)
Peripheral neuropathy	2 (3)
Other	2 (3)

Table 1: Demographics of the ITT population, NBD= neurogenic bladder dysfunction

Results: Mean number of flow-stop episodes [95% CI] was close to zero for the MHZC at both HCP-led catheterisation 0.20 [0.09; 0.43] and self-catheterisation 0.13 [0.04; 0.37] as opposed to CEC with mean flow-stop episodes of 1.32 [0.96; 1.80] and 0.96 [0.65; 1.43] at HCP-led catheterisation and self-catheterisation (both p<0.001) (Table 2).

Mean RV1 was significantly less for the MHZC with mean values [95%CI] of 18.0 mL [7.1; 28.9] and 8.2 mL [0; 22.1] for HCP-led and self-catheterisation, respectively, as opposed to the CEC with mean values [95%CI] of 63.9 mL [37.9; 90.0] and 36.8 mL [23.1; 50.5] for HCP-led and self-catheterisation, respectively (both p≤0.004) (Table 2).

The results of the primary endpoints were substantiated by a significantly smaller pressure peak at 1st flow-stop, equivalent to minimized mucosal suctions, for the MHZC (Table 2).

When asked about their perception, in comparison to CEC, users felt significantly less blocking sensation with MHZC (OR 3.12, p<0.001), found it easier to ensure complete bladder emptying with the MHZC (OR 2.73, p=0.004), and felt significantly more confident with the MHZC that their bladder was completely empty when the urine flow stops (OR 2.83, p=0.003).

		Mean [95% CI] [min; max] MHZC	Mean [95% CI] [min; max] CEC	P-value
Residual urine at 1st flow-stop, mL	**HCP**	18.0 mL [7.1; 28.9] [0; 208]	63.9 mL [37.9; 90.0] [2; 342]	0.001
	Self	8.2 mL [-5.6; 22.1] [0; 85]	36.8 mL [23.1; 50.5] [1; 314]	0.004
Flow-stop episodes, number	**HCP**	0.20 [0.09; 0.43] [0; 2]	1.32 [0.96; 1.80] [0; 8]	<0.001
	Self	0.13 [0.04; 0.37] [0; 2]	0.96 [0.65; 1.43] [0; 8]	<0.001
Intra-catheter pressure at 1st flow stop, mbar	**HCP**	-7.34 [-42.16; 27.48] [-65; 0]	-149.26 [-200.4; -98.08] [-460; 0]	<0.001
	Self	-13.30 [-20.12; -6.47] [-93; 0]	-146.02 [-193.9; -98.09] [-442; 0]	<0.001

Table 2. Residual urine at 1st flow-stop, number of flow-stops and intra-catheter pressure at 1st flow stop for the MHZC and the CEC, both for HCP lead catheterisation (N=49) and self-catheterisation (N=46). SpeediCath Flex (SC Flex) was the comparator product in 98% of the catheterizations by HCPs and in all self-catheterizations.

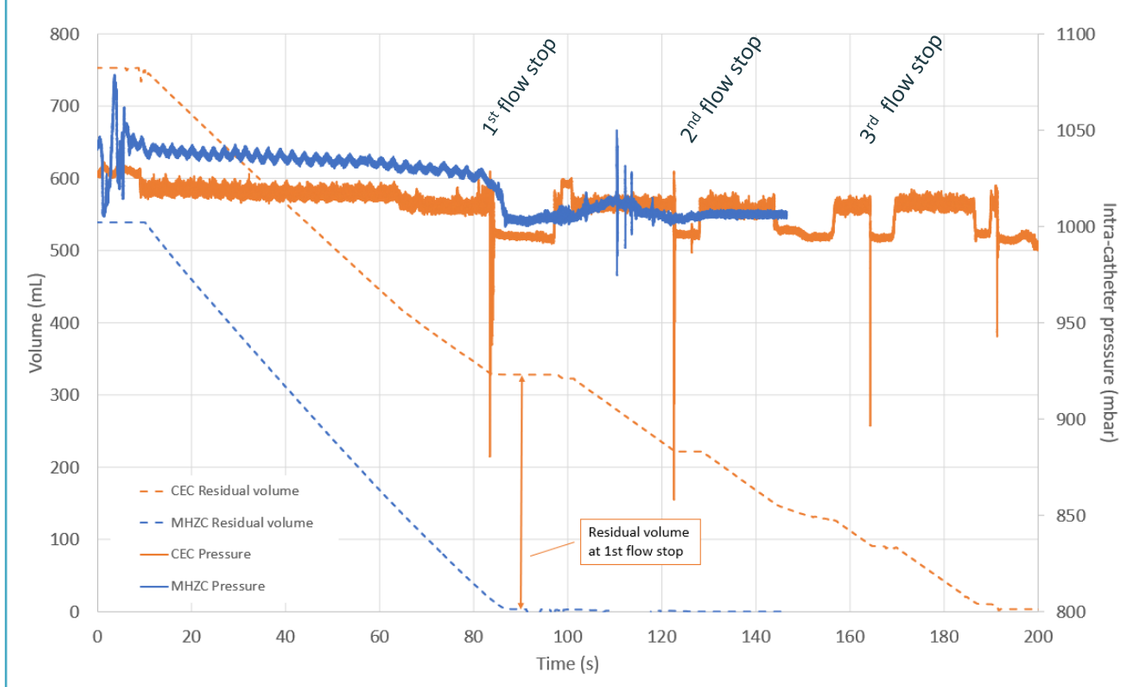

Figure 3. Illustrative example of pressure/ volume graph for one catheterization with CEC and one with MHZC.

Conclusion: The study demonstrated a superior performance of the MHZC over CEC in terms of a significantly reduced likelihood of flow-stops, a significantly reduced residual urine at 1st flow-stop (RV1), supported by a significantly reduced pressure peak (mucosal suction) after both HCP-led and self-led catheterizations.