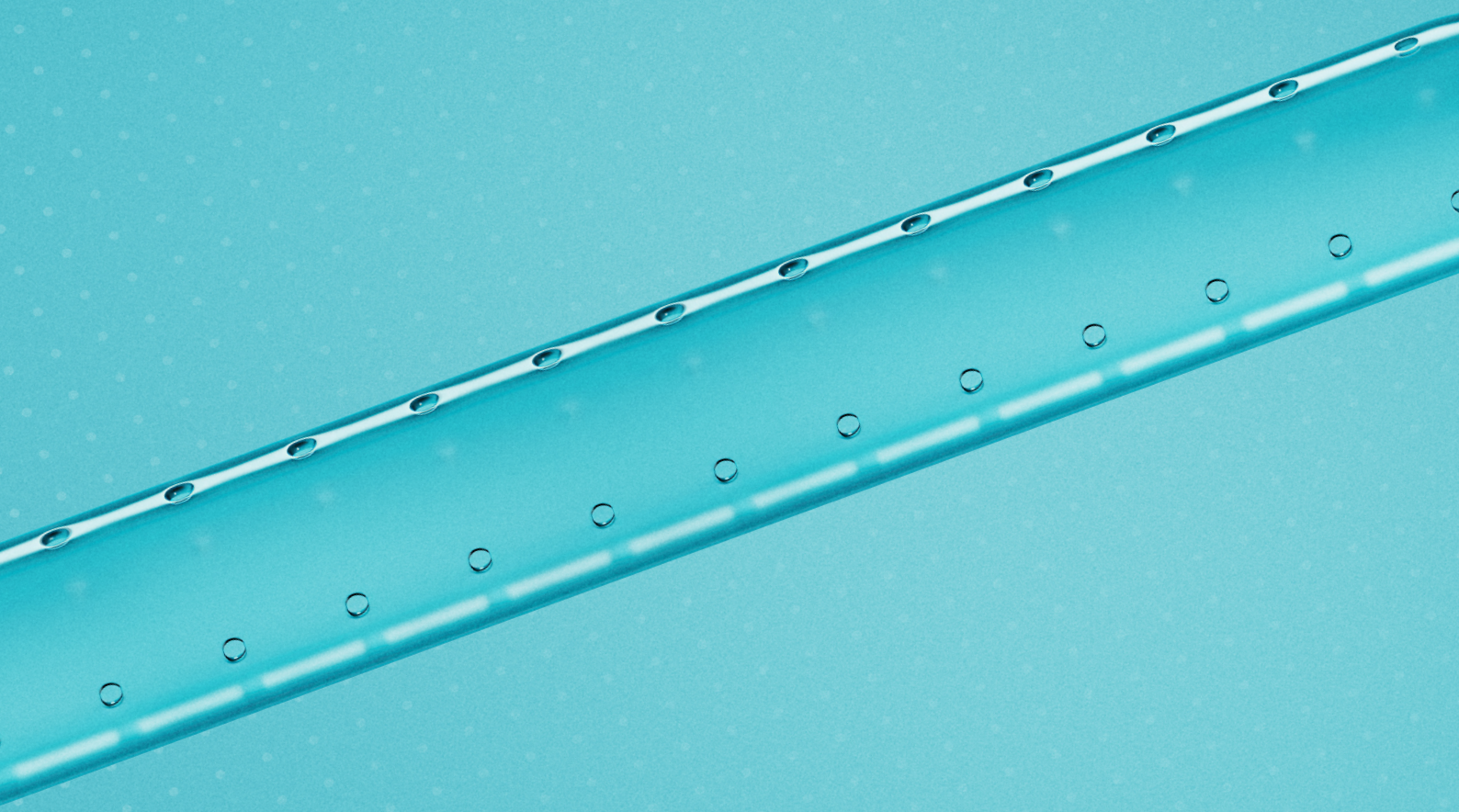
# Luja™ with Micro-Hole Zone Technology

## Evidence summary



Version 2 - January 2025

# Contents

Luja is the most clinically researched ISC catheter in Coloplast history:



**Abbreviations**

ISC: intermittent self-catheterisation

CIC: clean intermittent catheterisation

HCP: healthcare professional

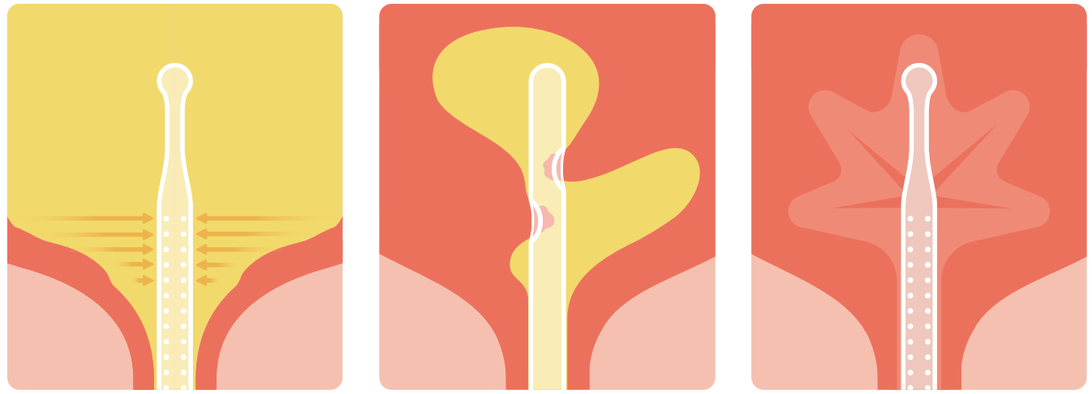
UTI: urinary tract infection

CEC: Conventional 2-eyelet catheter

MHZC:  Micro-hole Zone catheter

1. Luja male has close to no flow stops and complete bladder emptying is defined as <10 mL (Landauro MH et al (2023), DOI: 10.1097/WON.0000000000001029, N=42). Luja female ensured zero flow stops in 87% of catheterisations & <10 mL residual urine at first flow stop in 83% of catheterisations (Thiruchelvam et al. (2024), DOI: 10.12968/bjon.2024.0212 Individual results may vary.
2. Tested in a pre-clinical setting (ex vivo)
3. Defined by UTI risk factor model (Kennelly M., et al. (2019), 10.1155/2019/2757862)
4. Landauro, M.H.; Jacobsen, L.; Tentor, F.; et al. (2023). https://doi.org/10.3390/jcm12165266

# Luja™ with Micro-hole Zone Technology ensuring complete bladder emptying in one free flow[1]



**One free flow**

The urine flow stops when the bladder is completely empty[1]

**No repositioning**

There is no need to reposition the catheter as mucosal suction is reduced[2]

**Less risk of UTI[3]**

Designed to reduce the risk of UTIs by minimising residual urine and without causing bladder microtrauma[2,4]

**Scan** to learn more about Micro-hole Zone Technology

# Overview of evidence on Micro-hole Zone Technology™ from 2022-2024.

| | Study | Publication | Residual urine | | Microtrauma | | | Perception | Discomfort | Sediments | UTIs, QoL |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | RV1* | PVR** | Heamaturia | Flow-stops | Epithelial damage | | | | |
| UTI risk factors | Patient-reported outcome: User survey across 13 countries | Averbeck et al. Risk factors for urinary tract infections associated with lower quality of life among intermittent catheter users. BJN, 2023, Vol 32, No 18 Urology Supplement.[4] | | | | | | | | | ✓ |
| | UTI risk factors model | Kennelly et al. Adult Neurogenic Lower Urinary Tract Dysfunction and Intermittent Catheterisation in a Community Setting: Risk Factors Model for Urinary Tract Infections. Advances in Urology, Volume 2019, Article ID 2757862, 13 pages.[2] | | | | | | | | | ✓ |
| | UTI assessment tool | Lauridsen et al. UTI assessment tool for intermittent catheter users: a way to include user perspectives and enhance quality of UTI management BMC Nursing (2022) 21:272[26] | | | | | | | | | ✓ |
| Pre-clinical studies | Porcine bladder model 1+2. Blockage of eyelets, flow-stops, pressure, residual urine | Tentor et al. Development of an ex-vivo porcine lower urinary tract model to evaluate the performance of urinary catheters, Scientific Reports 2022;12:17818[10]<br><br>Schrøder et al. New micro-hole zone catheter reduces residual urine and mucosal microtrauma in a lower urinary tract model, Scientific reports 2024;14:2268[8] | ✓ | | | ✓ | | | | | |
| | In-vivo porcine cystoscopy model. Flow-stops, catheter pressure, microtrauma measured by histopatho-logical score and leucocyte infiltration | Stærk et al. Catheter-associated bladder mucosal trauma during intermittent voiding: An experimental study in pigs, BJUI Compass, 2023;1-7.[27] | ✓ | | | ✓ | ✓ | | | | |
| | Microtrauma in Glahn model Mucosal suction, microtrauma, bladder histology | Willumsen et al. Reduction in lower urinary tract mucosal microtrauma as an effect of reducing eyelet sizes of intermittent urinary catheters.Sci Rep. 2024 Jul 1;14(1):15035[28] | | | | | ✓ | | | | |
| | Urine composition Analysis of urine and sediments in the urine, Incl. glass bladder model | Bagi et al. Draining Urinary Sediments Through a Conventional Eyelet Catheters and New Intermittent Micro-Hole Zone Catheters. Submitted 2024[29] | | | | | | | | ✓ | |
| Clinical studies | Exploratory studies Flow-stops, residual urine, discomfort, haematuria (CP322-24) | Landauro et al. Improved Performance With the Micro-Hole Zone Intermittent Catheter: A Combined Analysis of 3 Randomized Controlled Studies Comparing the New Catheter Technology With a Conventional Eyelet Catheter. J Wound Ostomy Continence Nurs. 2023 Nov-Dec;50(6):504-511.[20] | ✓ | ✓ | ✓ | | | | ✓ | | |
| | Luja male MoA. Flow-stops, residual urine, haematuria, perception (CP334) | Thiruchelvam et al. Improved emptying performance with a new micro-hole zone catheter in adult male intermittent catheter users: A comparative multi-center randomized controlled cross-over study, Neurourol Urodyn. 2024:1-15[22] | ✓ | ✓ | ✓ | ✓ | | ✓ | ✓ | | |
| | Luja male vs. Vapro Flow-stops, residual urine, haematuria (CP353) | Landauro et al. New Intermittent Urinary Micro-Hole Zone Catheter Shows Enhanced Performance in Emptying the Bladder: A Randomised, Controlled Crossover Study, J. Clin. Med. 2023;12:526[19] | ✓ | ✓ | ✓ | ✓ | | | | | |
| Product evaluation | Product evaluation from HCPs and users | No articles, but two posters – one covering HCP feedback and one covering user feedback.[30-31] | | | | | | ✓ | ✓ | | |

*RV1: residual volume at first flow-stop. **PVR: post-void residual volume.

# Challenges and priorities of intermittent catheterisation users: results from an online user survey

Vaabengaard R., Zeeberg R., Athanasiadou S. Presented at the British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.

## Objective

Adherence to intermittent catheterisation (ISC) can be affected by the challenges and priorities of users. In this study, we explored the challenging ISC steps and views of non-clinical catheter features among different user groups.

## Study design and methods

An online survey was distributed to ISC users between June and August 2023. Participants were recruited through Coloplast databases. Descriptive data analyses were conducted.

## Population

3,784 ISC users (2,145 male and 1,635 female) from 11 European countries, Australia, and the USA.

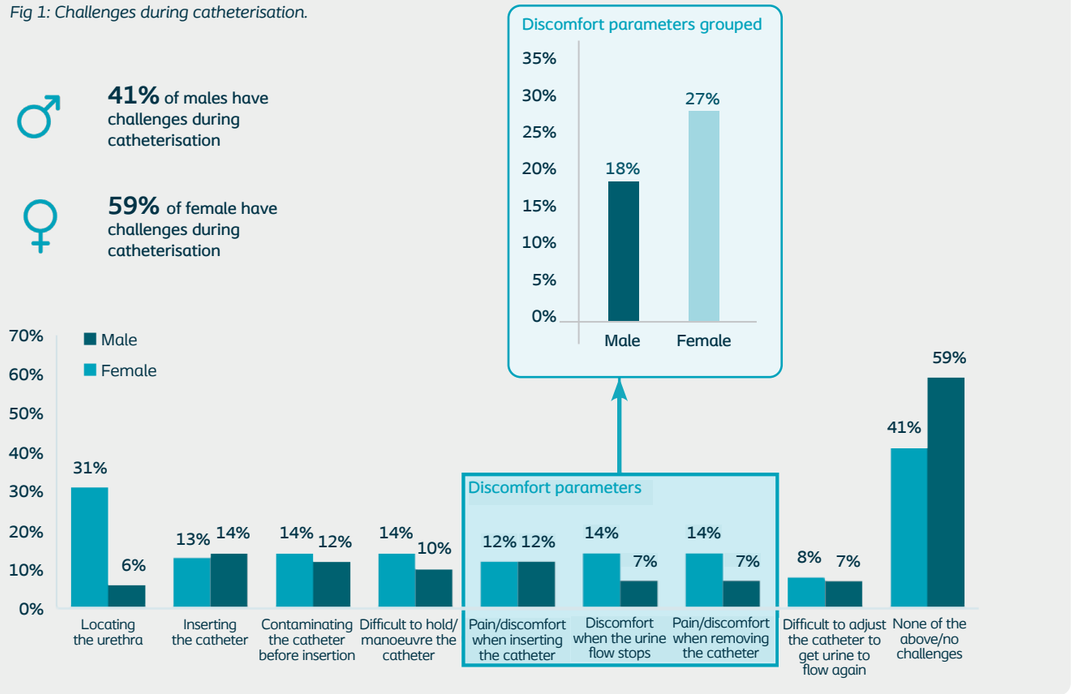
## Results

Overall, people with neurogenic conditions, females, and users aged 18-49 had more challenges. Locating urethra was the primary challenge for females (31%).

Discomfort at any step of the catheterisation (insertion, urine flow-stop or catheter removal) was higher among females (27%) and non-neurogenic users (24%) (Figure 1). Specifically, discomfort when the urine flow stops was experienced more in females (14%), a feeling primarily described as stinging, blocking sensation, or pinching (Figure 2).

Among non-clinical catheter features, 'easy to carry around' scored highest (74%) and 'attractive colour' lowest (4%). Finally, 63% of users were likely or extremely likely to separate and recycle parts of the catheter at home, yet only 25% would do so outside home (Figure 3).

*Fig 1: Challenges during catheterisation.*




Averbeck M.A., Kennelly M., Thiruchelvam N. et al. Risk factors for urinary tract infections associated with lower quality of life among intermittent catheter users. British Journal of NursingVol. 32, No. 18. DOI: 10.12968/bjon.2023.32.18.S8





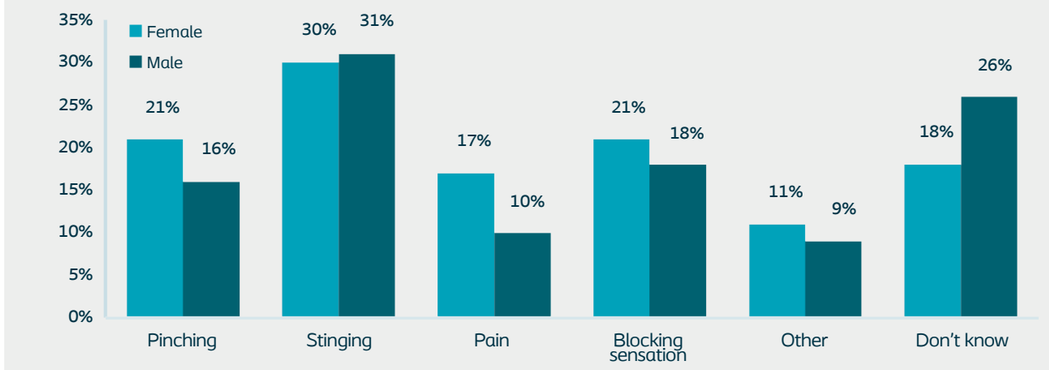



*Fig 2: What does discomfort feel like (only asked to people feeling discomfort while draining bladder).*

| | Male | Female | Total |
|---|---|---|---|
| Total | 2145 | 1635 | 3784 |
| Condition | | | |
| Neurogenic | 1132 | 980 | 2116 |
| Non-Neurogenic | 720 | 377 | 1097 |
| Not known | 293 | 278 | 571 |
| Age | | | |
| 18-49 | 314 | 472 | 786 |
| 50-59 | 363 | 375 | 738 |
| 60-69 | 527 | 539 | 886 |
| 70+ | 765 | 291 | 1056 |

*Table 1: Demographics.*

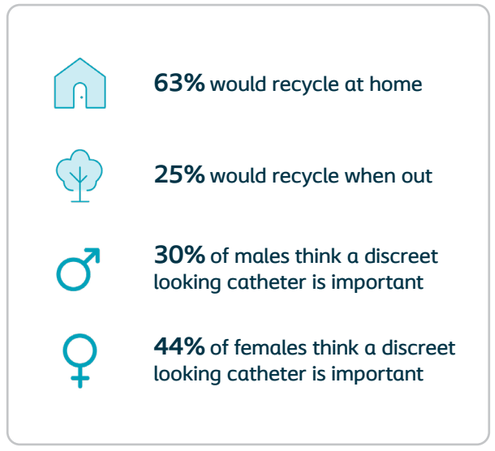



*Fig 3: Sustainability and discretion.*

## Conclusion

The results indicate that ISC user groups experience different challenges with the catheterisation process, and particularly females experience significantly higher discomfort and difficulty accessing the urethra. New solutions tailored to the needs of individual groups could potentially improve adherence to ISC.

# UTI assessment tool for intermittent catheter users: a way to include user perspectives and enhance quality of UTI management[1]

**Vahr S., Averbeck M.A., Krassioukov A., Vaabengaard R., Athanasiadou S.** Presented at the International Meeting of the European Association of Urology Nurses (EAUN), The Netherlands, July 2022.

## Objective

To develop a tool that allows healthcare professionals (HCPs) to systematically assess UTI risk factors for the individual ISC user while taking their perspective into account.

## Study design and methods

The content of the tool was built upon the UTI Risk Factors model by Kennelly et al. Insights were collected from the Coloplast Nurse Advisory Boards and a literature review on user perspectives and practices related to UTIs. Different methodologies were employed to develop the format, in accordance with the Design Thinking Process.

## Results

Approximately 90 nurses participated in the Coloplast Advisory Board meetings across Europe. Additionally, the literature search identified 3,544 articles, out of which 22 were included in the review.

The literature showed that users describe UTI symptoms in non-clinical terms and adapt their adherence and catheter choice based on personal needs and priorities. Furthermore, their knowledge on IC and UTIs may not be up to date.

The nurses emphasised the importance of correct diagnosis of UTIs and highlighted that the user's general condition, adherence, technique, and catheter type are potential areas of UTI risk factors. They also described a need to support users.

The UTI assessment tool for intermittent catheter users contains three elements: a guide for healthcare professionals, a dialogue board, and a notepad (Figure 1). The tool starts with a confirmation of the UTI incidence, and then assesses risk factors via questions on health, adherence, technique, and catheter, and concludes with a support section. (Figure 2) The three elements are packaged in a convenient folder.

## Strengths and limitations

The tool has been developed via a structured and robust process, that included both the user and HCP perspectives. Insights on the HCP perspectives were, however, only collected from nurses practicing in Europe, and therefore localisation of the tool may be needed to reflect the culture and best practices across different countries.


*Fig 2: The six sections of the UTI assessment tool for intermittent catheter users.*

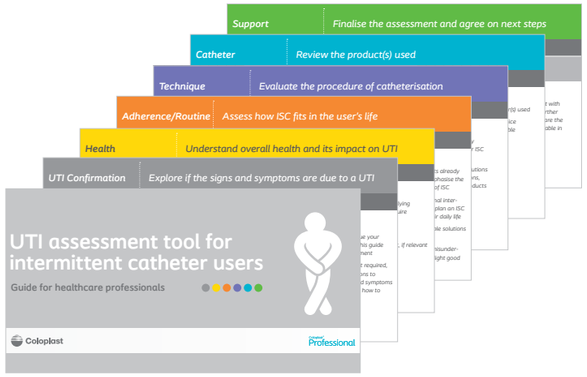
1. Lauridsen et al. BMC Nursing (2022) 21:272 DOI: 10.1186/s12912-022-01033-7



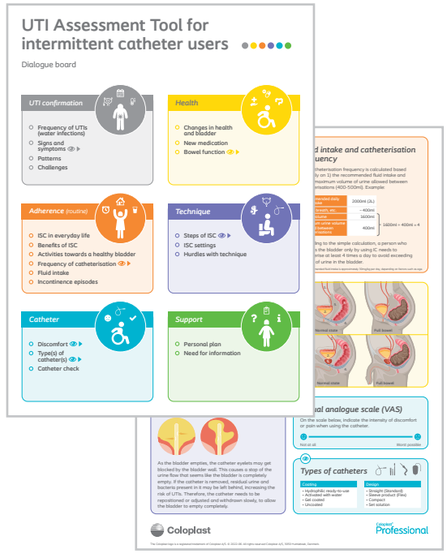


Folder


HCP Guide




Dialogue Board




Personal Form (notepad - UK version)

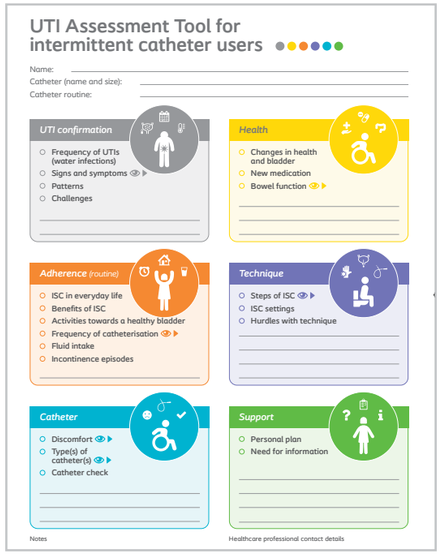



*Fig 1: The three elements of the UTI assessment tool for intermittent catheter users: A Guide for healthcare professionals, a Dialogue board, and a Personal form notepad (UK version), along with the folder containing them.*

# Patient-reported risk factors for urinary tract infections are associated with lower quality of life among users of clean intermittent catheterisation[1]

**Islamoska S., Landauro M.H., Zeeberg R., Jacobsen L., Vaabengaard R.** Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2022.

## Objective

To investigate the association between risk factors for UTI[2] – such as blood in the urine, residual volume, bowel dysfunction, recurrent UTIs, sex, and withdrawal technique – in relation to Quality of Life (QoL) and UTIs.

## Study design and methods

In March-April 2022, an online survey of 60 questions, including the disease specific 30-item Qualiveen questionnaire, was distributed among 55,235 CIC users recruited through a customer panel in 11 European countries, Australia and the US. QoL means and UTI relative risks (RR) were generated using linear mixed models.

## Results

A total of 3,464 individuals responded to the survey. There were 63% males, 57% had a neurogenic bladder disorder, 52% had bowel dysfunction, and 61% experienced minimum one antibiotic treated UTI within the last year. Overall, 68% worried about getting a UTI and 47% worried about not emptying their bladder completely. A statistically significant poorer QoL was observed when experiencing blood in the urine, residual urine, bowel dysfunction, recurrent UTIs, being female, and when applying specific withdrawal techniques.

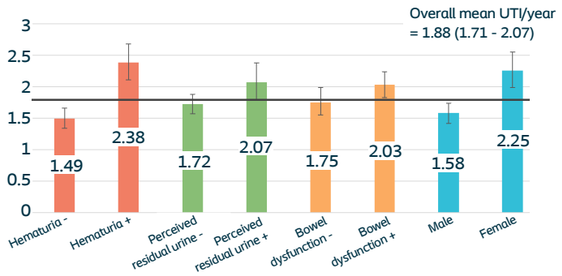


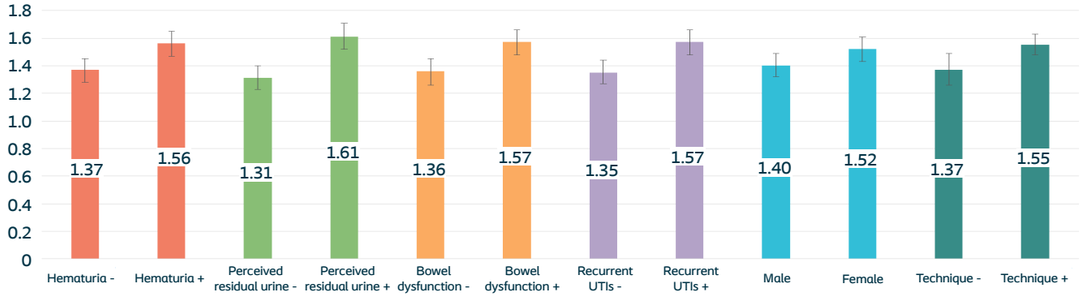

*Fig 1: Mean number of UTIs per year within patient reported UTI risk factors.*

There was a 37% lower risk of UTIs when blood was not apparent in the urine (RR: 0.63; 95% CI: 0.55-0.71), 17% lower risk when bladder was perceived empty (RR: 0.83; 95% CI: 0.72-0.96), 14% lower risk without having bowel dysfunction (RR: 0.86; 95% CI: 0.76-0.98), 30% lower risk in males (RR: 0.70; 95% CI: 0.62-0.79).

| Risk factors for urinary tract infections | Adjusted RR | P value |
|---|---|---|
| Not having haematuria vs. having haematuria | 0.63 (0.55-0.71) | <0.001 |
| Not having perceived residual urine vs. having perceived residual urine | 0.83 (0.72-0.96) | 0.012 |
| Not having bowel issues vs. having bowel issues | 0.86 (0.76-0.98) | 0.027 |
| Male vs. female | 0.70 (0.62-0.79) | <0.001 |

*Fig 2 (right): Relative risks (RR) of UTIs within patient reported UTI risk factors.*

*Fig 3 (below): Mean quality of life scores within patient reported UTI risk factors.*




## Conclusion

Findings from this cross-sectional study underlines the importance of risk factors and their impact on QoL and risk of UTIs. Despite these clear indications, further research using longitudinal study designs is needed to expand findings from the present study to other populations in order to improve QoL in CIC users.

1. Averbeck M.A., Kennelly M., Thiruchelvam N. et al. (2023). https://doi.org/10.12968/bjon.2023.32.18.S8
2. Kennelly M., et al. (2019), DOI: 10.1155/2019/2757862





# New Intermittent Urinary Micro-Hole Zone Catheter Shows Enhanced Performance in Emptying the Bladder: A randomised controlled crossover study[1]

**Landauro M.H., Jacobsen L., Tentor F., Pedersen T., Rovsing C., Feix do Nascimento O., Kennelly M.** J. Clin. Med. 2023

## Objective

To investigate the performance of a new Micro-hole Zone catheter (MHZC) (figure 1) designed to reduce urinary flow stops and minimise residual urine.

## Study design and methods

The investigation was a single-centre, crossover, randomised, controlled study performed at Sanos Clinic, Denmark*. The study consisted of one inclusion visit and two single test visits (figure 2). Subjects (table 1) were catheterised by a HCP. Primary study endpoints were number of flow-stop episodes, residual urine volume at 1st flow-stop, and probability of haematuria (dipstick), estimated by statistical analysis.

## Products

MHZC (Luja™, Coloplast) and CEC (VaPro™, Hollister).

## Population

42 adult male CIC users.

## Results

CIC 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 residual urine at 1st flow-stop was significantly lower at 5.10 mL (95% CI: 2.79-7.42) for MHZC vs. 39.40 mL (95% CI: 19.92-58.89) for CEC (p<0.001) (Figure 4).

A difference was found in probability of haematuria from 0.10 (95% CI: 0.03-0.24) to 0.29 (95% CI: 0.17-0.45) for CEC with an odds ratio of 0.26 (95% CI: 0.07-0.96) (Figure 5), corresponding to a 74% less likelihood of haematuria (p< 0.05).

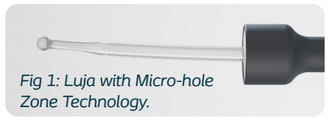


*Fig 1: Luja with Micro-hole Zone Technology.*

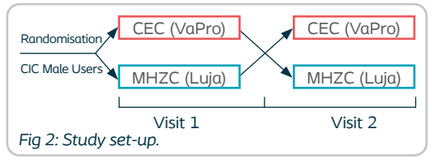



*Fig 2: Study set-up.*

| Total | N=42 |
|---|---|
| Age (years), mean (range) | 68 (41; 87) |
| Non-neurogenic bladder dysfunction, n (%) | 29 (69) |
| Neurogenic bladder dysfunction, n (%) | 13 (31) |
| Medical history | |
| Benign prostatic hyperplasia | 26 (62) |
| Spinal Cord Injury | 9 (21) |
| Multiple Sclerosis | 4 (10) |
| Stenosis | 2 (5) |
| Prostate cancer | 1 (2) |

*Table 1: Demographics.*

*Fig 3: Number of flowstops with Luja vs VaPro*

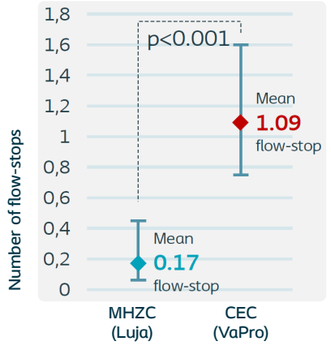



*Fig 4: Residual urine at 1st flow-stop with Luja vs VaPro*

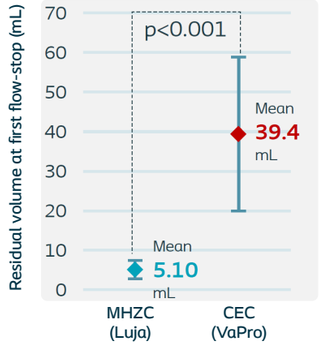
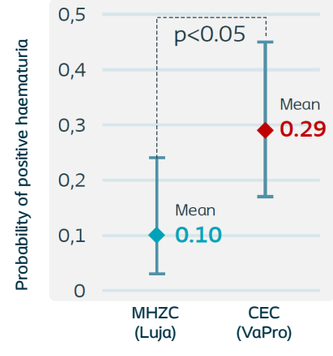



*Fig 5: Probability of positive haematuria*




## Conclusion

Results underline the superiority of MHZC: significantly lower number of flow stops and lower residual volume at first flow stop, and less likelihood of haematuria. Users will experience a simpler catheterisation process without flowstops and no need to reposition the catheter to completely empty their bladder, potentially lowering the risk for future UTIs.

1. Landauro M.H. et al. (2023) DOI: 10.3390/jcm12165266
* ClinicalTrials.gov NCT05485922

# Improved emptying performance with a new micro-hole zone catheter in adult male intermittent catheter users: A comparative multi-center randomised controlled cross-over study[1]

Thiruchelvam N, Landauro MH, Biardeau X et al. Neurourol Urodyn. 2024

## Objective

To investigate the performance and perception of a new Microhole Zone catheter (MHZC) designed to improve bladder emptying as a result of a free urinary flow without premature flow-stops.

## Study design and methods

Residual urine and trauma in the urethra are both risk factors for acquiring urinary tract infections (UTIs)[2]. Clean intermittent catheterisation with a conventional eyelet catheter (CEC) has been demonstrated[3] to cause mucosal suction during bladder emptying, leaving residual urine unless the catheter is repositioned. During catheter repositioning, there is a risk for the epithelial layer of the bladder wall to be teared off at the location of the catheter eyelets, leading to microtrauma.

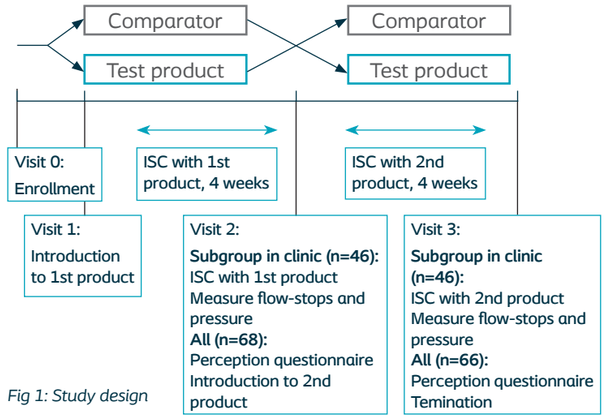



*Fig 1: Study design*

The investigation was a multi-centre, randomised, controlled crossover study* including 73 male CIC users. The MHZC was compared to a CEC with a sleeve.

All subjects completed two 4-week periods of home-use of either test or comparator catheter and completed a perception questionnaire. Additionally, for a subset of subjects flow-stop episodes and intra-catheter pressure peak were measured in a clinic visit following each home-use periods (Figure 1)

## Products

MHZC (Luja™, Coloplast) was compared to a CEC single-use hydrophilic sleeved soft catheter (SpeediCath® Flex§, Coloplast or VaPro™, Hollister).

## Population

73 adult male ISC users.

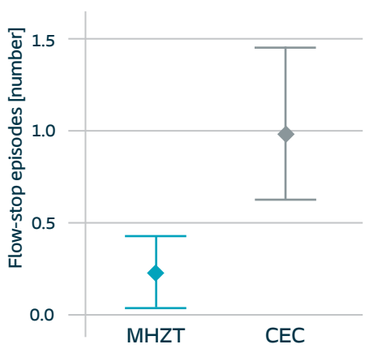



*Fig 2: Number of flow-stops with MHZC vs CEC*

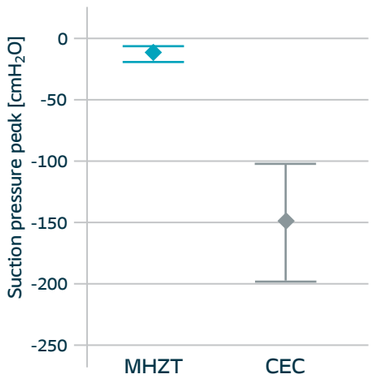



*Fig 3: Suction pressure peak with MHZC vs CEC*

1. Thiruchelvam N. et al (2024), DOI: 10.1002/nau.25383
2. Kennelly M., et al. (2019), DOI: 10.1155/2019/2757862
3. Tentor F., et al. (2022), 10.1038/s41598-022-21122-6

* ClinicalTrials.gov NCT05485935





## Results

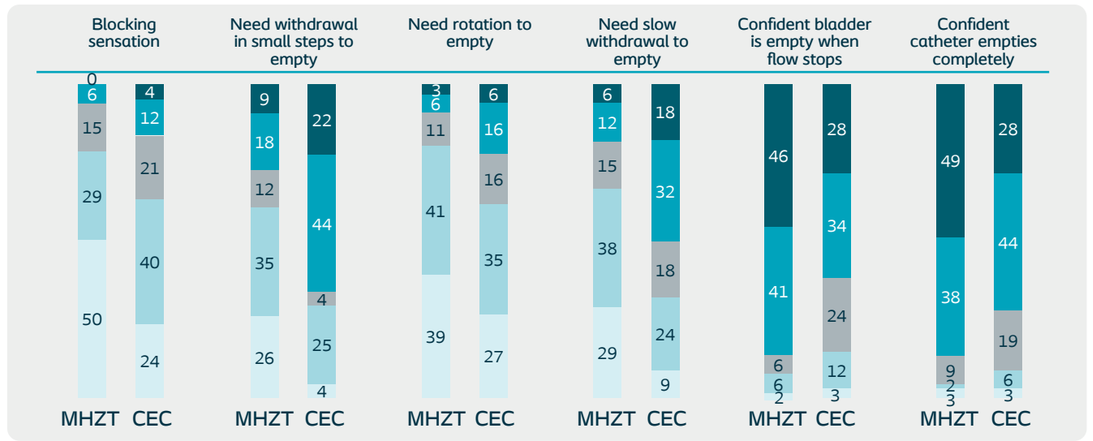
There was an 87% reduction in risk of flow-stop episodes with MHZC vs CEC during self-led ISC (RR=0.13, 95% CI:0.04;0.40, p<0.001, Figure 2) and suction pressure peak, a proxy for mucosal suction, was significantly lower with MHZC (-13.56cm H2O, 95% CI:-20.52; -6.6) vs CEC (-148.9cm H2O, 95% CI: 197.73; -100.03, Figure 3). Users were positive to both catheters in terms of handling, however, bladder emptying, and hygienic handling were twice as easy with MHZC (p=0.004 and p=0.025 respectively). A blocking sensation was three times less likely with MHZC (p<0.001).

Repositioning actions to completely empty the bladder were 2-4 times less likely with MHZC. The perceived confidence of bladder emptying at flow-stop and overall complete bladder emptying was increased with MHZC compared to CEC (Figure 4). Satisfaction was high for both catheters and Quality-of-Life scores were comparable.

| Total | N=73 |
|---|---|
| Age (years), mean (range) | 64 (28;87) |
| Reason for ISC | |
| **Non-neurogenic bladder dysfunction, n (%)** | **45 (62)** |
| Benign prostatic hyperplasia | 26 (36) |
| Chronic urine retention | 7 (10) |
| Atonic bladder | 6 (8) |
| Coloproctectomy | 1 (1) |
| Other | 5 (7) |
| **Neurogenic bladder dysfunction, n (%)** | **28 (38)** |
| Spinal cord injury | 17 (23) |
| Multiple sclerosis | 7 (10) |
| Peripheral neuropathy | 2 (3) |
| Cauda equina syndrome | 1 (1) |
| Other | 1 (1) |
| **Urethral sensation, n (%)** | |
| Normal | 58 (79) |
| Impaired | 14 (19) |
| Hypersensitive | 1 (1) |

*Table 1: Baseline characteristics*

*Fig 4: Perception data (%)*




## Conclusion

The study demonstrated a superior performance of the MHZC over CEC in terms of significantly reducing the likelihood of flow-stops; significant reduction in suction pressure peak at flow-stop; and significantly improved perception regarding blocking sensation, complete bladder emptying and the need for repositioning. Using Luja, ISC users will experience a simpler catheterisation process without flow-stops and no need to reposition the catheter, ensuring complete bladder emptying.

# Improved performance with the intermittent urinary micro-hole zone catheter: a combined analysis of three randomised controlled studies

**Landauro M.H., Vaabengaard R., Jacobsen L., Tentor F., Hannibalsen J., Permild R., Bagi P.** Presented at United Kingdom Continence Society (UKCS) Annual Scientific Meeting, United Kingdom, March 2023.

## Objective

**To evaluate the performance of new intermittent catheter prototypes with a drainage zone featuring micro-holes, designed to reduce mucosal suction, flow stops, microtrauma, and to improve bladder emptying.**

## Study design and methods

Three similar randomised controlled cross-over studies* evaluated the Micro-hole Zone Catheter (MHZC) and a conventional eyelet catheter (CEC) during three single test visits. Subjects were randomised to evaluate one of three catheters at each visit.

Primary endpoints were residual urine volume at 1st flow-stop (total urine catheterised minus urine catheterised at 1st flow-stop), and number of flow-stop episodes (figure 1), combining results from the three studies, assuming same effects for healthy volunteers and ISC users, but separated on sex.
For incidents of haematuria, an effect of under-lying condition was assumed, and results were separated for HV and ISC but combined on sex.

## Products

Conventional 2-eyelet intermittent catheters and two prototypes of the Micro-hole Zone catheter (differing by the length of drainage zone and number of drainage holes).

## Population

Study 1: 15 males and 15 females HV. Study 2: 15 male ISC users. Study 3: 15 female ISC users.

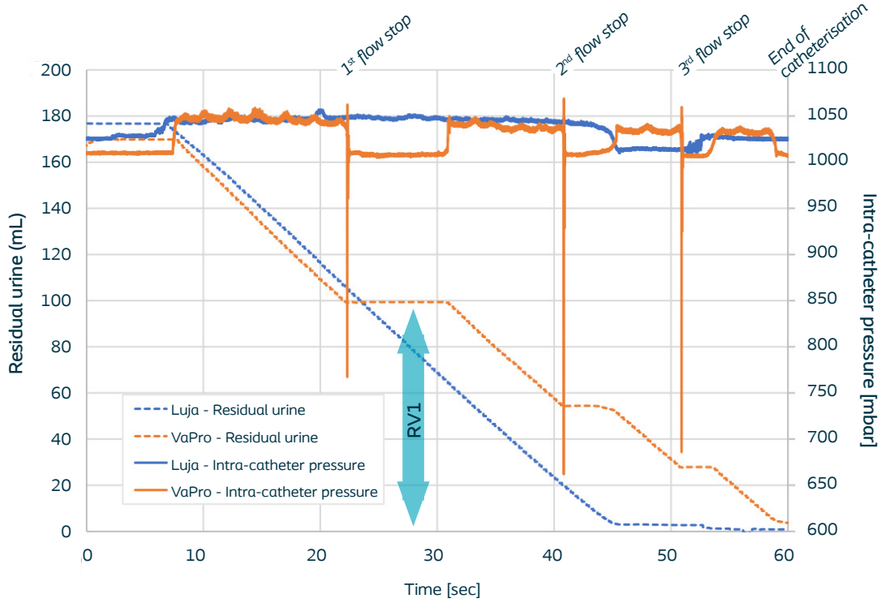



*Fig 1: Illustrative example of pressure/volume graph for one catheterisation with CEC and one with MHZC. RV1 (light blue arrow) represents the level of residual volume in worst case when CEC is withdrawn without proper repositioning to reinitiate urine flow.*

* ClinicalTrials.gov: NCT04445051, NCT04543136 and NCT04557787





## Results

Compared to catheterisations with CEC, MHZC resulted in a significantly lower mean residual urine at 1st flow-stop (mean difference: 49mL in males and 32mL in females, both p<0.001) (figure 2) and lower average number of flow-stop incidents (8 and 21 times less frequent for males and females, respectively, both p<0.001) (figure 3).

During normal micturition in HV, the likelihood for haematuria post-catheterisation was 5.84 higher with CEC compared to MHZC, p=0.053, whereas there was no difference in haematuria between IC catheter users.

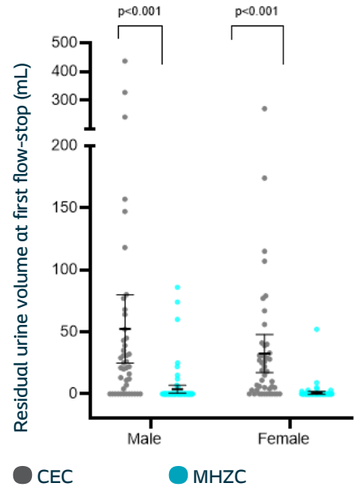



*Fig 2: Residual urine at 1st flow-stop with CEC and MHZC, in male and female subjects*

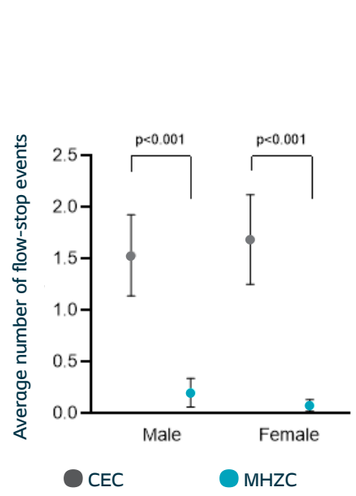



*Fig 3: Average number of flow-stops with CEC and MHZC, in male and female subjects*

## Conclusion

**MHZC shows the ability to reduce premature flow-stops and secure complete bladder emptying, measured as residual urine at 1st flow-stop, compared to a CEC. The new MHZC provides IC users with a simple catheterisation process without the need to reposition the catheter escaping potential UTI risk factors, common in ISC users.**

# The perception of a new compact MHZC by female users of ISC is significantly higher for handling, sensation, confidence, and satisfaction compared with a CEC

**R. Vaabengaard, Riis Forman C., Bundvig Barken K., Sperup T.** Presented at the International Spinal Cord Society Annual Scientific Meeting, Belgium, 2024.

## Objective

Conventional eyelet catheters can cause flow stops during catheterisation. These flow-stops require catheter repositioning but they also risk being mistaken for an empty bladder and can leave the user feeling uncertain about residual urine in the bladder and the associated increased risk of urinary tract infections. This evaluation compared the catheter perception of the new MHZC to a compact CEC in female IC users.

## Study design and methods

All data was collected at V2 and V3 after each of the two 2-week test periods at home exclusively using either the MHZC or the CEC (Figure 1).

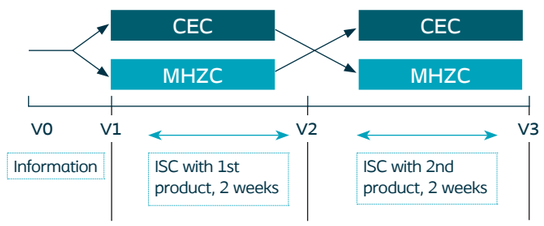
A perception questionnaire included questions on 'Handling', 'Sensation', 'Confidence and Control', and 'Satisfaction' scored on a 5-point Likert scale. Scores were based on the previous 14 days of home use.

Discomfort was scored on a 10 cm Visual Analogue Scale (VAS) in relation to insertion, emptying, completion, and withdrawal of the catheter during self-catheterisation performed during the site visits.

## Population

82 female adults who had been using ISC as their primary bladder emptying method for at least one month prior to participation.

*Fig 1: Design of evaluation*




## Results - Perception

More users had a positive perception of the MHZC compared to the CEC on all six handling-related questions (p-values <0.05); six out of seven confidence-related questions (p-values <0.05); all four sensation-related questions (p-values <0.001); all three satisfaction-related questions (p-values <0.001).

Significantly more users felt confident that the MHZC emptied their bladder completely compared to the CEC (Figure 2) and the MHZC was easy to use compared to the CEC (Figure 3). Significantly more users would recommend the MHZC to others compared to the CEC (Figure 4).

With CEC, 25% of users felt pinching/ stinging whereas 5% of users felt pinching/ stinging with MHZC

## Results - Discomfort

Discomfort scores relating to catheter insertion, emptying, completion, and withdrawal using VAS were very low for MHZC, with means ranging from 0.24 to 0.37 cm (Figure 5).



NEW: Luja female clinical study

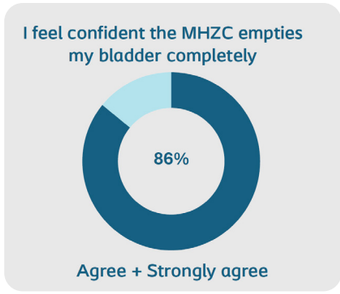



*Fig 2: bladder emptying*

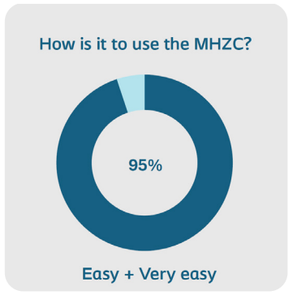



*Figure 3: ease of use*

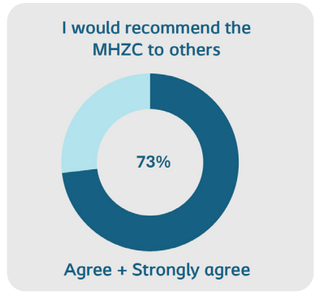
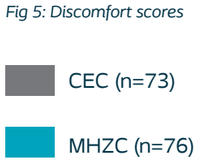
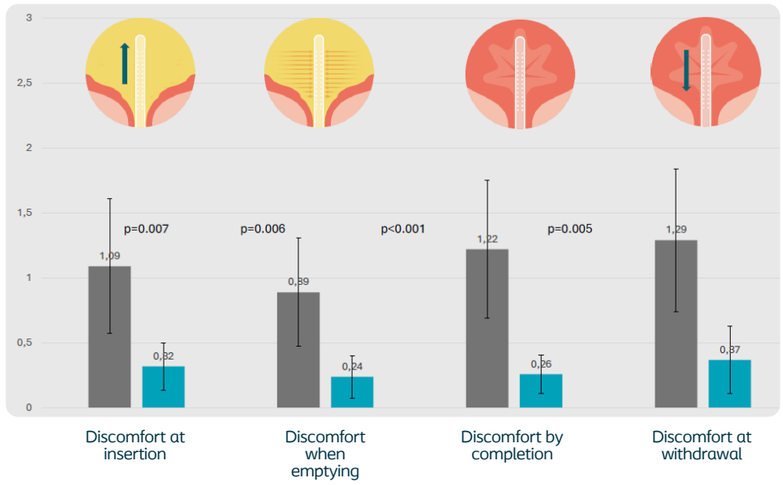



*Figure 4: recommending MHZC*

*Fig 5: Discomfort scores*




## Conclusion

After using the compact MHZC, experienced female ISC users reported significantly higher rates of positive perception of the handling, sensation, confidence and control, as well as satisfaction, than after using the CEC. The results demonstrated that using the MHZC enabled ISC users to feel secure about having emptied their bladders fully while experiencing minimal discomfort and reducing the risk of feeling a pinching sensation.

# New Micro-hole Zone catheter prevents flowstops and bladder microtrauma during intermittent catheterization.

**Schrøder B., Tentor F., Schertiger L., Stærk K., Emil Andersen T., Willumsen A., and Nielsen L.F.** Presented at International Neuro-Urology Society, Greece 2023.

## Objective

**To compare the performance of urinary intermittent catheters in terms of flow rate, residual urine at first flow-stop and mucosal suction.**

## Study design and methods

In a previously published study[1], results were presented from the use of three male CEC in an ex vivo bladder model mimicking the in vivo conditions of the lower urinary tract (LUT).

Mucosal suction was perceived by the operator in 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 for intermittent catheters.

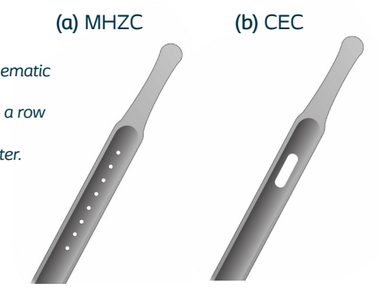



*Fig 1: Conceptual schematic overview of:*
*(a) MHZC shown with a row of many micro-holes,*
*(b) CEC control catheter.*

UTI-related parameters were measured for innovative MHZC with a drainage zone featuring 80+ micro-holes and compared it to a CEC in CH12 size. The flowrate, residual volume at first flow-stop, and incidence of mucosal suction for each catheter type was assessed in an ex vivo porcine LUT model. Four different micro-hole diameters were investigated. Furthermore, cystoscopy images were collected from inside the catheter lumen, in vivo, in pigs to expand the mechanistic understanding of the MHZC functionality. All results presented were conducted at a simulated abdominal pressure of 50mmH2O, which is the highest abdominal pressure described in the literature for a person standing, and therefore considered as worst case.

## Products

MHZC and CEC control catheter.

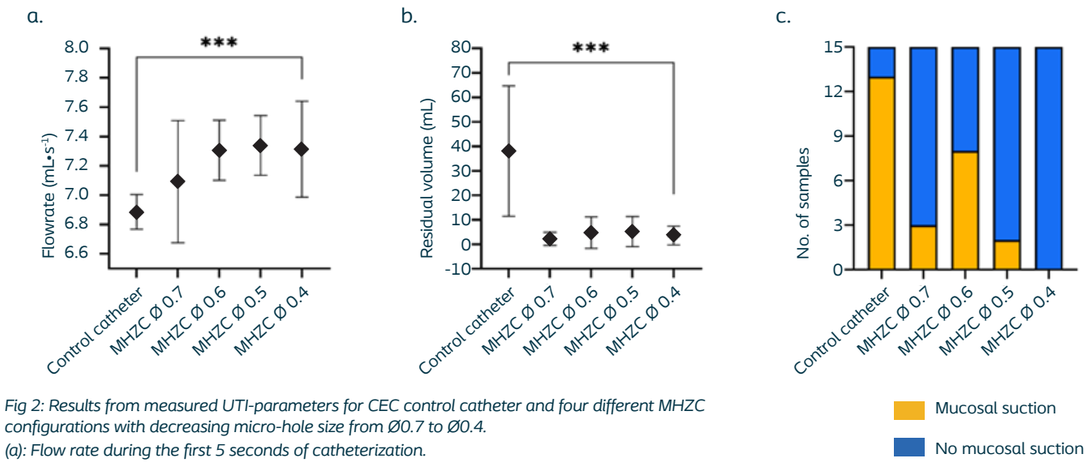



*Fig 2: Results from measured UTI-parameters for CEC control catheter and four different MHZC configurations with decreasing micro-hole size from Ø0.7 to Ø0.4.*
*(a): Flow rate during the first 5 seconds of catheterization.*
*(b): Residual volume in the bladder at first flow stop,*
*(c): the occurrence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





## 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.

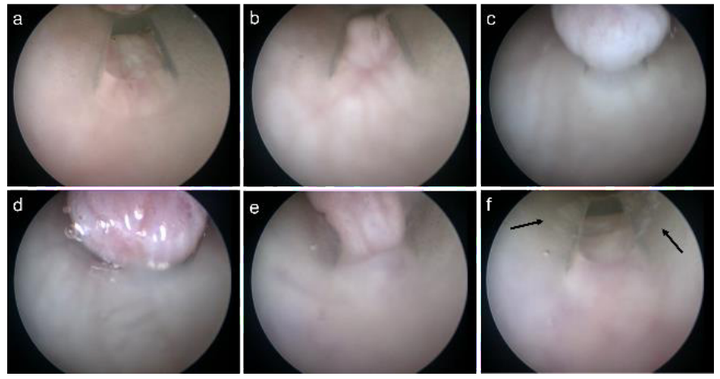



*Fig 3: In vivo cystoscopy from pig study showing different stages of a mucosal suction in a CEC, showing large ingress of tissue into the catheter lumen, and leaving visible residue from the tissue inside the catheter (f) (from published journal article.)*

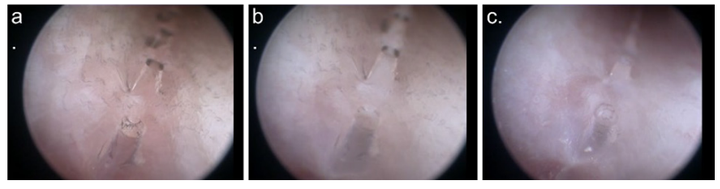



*Fig 4: In vivo cystoscopy using the Ø0.4 MHZC. Here, the ingress of tissue into the catheter lumen is limited to the eyelets, avoiding the scraping effect seen in Figure 3.*

## Conclusion

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

1. Tentor F., Schrøder B.G., Nielsen S. et al. (2022) 12:17818 | https://doi.org/10.1038/s41598-022-21122-6

# Catheter-associated bladder mucosal trauma during intermittent voiding: An experimental study in pigs

Stærk K., Schrøder B., Jensen L.K., Petersen T., Andersen T.E., Nielsen L.F. BJUI Compass. 2023.

## Objective

To characterise bladder mucosal trauma associated with intermittent catheterisation with conventional eyelet catheters (CECs), and to assess if a Micro-hole Zone (MHZC) catheter design concept reduces this adverse effect.

## Study design and methods

A porcine model was developed to reflect human catheterization and bladder drainage. Nine pigs were randomized for drainage with CEC (n=6) or MHZC (n=3). The bladder was drained repeatedly 20 times through the catheter. Cystoscopy was performed before and after the procedure, and bladders were analysed by histopathology. Two additional pigs were used for cystoscopy visualization of suction events in vivo.

Histopathological score, leucocyte infiltration and intra-catheter pressure at first flow stop during voiding was compared for each group using Mann-Whitney test.

## Results

A significantly higher pressure-gradient was measured inside the CECs compared to MHZCs during flow-stop.

Consequently, CECs resulted in suction events inflicting bladder trauma characterised by loss of epithelium, edema, hemorrhage, and neutrophil tissue infiltration. No significant trauma was identified when using MHZC.

## Strengths and limitations

This is the first study of its kind studying bladder trauma associated with intermittent catheterisation in vivo - similar findings in humans indicate that findings from a pig model may be translational to humans.

A limitation is the experimental approach of 20 repeated catheterisations which does not reflect the human use (~5-6 catheterisations/day). Yet, the individual lesions may be an acceptable approximation to what may happen in humans, and the use of 20 catheterisations mainly increase the likelihood of identifying such catheter-associated injuries without increasing injury severity overall.

In addition, this study only investigated the immediate trauma and acute inflammation in pigs, which may be different from inflammation following daily, prolonged use in humans.

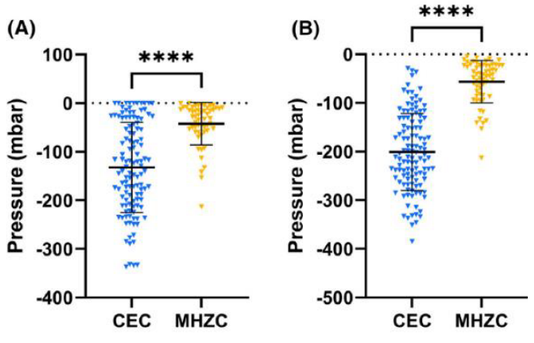



*Fig 1: Intraluminal pressure measured inside the catheter at first flow stop (A) and as the highest pressure peak within each drainage (B).*

*A lower negative pressure means a larger pressure impact for the respective catheter type.*

*CEC, conventional eyelet catheter; MHZC, micro-hole zone catheter.*

*****P < 0.0001.*

1. Stærk K, et al. (2022) 12:17818 | DOI: 10.1002/bco2.295





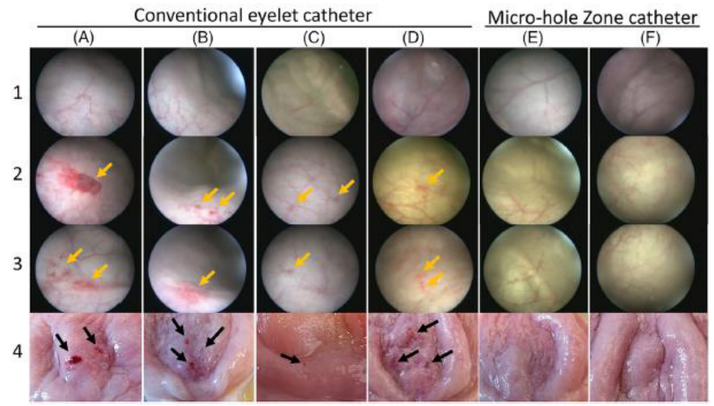



*Fig 2: Catheter-associated mucosal lesions observed by cystoscopy. All bladders appeared normal at baseline (row 1).*

*Significant lesions were observed in the bladder mucosa after the drainage procedures using conventional eyelet catheters, determined by cystoscopy (A–D, rows 2 and 3, yellow arrows) or gross pathology (A–D, row 4, arrows).*

*Lesions were not detected in the bladders from pigs drained by micro-hole zone catheters (E and F) nor in two of the six pigs drained by conventional eyelet catheters (from two different catheter manufacturers; not shown in the figure).*

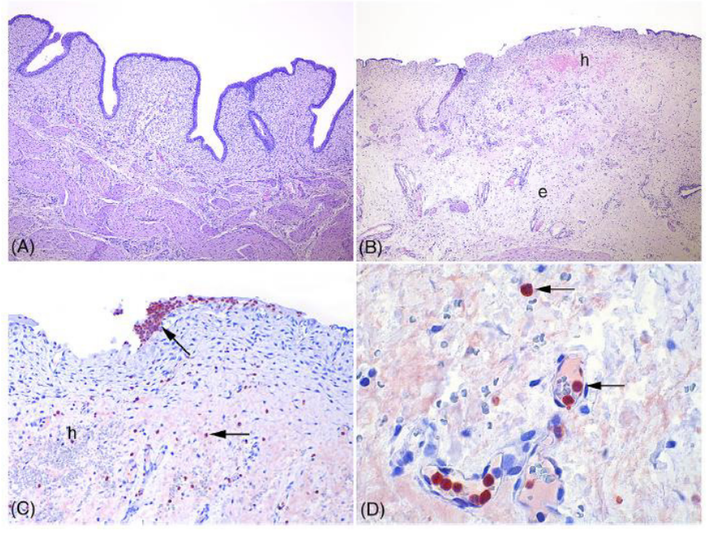



*Fig 3: Histology and immunohistochemistry of bladder tissue exposed to repeated catheterisations.*

*(A) Bladder mucosa from a pig catheterised with a micro-hole zone catheter showing no apparent pathologies. Haematoxylin and eosin stain, 200x magnification.*

*(B) Bladder mucosa from a pig catheterised with conventional eyelet catheter showing loss of bladder epithelia, haemorrhage (h), and massive oedema (e) of the mucosa. Haematoxylin and eosin stain, 200x magnification.*

*(C) Close up of picture (B). Massive neutrophil infiltration (red cells, arrows) is seen across the mucosa. Immunohistochemistry, 400x magnification.*

*(D) Close up of picture (C). Neutrophils within and outside vessels (red cells, arrows). Immunohistochemistry, 600x magnification.*

## Conclusion

Considerable mucosal bladder trauma is inflicted by CECs which may be an overlooked risk factor for UTI. Catheters designed to minimize mucosal suction may be a solution to reduce associated trauma. Furthermore, the study demonstrates the potential of pigs as an attractive animal model for investigating urinary catheter performances.

# Reduction in Eyelet Size in Intermittent Urinary Catheters Results in Less Urothelial Microtrauma in the Bladder

**Willumsen A., Reza T., Schertiger L., and Nielsen L.** Presented at United Kingdom Continence Society (UKCS) Annual Scientific Meeting, United Kingdom, March 2023.

## Objective

To compare mucosal suction caused by negative pressure with a conventional eyelet catheter (CEC) and a Micro-hole Zone catheter (MHZC)

## Study design and methods

A Conventional Eyelet Cather (CEC) and a Micro-hole Zone Catheter (MHZC) were compared in an ex-vivo porcine mucosal suction model able to recreate the pressure conditions of the bladder. The model was used to record intra-catheter pressures, and subjected tissue to mucosal suction with the different catheter technologies to be analysed 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.

## What is Mucosal Suction?

Mucosal suction describes the suction of the mucosa of the bladder into a catheter eyelet during drainage due to localised 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.

By replacing the CEC (Figure 1a) with a MHZC (Figure 1c) with many holes, the negative pressure peaks during a mucosal suction (Figure 1d) and the level of microtrauma can both be lowered.

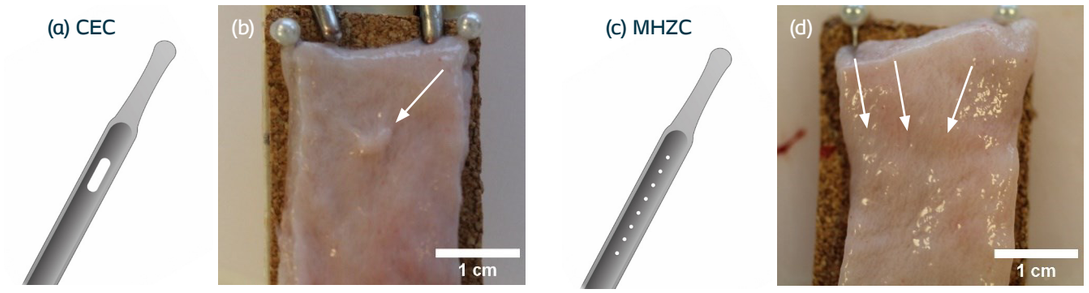



*Fig 1: Catheter overview and mucosal suction*
*(a): Overview of CEC, (b): Suction mark from mucosal suction with CEC, (c): Overview of MHZC, and (d): Small micro-suction marks from MHZC.*

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

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


*Fig 2 (right): 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 ($p < 0.0001$).*





## Results

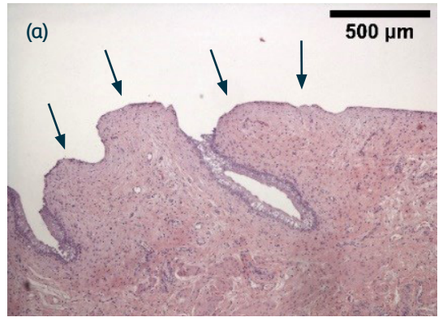
### Pressure Dynamics

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

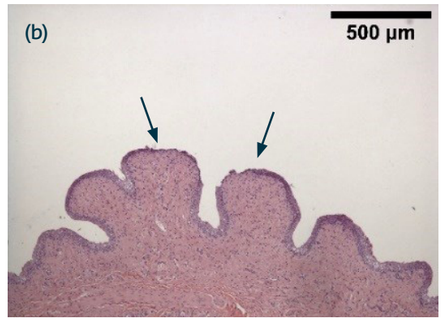
### Histological analysis

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

Conventional Eyelet Catheter




Micro-hole Zone




Negative Control

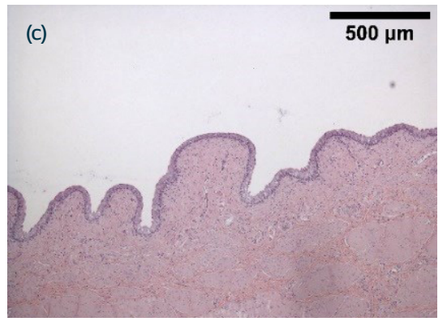



*Fig 3: H&E stained histological sections of porcine tissue samples subjected to mucosal suction with CEC and MHZC. Arrows point to areas of interest, such as thinning and exfoliation of urothelium.*
*(a): Microtrauma from CEC,*
*(b): Microtrauma from MHZC, and*
*(c): Negative control.*

## Conclusion

A catheter utilising a Micro-hole Zone catheter (MHZC) was shown to significantly lower the localised pressure peaks near the micro-holes compared to a CEC. Therefore, less suction is available to deform the tissue and the smaller micro-holes completely removed the ingress of the bladder tissue into the catheter lumen. This resulted in a lower level of microtrauma in the bladder compared to a CEC. The lower level of microtrauma may lead to fewer instances of urinary tract infections in vivo.

# The effect of Micro-hole Zone Technology in female intermittent urinary catheters as examined in an ex-vivo setting

**Willumsen A., Sulvart B., Bagi P., Feldskov Nielsen L.** Presented at the International Spinal Cord Society Annual Scientific Meeting, Belgium, 2024.

## Objective

Urinary tract infections remain the primary complication for users of clean intermittent catheterisation. Several potential risk factors associated with UTI like residual urine and microtrauma have been identified and used to develop an intermittent catheter with an innovative Micro-hole zone. The design has been shown to mitigate UTI related risk parameters in men. This study investigates if the same effects are observed in a compact female catheter with Micro-hole Zone Technology.

## Study design and methods

Five commercially available female CEC* and the female MHZC were compared in an ex-vivo setting using a porcine lower urinary tract (LUT) model, which replicated the in-vivo pressure conditions (20 $cmH_2O$) acting on a porcine bladder filled with 200 ml of isotonic saline. Each catheter type was tested 10 times in three bladders for a total of 30 replicates per catheter.

Endpoints included the residual volume at first flow-stop, total time for catheterisation (190 of 200 ml drained including repositioning) and the occurrence of flow-stops until complete emptying.

Additionally, endoscopic images were captured inside the catheter during draining with all catheters to assess the tissue/eyelet interactions. Histology was performed to assess bladder microtrauma in the Glahn model** (catheter test: n=15; negative controls: n=15).

## Results

The female Micro-hole Zone catheter performed better than all other catheters regarding the residual volume at first flow-stop with a statistically significant difference. Additionally, the occurrence of flow-stops was statistically higher for the comparator catheters than the Micro-hole Zone catheter.

Figure 1 shows examples of typical flow curves for MHZC and one of the comparables. Both catheterisations were the median run for the given catheter with respect to total catheterisation time. Dotted lines denote when the accumulated drained volume reaches 190 of 200 ml. This value is then noted as the drainage time for the given catheterisation. Arrow denotes location of flowstop for Infyna Chic, where Luja continues to drain. While Infyna Chic exhibits a flow-stop there is no statistically significant difference between the two catheters with regard to total catheterisation time (Figure 2b).

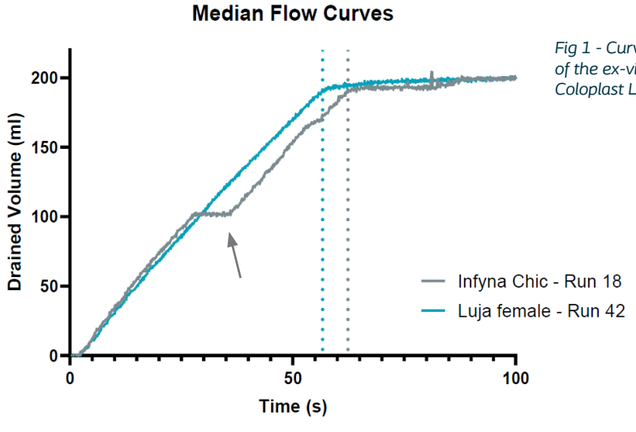



*Fig 1 - Curves of the volume of liquid collected from the drainage of the ex-vivo porcine bladder with a Hollister Infyna Chic and a Coloplast Luja female catheter (examples of typical flow-curves).*

* Infyna Chic™ (Hollister®); LoFric® Elle™ (Wellspect®); SpeediCath® Compact Plus, SpeediCath® Compact Eve and SpeediCath® Standard female length (Coloplast)

**Willumsen et al. Scientific Reports (2024) 14:15035. DOI.org/10.1038/s41598-024-65879-4



NEW: Luja female pre-clinical study

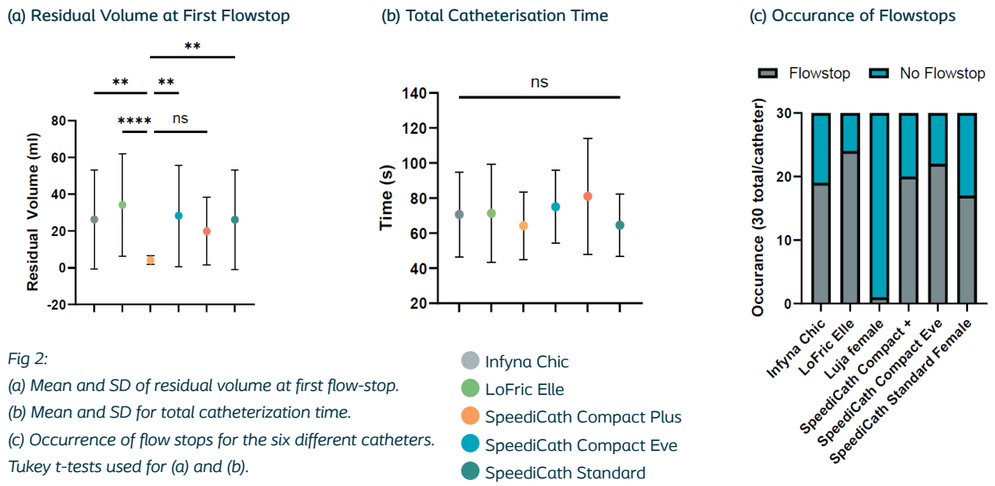
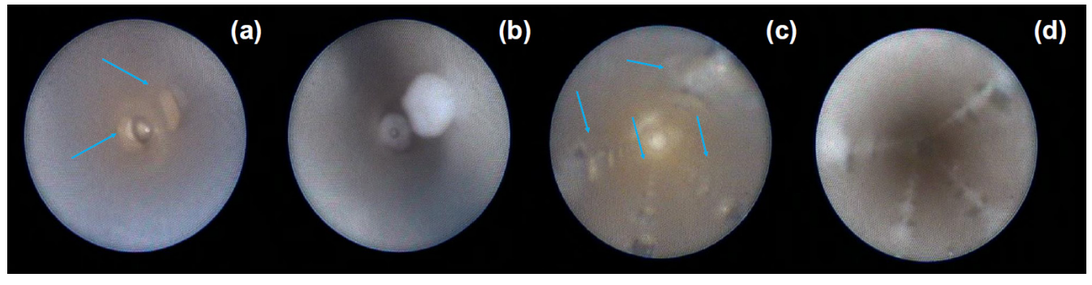



*Fig 2:*
*(a) Mean and SD of residual volume at first flow-stop.*
*(b) Mean and SD for total catheterization time.*
*(c) Occurrence of flow stops for the six different catheters.*
*Tukey t-tests used for (a) and (b).*

The endoscopic images showed that the tissue is sucked into the catheter lumen for all comparator catheters. In Figures 3a and 3b, Wellspect LoFric Elle shows a representative image of all conventional catheters, showing the ingress of tissue into the catheter lumen during a flow-stop. This phenomenon was not observed for the Micro-hole Zone catheter (Figures 3c and 3d).

Microtrauma is measured by loss of bladder urothelium due to ingress of tissue into the catheter lumen during a flow-stop in the Glahn model and histology results showed no difference in level of bladder microtrauma between the tested catheters (n=15) and controls (n=15).

*Fig 3 - Endoscopic images inside all catheters during emptying with and without flow-stop. Arrows mark the location of eyelets or micro-holes.*




## Conclusion

By using the female MHZC in an ex-vivo setting, both the residual volume at first flow-stop and the occurrence of flowstops during voiding were significantly lower than all the comparator catheters. No tissue was seen inside the catheter during suction episodes in contrast to the comparator catheters, which all had tissue inside the catheter lumen. Histology evaluations showed no difference between Luja female and the negative controls. MHZC can mitigate UTI-related risk factors, such as residual volume and microtrauma by limiting flow-stops and the need for repositioning of the catheter.

# Sediment in clear and cloudy urine: Can intermittent catheters drain it?

**Nielsen L., Athanasiadou S., Suldvart B., Bagi P.** Presented at European Renal Association (ERA) Annual Congress, Italy, June 2023.

## Objective

**This study characterised the types and size of sediment in clear and cloudy urine and subsequently investigated the ability of conventional eyelet intermittent catheters and a novel Micro-hole Zone catheter to drain them (figure 1).**

## Study design and methods

Clear urine was collected from three clinical studies. The sediment in the samples was analysed via automated microscopy.

Cloudy urine was collected from patients during their visits to a Urology Department. The samples were collected after spontaneous voiding, or via a conventional eyelet catheter and were analysed via automated microscopy. An in vitro drainage test with the two catheters was subsequently performed.

## Products

Conventional 2-eyelet intermittent catheters and two prototypes of the Micro-hole Zone catheter.

## Population

60 participants, equally distributed between male and female, healthy volunteers and ISC users.

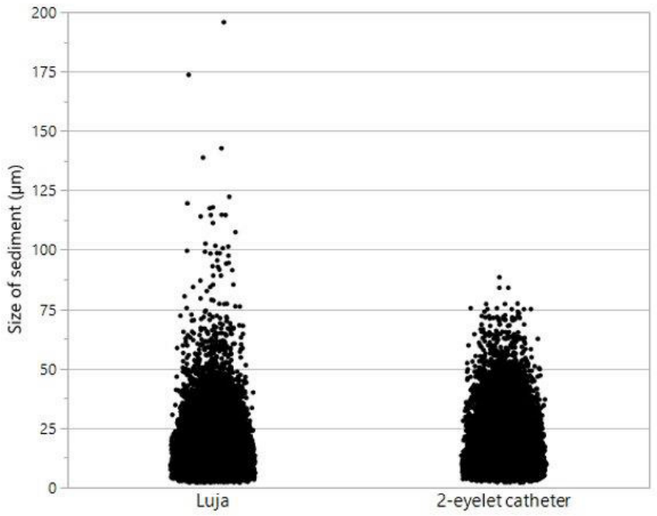



*Fig 1: Sediment size distribution in urine drained through Micro-hole Zone and conventional eyelet catheters.*

## Results

The analysis of clear urine (n=180) showed most sediment to be smaller than 50 µm, with the largest sediment up to 200 µm (2.05 to 195.76 µm). The sediment included primarily crystals, cells, and bacteria, in line with published literature (fig 1).

Cloudy urine was divided into two categories, based on the presence of large particles visible to the naked eye. The cloudiness was associated with particles with a mean size of 12.68 µm (min 1.65µm, max 183.24µm).

The sediment identity corresponded to the sediment in clear urine, but the quantity was higher (figure 2, sample A, B, C). Visible particles could not be analysed due to lack of light diffraction. These particles were soft and in various shapes and sizes (figure 3, sample D, E, F).





The Micro-hole Zone catheter drained sediment of larger size in clear urine compared to the conventional eyelet catheter. Both catheters drained cloudy urine efficiently but had challenges draining samples with visible particles (n=20); the Micro-hole Zone catheter drained 12 samples, either directly or after light wiggling, while the conventional eyelet catheter drained 18.

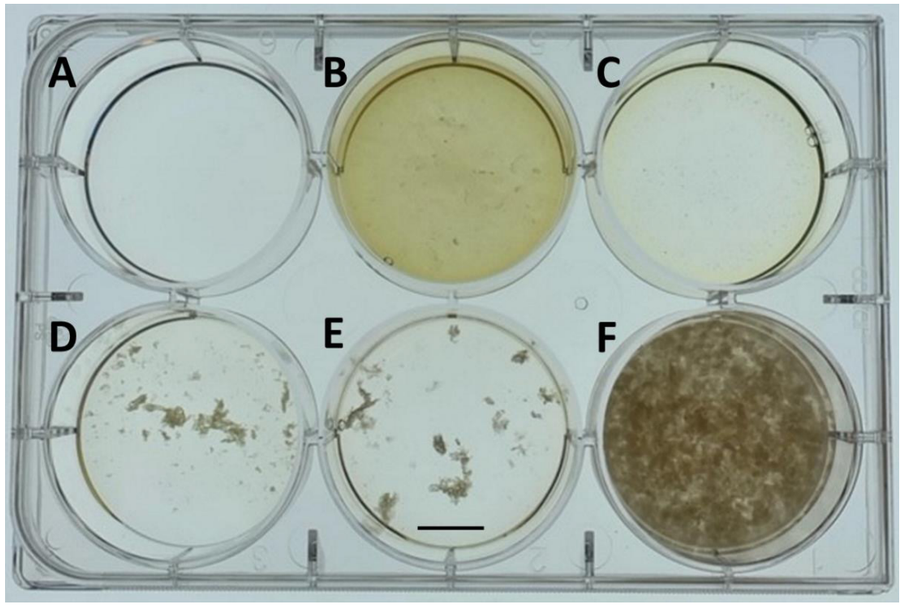



*Fig 2: Representative samples (10ml) were placed in a 6 well plate as follows:*
*A. clear urine*
*B and C. Samples of cloudy urine without debris visible to the naked eye.*
*D and E. Samples of cloudy urine containing debris visible to the naked eye.*
*F. Sample of cloudy urine with a high content of debris visible to the naked eye.*

## Conclusion

**The study showed that the novel catheter could efficiently drain urine and sediment. Larger particles visible to the naked eye posed a challenge for the micro-holes and, to a lesser extent, to the conventional eyelets. Therefore, the number and size of visible particles should be considered when deciding on the appropriate bladder management option. However, only 20 such samples were procured, likely reflecting that such sediment is a rare occurrence in clinical practice.**

# Healthcare professionals feel confident and less worried about bladder emptying and urinary tract infections when patients use the Micro-hole Zone catheter Luja™

**Vaabengaard R., Islamoska S., Zeeberg R., Jacobsen L.** Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.

## Objective

**When educating patients on intermittent catheterisation using conventional eyelet catheters, it is necessary to educate about repositioning the catheter to ensure complete bladder emptying and subsequently reduce the risk of urinary tract infections (UTIs). In this study, healthcare professionals (HCPs) evaluated a new catheter, Luja with Micro-hole Zone Technology.**

## Study design and methods

From February to July 2023, HCPs enrolled male adult users using ISC daily and evaluated on ease of training, worries of complete bladder emptying and UTI risk, and preference and recommendation of MHZC. Descriptive data analyses were conducted.

## Population

816 male adults and 62 HCPs from Denmark, Finland, the Netherlands and Switzerland.

## Results

Among the HCPs, 90% worked daily with men with prostate issues, 60% worked with MS patients, and 45% with spinal cord injuries (Figure 1). In addition, 69% had >10 years of ISC experience.

There were 87% who found training with Luja easy because there was no need to educate on repositioning. With Luja, 76% of HCPs were less worried of patients acquiring UTIs due to incomplete bladder emptying, and 71% preferred Micro-hole Zone Technology over conventional eyelets. Most HCPs (95%) would recommend Luja to their patients to a different degree (Figure 2).

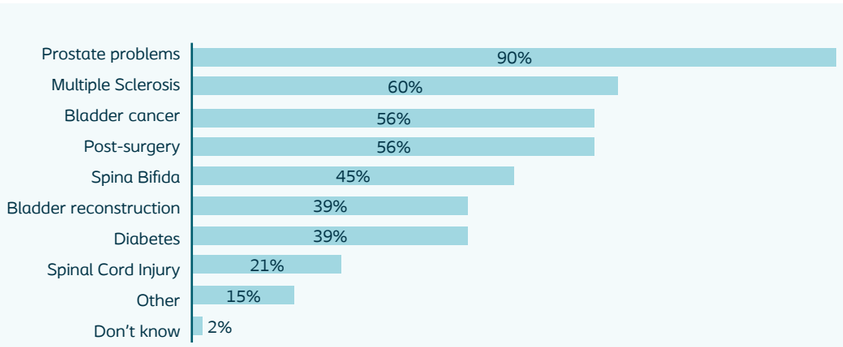



*Fig 1: HCP study demographics*





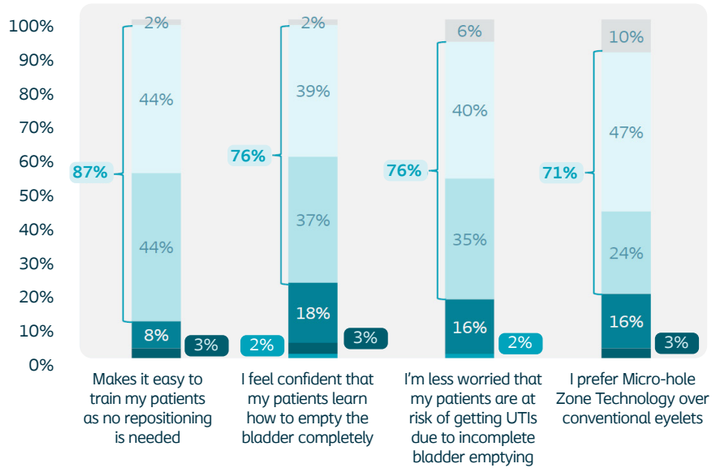
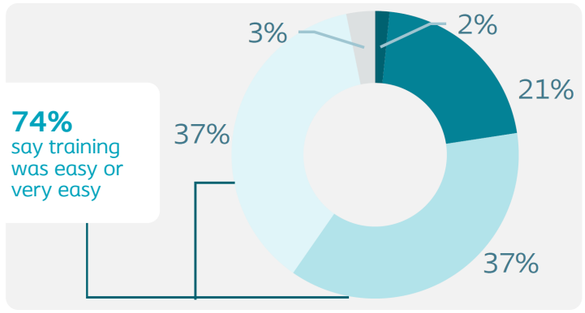
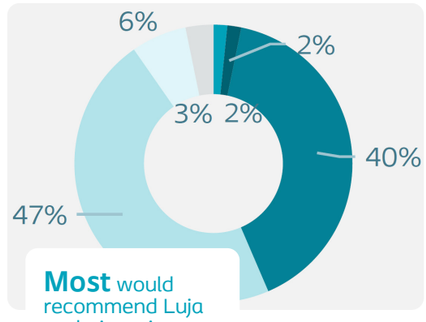



*Fig 2 (right): Statements about Luja*



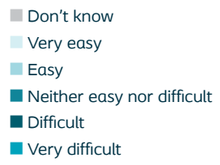
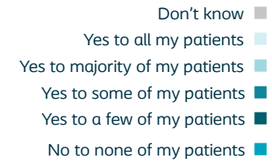




*Fig 3 (left): How was it training patients with Luja?*

*Fig 4 (right): Recommending Luja to patients*




## Conclusion

**The results indicate that the majority of HCPs felt confident that Luja enabled complete bladder emptying without the need for repositioning the catheter, preferred the Micro-hole Zone Technology, and they were less worried about patients acquiring UTIs - a general concern for the IC user population.**

# Users of intermittent catheters feel more confidence and less worries of bladder emptying and urinary tract infections when using the Micro-hole Zone catheter

**Vaabengaard R., Islamoska S., Zeeberg R., Jacobsen L.** Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.

## Objective

Intermittent catheters with conventional eyelets can cause flowstops leaving residual urine in the bladder if the catheter is not repositioned hereby increasing the risk of urinary tract infections (UTIs). In this study, intermittent catheterisation (IC) users evaluated the performance of a new Micro-hole Zone catheter, Luja.

## Study design and methods

A new catheter was evaluated from February to July 2023. After testing 30 Luja catheters each, the users answered a questionnaire regarding ease of use, ability to learn how to use it, ability to empty the bladder, confidence and worries related to bladder emptying and UTI risk. Descriptive data analyses were conducted.

## Population

816 male adults from Denmark, Finland, the Netherlands and Switzerland.

## Results

Causes for using ISC are shown in Figure 1, and current type of catheters used is shown in Figure 2 with 64% using a flexible catheter (Luja, SpeediCath Flex and VaPro, n=522), and 43% using a firm catheter (SpeediCath and LoFric, n=352).

*Fig 1: Cause of urinary problems*

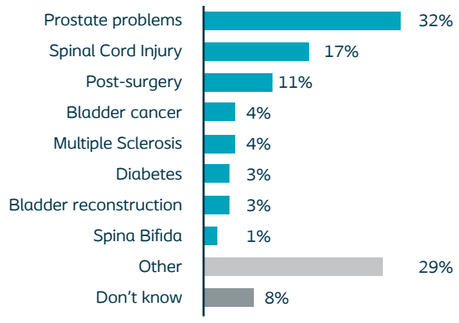
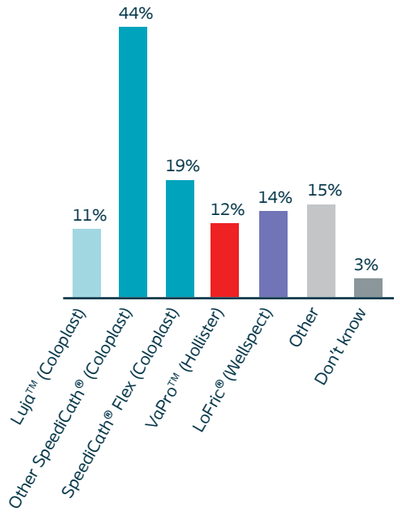



*Fig 2: Current product(s) used*




After testing Luja, 66% found it easy to use, however, this depended on current catheter used, as it was higher among new users (86%) and current flexible catheter users (83%, Figure 3).

Without having to adjust (reposition) Luja, 69% users felt confident that their bladder was completely empty, and 75% did not worry about residual urine (Figure 4). There were 55% of all users worrying less about acquiring UTIs due to residual urine (Figure 4), and this number was 67% for new users (not shown).

Overall, 68% would recommend Luja to other IC users (Figure 5), and 84% of new users would continue using Luja (Figure 6).





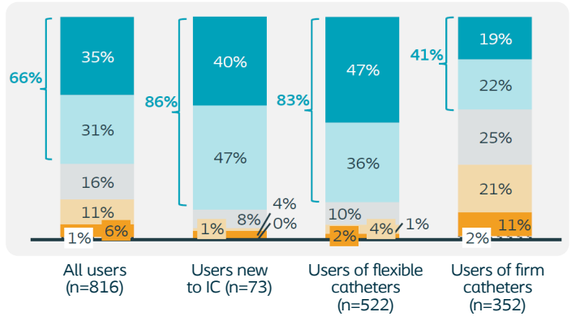



*Fig 3: Ease of use depended on current catheter used*

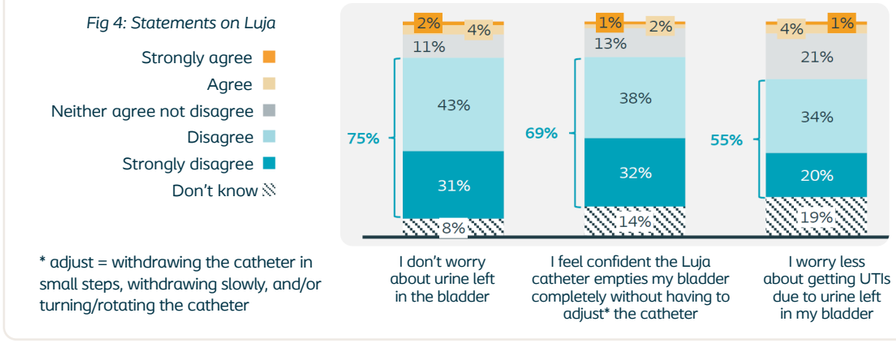



*Fig 4: Statements on Luja*

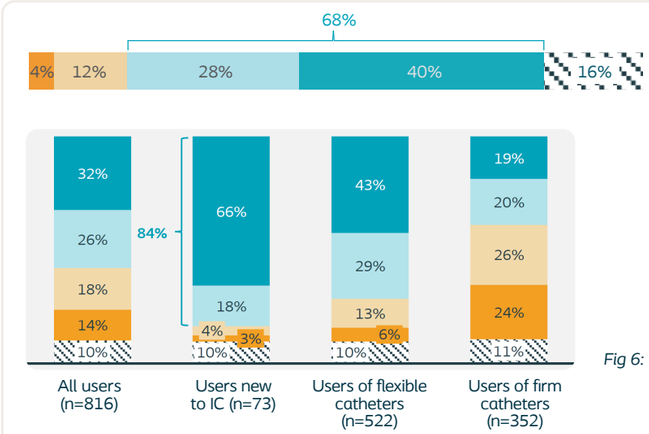



*Fig 5: Recommending Luja to other ISC users*

*Fig 6: Continue to use Luja*

## Conclusion

Results of the study indicate that the Luja catheter can help ISC users feeling less worried and more confident that their bladder is completely emptied without the need for adjusting or repositioning the catheter, thus lowering the mental burden for the individual ISC user.

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Nielsen L., Athanasiadou S., Suldvart B., Bagi P. Sediment in clear and cloudy urine: Can intermittent catheters drain it? Poster presented at ERA Congress, Milan, Italy June 2023.

Vaabengaard R., Islamoska S., Zeeberg R., Jacobsen L. Healthcare professionals feel confident and less worried about bladder emptying and urinary tract infections when patients use the Micro-hole Zone catheter Luja. Poster presented at BAUN, Liverpool, UK 2023.

Vaabengaard R., Islamoska S., Zeeberg R., Jacobsen L. Users of intermittent catheters feel more confidence and less worries of bladder emptying and urinary tract infections when using the Micro-hole Zone catheter Luja. Poster presented at BAUN, Liverpool, UK 2023.

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