Coloplast 2025

Evidence Summary

Addressing urinary tract infection risk factors with Micro-hole Zone Technology™

Contents

Abbreviations

CEC	Conventional eyelet catheters
HCIC	Hydrophilic-coated intermittent catheters
IC	Intermittent catheterisation
MHZC	Micro-hole Zone Catheter
MHZT	Micro-hole Zone Technology
NLUTD	Neurogenic lower urinary tract dysfunction
PVR	Post-void residual urine
QoL	Quality of Life
TACT	Triple Action Coating Technology
UTI	Urinary tract infection

Introduction

The purpose of this evidence summary is to describe how Micro-hole Zone Technology (MHZT) can help address unmet needs among individuals with bladder problems who are dependent on intermittent catheterisation to empty their bladder. Discover our biggest clinical evidence package in Coloplast intermittent catheterisation history in the following collection of scientific materials.

Urinary tract infections and quality of life

Urinary tract infections (UTIs) are a major burden for individuals with neurogenic lower urinary tract dysfunction (NLUTD), and many experience in the range of 0.8-3.5 UTIs/year (>12 months after injury).[1] Intermittent catheterisation (IC) is used as the gold standard of care for voiding disorders in individuals with and without NLUTD.[2] Yet, individuals using IC also experience UTIs, and NLUTD complexity can make individuals more prone to severe infections and longer hospital stays.[3]

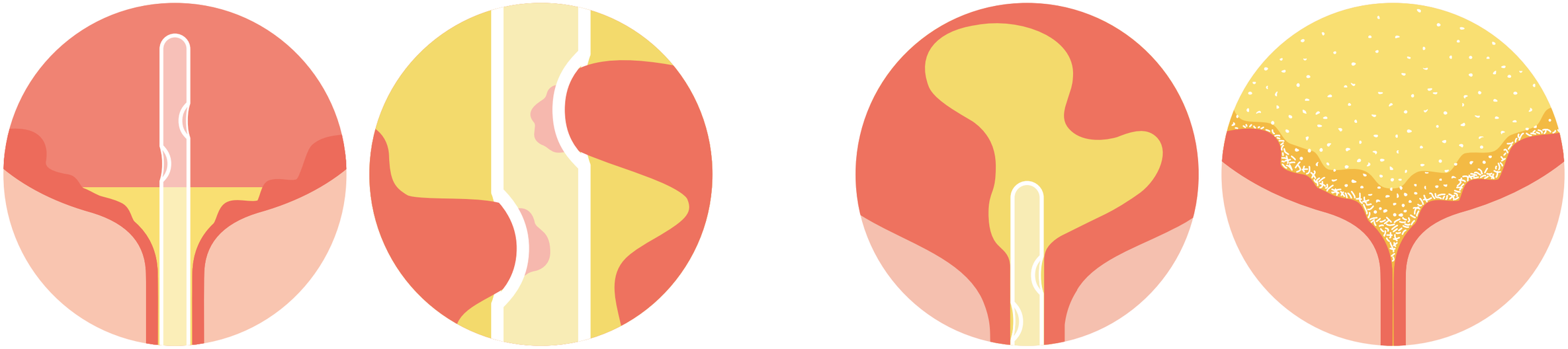
In a research study among 3464 IC users, it has been observed that quality of life (QoL) is negatively influenced by:
- UTIs
- Experiencing residual urine
- Applying different withdrawal techniques during IC
- Having blood in the urine
- Having bowel dysfunction[4]

From the same study[4], the risk of acquiring UTIs was:
- 37% lower for IC users without haematuria
- 17% lower when the bladder was perceived empty
- 14% lower in the absence of bowel dysfunction

Thus, the presence of risk factors in individuals' lives can dramatically affect QoL and the risk of UTIs, highlighting the importance of addressing symptoms in individuals using IC before potentially developing UTIs. Besides impacting individuals' QoL, UTIs also present an economic burden on society due to healthcare costs associated to UTIs.[5-7]

Pete | Luja user

Challenges with intermittent catheterisation



Residual urine

When using IC for bladder emptying, some individuals may experience post-void residual urine. As part of the catheterisation technique, repositioning the catheter is fundamental to ensure a completely empty bladder.[4]

Residual urine is a recognised risk factor for UTIs in the neurogenic population.[2, 8-9] In addition, residual urine can also become an issue if flow-stops occur during catheterisation and if the catheter is withdrawn without repositioning.[10]

Microtrauma

During catheterisation, bladder mucosa may be sucked in through the two catheter eyelets resulting in a flow-stop. This may result in microtrauma that can range from minor changes to more severe tears of the epithelia tissue thereby increasing the risk of UTIs.[2, 8, 10]

Mucosal suction occurs from the negative pressure inside the catheter during drainage and the tissue of the bladder mucosa is being abruptly sucked into the catheter lumen.[10] A compromised bladder may give easier access for bacteria to adhere and potentially lead to a higher risk of UTI.[2,10]

Discomfort

As mucosal suction occurs intensely, this may lead to discomfort in IC users when repositioning the catheter to resume the urine flow.[10]

Discomfort and pain have been observed by IC users and especially women experience this more than men (41% vs. 31%).[11] Based on the condition causing need for IC, differences may exist in users' discomfort level due to reduced sensitivity specifically for some conditions.[12] Overall, pain related to IC could impact the likelihood of performing IC within the optimal number of catheterisations per day, as pain can significantly impact health state utilities and thereby QoL.[13]

Sediment

Urine mainly consists of up to 96% water and solid urinary sediments as inorganic salts, urea, organic compounds, and organic ammonium salts.[14]

Urinary sediments may vary in terms of physical and chemical properties depending on different pathologies and factors with most sediments being smaller than 50 µm.[15-17] By observing urine from IC users, a study has shown that sediments range from 1-200 µm with a mean of 12.7 µm.[17] To maintain blader health and remove debris, it is shown that increasing one's fluid intake and switching to IC use can help with complete bladder emptying.[18]

Micro-hole Zone Technology™

Micro-hole Zone Technology

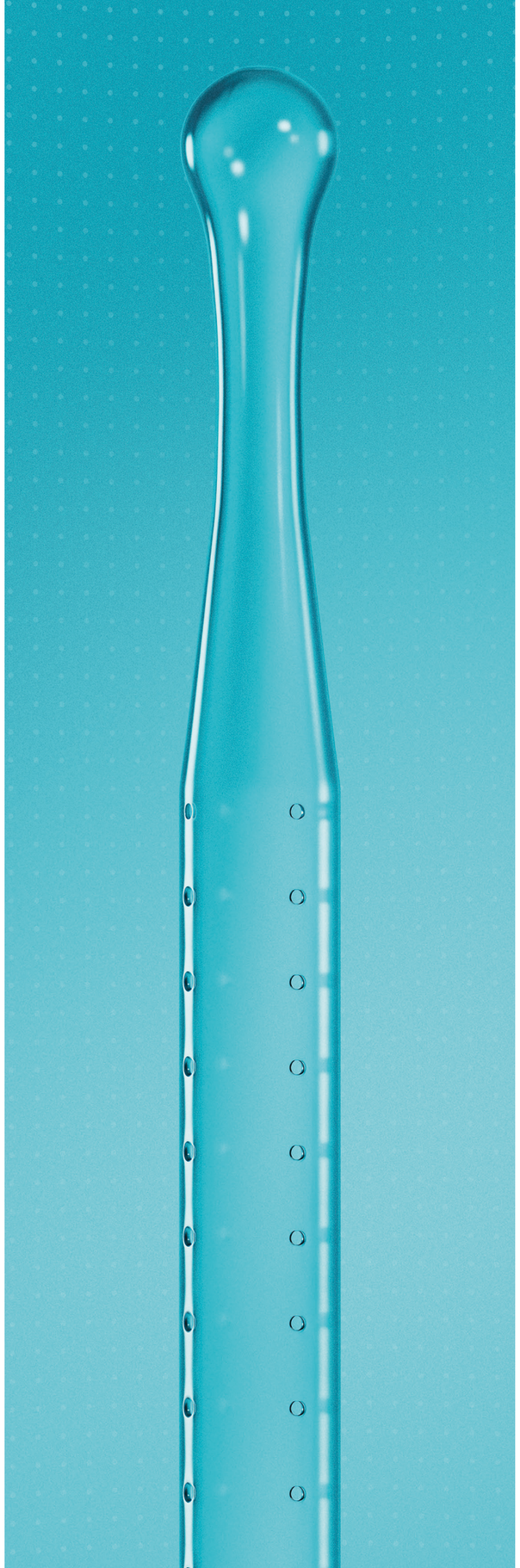
After six years of development with more than 270+ healthcare professionals, 430+ IC users, and 80+ Coloplast employees, Micro-hole Zone Technology was developed to set a new standard for bladder emptying.[19-20] Micro-hole Zone Technology is acknowledged in the guidelines by the European Association of Urology Nurses (EAUN) in 2024 as a catheter enabling complete bladder emptying in one free flow without the need for repositioning, potentially preventing suction in the bladder, and thus reducing the risk of microtrauma and residual urine.[21]

Luja is a catheter with Micro-hole Zone Technology that has close to no flow-stops and is a technology that enables complete bladder emptying* in one free flow.

As urine is drained across the entire Micro-hole Zone, the intra-catheter pressure stays low, hereby preventing mucosal suctions and risk of microtrauma[19]. Thus, drainage is rarely interrupted making bladder emptying less dependent of user technique, as catheter repositioning or adjustment is unnecessary.

Micro-hole Zone Technology is designed to address catheter-related UTI risk factors as a lack of proper hygiene introducing bacteria upon insertion, residual urine, and microtrauma caused by mucosal suction, which is usually experienced with conventional eyelet catheters (CEC).[2, 19-20]

*Complete bladder emptying is defined as <10 mL (19. Landauro et al 2023, DOI: 10.3390/jcm12165266, N=42). Individual results may vary.



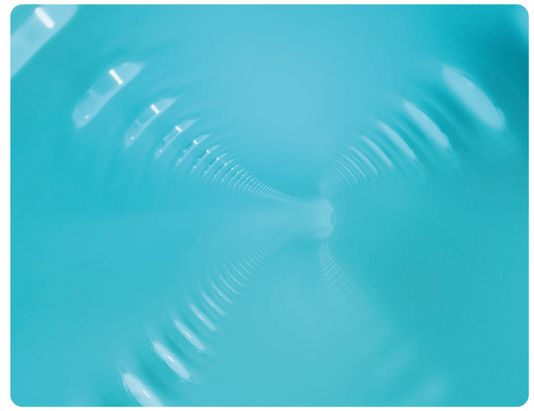
Clinical evidence

Clinical evidence on Micro-hole Zone Technology shows superior performance over conventional eyelet catheters (CEC) through significantly less flow-stops and reduced residual volume (<10 mL) at first flow-stop.[19-20,22-24]

Compared with CEC, individuals have a significantly improved perception of a MHZC regarding bladder emptying, less blocking sensation, and improved hygienic catheterisation.[22]

Micro-hole Zone Technology is designed to drain sediments from the bottom of the bladder and it drains cloudy urine with sediments.[17] If a patient produces urine with many particles clearly distinguishable by the naked eye, Luja should be applied with caution, as it may lead to transient urine retention.

Overall, clinical evidence on this new generation of IC catheters shows that Micro-hole Zone Technology addresses more catheter related UTI risk factors than ever by enabling complete bladder emptying in one free flow, reducing suction to reduce risk of bladder microtrauma**, reduce risk of urethral trauma, and supporting a hygienic procedure with no-touch handling.



Microholes seen from the inside of a catheter.

As UTIs can affect IC users' QoL considerably, Micro-hole Zone Technology may help addressing the worries of UTIs and potentially help reducing healthcare costs related to UTIs in the future.

On the following pages, you will find an overview of different scientific posters and materials covering the biggest clinical evidence package in Coloplast IC history. The posters are based on several studies presented at scientific conferences whereof some posters have been published as scientific articles in medical journals.

**Tested in a pre-clinical ex vivo setting

Triple Action Coating Technology™

Triple Action Coating Technology – A part of Luja

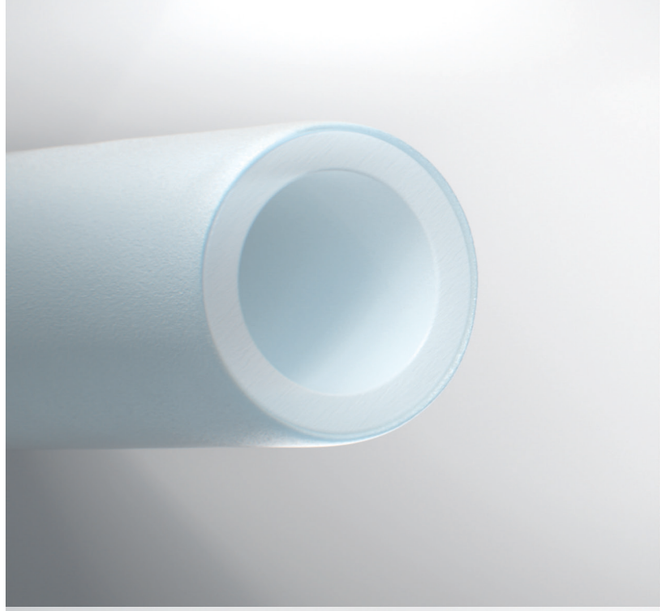
Single-use hydrophilic-coated intermittent catheters (HCIC) is considered the gold standard for bladder emptying, due to IC being the saftest method in terms of lower risk of urological complications urological complications and higher patient preference.[2, 21, 25]: Luja is a catheter that includes both Triple Action Coating Technology and Micro-hole Zone Technology.

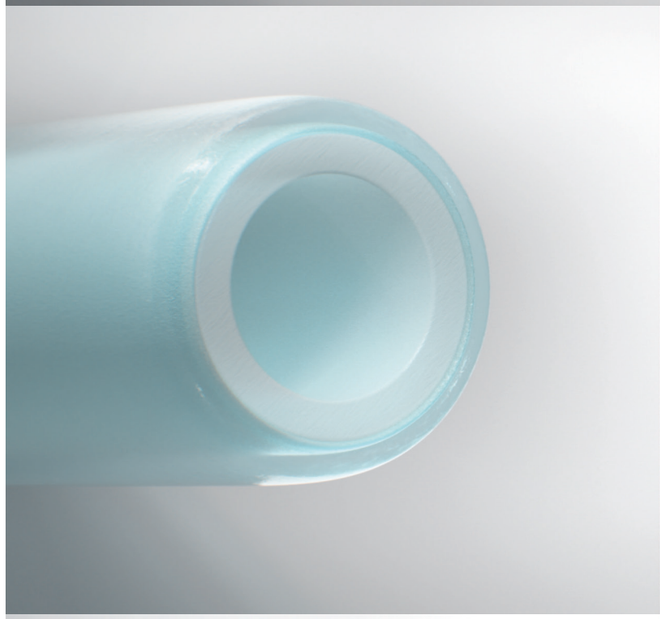
Strong evidence recognizes HCIC as the preferred choice, as this technology is associated with improved satisfaction, higher preference, better QoL, less UTIs and adverse events, and more cost-effectiveness.[21]

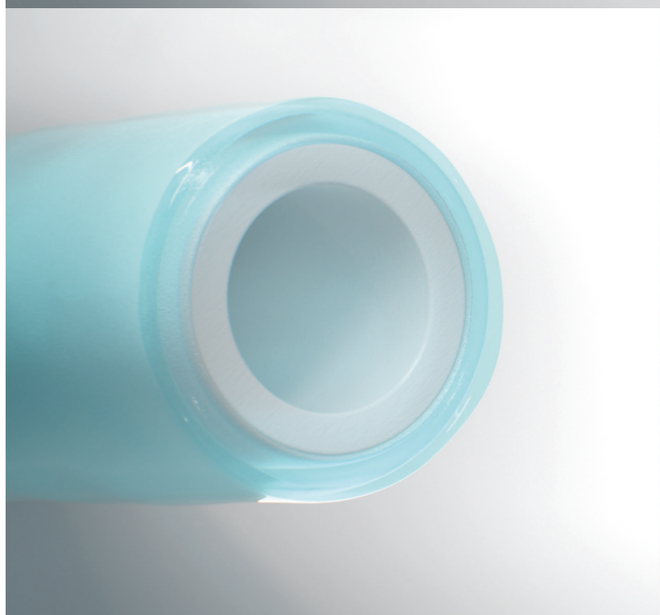
Triple Action Coating Technology is a hydrophilic coating that reduces friction in the urethra*, and which:

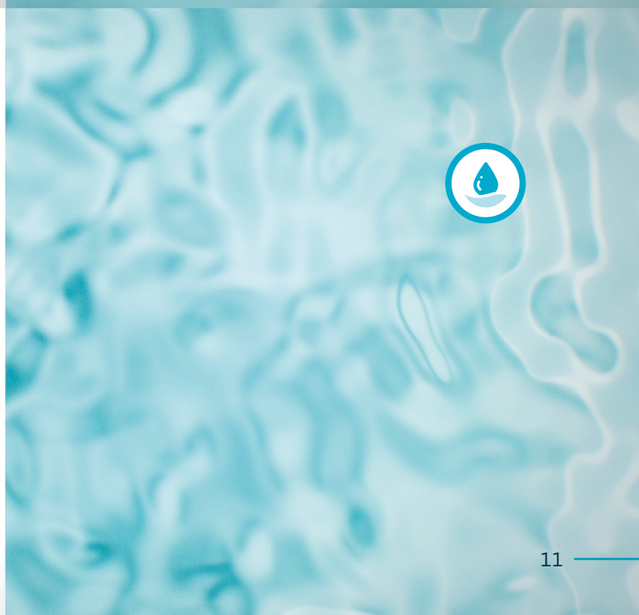
- Stays bonded for an even coating without dry spots
- Stays smooth to reduce friction on the urethra
- Staying hydrated with a special water-based solution that swells the coating and makes it instantly ready to use

* compared to uncoated catheters









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

	Study	Publication	Residual urine		Microtrauma			Perception	Discomfort	Sediments	UTIs, QoL	More info
			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] 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.

Scientific posters

UTI risk factors
Pre-clinical studies
Clinical studies
Product evaluation

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

Islamoska S., Landauro M.H., Zeeberg R., Jacobsen L., Vaabengaard R.[32]
Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2022.

Introduction

Based on outcomes reported by clean intermittent catheter (CIC) users, we have investigated the association between risk factors for urinary tract infections (UTI) – 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 respectively.

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. There was a 37% lower risk of UTIs when blood was n ot apparent in the urine (RR: 0.63; 95% CI: 0.55-0.71), a 17% lower risk when bladder was perceived empty (RR: 0.83; 95% CI: 0.72-0.96), a 14% lower risk without having bowel dysfunction (RR: 0.86; 95% CI: 0.76-0.98), and a 30% lower risk in males (RR: 0.70; 95% CI: 0.62-0.79).

Figure 1: Mean number of UTIs per year within patient-reported UTI risk factors.

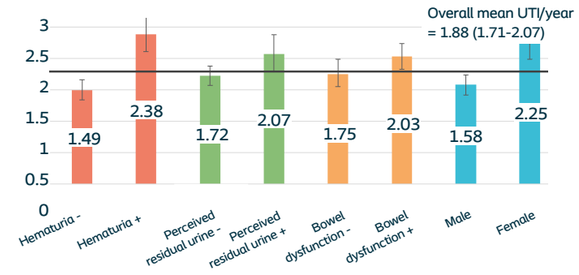
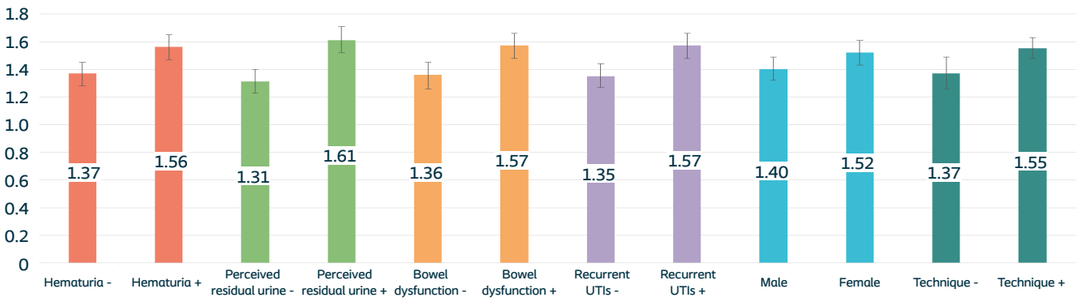


Figure 2: Relative risks (RR) of UTIs within patient-reported UTI risk factors.

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 dysfunction vs. having bowel dysfunction	0.86 (0.76-0.98)	0.027
Male vs. female	0.70 (0.62-0.79)	<0.001

Figure 3: Mean quality of life scores within patient-reported UTI risk factors (impact of urinary issues: range 0-4; 0 = no impact; 4 = high impact).



Discussion

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.

Adult neurogenic lower urinary tract dysfunction (ANLUTD) and intermittent catheterisation (IC) in a community setting: Risk factors model for urinary tract infections (UTIs)

Thiruchelvam N., Kennelly M., Averbeck M.A., Konstantinidis C., Chartier-Kastler E., Trøjgaard P., Krassioukov A., Jakobsen B.P., Vaabengaard R.[33]
Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2019.

Introduction

For community patients, living with ANLUTD, clean intermittent catheterisation (CIC) is the gold standard for bladder emptying, as CIC is the safest method in terms of having the lowest potential for urological complications.[34] From daily clinical experience, clinical studies, and surveys, it is evident that UTIs are the commonest complication to IC and constitutes a major reason for concern in patients, their clinicians and care givers.[35]

Purpose of this review is

- To remind clinicians that the correct diagnosis and thereby treatment/management of UTI/bacterial contamination in the ANLUTD patient population is challenging and far from simple.
- To update and discuss the UTI risk factors associated to IC in community settings.
- To provide a simple, holistic and useful risk factors model that can be used by the clinician in daily practice and come to the benefit of the individual catheter user in terms of fewer UTIs.

Methods

The model is based on comprehensive literature reviews and author consensus in case of lacking evidence. The model primarily concerns patients with spinal cord injury, spina bifida, multiple sclerosis or cauda equina using IC as part of their bladder management.

Results/Outcome

The model provides an overview of the risk factors involved in UTIs, with specific emphasis on those that can be handled and modified by the clinician in daily practice. The model is divided into four categories:

- General (systemic) conditions in the patient.
- Individual urinary tract conditions in the patient.
- User (patient) compliance/adherence to treatment.
- Factors related to intermittent catheters per se.

Conclusion

There is a need for alignment of the definition and diagnosis of UTI. It may be done disease per disease or more generally. Even with less complications than other bladder management methods, CIC still expose ANLUTD patients with a high risk of UTIs, a condition associated with increased morbidity and mortality in this patient group. There is a paucity of evidence describing the UTI risk profile, and well designed clinical trials are warranted to provide the clinician a better platform for adequate management of the UTI risk profile to the benefit of these patients. Guidelines, when available, should be adhered to.

UTI risk factors model[2]

Intermittent catheterisation

Bacteria inserted by product and no urethral rinsing

Urethral and bladder trauma from product

Post void residual urine due to product design

General conditions

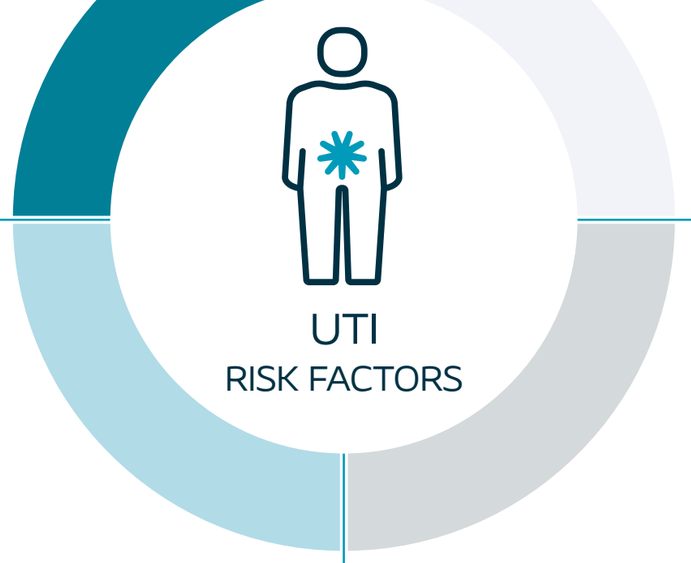
High intravesical pressure/impaired bladder compliance

Host deficiencies

Bowel dysfunction

Diabetes

Age and gender



User compliance/adherence

Voiding frequency

Fluid intake

Non-hygienic procedure

Insufficient education

Post void residual urine due to incorrect handling

Residence country and social support system

Local urinary tract conditions

Bacterial virulence

Previous UTI

Botulinum toxin A injections

Urodynamic investigations

Bladder and kidney stones

Post void residual urine caused by bladder shape

A collaborative tool to assess risk factors of urinary tract infection among intermittent catheter users

Athanasiadou S., Vaabengaard R., Lauridsen, SV.[36]
Presented at the International Meeting of the European Association of Urology Nurses (EAUN), The Netherlands, July 2022.

Introduction & Objectives

Urinary tract infections (UTIs) are a significant burden for users of intermittent catheterisation (IC). The variety of risk factors associated with UTIs complicates the detection and management of the causes for the individual user. Our project aimed at developing a UTI assessment tool that supports healthcare professionals (HCPs) in evaluating risk factors in a systematic and collaborative way in the clinical practice, while taking the user's perspective into account.

Materials & Methods

The tool was developed based on the steps of the Design Thinking process: Empathise, Define, Ideate, Prototype and Test (Figure 1).[37]

Two methodologies were used to develop the content: a literature review on the users' perspectives and practices related to UTIs and consensus meetings with Nurse Advisory Boards in 8 European countries. Initially, the nurses reviewed the published UTI Risk Factors Model[2] and pinpointed the risk factors relevant for them to assess. Then they developed questions that, if posed to the patient, would reveal these risk factors. The outcome was reviewed and further evolved in a second round of sessions, and the compiled content was revised, structured, and aligned with the literature findings.

The prototype of the tool was tested in a third round of Advisory Board sessions and the nurses provided qualitative and quantitative feedback that was used to develop the final tool.

Results

The literature showed that the users are uncertain of the causes and symptoms of UTIs. Fitting IC into daily life and adhering is a challenge, and the technique may be unclear. The importance of education and the selection of a catheter that fits the individual needs is highlighted. Based on the Advisory Boards' input, *the UTI assessment tool for intermittent catheter users* was created, including 6 sections, namely UTI Confirmation questions to assess if the case is indeed a UTI, questions on risk factors associated with Health, Adherence, Technique and Catheter, and finally a Support section to ensure that the user has all the needed information and a plan on next steps. Additionally, based on the input, guidance and suggested actions was developed for the questions, and the content was compiled in an HCP guide.

The tool was supplemented with a dialogue board to be shared with the users, including additional illustrations and text, to facilitate the users' understanding and support the dialogue between the HCP and the user. Additionally, a notepad with copies of the dialogue board was included, so that each sheet be used as a personal form to take notes from the assessment and share it with the users to take home.

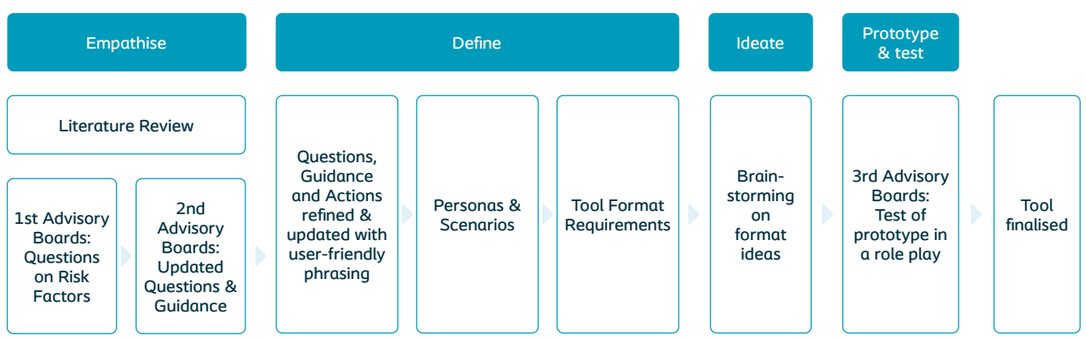
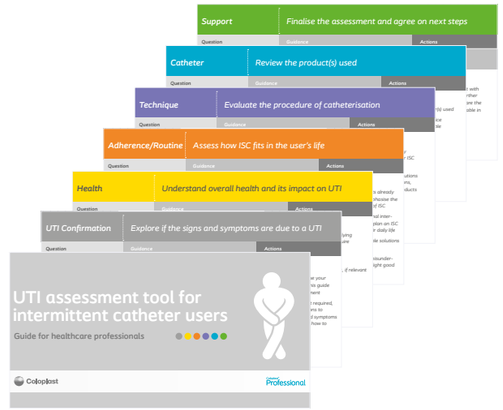


Figure 1. Process of developing the UTI assessment tool for intermittent catheter users, according to the Design Thinking Process.

Folder

HCP Guide



Dialogue Board

Personal Form (Notepad)

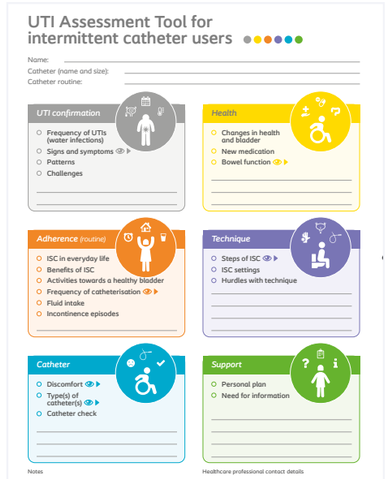


Figure 2: The elements of the UTI assessment tool for intermittent catheter users: a Guide for healthcare professionals, a Dialogue board, and a Personal form notepad.

Conclusions

The *UTI assessment tool for intermittent catheter users* has been developed to allow a systematic assessment of the UTI risk factors for IC users, while considering the user's perspective. It supports the education of new nurses and the clinical practice for HCPs by providing a structured dialogue approach to identify and handle UTI risk factors for the individual user. Therefore, it may help prevent future UTIs and unnecessary antibiotic treatment.

New Micro-hole Zone catheter prevents flow-stops and bladder microtrauma during intermittent catheterization.

Schrøder B., Tentor F., Schertiger L., Stærk K., Emil Andersen T., Willumsen A., and Nielsen L.F.[38]
Presented at International Neuro-Urology Society, Greece 2023.

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 flow rate, residual volume at first flow-stop, intra-catheter pressure, and incidence of mucosal suctioning in an ex vivo porcine LUT model. 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 mmH2O, which is the highest pressure described in the literature, and therefore considered as worst case.

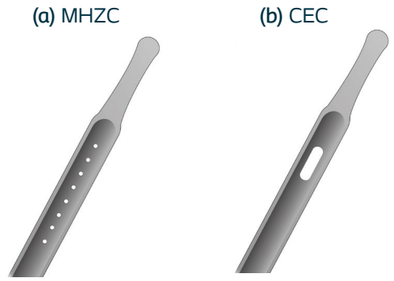


Figure 1: Conceptual schematic overview of:
(a) MHZC shown with a row of many micro-holes,
(b) CEC control catheter.

Results

All MHZCs had significantly higher flow rates (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.

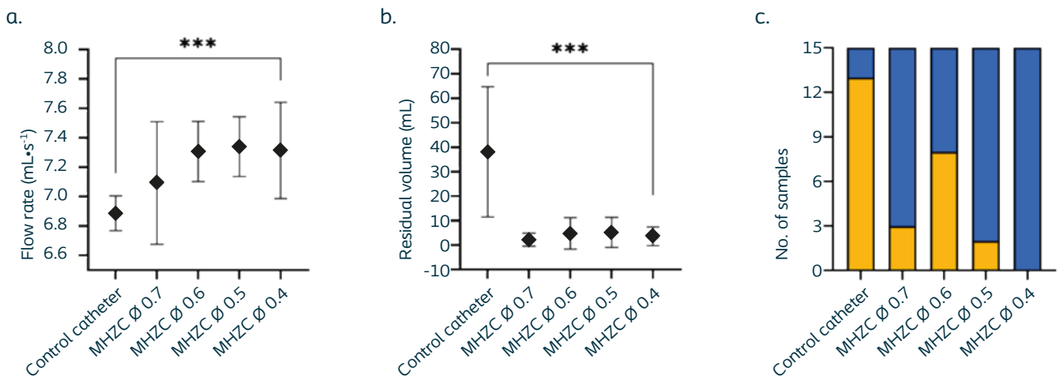


Figure 2: Results from measured UTI-parameters for CEC control catheter and four different MHZC configurations with decreasing micro-hole size from Ø0.7 to Ø0.4.
(a): Flow rate during the first 5 seconds of catheterization.
(b): Residual volume in the bladder at first flow-stop,
(c): Occurrence of mucosal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

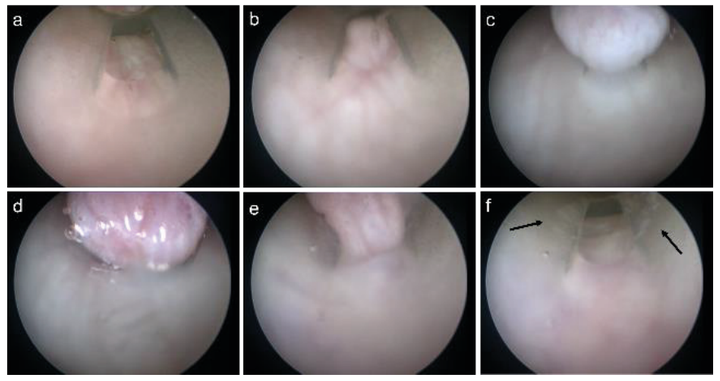


Figure 3: In vivo cystoscopy from pig study showing different stages of a mucosal suction in a CEC, showing large ingress of tissue into the catheter lumen, and leaving visible residue from the tissue inside the catheter (f) (from published journal article.[12])

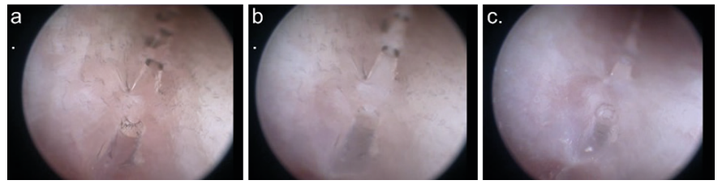


Figure 4: In vivo cystoscopy using the Ø0.4 MHZC. Here, the ingress of tissue into the catheter lumen is limited to the eyelets, avoiding the scraping effect seen in Figure 3.

Conclusion

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

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.[27]
Article published in BJUI Compass, 2023: doi.org/10.1002/bco2.295

Objective

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

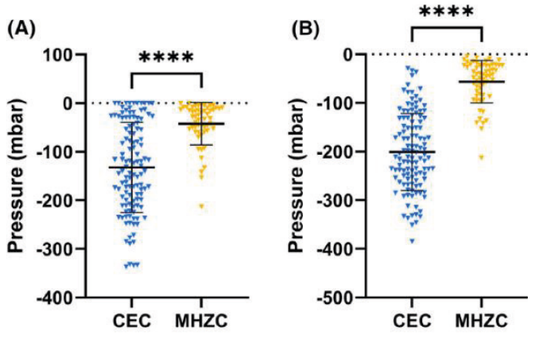


Figure 1: Intraluminal pressure measured inside the catheter at first flow-stop (A) and as the highest pressure peak within each drainage (B). A lower negative pressure means a larger pressure impact for the respective catheter type.

CEC, conventional eyelet catheter; MHZC, Micro-hole Zone catheter.

****p < 0.0001.

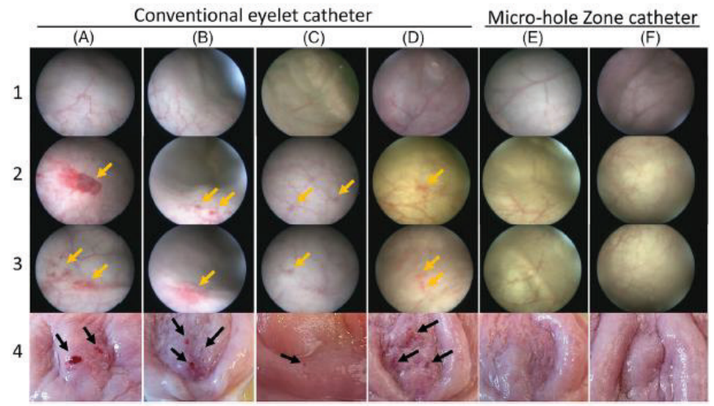


Figure 2: Catheter-associated mucosal lesions observed by cystoscopy. All bladders appeared normal at baseline (row 1).

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).

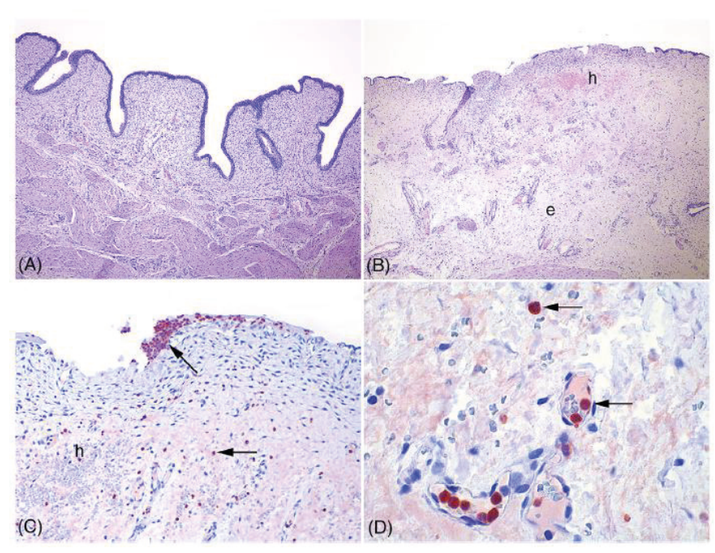


Figure 3: Histology and immunohistochemistry of bladder tissue exposed to repeated catheterisations.

(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.[39]
Presented at United Kingdom Continence Society (UKCS) Annual Scientific Meeting, United Kingdom, March 2023.

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 with many holes (Figure 1c), we can lower the negative pressure peaks during a mucosal suction (Figure 1d) and lower the level of microtrauma.

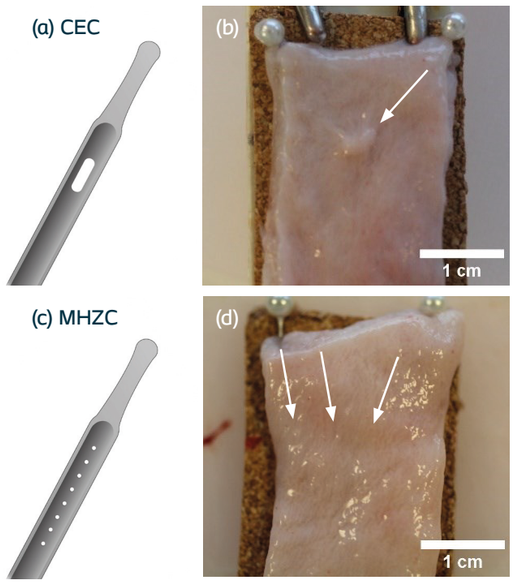


Figure 1: Catheter overview and mucosal suction
(a): Overview of conventional eyelet catheter (CEC), (b): Suction mark from mucosal suction with CEC, (c): Overview of Micro-hole Zone catheter (MHZC), and (d): Small micro-suction marks from MHZC.

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 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.

Results

Pressure dynamics during drainage
Recorded pressures (Figure 2) near the eyelet was significantly higher for the CEC than the pressures recorded for the catheter featuring 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 (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.

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. There were 7 catheters tested in 3 different bladders for a total of 21 runs per catheter type.

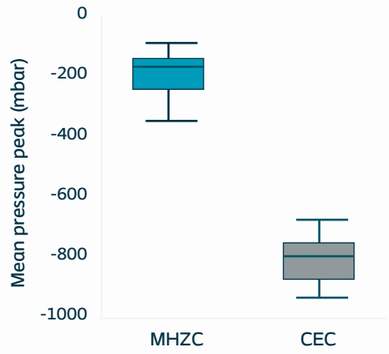
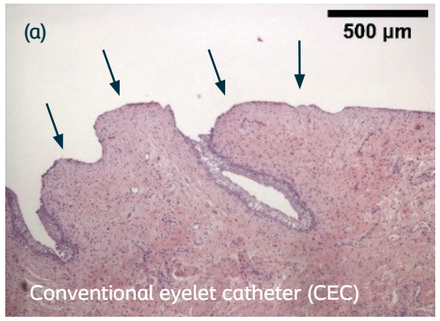
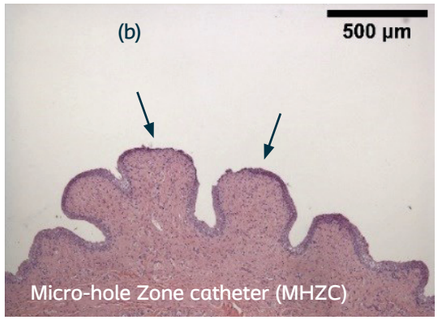


Figure 2 (right): Pressure recordings of negative pressure peaks, or suction, during mucosal suction in CEC and MHZC. A significant difference was found between the negative pressure peaks of the catheter types ($p < 0.0001$).





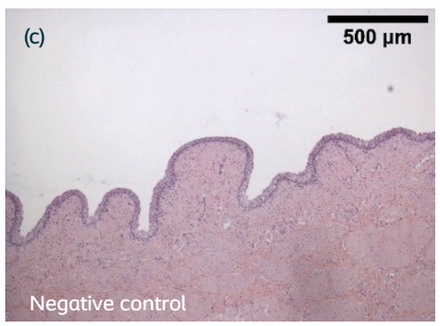


Figure 3: H&E stained histological sections of porcine tissue samples subjected to mucosal suction with CEC and MHZC. Arrows point to areas of interest, such as thinning and exfoliation of urothelium.
(a): Microtrauma from CEC
(b): Microtrauma from MHZC
(c): Negative control

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 micro-holes 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.

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

Nielsen L., Athanasiadou S., Suldvart B., Bagi P.[17]
Presented at European Renal Association (ERA) Annual Congress, Italy, June 2023.

Background and Aims

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).

Methods

Clear urine was collected from three clinical studies (NCT04445051, NCT04543136 and NCT04557787) where subjects drained with the conventional eyelet catheter and two prototypes of the Micro-hole Zone catheter. The studies included 60 subjects, equally distributed between male and female, healthy volunteers and intermittent catheterisation users. The sediment in the samples was analysed via automated microscopy (oCelloscope). Cloudy urine was collected from patients during their visits at the Urology Department of Rigshospitalet, Denmark. The samples were collected after spontaneous voiding, or via a conventional eyelet catheter and were analysed with the oCelloscope. An in vitro drainage test with the two catheters was subsequently performed (Figure 1).

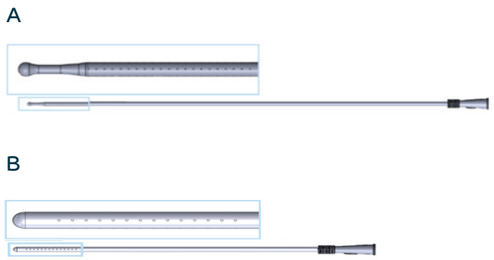


Figure 1: Investigational Micro-hole Zone catheters for A. male users, and B. female users

Results

The analysis of clear urine (n=180) showed most sediment to be smaller than 50 µm with the largest sediment being up to 200 µm (2.05 to 195.76 µm). The sediment included primarily crystals, cells, and bacteria, in line with published literature (Figure 2).

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 3, sample A, B, C). Visible particles could not be analysed in the oCelloscope 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 of the samples.

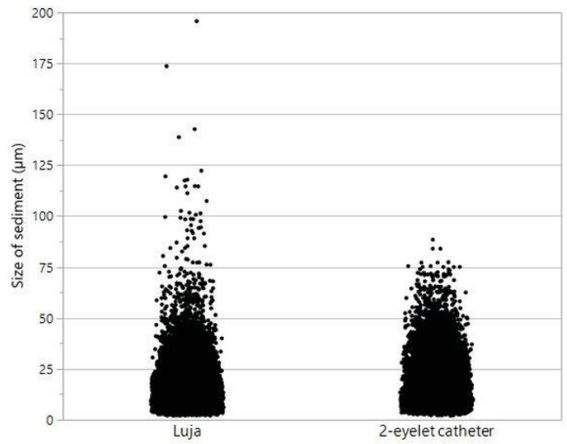


Figure 2: Sediment size distribution in urine drained through Micro-hole Zone catheters (Luja) and conventional 2-eyelet catheters.

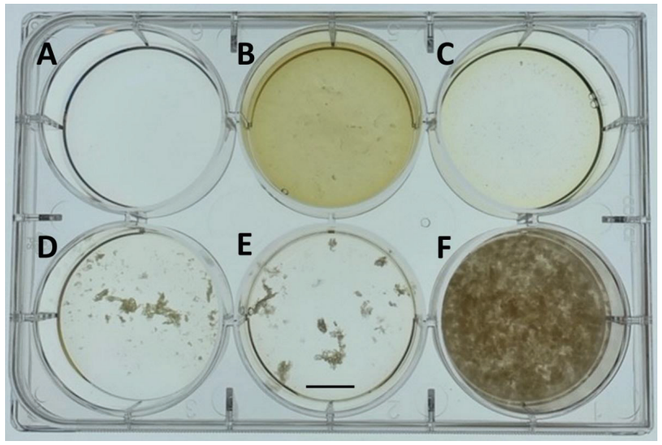


Figure 3: Representative samples (10ml) were placed in a 6 well plate as follows:
A. Clear urine
B and C. Samples of cloudy urine without debris visible to the naked eye.
D and E. Samples of cloudy urine containing debris visible to the naked eye.
F. Sample of cloudy urine with a high content of debris visible to the naked eye.

Discussion & Conclusion

The analysis showed that the type of sediment does not differ between clear and cloudy urine without visible particles, but it is rather the abundance of sediment that induces the nontransparent appearance. The sediment was smaller than the size of the micro-holes (400 µm), therefore the novel catheter could efficiently drain urine and sediment and even larger size sediment.
The latter could be explained by the design of the Micro-hole Zone that allows urine and sediment to be drained continuously through a larger area, starting below the catheter tip, and extending to the bottom of the bladder neck. However, 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.

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

Vaabengaard R., Landauro M.H., Jacobsen L., Nascimento O.F., Kennelly M.[40]
Presented at The International Spinal Cord Society (ISCoS) Annual Scientific Meeting, Scotland, October, 2023.
Article[1] published in J. Clin. Med., 2023: 10.3390/jcm12165266

Introduction

Residual urine is an important risk factor for acquiring urinary tract infections (UTIs) and many who perform clean intermittent catheterisation (CIC) are uncertain about having residual urine after CIC. With conventional eyelet catheters (CEC), CIC users can experience urine flow-stops during CIC, potentially leading to residual urine. This study investigated the performance of a new Micro-hole Zone Technology catheter (MHZC) (Figure 1) designed to reduce urinary flow-stops and minimise residual urine.

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 healthcare professional with a MHZC (Coloplast Luja™) and a CEC (Hollister Vapro™). 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.

Figure 1: Luja™ with Micro-hole Zone Technology.

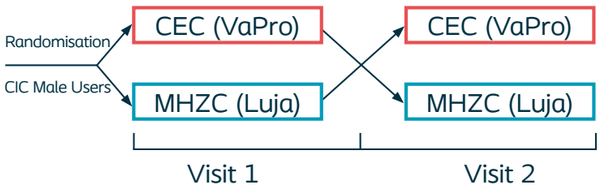


Figure 2: Study set-up.

Results

Among 42 male CIC users (Table 1), results showed that 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 ($p < 0.05$).

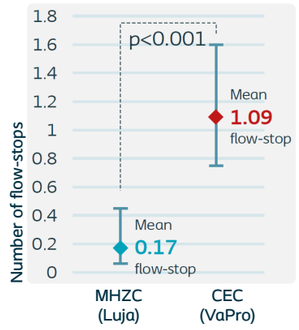


Figure 3: Number of flow-stops with Luja vs VaPro.

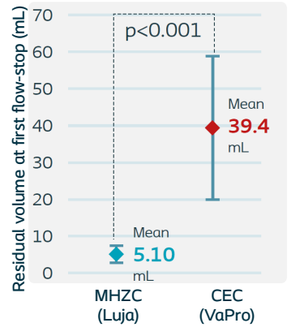


Figure 4: Residual urine at 1st flow-stop with Luja vs VaPro.

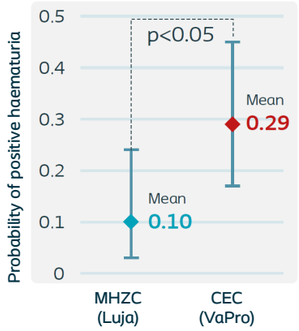


Figure 5: Probability of positive haematuria.

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 Prostate Hyperplasia	26 (62)
Spinal Cord Injury	9 (21)
Multiple Sclerosis	4 (10)
Stenosis	2 (5)
Prostate cancer	1 (2)

Table 1: Demographics.

Conclusion

Results underline the superiority of the new Luja catheter with Micro-hole Zone Technology: significantly lower number of flow-stops, significantly lower residual volume at 1st flow-stop, and less likelihood of haematuria. 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.

Users of intermittent catheterisation experience an improved bladder emptying with a new Micro-hole Zone catheter: Results from a multi-centre randomised controlled study.

Vaabengaard R., Landauro M.H., Jacobsen L., Thiruchelvam N., Athanasiadou S.[41]
Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.

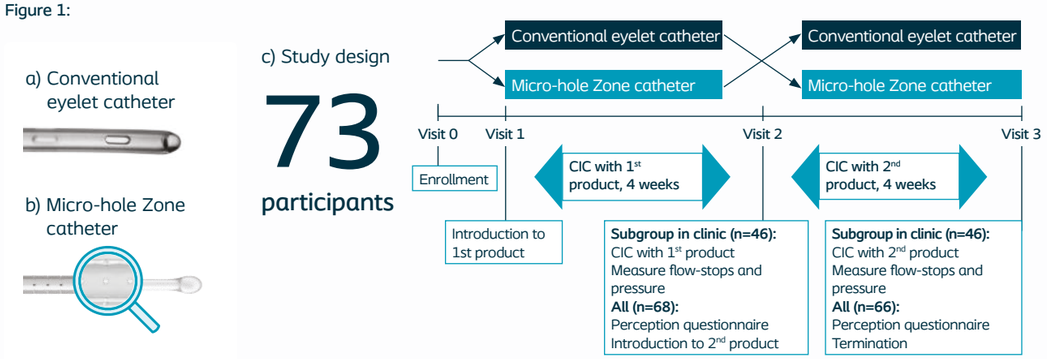
Introduction

Residual urine and trauma in the urethra are both risk factors for acquiring urinary tract infections (UTIs)[1]. Clean intermittent catheterisation (CIC) with a conventional eyelet catheter (CEC, Figure 1a) has been demonstrated[2] 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. This study investigated the performance and perception 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.

Method

The investigation was a multi-centre, randomised, controlled crossover study including 73 male CIC users (ClinicalTrials.gov NCT05485935) (Figure 1c). The MHZC (Luja™, Coloplast A/S) was compared to a CEC with a sleeve (SpeediCath® Flex, Coloplast A/S (95%) or Vapro™, Hollister, Inc (5%)). 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:



Results

There was an 87% reduction in risk of flow-stop episodes with MHZC vs CEC during self-led catheterisations (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 H_2O, 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.

Figure 2: Number of flow-stops with MHZC vs CEC

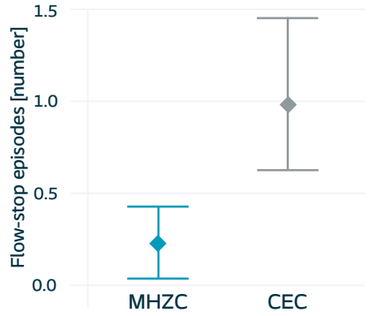


Figure 3: Suction pressure peak at flow-stop with MHZT vs CEC

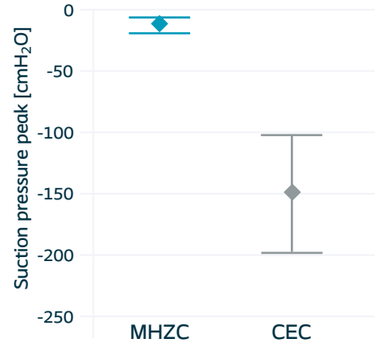
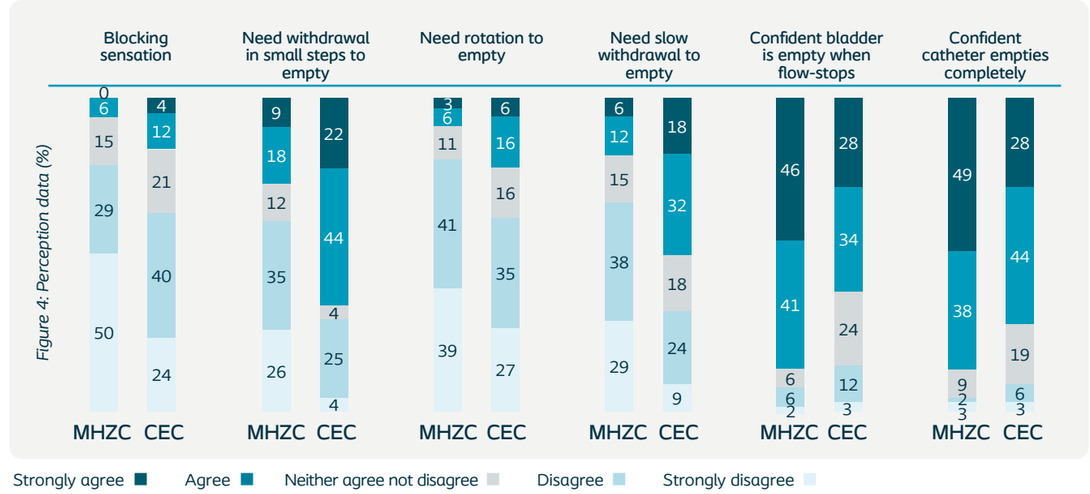


Table 1: Baseline characteristics.

Total	N=73
Age (years), mean (range)	64 (28-87)
Reason for CIC	
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)



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
- Significantly improved perception regarding blocking sensation, complete bladder emptying and the need for repositioning

Using Luja™ with Micro-hole Zone Technology, CIC 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.[42]
Presented at United Kingdom Continence Society (UKCS) Annual Scientific Meeting, United Kingdom, March 2023.

Introduction

Risk for urinary tract infections (UTIs) in intermittent catheter (IC) users centres around underlying conditions, IC compliance and technique, and factors related to the individual IC device and process. Conventional two-eyelet catheters (CEC) have been associated with premature flow-stops due to mucosal suctions during bladder emptying, which increases the risk for residual urine and microtrauma. The objective was therefore 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.

Methods

Three similar randomized controlled cross-over studies evaluated the Micro-hole Zone Catheter (MHZC) and CEC during three single test visits in study 1) 15 males and 15 females healthy volunteers (HV) study; 2) 15 male IC users; and study 3) 15 female IC users (ClinicalTrials.gov: NCT04445051, NCT04543136 and NCT04557787). Subjects were randomized to evaluate one of three catheters at each visit, including two different prototypes of the MHZC (Figure 1+2), differing by the length of drainage zone and number of drainage holes, and one CEC.

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 3), combining results from the three studies, assuming same effects for HV and IC users, but separated on sex. For incidents of haematuria, an effect of underlying condition was assumed, and results were separated for HV and IC users but combined on sex.

Figure 1. Male prototype catheter. Hole size: 0.4mm, 4 rows of holes. Short variant 1: 21x4 holes. Long variant 2: 38x4 holes.

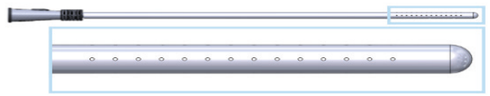


Figure 2. Female prototype catheter. Hole size: 0.4mm, 4 rows of holes. Short variant 1: 14x4 holes. Long variant 2: 17x4 holes.

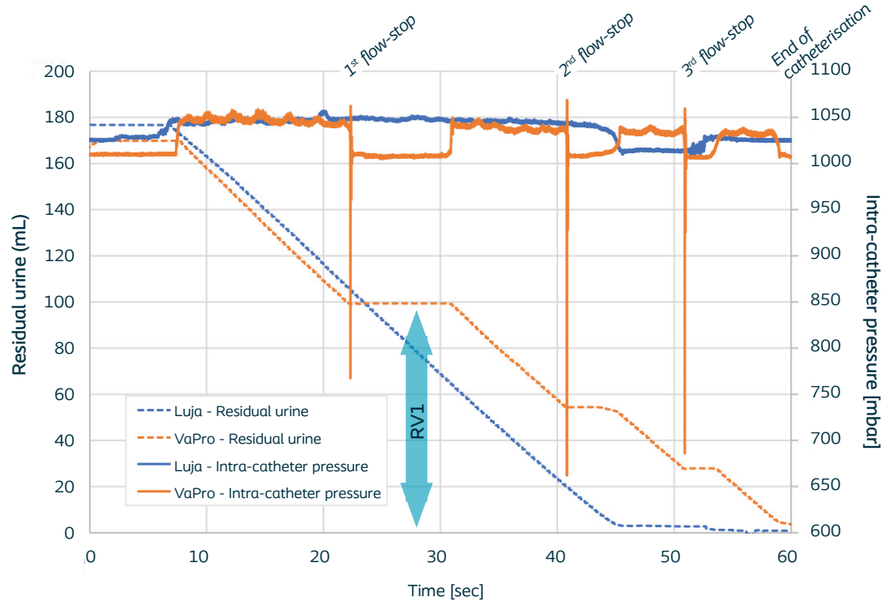


Figure 3. Illustrative example of pressure/volume graph for one catheterisation with CEC and one with MHZC.
Residual volume at 1st flow-stop (RV1) represented by the light blue arrow, calculated as total catheterised volume minus catheterized volume at first flow-stop.
RV1 represent level of residual volume in worst case when CEC is withdrawn without proper repositioning.
At flow-stops, repositioning of the catheter is needed to reinitiate urinary flow.

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 4) and lower average number of flow-stop incidents (8 and 21 times less frequent for males and females, respectively, both p<0.001) (Figure 5). During normal micturition in HV, the likelihood for haematuria post-catheterisation was 5.84 igher with CEC compared to MHZC, p=0.053, whereas there was no difference in haematuria between catheter IC users.

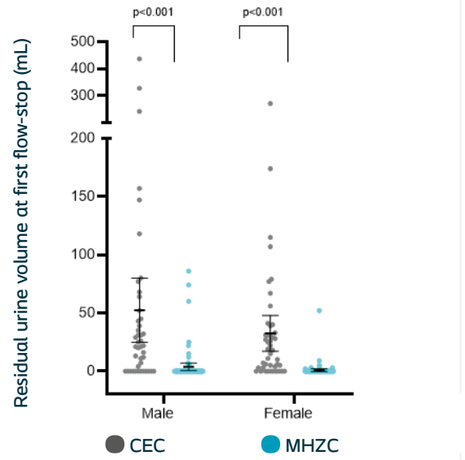


Figure 4. Residual urine at 1st flow-stop with CEC and MHZC in male and female subjects.

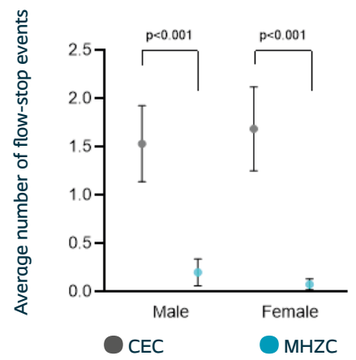


Figure 5. Average number of flow-stops with CEC and MHZC in male and female subjects.

Conclusion

The new 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 thus provides IC users with a simple catheterisation process without the need to reposition the catheter escaping potential UTI risk factors, which is common in users depending on IC.

The Lived Experiences of Male Intermittent Catheterisation Users After Using a New Micro-hole Zone Catheter: A Series of Case Stories

Tomlin K., Caddick C., Islamoska S., Vaabengaard R., Sperup T.[43]
Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2024.

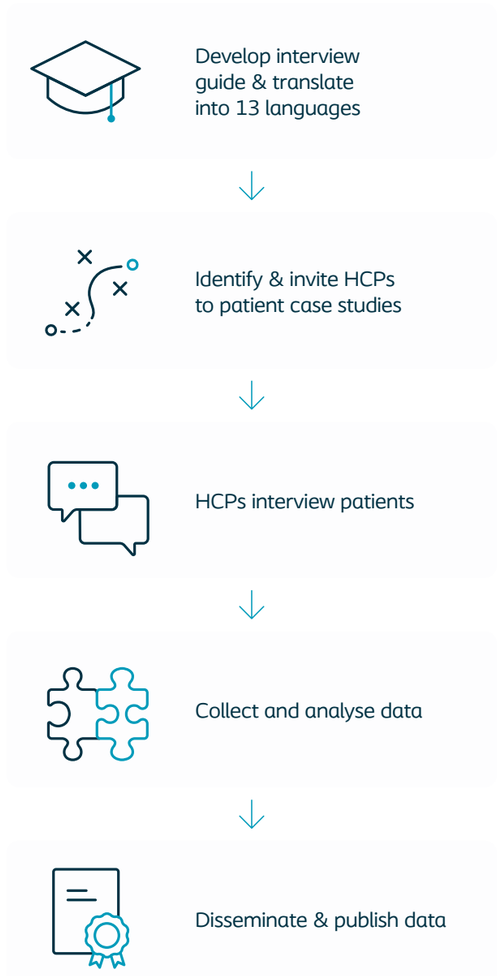
Introduction

The Micro-hole Zone catheter (MHZC) is a recent innovation for intermittent catheterisation (IC), featuring >80 micro-holes for male IC users in contrast to conventional two-eyelet catheters. When new treatment options are introduced, users are often motivated to share their lived experiences of the change with their healthcare professionals (HCPs), providing important early feedback and indicators of real-world treatment impact. This project aims to record structured case stories from male IC users to generate hypotheses for future studies of the effects of MHZC use.

Methods

An interview guide was developed for specialised IC nurses in 13 countries to record lived experiences of male IC users who had switched from using conventional two-eyelet catheters to using MHZC for minimum six months. The questions related to the users' symptoms and HCP interactions associated with urinary tract infections (UTIs), their perception of the catheterisation procedure, and how their daily lives were affected by the choice of catheter.

Figure 1. Data collection process.



Case 1

- 78 years old male
- Used IC for >6 years, SpeediCath Flex
- 8 months on Luja
- Bladder issue due to prostate cancer
- Urge, incontinence and nocturia
- UTI symptoms: strong smell, cloudy urine, discomfort in bladder, feels unwell generally
- UTI history: frequent UTIs, previously had trimethoprim at home for 2-3 years, now doing urinalysis for confirmation.

Started mixed use of SpeediCath Flex and Luja, but when only using Luja, no UTIs or symptoms were observed since starting. Has not taken any antibiotics since using Luja full time. Patient perceives overall flow to be better and perceiving the bladder as empty.

Patient feels a relief to have less UTIs and is sleeping better – now only wakes up 1 time/night vs 2-3 times/night before Luja.

Before Luja, he worried when not having medications and about complications if UTI is not treated promptly but feels better now after Luja.

Case 2

- 34 years old male
- Used IC for >3 years, SpeediCath Flex
- 7 months on Luja
- Bladder issue caused by type 1 diabetes
- No urge and bladder sensation (up to 1.3 L urine)
- UTI symptoms: incontinence, urge, smell and back pain
- UTI history: in 2023, frequent UTIs, constant cycle of antibiotics 3-4 weeks, and sepsis twice.

After trying Luja, no UTIs observed. Returned to SpeediCath Flex due to general practitioner (GP) decision and experienced UTI again after 5 days. In agreement with GP, patient started using Luja permanently.

Patient no longer feels need to reposition, bladder is emptied quicker, and no UTIs since starting Luja. This had a big impact on his wider family as anxiety about health has reduced. Especially, his child's physical and psychological reactions have improved.

Regular 3 months reviews in hospital have now changed to annual reviews.

Results/Conclusion

We present here the first two patient case stories of switching to MHZC use. Despite different medical histories causing their need for IC, similarities emerged in how they felt their lives were less affected by UTIs after using the MHZC. Both cases detailed the negative impact that UTIs had had on their physical and mental well-being but further described how they had experienced fewer UTIs since switching to MHZC use, which had helped to minimize their concerns. Collecting these lived experiences will inspire further research into the effect of catheter choice on the users' lives and well-being.

Efficient bladder emptying with Micro-hole Zone Technology in male users of intermittent catheters

Willumsen A., Schrøder B., Bagi P., Nielsen L.F.[44]
Presented at the International Spinal Cord Society Annual Scientific Meeting (ISCoS), Belgium, September 2024.

Introduction

Following the introduction of the new intermittent catheter Luja™ male with Micro-hole Zone Technology (MHZT), users have reported that their bladder emptied faster than with conventional catheters. To confirm this observation, we investigated the speed of bladder emptying using six different catheters in an ex-vivo setting using a porcine lower urinary tract (LUT) model[1].

Methods

Six different male CH12 intermittent catheters were tested 10 times in randomised order using the ex-vivo porcine LUT model. The catheters were tested at physiologically relevant bladder pressure conditions of 50 cmH2O and a total bladder volume of 200 ml isotonic saline. A triplicate of the setupperformed each with a fresh porcine bladder for a total of 30 catheterisations per catheter. The primary outcomes captured from each catheterisation were:

Residual volume at first flow-stop (RV1) defined as the volume remaining in the bladder at first flow-stop. A flow-stop was defined as no drainage for more than one second. If a flow-stop occurred before there was less than 10 ml left in the bladder, the catheter would be repositioned. Repositioning was repeated if necessary. The occurrence of flow-stops before drainage of 190 ml urine was noted for each catheter type.

Total time for catheterisation was the time it took for *the catheter to empty 190 ml simulated urine from the ex-vivo bladder, including repositioning if needed. This cutoff was set as the last milliliters could be difficult to empty, especially with conventional catheters, to account for the differences in bladder shapes and morphology.

Results

Statistically significant better bladder emptying performance was shown for Luja male than comparator catheters. Conventional catheters (mean range = 26 - 50 ml residual volume), Luja male (mean = 5 ml residual volume), p = 0.0001.

Luja male was shown to be 45% faster at emptying the bladder completely (mean = 28 seconds) than conventional eyelet catheters (mean range = 50-54 seconds) showing a statistically significant difference (p< .0001).

No occurrence of flow-stops before the draining of 190 of 200 ml for Luja male, while comparators experienced flow-stops at least once before 190 of 200 ml was drained in minimum 24 of 30 catheterisations.

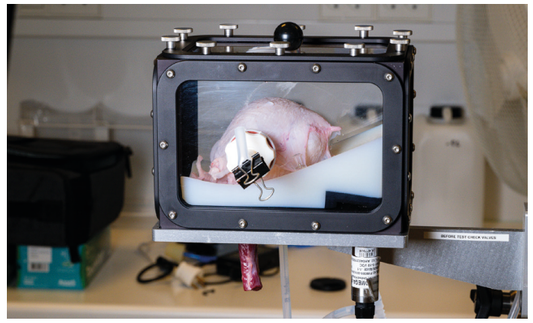


Figure 1 - Image of the test setup for the ex-vivo model using physiologically relevant pressure conditions and a porcine bladder.

Figure 2 - Overview of the products tested. Hollister VaPro™ and VaPro Pocket™, Coloplast SpeediCath® Flex and Luja™ male, Convatec GentleCath Air™ and Wellspect LoFric™. All size CH12.

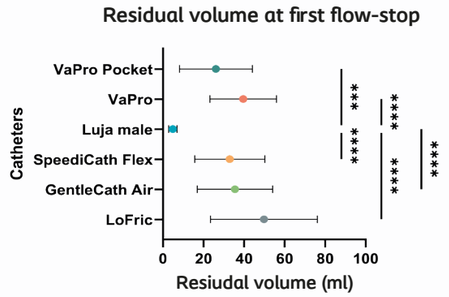


Figure 3 - Graph of the mean and standard deviation for residual volume in the bladder at the first flow-stop, n=30. Statistical significance (Tukey) presented for Luja male compared to all comparators.

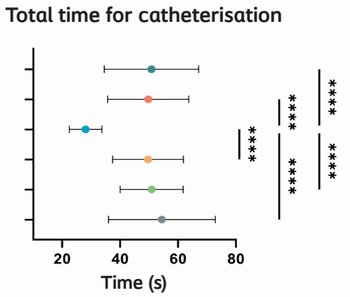


Figure 4 - Graph of the mean and standard deviation for total time for catheterisation, n=30. Statistical significance (Tukey) presented for Luja male compared to all comparators.

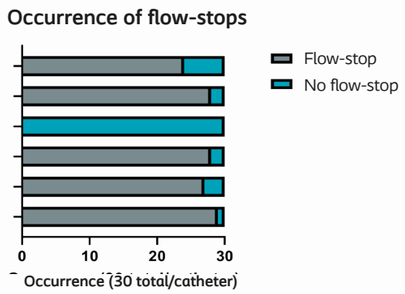


Figure 5 - Summary of the occurrence of flow-stops during catheterisation.

Discussion

The Luja male catheter drains the bladder efficiently with a significantly lower RV1 and less time required to empty the bladder. Therefore, based on the measured performance parameters in this study, results support user feedback underlining the strong efficiency of the Luja male catheter compared with other catheters.

Luja male is 45% faster at emptying the bladder completely compared to conventional eyelet catheters while simultaneously reducing the residual volume and occurrence of flow-stops.

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.[30]
Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.

Introduction

When educating patients on intermittent catheterisation (IC) 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™.

Methods

From February to July 2023, the Luja catheter was assessed by 62 HCPs (nurses) across Denmark, Finland, the Netherlands, and Switzerland. The HCPs enrolled 816 male adult users using IC daily and evaluated Luja on ease of training, worries of complete bladder emptying and UTI risk, and preference and recommendation of Luja. Descriptive data analyses were conducted.

Results

Among the HCPs, 90% worked daily with men with prostate issues, 60% worked with MS patients, and 45% with spinal cord injuries. In addition, 69% had more than 10 years of IC experience (Figure 1). There were 87% who found training with Luja easy because there was no need to educate on repositioning the catheter. 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 (Figure 2). Most HCPs (95%) would recommend Luja to their patients to a different degree (Figure 4).

69%
had more than 10 years of IC experience

62
HCPs assessed the Luja catheter

Micro-hole Zone Technology

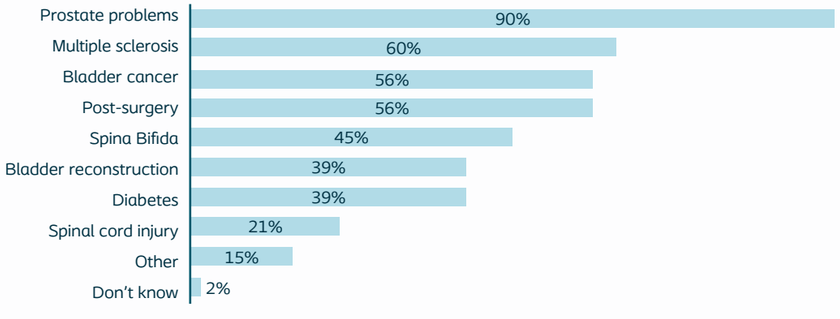


Figure 1: Healthcare professionals (HCPs) study demographics (N = 62).

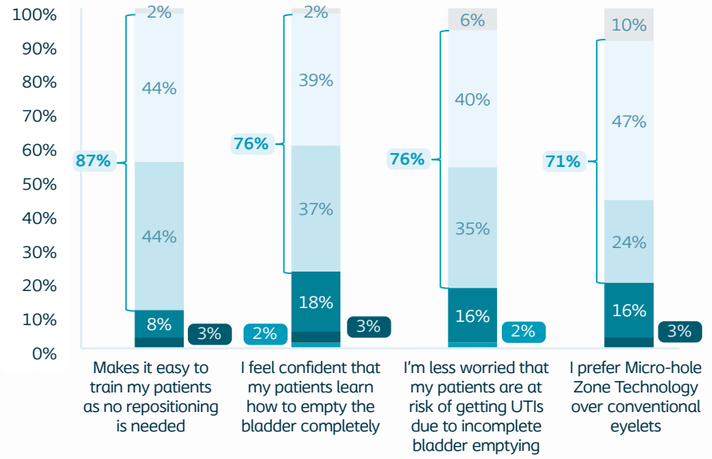


Figure 2: Statements about Luja (N = 62).

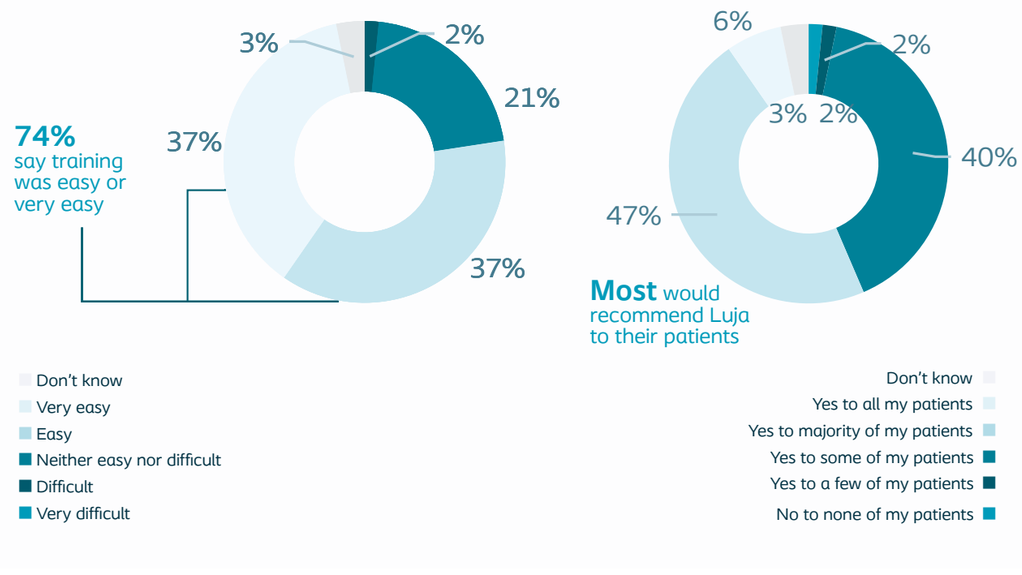


Figure 3 (left): How was it training patients with Luja? (N = 62).

Figure 4 (right): Recommending Luja to patients (N = 62).

Discussion

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 Luja™

Vaabengaard R., Islamoska S., Zeeberg R., Jacobsen L.[31]
Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.

Introduction

Intermittent catheters with conventional eyelets can cause flow-stops leaving residual urine in the bladder if the catheter is not repositioned hereby increasing the risk of urinary tract infections (UTIs)[1]. In this study, intermittent catheterisation (IC) users evaluated the performance of a new Micro-hole Zone catheter, Luja™.

Methods

A new catheter was evaluated from February to July 2023 by 816 adult men using IC daily from Denmark, Finland, the Netherlands, and Switzerland. 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.

Results

Causes for using IC 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).

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 (repositioning) 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).

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

Figure 1: Cause of urinary problems.

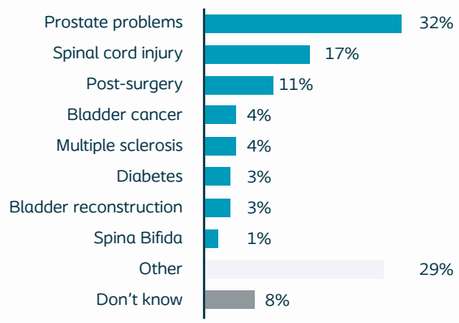
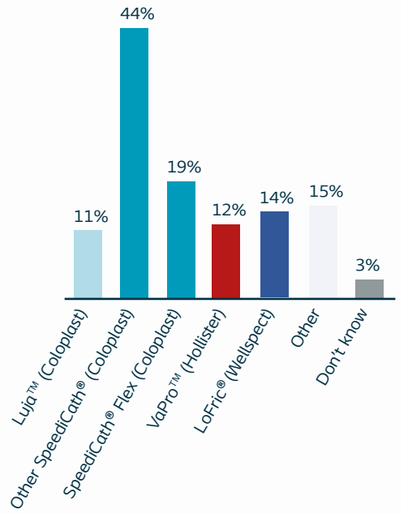


Figure 2: Current product(s) used



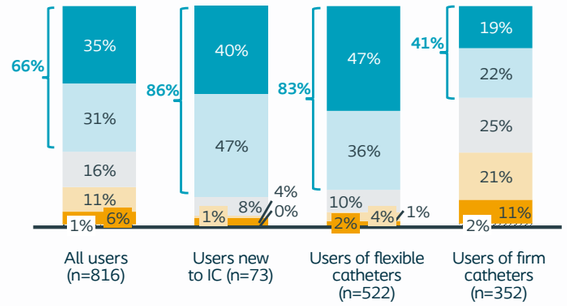


Figure 3: Ease of use depended on current catheter used.

- Very easy
- Easy
- Neither easy nor difficult
- Difficult
- Very difficult
- Don't know

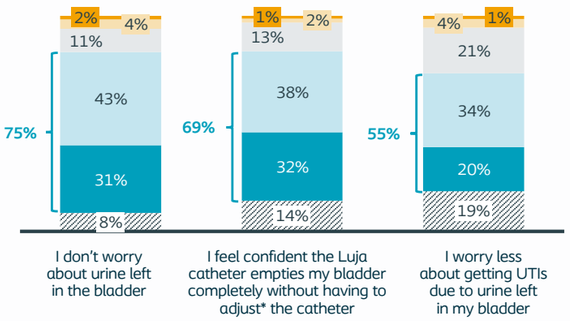


Figure 4: Statements on Luja.

- Strongly agree
- Agree
- Neither agree not disagree
- Disagree
- Strongly disagree
- Don't know

* adjust = withdrawing the catheter in small steps, withdrawing slowly, and/or turning/rotating the catheter

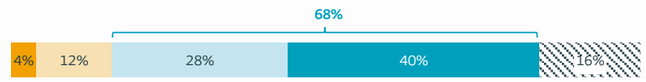


Figure 5: Recommending Luja to other ISC users.

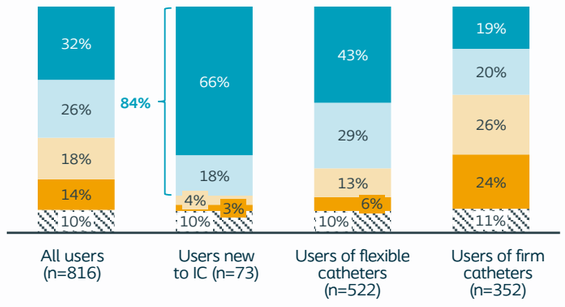


Figure 6: Continue to use Luja.

- Yes, definitely
- Yes, probably
- No, probably not
- No, definitely not
- Don't know

Discussion

Results of the study indicate that the Luja catheter can help IC 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 IC user.

References

1. Dinh, A., et al., Urinary tract infections in patients with neurogenic bladder. Med Mal Infect, 2019. 49(7): p. 495-504.
2. Kennelly, M., et al., Adult Neurogenic Lower Urinary Tract Dysfunction and Intermittent Catheterisation in a Community Setting: Risk Factors Model for Urinary Tract Infections. Adv Urol, 2019. 2019: p. 2757862.
3. Welk, B., et al., Differences in the incidence of urinary tract infections between neurogenic and non-neurogenic bladder dysfunction individuals performing intermittentcatheterization. Neurourol Urodyn, 2022. 41(4): p. 1002-1011.
4. Averbeck, M.A., et al., Risk factors for urinary tract infections associated with lower quality of life among intermittent catheter users. Br J Nurs, 2023. 32(18): p. S8-s16.
5. Hearn, J.H., et al., Stigma and self-management: an Interpretative Phenomenological Analysis of the impact of chronic recurrent urinary tract infections after spinal cord injury. Spinal Cord Series and Cases, 2018. 4(1): p. 12.
6. Welk, B., Quality of Life in Neurourology Patients. Eur Urol Focus, 2020. 6(3): p. 531-533.
7. Buchter, M.L., et al., Burden of illness the first year after diagnosed bladder dysfunction among people with spinal cord injury or multiple sclerosis - a Danish register study. Expert Rev Pharmacoecon Outcomes Res, 2022: p. 1-8.
8. Schrøder, B., et al., New micro-hole zone catheter reduces residual urine and mucosal microtrauma in a lower urinary tract model. Scientific Reports, 2024. 14(1): p. 2268.
9. Averbeck, M.A. and Madersbacher, H. Follow-up of the neuro-urological patient: a systematic review. BJU Int, 2015. 115 Suppl 6: p. 39-46.
10. Tentor, F., et al., Development of an ex-vivo porcine lower urinary tract model to evaluate the performance of urinary catheters. Scientific Reports, 2022. 12(1): p. 17818.
11. Lauridsen, S.V., et al, Females have a higher risk of urinary tract infections and experience more worries than males. Int J Urol Nurs, 2024. 18:e12405.
12. Musco, S., et al., How to Prevent Catheter-Associated Urinary Tract Infections: A Reappraisal of Vico's Theory-Is History Repeating Itself? J Clin Med, 2022. 11(12).
13. Averbeck, M.A., et al., The impact of different scenarios for intermittent bladder catheterization on health state utilities: results from an internet-based time trade-off survey. Journal of Medical Economics, 2018. 21(10): p. 945-952.
14. Rose, C., et al., The Characterization of Feces and Urine: A Review of the Literature to Inform Advanced Treatment Technology. Crit Rev Environ Sci Technol, 2015. 45(17): p. 1827-1879.
15. Simerville, J.A., et al., Urinalysis: a comprehensive review. Am Fam Physician, 2005. 71(6): p. 1153-62.
16. Groah, S.L., et al., Redefining Healthy Urine: A Cross-Sectional Exploratory Metagenomic Study of People With and Without Bladder Dysfunction. J Urol, 2016. 196(2): p. 579-87.
17. Nielsen L., Athanasiadou S., Suldvart B., Bagi P. Sediment in clear and cloudy urine: Can intermittent catheters drain it? Presented at European Renal Association (ERA) Annual Congress, Italy, June 2023.
18. Subramanian, V., et al., Large amounts of debris in the neuropathic bladder in persons with spinal cord injury; value of ultrasound scan in detection and management of vesical debris. Radiol Case Rep, 2022. 17(8): p. 2784-2789.
19. Landauro M.H., 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, 5266.
20. Landauro, M.H., 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. 50(6): p. 504-511.
21. Lauridsen, S.V, et al., Evidence-based Guidelines for Best Practice in Urological Health Care: Urethral intermittent catheterisation in adults – Including urethral intermittent dilatation. 2024.
22. Thiruchelvam, N., 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. 43(2): p. 464-478.
23. Coloplast. Exploratory Investigation on Performance and Safety of New Intermittent Catheters in Healthy Volunteers. 2023 [cited 2024 24 April]; Available from: https://clinicaltrials.gov/study/NCT04445051.
24. Coloplast. Exploratory Investigation on Performance and Safety of Newly Developed Intermittent Catheters in Male Users of Intermittent Catheters. 2023 [cited 2024 24 April]; Available from: https://clinicaltrials.gov/study/NCT04543136.
25. Barken, K.B. and Vaabengaard, R., A scoping review on the impact of hydrophilic versus non-hydrophilic intermittent catheters on UTI, QoL, satisfaction, preference, and other outcomes in neurogenic and non-neurogenic patients suffering from urinary retention. BMC Urol, 2022. 22(1): p. 153.
26. Lauridsen S.V., et al., UTI assessment tool for intermittent catheter users: a way to include user perspectives and enhance quality of UTI management. BMC Nurs. 2022, 21, 272. Presented at the International Meeting of the European Association of Urology Nurses (EAUN), The Netherlands, July 2022.
27. Stærk K., et al., Catheter-associated bladder mucosal trauma during intermittent voiding: An experimental study in pigs. BJUI Compass. 2024; 5(2): 217–223. 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. 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.
29. Bagi P., et al. Draining Urinary Sediments Through a Conventional Eyelet Catheters and New Intermittent Micro-Hole Zone Catheters. Submitted 2024.
30. 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. Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.
31. 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. Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.
32. Islamoska S., Landauro M.H., Zeeberg R., Jacobsen L., Vaabengaard R. Patient-reported risk factors for urinary tract infections are associated with lower quality of life among users of clean intermittent catheterisation. Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2022.
33. Thiruchelvam N., et al., Adult neurogenic lower urinary tract dysfunction (ANLUTD) and intermittent catheterisation (IC) in a community setting: Risk factors model for urinary tract infections (UTIs). Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2019.
34. Weld K.J. and Dmochowski R.R. Effect of bladder management on urological complications in spinal cord injured patients, Journal of Urology, vol. 163 (3), pp. 768–772, 2000.
35. Game X., et al. Neuropathic bladder dysfunction, Trends in Urology, Gynaecology & Sexual Health, vol. 15, no. 1, pp. 23–28, 2010.
36. Athanasiadou S., Vaabengaard R., Lauridsen, SV. A collaborative tool to assess risk factors of urinary tract infection among intermittent catheter users. Presented at the International Meeting of the European Association of Urology Nurses (EAUN), The Netherlands, July 2022.
37. An Introduction to Design Thinking: Process Guide. Hasso Plattner Institute of Design at Stanford: standford.edu.
38. Schrøder B., Tentor F., Schertiger L., Stark K., Emil Andersen T., Willumsen A., and Nielsen L.F. New Micro-hole Zone catheter prevents flow-stops and bladder microtrauma during intermittent catheterization. Presented at International Neuro-Urology Society, Greece 2023.
39. Willumsen A., Reza T., Schertiger L., and Nielsen L. Reduction in Eyelet Size in Intermittent Urinary Catheters Results in Less Urothelial Microtrauma in the Bladder. Presented at United Kingdom Continence Society (UKCS) Annual Scientific Meeting, United Kingdom, March 2023.
40. Vaabengaard R., Landauro M.H., Jacobsen L., Nascimento O.F., Kennelly M. Micro-hole Zone Technology shows superior ability to empty the bladder: A crossover randomized controlled trial in users of intermittent catheters. Presented at The International Spinal Cord Society (ISCoS) Annual Scientific Meeting, Scotland, October, 2023.
41. Vaabengaard R., Landauro M.H., Jacobsen L., Thiruchelvam N., Athanasiadou S. Users of intermittent catheterisation experience an improved bladder emptying with a new Micro-hole Zone catheter: Results from a multi-centre randomised controlled study. Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2023.
42. Landauro M.H., Vaabengaard R., Jacobsen L., Tentor F., Hannibalsen J., Permild R., and Bagi P. Improved performance with the intermittent urinary micro-hole zone catheter: a combined analysis of three randomised controlled studies. Presented at United Kingdom Continence Society (UKCS) Annual Scientific Meeting, United Kingdom, March 2023.
43. Tomlin K., Caddick C., Islamoska S., Vaabengaard R., Sperup T. The Lived Experiences of Male Intermittent Catheterisation Users After Using a New Micro-hole Zone Catheter: A Series of Case Stories. Presented at British Association of Urological Nurses (BAUN) Annual Conference, United Kingdom, November 2024.
44. Willumsen A., Schrøder B., Bagi P., Nielsen LF. Efficient bladder emptying with Micro-hole Zone Technology in male users of intermittent catheters. Presented at the International Spinal Cord Society Annual Scientific Meeting (ISCoS), Belgium, September 2024.

Acknowledgement of authors

Andreas Willumsen, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Andrei Krassioukov, International Collaboration on Repair Discoveries (ICORD), Faculty of Medicine, The University of British Columbia; GF Strong Rehabilitation Centre, Vancouver Coastal Health Authority; Division of Physical Medicine and Rehabilitation, Faculty of Medicine, The University of British Columbia, Vancouver, BC, Canada.

Betina Suldvart, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Birte Petersen Jakobsen, MedDevHealth, Holte, Denmark.

Brit Grønholt Schrøder, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Cecilie Rovsing, Sanos Clinic, 9362 Gandrup, Denmark.

Charalampos Konstantinidis, Urology and Neuro-Urology Unit, National Rehabilitation Center, Athens, Greece.

Christian Kamp Nielsen, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Claudia Rendeli, Department of Pediatrics, Università Cattolica del Sacro Cuore, Rome, Italy.

Emmanuel Chartier-Kastler, Urology, Sorbonne Université, Academic hospital Pitié Salpétrière, Paris, France.

Fabio Tentor, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Gérard Amarenco, Department of Neuro-Urology, Tenon Hospital, Paris, France.

Giulio Del Popolo, Neuro Urology Department, Azienda Ospedaliero-Universitaria Careggi, Florence, Italy.

Kristian Stærk, Department of Clinical Microbiology, Odense University Hospital, Odense, Denmark; Research Unit of Clinical Microbiology, University of Southern Denmark, Odense, Denmark.

Lars Schertiger, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Lene Feldskov Nielsen, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Lotte Jacobsen, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Louise Kruse Jensen, Pathobiological Sciences, University of Copenhagen, Copenhagen, Denmark.

Malene Hornbak Landauro, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Marcio Augusto Averbeck, Neuro-Urology, Moinhos de Vento Hospital, Porto Alegre, Brazil.

Markus Hahn, ARTIMED Medical Consulting GmbH, Kassel, Germany.

Michael Kennelly, Atrium Health, Carolinas Medical Center, Charlotte, NC, USA.

Michele Spinelli, Spinal Unit, Niguarda Hospital, Milan, Italy.

Nica Bell Chambers, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Nikesh Thiruchelvam, Cambridge University Hospitals NHS Trust, UK.

Per Bagi, Rigshospitalet, Department of Urology, Blegdamsvej 9, 2100, Copenhagen, Denmark.

Pernille Trøjgaard, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Omar Feix do Nascimento, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Rikke Vaabengaard, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Sabrina Islamoska, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Sharryn Gardner, Hazelwood House, Macclesfield, UK.

Simon Nielsen, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Sotiria Athanasiadou, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Susanne Vahr Lauridsen, Herlev Hospital & WHO-CC Parker Institute, Frederiksberg Hospital, Denmark.

Tabasum Reza, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Teodora Miclăuş, AML Christensen, Nivaa Strandpark 21, Nivaa, Denmark.

Thomas Emil Andersen, Department of Clinical Microbiology, Odense University Hospital, Odense, Denmark; Research Unit of Clinical Microbiology, University of Southern Denmark, Odense, Denmark.

Troels Pedersen, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark.

Xavier Biardeau, Centre Hospitalier Universitaire de Lille, Lille Cedex, France.

Coloplast was founded on passion, ambition, and commitment. We were born from a nurse's wish to help her sister and the skills of an engineer.

Guided by empathy, our mission is to make life easier for people with intimate healthcare needs. Over decades, we have helped millions of people live more independent lives and continue to do so through innovative products and services.

Globally, our business areas include Ostomy Care, Continence Care, Wound and Skin Care, Interventional Urology and Voice and Respiratory Care.

Coloplast A/S, Holtedam 1
3050 Humlebaek, Denmark