

Single-use hydrophilic coated intermittent catheters improve quality of life:

Report from a clinical trial on catheter reuse in the United States.

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Hypothesis / aims of study

- Intermittent catheterization (IC) is a common therapy for people with neurogenic lower urinary tract dysfunction (NLUTD).
- Reuse of urethral catheters for IC is common in different regions depending on healthcare system.
- There is an ongoing debate whether catheter reuse is as safe as single-use catheterization as there is a general lack of clinical evidence.
- **Study objective** = To explore real life patient-related clinical data on safety and satisfaction of reuse vs. single-use catheters for IC.

Results

- Challenging recruitment due to prophylactic antibiotic use.
- U.S. cohort = 21 patients (67% male, 33% females), mean age 55 (SD = 13), 81% with normal hand function, and 33% with normal urethral sensitivity. All practiced self-catheterization at least 4 times/day for a mean time of 7 years (SD = 8). At inclusion, all patients reused catheters for a mean of 10 days (SD = 20) per catheter.
- **Patient satisfaction and QoL:** The ISC-Q score increased by 11.4 (SD = 21.1) units (p = 0.0204) when patients switched to the single-use HC catheters. This corresponds to a **20% increase in health related QoL**. Patient reported outcomes on the two catheter techniques are specified in Table 1. At the end of the study, **89% preferred to continue using single-use HC catheters**.

Study design, material and methods

- Prospective, multi-center, clinical trial conducted in the United States.(U.S.) and in Australia.
- Sample size = 20 patients per country
- **Target population:** Patients who currently practiced catheter reuse, and who agreed to prospectively evaluate single-use hydrophilic-coated (HC) catheters for 4 weeks.
- **Outcomes:** Patient reported outcomes and the validated Intermittent Self-Catheterization Questionnaire (ISC-Q) for patient satisfaction and quality of life (QoL). Safety measures included bacteria contamination of reused catheters and urethral complications.

Table 1. Patient reported outcomes

	Reuse catheter (n = 21)	Single-use hydrophilic catheter (n = 19)	p-value ¹
Sensation during catheterization, n (%)			0.0361
- Comfortable	2 (9.5%)	5 (26.3%)	
- No discomfort	8 (38.1%)	8 (42.1%)	
- Slight discomfort	8 (38.1%)	6 (31.6%)	
- Slight pain	2(9.5%)	-	
- Disturbing pain	1 (4.8%)	-	
Satisfaction, n (%)			0.0008
- Very satisfied	3 (14.3%)	12 (63.2%)	
- Satisfied	6 (28.6)	6 (31.6%)	
- Neutral	9 (42.9%)	1 (5.3%)	
- Not satisfied	2 (9.5%)	-	
- Absolutely not satisfied	1 (4.8%)	-	

¹p-value calculated with non-parametric tests for paired observations, i.e. Wilcoxon signed rank tests for paired observations.

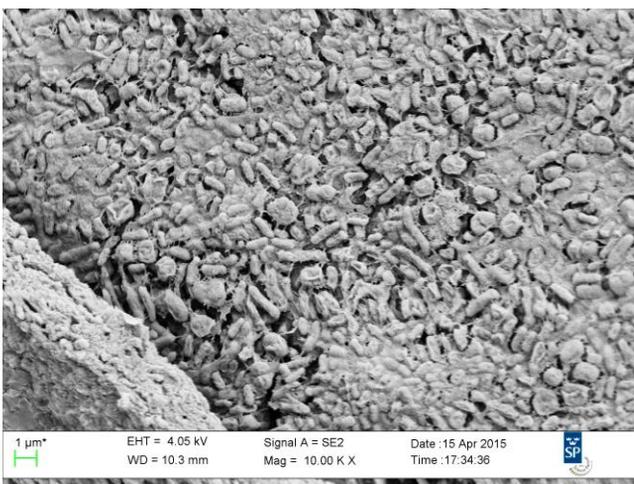


Figure 1. Bacteria contamination and occurrence of biofilm in reused catheter

- **Safety measures:** **90%** of collected reused catheter samples were **contaminated by bacteria** and biofilms were identified in 29%. See example in Figure 1. The most common species were Enterococcus faecalis, Staphylococcus epidermidis and Klebsiella pneumoniae. At the start of the study, 62% of the patients reported to have experienced urological complications in the last 12 months, mainly urinary tract infections (UTI). During the prospective test period, 79% did not experience any urological complications.

Interpretation of the results

- Clinicians should prescribe single-use IC
- HC catheters should be the first and standard choice for catheter type.

Disclosures Statement

- The study was funded by Wellspect HealthCare, DENTSPLY IH AB (Sweden).
- University of Pennsylvania IRB approval 820448
- Clinical study is registered in clinicaltrials.gov with the identifier NCT02129738.

Concluding message

- Single-use HC catheters improve QoL.
- Single-use HC catheters are preferred over catheter reuse among people practicing IC.
- Catheter reuse poses a potential patient safety concern.