

# New intermittent urinary micro-hole zone catheter shows enhanced performance in emptying the bladder: a randomized controlled crossover study (CP353) (1)

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## Objective

To demonstrate the performance of the Micro-hole Zone catheter (MHZC) compared to a conventional 2-eyelet catheter (CEC).

## Study Design & Methods

The performance of the test (MHZC) and comparator (CEC) devices was assessed in a randomized, single-center, controlled, crossover study, where catheterization was performed by a healthcare professional at two single-day test visits. The primary endpoints included number of flow-stop episodes and residual urine at first flow-stop. Secondary and exploratory endpoints included intra-catheter pressure, residual urine post-catheterization and hematuria.

## Product compared

The MHZC catheter (Luja™, Coloplast) versus a CEC single-use hydrophilic sleeved soft catheter (VaPro™, Hollister).

## Population

42 adult male intermittent catheterization (IC) users.

## Results

The number of flow-stop episodes was significantly lower for the MHZC (mean 0.17, 95% CI [0.06, 0.45]) compared to CEC (mean 1.09, 95% CI [0.75, 1.6]),  $p < 0.001$  (Figure 1). The residual urine at first flow-stop was significantly less for the MHZC (mean 5.10 mL, 95% CI [2.79; 7.42]) versus the CEC (mean 39.40 mL, 95% CI, [19.92; 58.89]),  $p < 0.001$  (Figure 2). Hematuria was 74% less likely with MHZC compared to CEC,  $p < 0.05$ . No adverse events were observed in this study.

## Conclusion

This study confirms the superior performance of the Micro-hole Zone catheter (Luja) compared to conventional eyelet catheters (VaPro). The MHZC secures bladder emptying in an uninterrupted free flow, with no need to reposition or adjust the catheter, potentially minimizing the risk for UTIs in an already susceptible group of subjects.

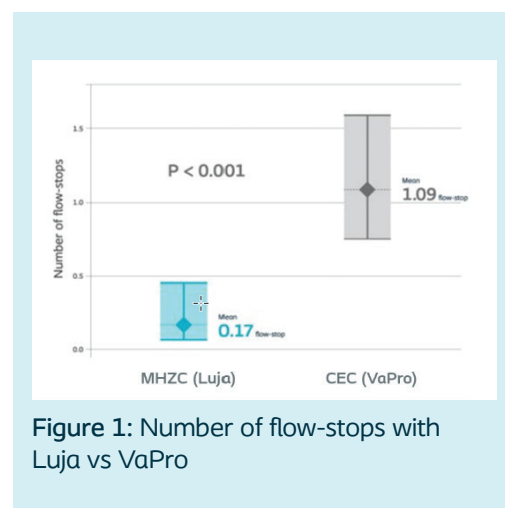


Figure 1: Number of flow-stops with Luja vs VaPro

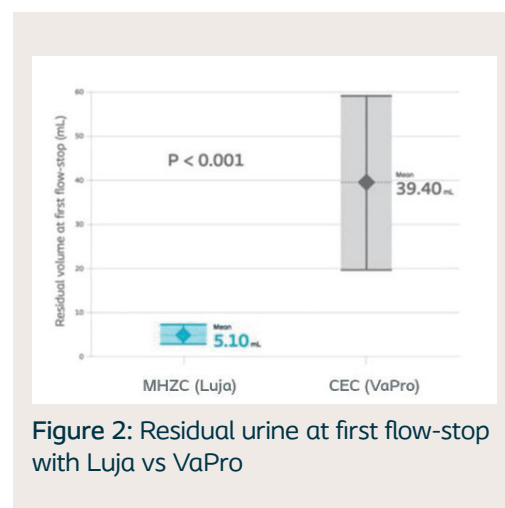


Figure 2: Residual urine at first flow-stop with Luja vs VaPro

Luja™ is a European representative (not available in US) device of Luja™ Coudé

1. Landauro MH, Jacobsen L, Tentor F, Pedersen T, Rovsing C, Feix do Nascimento O, Kennelly M. New Intermittent Urinary Micro-Hole Zone Catheter Shows Enhanced Performance in Emptying the Bladder: A Randomised, Controlled Crossover Study. *J Clin Med*. 2023 Aug 13;12(16):5266. doi: 10.3390/jcm12165266. PMID: 37629309; PMCID: PMC10455232. Study supported by Coloplast.