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ABILITY OF NEW MICRO-HOLE ZONE CATHETERS TO DRAIN SEDIMENT COMPARED TO CONVENTIONAL EYELET CATHETERS

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Aim

This study investigated the ability of a novel Micro-hole Zone urinary intermittent catheter to drain sediment present in urine, compared to a conventional eyelet catheter.

Methods

Three randomized, cross-over clinical studies investigated the performance of Micro-hole Zone catheters (featuring 80+ micro-holes), compared to conventional eyelet catheters. The subjects included were healthy male and female volunteers, and male and female intermittent catheterisation (IC) users. Urine samples were collected after draining with both catheters. The number and size of sediment in the urine was analysed via automated microscopy.

Results

The analyses showed most sediment to be smaller than 50 µm, with the largest sediment reaching approximately 200 µm.

There was no statistical difference in the ability of the two catheter types to drain sediment from urine. However, the Micro-hole Zone catheter drained sediment with larger size compared to the conventional eyelet catheter (Figure 1).

The types of sediment identified corresponded to that reported in the literature; therefore, these urine samples were considered uncomplicated.

Discussion & Conclusion

The analysis showed that the sediment passing through either type of catheter was smaller than the size of the micro-holes (400 µm). It also demonstrated that Micro-hole Zone catheters drained larger size sediment in samples collected from healthy volunteers and IC users. The improved performance of the Micro-hole Zone catheters is most likely due to the design of the drainage zone, that extends all the way to the bottom of the bladder neck, ensuring continuous drainage of urine and sediment from the base of the bladder.

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

Ethical approval

The studies described in the abstract (NCT04445051, NCT04543136 and NCT04557787) were conducted in accordance with the Declaration of Helsinki II, 1964 (amended 2013), and were approved by the Danish Medicines Agency (records No. 2020030463, 2020032970, 2020032971) and the regional ethical committee (De Videnskabsetiske komitéer for Region Hovedstaden, cases No. H-19089779, H-20015021, H-20020163). All subjects gave an oral and written informed consent before enrolment.