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

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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).

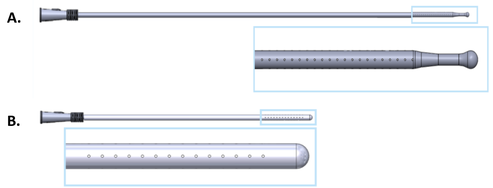

Figure 1: Investigational Micro-hole Zone catheters for A. male users, B. female users

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.

Results

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

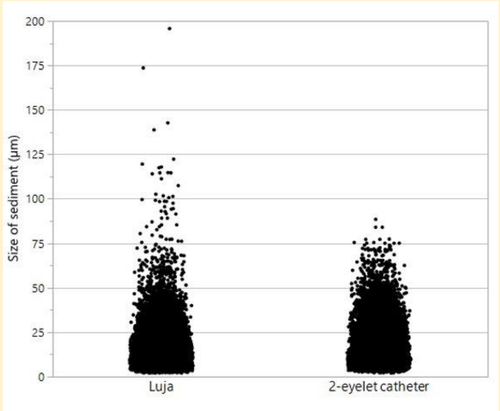

Figure 2: Sediment size distribution in urine drained through Micro-hole Zone and conventional eyelet catheters

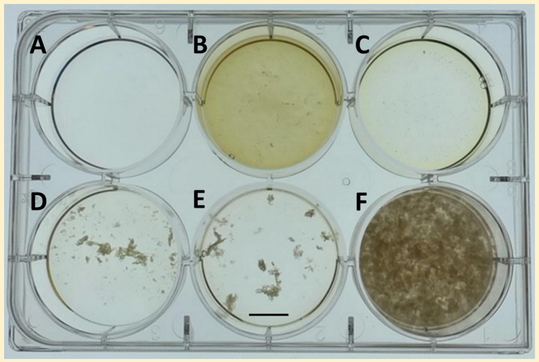

Figure 3: Representative samples (10ml) were placed in a 6 well plate as follows: A. clear urine B and C. Samples of cloudy urine without debris visible to the naked eye. D and E. Samples of cloudy urine containing debris visible to the naked eye. F. Sample of cloudy urine with a high content of debris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

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