Novel Tipless Urinary Catheter Reduces the Rates of Catheter Tip Bacterial Colonization

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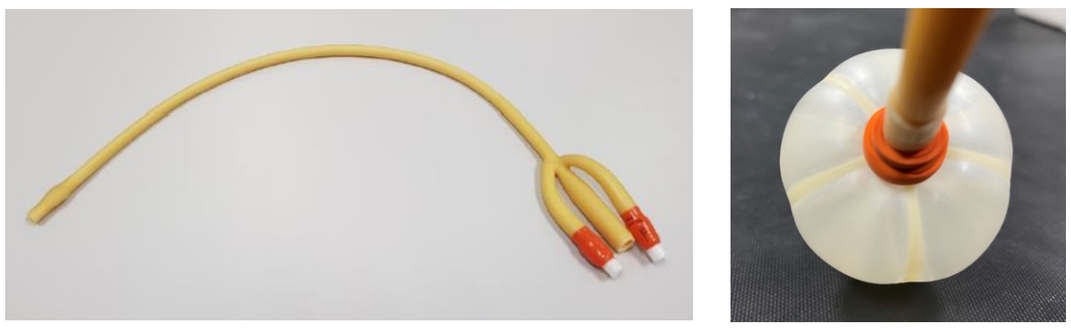
INTRODUCTION AND OBJECTIVE

Catheter related urinary tract infections (CAUTI), the most common type of nosocomial infection, amounting to 30-40% of all hospital infections and lead to over 50,000 deaths each year [1]. Extended usage of an indwelling urinary catheter results in blockage of the catheter by sediments, accidental dislodgment, bladder spasm, bleeding from catheter cystitis as well as pain, a dire problem that afflicts millions of patients worldwide.

We devised a Tipless Urinary Catheter (TUC), that has Institution Biosafety Committee approval, and hypothesize that its potential to reduce catheter cystitis, pain from the catheter tip irritation and perforation for the post surgery bladders. An end-on drainage may result in obstruction from mucosa folds, therefore, a flushing mechanism with a pumpkin design seeks to overcome this problem. See Figure 1.

Figure 1. Prototype of TUC on the left with the pumpkin balloon design on the right



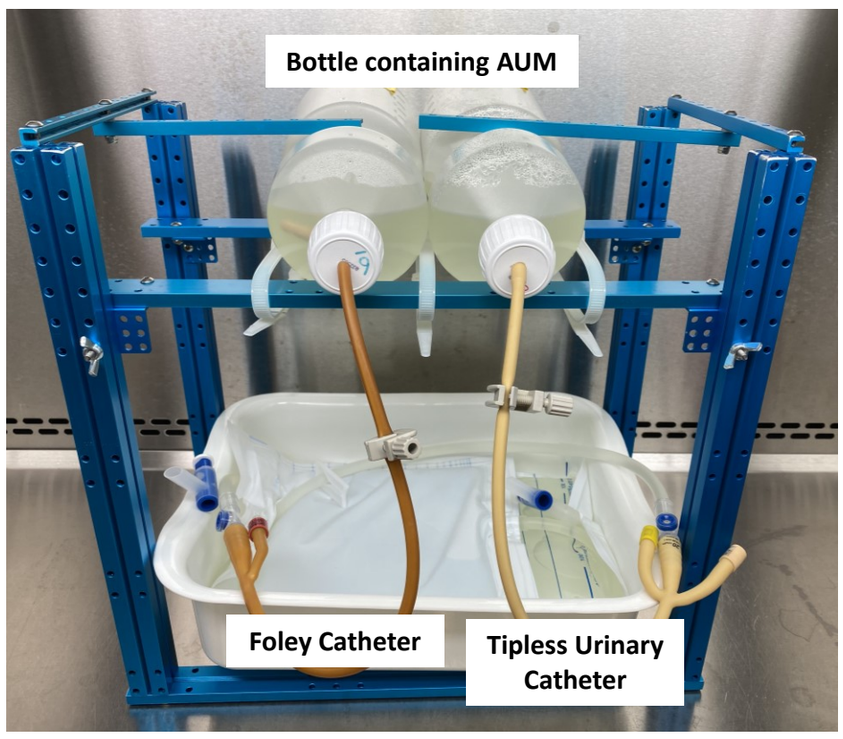
In vitro experiments were conducted to demonstrate the following:

- Confirmation of our hypothesis that bacterial colonization is due to environmental contamination from the urinary bag.
- Daily flushing of the TUC does not increased rates of bacteria colonization compared to market available Foley Catheter (FC).

MATERIAL & METHODS

In a 37°C incubator, a bottle containing Artificial Urine Medium (AUM) was used as a reservoir at the top of a rack. TUC and Foley catheter (FC) was secured at the bottom of the rack with the balloons inflated. See Figure 2.

Figure 2. Experimental setup



AUM was added to the reservoir and drained by individual catheters into respective urine bag. Uropathogenic Green fluorescent protein transfected *Escherichia coli* (GPF-*E. coli*) was inoculated into the urine bag on day 0 to simulate exposure to environmental bacteria contamination. TUC was flushed using 10ml 0.9% saline daily to simulate its use. Data from 5 biological replicates were used in the analysis. Biofilm from the catheter tip was retrieved via vortex and sonication, bacterial cells were then collected in a suspension and subjected to flow cytometry to determine bacterial colonization on day 7.

RESULTS

In-vitro fluorescence study demonstrated that inoculation of the urine bag results in the upward movement *E. coli* into the urinary bladder, as evident by an upward trend in GFP-*E. coli* indicating an increase in *E. coli* growth with time (Figure 3).

Figure 3. Fluorescence study of *E. coli* growth in the reservoir and urinary bag of both FC and TUC from Day 1 to 7

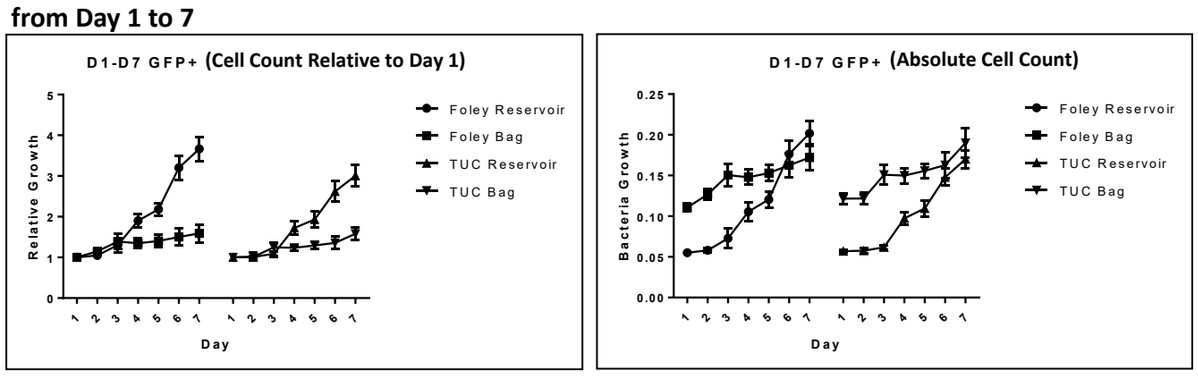


Figure 4 shows a flow cytometry analysis demonstrating that TUC had 32% lower bacterial colonizers at the catheter tips compared to FC on Day 7 of the *in-vitro* experiment ($p<0.05$).

Figure 4. Flow cytometry of biofilm on catheter tips of FC and TUC on Day 7.

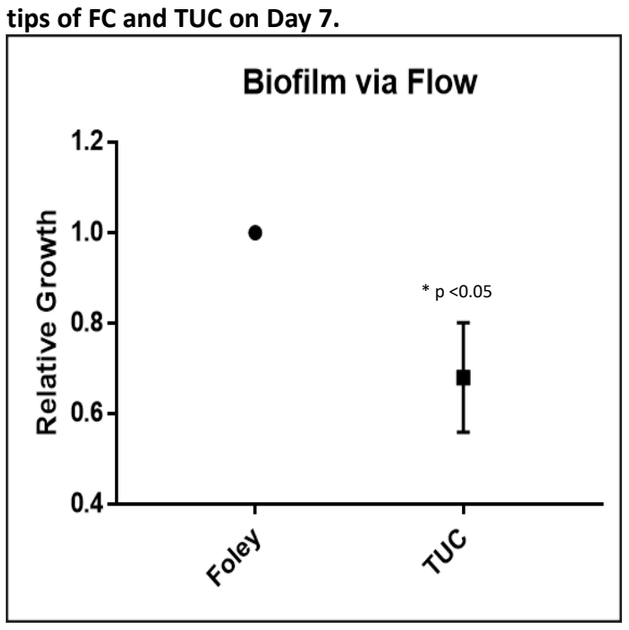
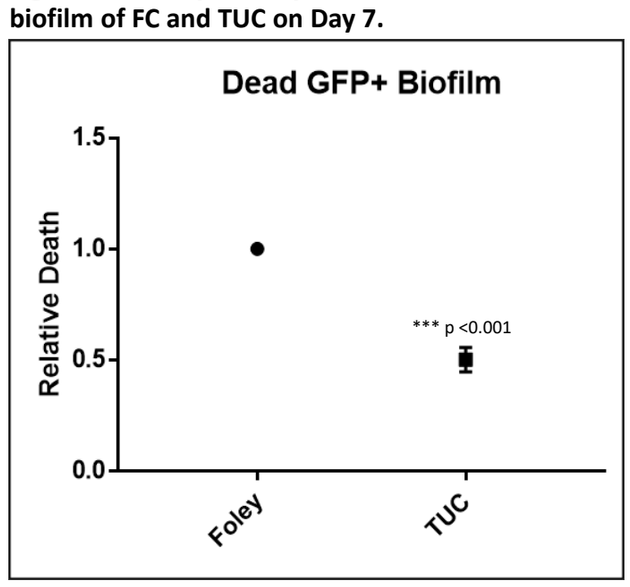


Figure 5 demonstrates that on Day 7 of the bench study, the biofilm from the FC had twice the amount of dead GFP-*E. coli* as compared to the TUC ($p<0.001$).

Figure 5. Flow cytometry of dead *E. coli* in the biofilm of FC and TUC on Day 7.



SUMMARY/CONCLUSION

The increasing *E. coli* growth in the reservoir containing AUM confirms our hypothesis that an upward movement of bacterial contaminants occur from the urine bag into the bladder in a closed urinary drainage system.

We have also demonstrated that daily flushing with the TUC is safe and lowers the rate of bacterial colonization compared to the FC, possibly due to its reduced intravesical surface area and flushing capabilities.

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Product Patent: Singapore Provisional Patent Application No. 10202102072Y
Reference: 1. Hu FW, Yang DC, Huang CC, Chen CH, Chang CM. Inappropriate use of urinary catheters among hospitalized elderly patients: Clinician awareness is key. Geriatr Gerontol Int. 2015 Dec;15(12):1235-41.