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Initial Antimicrobial Testing of a Novel Reusable Intermittent Urinary Catheter System and Catheter Reprocessing Device

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OBJECTIVE:

To evaluate the efficacy of the Aurie System, a preclinical prototype allowing for standardized intermittent catheter (IC) reuse of novel reusable no-touch ICs. Individuals with neurogenic bladder often require single-use ICs to urinate, but urinary tract infection (UTI) is a common cause of morbidity for IC users. Safer no-touch catheters are not easily affordable, and the Aurie System attempts to provide no-touch catheters at a fraction of the price by allowing for standardized and safe IC reuse.

METHODS:

Standard ICs were inoculated with *E. coli* and *P. aeruginosa* and incubated for 48 hours to assess microbial burden and biofilm formation (the latter using infrared fluorescence imaging). This procedure was repeated with Aurie ICs, focusing on evaluating catheter microbial burden after inoculation and reprocessing with the prototype washer-disinfector. This was repeated with up to 100 cycles to evaluate repetitive use.

RESULTS:

Standard ICs showed bacterial attachment and biofilm development peaking at 24 hours of incubation. The Aurie catheters produced a similar outcome but, after reprocessing, microbial burden was reduced below the level of detection. Repeat cycles showed pathogen clearance to similar levels. One catheter reached 100 cycles and there was no viable pathogen load after reprocessing.

CONCLUSIONS:

Intermittent urinary catheters, when cleaned inappropriately, can harbor viable bacteria and biofilm. The Aurie System, when used to disinfect novel reusable ICs within a prototype reprocessing device, can reduce microbial burden below level of detection even after 100 cycles. This suggests the Aurie System may be a feasible technology for safe IC reuse.

Introduction

Greater than 600,000 people use intermittent catheters (ICs) in the United States, including 300,000 with neurogenic bladder (NB) caused by various neurologic disorders, including spinal cord injury/disease, spina bifida and multiple sclerosis[1]. These individuals must catheterize 4-6 times per day with, according to current FDA guidelines, sterile single-use ICs, which are disposed of after use[1]. Despite a variety of novel catheter footprints and technologies developed by catheter manufacturers, the standard single-use sterile catheter has remained the mainstay of IC practice. This continues even though no-touch additions – including introducer tips and insertion sleeves –

have been shown to reduce the typically high urinary tract infection (UTI) risk associated with IC, which nears 2.5 complicated UTI per year[2-6].

In addition to this high risk, many catheter users will reuse catheters for financial or accessibility reasons, leading to an even higher risk of UTI for these individuals[2]. Still, as more recent work has suggested that careful and standardized IC reuse does not increase UTI risk significantly, the concept of a safely reusable IC has become more palatable[7]. To this end, a reusable IC system has been developed with the goal of improving usability and affordability of safer ICs: the Aurie System (CathBuddy, Inc., Syracuse, New York) includes a 100x-reusable catheter with insertion sleeve and introducer tip as well as smart catheter-cleaning and disinfection device that automates catheter reprocessing for the IC user.

Significant research has been done to evaluate causes, treatments, and prevention of catheter-associated UTI, although this work has mostly been focused on indwelling catheters[8]. In this study, we sought to understand the microbial burden associated with bacterial growth in an intermittent catheterization setting as well as the effectiveness of cleaning/disinfection seen with this novel reusable intermittent catheter system, utilizing a first-generation prototype device.

Methods

The prototype Aurie reusable intermittent catheter system

This novel reusable intermittent system comprises a reusable catheter with no-touch insertion sleeve and insertion aid (**Figure 1A-C**) as well as the tabletop reprocessing device. The catheter is built to withstand over 100 uses and reprocessing cycles. The insertion sleeve and introducer tip are designed to reduce contact contamination during catheterization. The smart catheter-reprocessor simplifies and standardizes the catheter reuse process by using an automated

and proprietary cleaning and disinfection methodology that also automatically lubricates the catheter for the next insertion. While the current version of the system (**Figure 1B**) is portable and can be used in and outside the home, the prototype version utilized for this study was the initial breadboard tabletop system as seen in **Figure 1D**.

Human urine collection

Human urine was collected and pooled from at least two healthy female donors between 20 and 40 years of age. Donors had no history of kidney disease, diabetes, or recent (within 6 months) antibiotic treatment. Urine was sterilized using a 0.22 μm filter (Sigma-Aldrich) and pH adjusted to 6.0–6.5. All participants signed an informed consent form and protocols were approved by the institutional Internal Review Board under study #19-04-5273.

Microbial strains and growth conditions

Uropathogenic *E. coli* UTI89 and *Pseudomonas aeruginosa* PA01 were grown in Luria-Bertani (LB) medium (MP Biomedicals) under shaking conditions at 37 °C for 4 h. Cultures were then diluted in LB (1:1000) and grown for 24 h in static conditions, then diluted once more in LB (1:1000) and grown again for 24 h in static conditions. All cultures were washed in 1X Phosphate Buffered Saline (PBS; Sigma) solution three times and resuspended in human urine to an OD_{600} of 0.5.

Assessment of bacterial attachment and biofilm growth in simulated intermittent catheterization

Initial analysis of bacterial attachment to urinary catheters was performed with two different brands of catheters made from the same material - Dover 100% Silicone Foley and Bardex All Silicone Elastomer Foley. The catheters were dipped for five minutes (consistent with intermittent catheter use) in a bacterial solution containing 10^6 colony forming units per mL of uropathogenic *Escherichia coli* UTI89. The catheters were placed inside of a sterile 50 ml conical tube; then they were moved into a laminar flow hood to avoid contact with other contaminants[9]. Catheters were incubated at different time points (3, 6, 9, 24, and 48 hours) at room temperature to assess attachment and biofilm formation progression. Following incubation, catheters were fixed with 10% neutralized formalin for 20 minutes. To visualize initial bacterial attachment, a group of catheters were fixed immediately after the bacterial incubation (time 0). Fixed catheters were then washed 3 times with PBS and blocked with 1.5 % BSA and 0.1 % sodium azide in PBS at room temperature for 2 hours. Catheters were then washed 3 times with PBS-T (PBS with 0.05% Tween 20) and stained with rabbit antibodies against *E. coli* (Invitrogen Cat# PA1-25636). Then catheters were washed 3 times with PBS-T and incubated with donkey anti-rabbit IRDye 800CW secondary antibodies and scanned for infrared signal. Images were analyzed using Odyssey Infrared Imaging software (version 3.0.16) to measure infrared fluorescence at 800 nm, corresponding to *E. coli*. Auto-fluorescence was determined from non-dipped catheters incubated with the secondary antibody[9].

Assessment of bacterial growth after use of the automated cleaning system prototype

Catheters were inoculated with either 10^6 colony forming units per mL of *E. coli* or *Pseudomonas aeruginosa* as described in the previous section – and then either washed in the prototype catheter washer-disinfector or maintained as an unwashed control. The catheters were

then divided into their catheter, the insertion sleeve, and catheter insertion aid. Each section was incubated in 10 mL of 1x PBS and sonicated for 10 minutes followed by centrifugation for 10 minutes. Nine mL of 1X PBS were aspirated out and the remaining 1 mL was vortexed to resuspend the cells. Then, PBS solution containing the bacterial cells were serial diluted 1:10 and plated on LB agar plates for analysis of colony forming units with the limit of detection being 50 CFU per catheter.

Assessment of bacterial growth after use of lubrication in simulated intermittent catheterization

Approximately 1 mL of sterile lubricant (A, B, or C) was used to evenly coat the entire catheter. Lubricated catheters were then incubated as previously described with either *E. coli* or *P. aeruginosa* (10^6 colony forming units per mL). The catheters were removed from the microbial solution and allowed to incubate for 6 hours prior to sonication, dilution, and plating as above. Specimens were then analyzed for colony forming units in a similar fashion.

Assessment of E. coli growth after reprocessing of lubricated and inoculated catheter

Catheters were lubricated and inoculated with 10^6 colony forming units per mL of *E. coli* and left to incubate for 6 hours. Experimental catheters were run through the standard washer-disinfector prototype cycle or kept as unwashed controls. Catheters were then divided into 9 segments: insertion aid, tip overlap, end overlap, catheter (proximal, mid, distal) and insertion sleeve (proximal, mid, distal); and colony forming were used to assess burden.

Assessment of repeat inoculation and reprocessing of catheter to determine feasibility of repeat use

Catheters were inoculated and cleaned/disinfected using the prototype washer-disinfector. The same catheter was then re-inoculated in the same fashion. This was repeated to a total of 20 times, with the experimental catheter being inoculated and cleaned 20 times and the controls being inoculated and cleaned 19 times followed by a 20th inoculation. Catheters were processed for colony forming unit assessment as described above. This experiment was repeated with catheters undergoing 100 cleaning and disinfection cycles. For all of the repeated catheter inoculation and reprocessing experiments, we washed both the control and experimental catheter after every inoculation. These same catheters were used repeatedly for back-to-back inoculation and reprocessing/cleaning cycles. After the final inoculation, only the experimental catheter was washed.

The experimental catheter was assessed for colony forming units after the 100th cleaning and disinfection cycle. The control catheter was tested out to 90 inoculation and cleaning cycles as it developed a tear in the sleeve that prevented additional reprocessing – this catheter was inoculated one final time (91st) and utilized as the control for colony forming unit assessment. Due to time constraints, this experiment could not be repeated.

Results

Six Dover and six Bardex silicone catheters were inoculated for the initial biofilm testing. As can be seen in **Figure 2**, with 5 minutes of inoculation time, water rinse, and various incubation periods, *E. coli* was able to attach to the catheters, replicate, and form biofilms. Biofilms appeared to preferentially develop at the ends of the catheter, although multiple areas were noted throughout

the catheter length. Utilizing fluorescence intensity, both catheter types appeared to develop maximum biofilm formation at 24 hours of incubation.

Subsequently, the novel reusable catheters (five within each test group) were inoculated with *E. coli* or *P. aeruginosa* to assess initial cleaning and disinfection capabilities of the prototype catheter washer-disinfector. For the two pathogens (**Figure 3**), the washed catheters had colonization levels below the limit of detection (<50 CFUs per catheter piece) and had significantly lower microbial burden compared to the non-treated catheters. These differences were noted across all three sections of the novel catheter – the catheter itself, the insertion sleeve, and the insertion aid.

Changes in bacterial growth with use of lubrication was assessed by inoculating catheters with lubricants A, B, or C and evaluating *E. coli* or *P. aeruginosa* colonization (at least three samples per group) on the catheter after a 6-hour incubation (**Figure 4**). While lubricant A was able to reduce bacterial growth below the limit of detection, lubricant B performed similarly and was commercially available for future testing. Lubricant C use was not statistically different from no lubricant use; these were the methods that produced the most bacterial growth in lubrication testing. In an attempt to focus the future testing on a method of catheter use most consistent with the expected use case of the Aurie System, lubricant B was used for the completion of this study.

To assess changes in washer-disinfector efficacy with introduction of lubrication, novel reusable catheters (five within each test group) were similarly inoculated with *E. coli* and incubated for 6 hours, but this was done after lubricant B was used to prelubricate the catheters. As can be seen in **Figure 4**, while each of the 9 catheter unit sections of the control catheters noted some detectable level of *E. coli* growth after lubrication, inoculation, and incubation, the experimental catheters that were washed in the prototype device all had a reduction in bacterial growth below

the level of detection. A number of these locations (all along the catheter, the end of the insertion sleeve, and the end overlap) showed a statistically significant difference in bacterial burden after washing in the prototype device.

To prove feasibility of catheter reuse and reprocessing, the novel reusable catheters (four within each group) were lubricated, inoculated with *E. coli*, incubated, and cleaned/disinfected up to 20 times, with the control catheters not undergoing the final cleaning and disinfection step. All catheters that completed 20 cycles had no detectable bacterial burden whereas the catheters that received the 20th inoculation without a corresponding cleaning and disinfection cycle had more bacterial growth across all catheter locations (**Figure 4C**). This difference was statistically significant across the entire catheter and insertion aid sections but was not significant when focusing on the insertion sleeve sections. This trend continued when evaluating the catheter with the 91st inoculation (control) compared to the catheter with the 101st inoculation and cleaning cycle (**Figure 4D**), where the differences between *E.* coli growth upon the experimental and control catheters remained consistent.

Discussion

In this study, we have shown that urinary pathogenic bacteria are able to bind to urinary catheters and form biofilm in a setting consistent with intermittent use. Utilizing a prototype for a novel reusable intermittent catheter system – the Aurie System – with or without water-based lubrication, the system's automatic washer-disinfector reduces bacterial presence below the level of detection, suggesting that safe reusability of these urinary catheters may be feasible.

Standard of care for intermittent urinary catheterization in the United States, per the FDA, remains single-use clean intermittent catheterization with sterile catheters. Despite this, studies

suggest up to 56% of individuals with neurogenic bladder reuse intermittent catheters, often for financial or accessibility reasons[10]. In 2014, a Cochrane review was published suggesting that, based on current work at that time, single-use catheterization was safer than catheter reuse – since that time, there have been significant changes to the narrative[11]. This Cochrane review was eventually withdrawn as a reevaluation of the data suggested that the current state of publications was not sufficient to favor one over the other[12, 13]. A number of studies have since shown that, when performed properly, catheter reuse may be as safe as single-use catheterization[7, 14]. In fact, a large prospective trial (COMPaRE) is currently being performed to evaluate single-use vs reusable catheters, following 456 patients for symptomatic UTI as an endpoint – this study will hopefully give greater clarity on the safety of reusable catheters in this population[15].

While various cleaning methodologies have been tested, including rinsing, microwaving, boiling, steam-heat, ultrasonic cleaning, detergent, vinegar, and Milton sterilizing fluid, there has not been a consensus standard catheter cleaning or sterilization method[14]. In this study, the Aurie System tabletop prototype was able to significantly reduce the presence of various uropathogenic organisms, suggesting that this automated methodology may be an easy-to-implement and adequate disinfection process. Notably, the catheters have been tested for residual cleaning solutions and have been found to be at safe levels, under 0.03% concentration of the active ingredient. This minimizes the possibility of an allergic or inflammatory response. Additionally, the cleaning fluid generated is safe for the environment since it is composed of a number of non-hazardous liquids, all of which are safe for sink disposal per labeling and EPA guidance.

A majority of urinary catheter-related microbiologic research focuses on long-term indwelling urinary catheters; the data in this study suggest that biofilm formation and catheter colonization can occur in an intermittent use-type setting (within 24 hours of initial catheter use).

The current paradigm in which some individuals reuse their single-use intermittent catheters against FDA recommendations has been shown to lead to increased risk of UTI; our data are consistent with this increased risk that has been observed[2]. As noted above, our study shows that use of the reprocessor was able to reduce the observed uropathogen growth below the level of detection with or without lubrication, with up to 101 repeat inoculations and cleaning/disinfection cycles producing catheters with a microbial burden consistent with unused catheters. Furthermore, use of the Aurie system provides cost benefits to the user with its safe reusability of intermittent catheters as well as being environmentally conscious due to reduced one-use catheter waste.

While this study shows the cleaning and disinfection capabilities of this tabletop catheter reprocessor, there are a few limitations to note. Firstly, the urinary catheters used in this study were prepared by soaking the catheters in urine that was inoculated with uropathogenic bacteria; while this attempts to mimic intermittent catheter use, these catheters were not used in individuals for actual catheterization and the microbial burden may not be consistent with true neurogenic bladders. We suggest this is not in fact a limitation, as the microbial burden we were able to introduce was higher than standard colonized urine and utilized well-established and virulent uropathogens. Still, the mechanical passage of the catheter in true urethral catheter use may affect the outcomes of this study, although unlikely. Additionally, while both *E. coli* and *P. aeruginosa* were used for portions of this testing, once the *E. coli* was noted to have sufficient growth within the catheters to serve as a reasonable positive control, no further testing was done with other pathogens due to time and budgetary constraints. *E. coli* and *P. aeruginosa* were selected as critical pathogens to test in our disinfection system since *E. coli* is the most prevalent causative agent during intermittent and indwelling catheter-associated urinary tract infections[8, 16]; and in the case of *P. aeruginosa*, it has been found in unpublished and published data to be a frequent colonizer

of intermittent catheters[17]. Furthermore. *P. aeruginosa* is a microbial contaminant of 0.02% benzalkonium chloride, a solution used in catheter kits for intermittent self-catheterization[18-20]. However, it is important to note that various microbial species (including *Enterococcus faecalis, Klebsiella pneumonia*, *Candida spp*, *Proteus mirabilis, S. aureus*, *Mycobacterium spp*. and other prevalent causative pathogens of catheter-associated urinary tract infections)[8, 21-24] will likely require testing prior to ensuring the successful disinfection abilities and broad applicability of this system. Furthermore, lubricant use clearly had some effect on the microbial burden and thus the use of lubricant B in this study may have overestimated the antibacterial effect of the Aurie System; the planned use for the system will include a lubricant that will similarly affect microbial burden; thus, this study accurately characterizes the interaction between lubrication and uropathogen growth. Another concern is that use of the Aurie system may result in microbial resistance. Our cleaning and disinfection protocols include different detergents and washes, and microbial survival after the washes was not observed (no CFU detected) in all reprocessed catheters, except on one occasion with the astroglide lubricated catheter, suggesting that resistance was developed. Since survival was not observed in the majority of reprocessed catheters, we did not further evaluate for resistance to the cleaning and disinfection protocol. There is indeed theoretical concern for resistance with continued use. However, in our 100x cleaning process (**Figure 4C**), CFUs were not recovered. Lastly, while the final portion of this study attempted to compare a catheter reprocessed 101 times vs a catheter reprocessed 100 times, our control catheter was noted to have a tear after 91 reprocessor runs, preventing the planned comparison; this portion of the study was a proof of concept towards the 100 expected reuses targeted by the Aurie System and will require further evaluation in the future. This experiment was not repeated due to time and budgetary constraints.

Conclusion

A purpose-built catheter washer-disinfector system (Aurie System) was able to remove viable uropathogenic bacteria from a novel no-touch intermittent urinary catheter in an *in vitro* setting that simulated intermittent catheterization and catheter reuse. While the Aurie System is not currently approved for clinical use, this early prototype suggests promising antimicrobial activity and may be a reasonable platform for simplifying and automating intermittent catheter reuse.

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Support/Financial Disclosures:

SP and DAW are co-founders of CathBuddy, Inc.; DAW is a consultant for Boston Scientific.

Author statement:

ALB – conceptualization, investigation, review & editing
AM – conceptualization, investigation, review & editing
DAW – conceptualization, formal analysis, writing, review & editing
SP – conceptualization, formal analysis, review & editing, project administration
ALFM – conceptualization, formal analysis, review & editing, supervision

Figure Legend

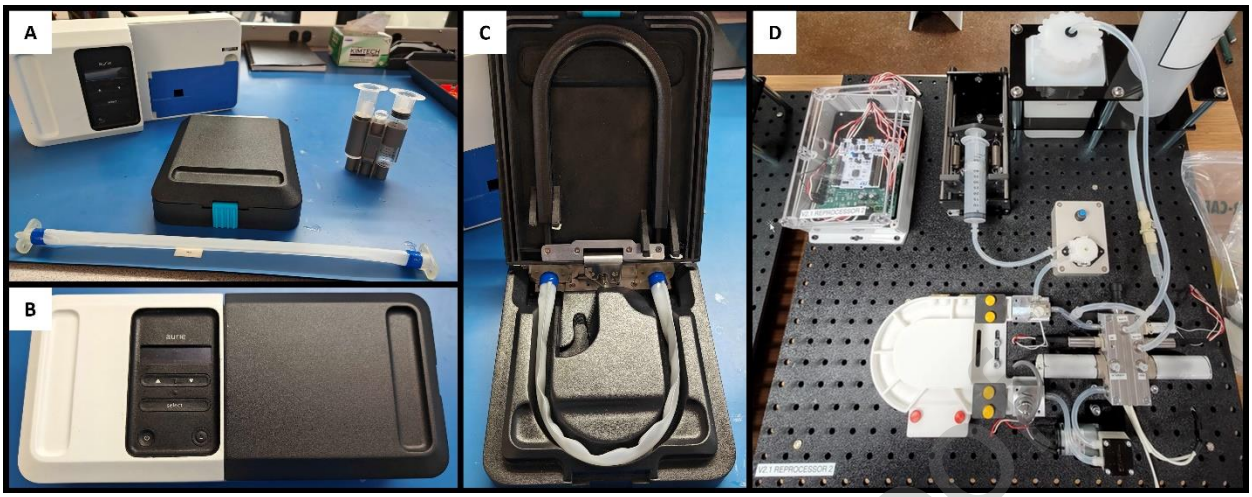

Figure 1: Aurie reprocessing unit current version and prototype. The current version of the system can be seen in **A-C**. (**A**) Base, carrying case, cleaning supply pod, and catheter (**B**) Base with docked carrying case (**C**) Open carrying case with catheter seated and (**D**) Tabletop prototype used in this study.

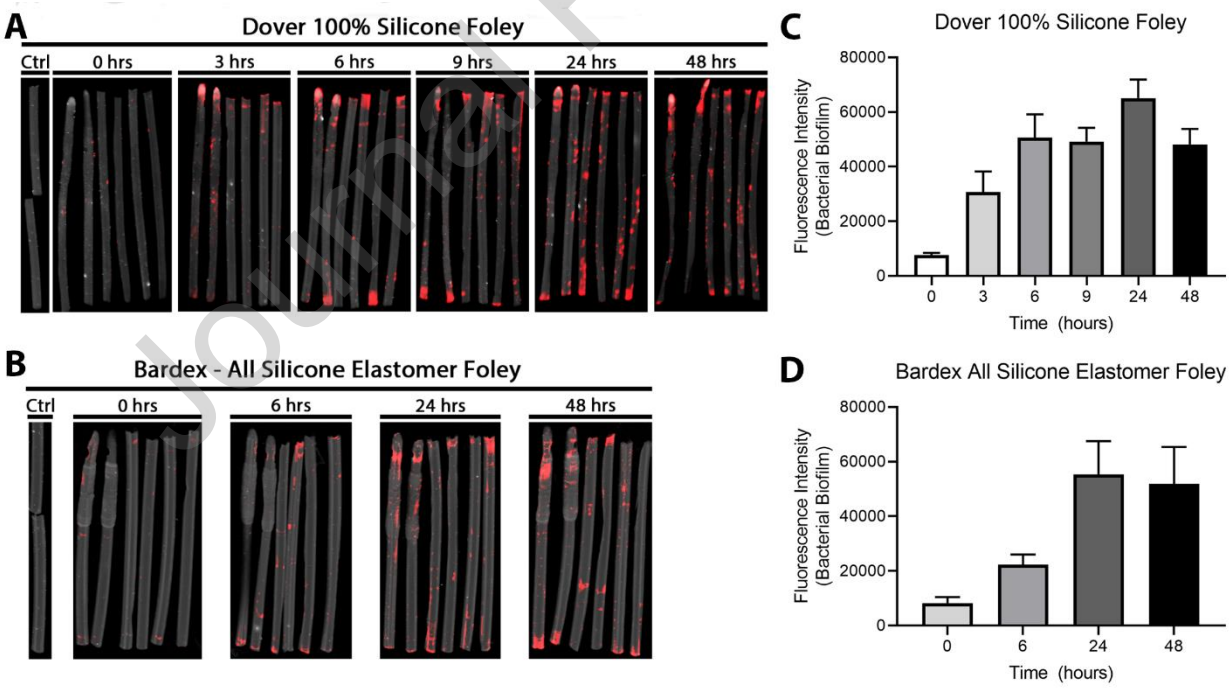

Figure 2. Intermittent catheter use allows for bacterial attachment and biofilm formation. Two different catheter brands (**A**) Dover 100% Silicone Foley (n=6) and (**B**) Bardex All Silicone

Elastomer Foley (n=6) were incubated in urine and *E. coli* for 5 minutes and assessed for biofilm formation (red) via fluorescence intensity over the course of 48 hours. The Bardex All Silicone Elastomer Foley lacked timepoints 3 and 9 hours due to limited catheter inventory. (**C-D**) Fluorescence intensity quantified to show bacterial biofilm progression over 48 hours.

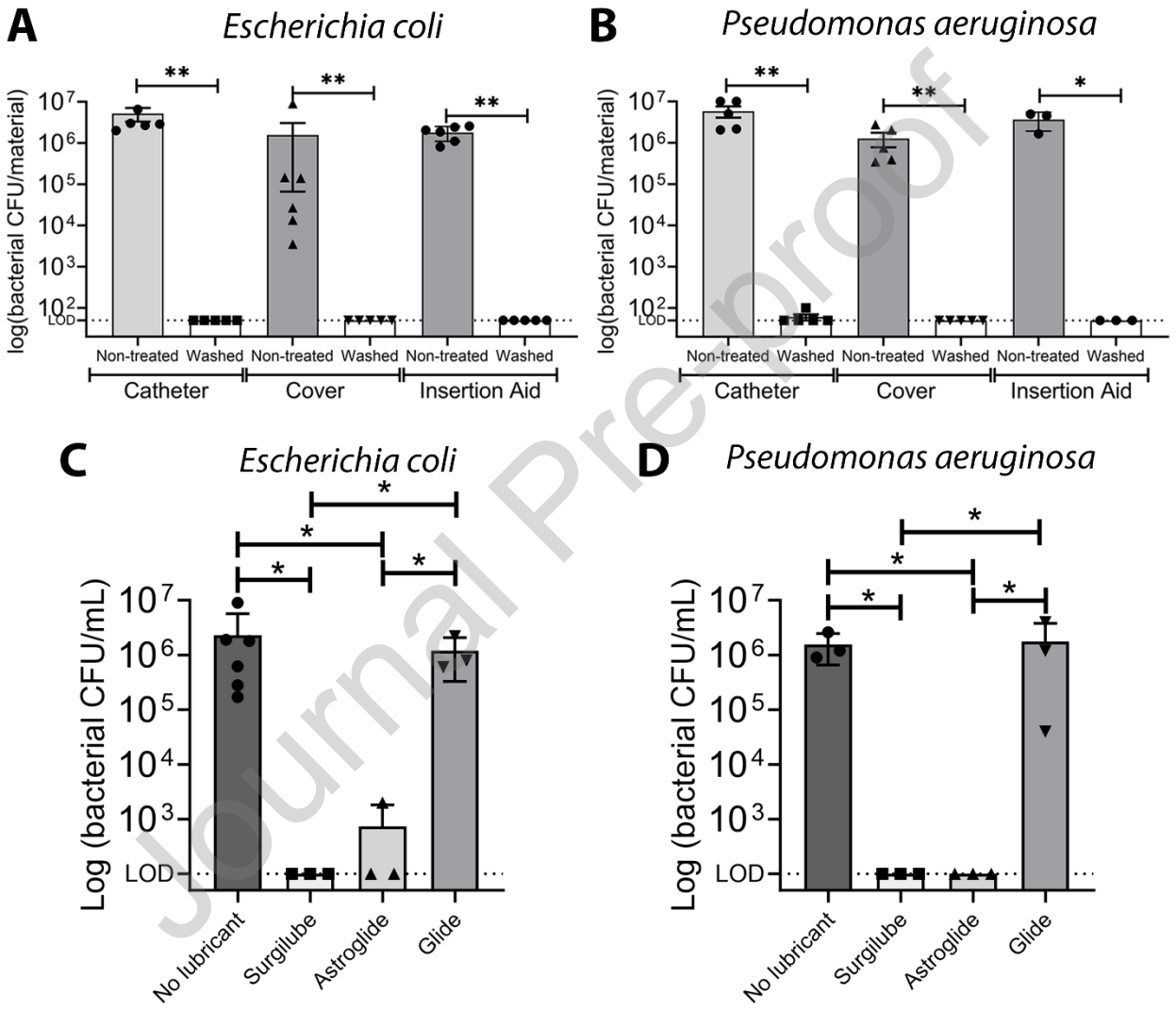

Figure 3. Microbial attachment and burden are reduced following reprocessor treatment and lubricant products can aid urinary catheter colonization. Urinary catheters (n=5) were inoculated with the bacterial pathogens *E. coli* (**A**) and *P. aeruginosa* (**B**). The catheter, insertion sleeve, and insertion aid were assessed for microbial colonization following incubation (control, C) or post-incubation reprocessing (R). Urinary catheters (at least n=3) were treated with lubricants

A, B, C, or no lubricant prior to incubation with uropathogenic *E. coli* (**C**) and *P. aeruginosa* (D) and assessed for microbial burden via CFU enumeration. The Mann-Whitney U test; *$P < 0.05$ and **$P < 0.005$. LOD: limit of detection.

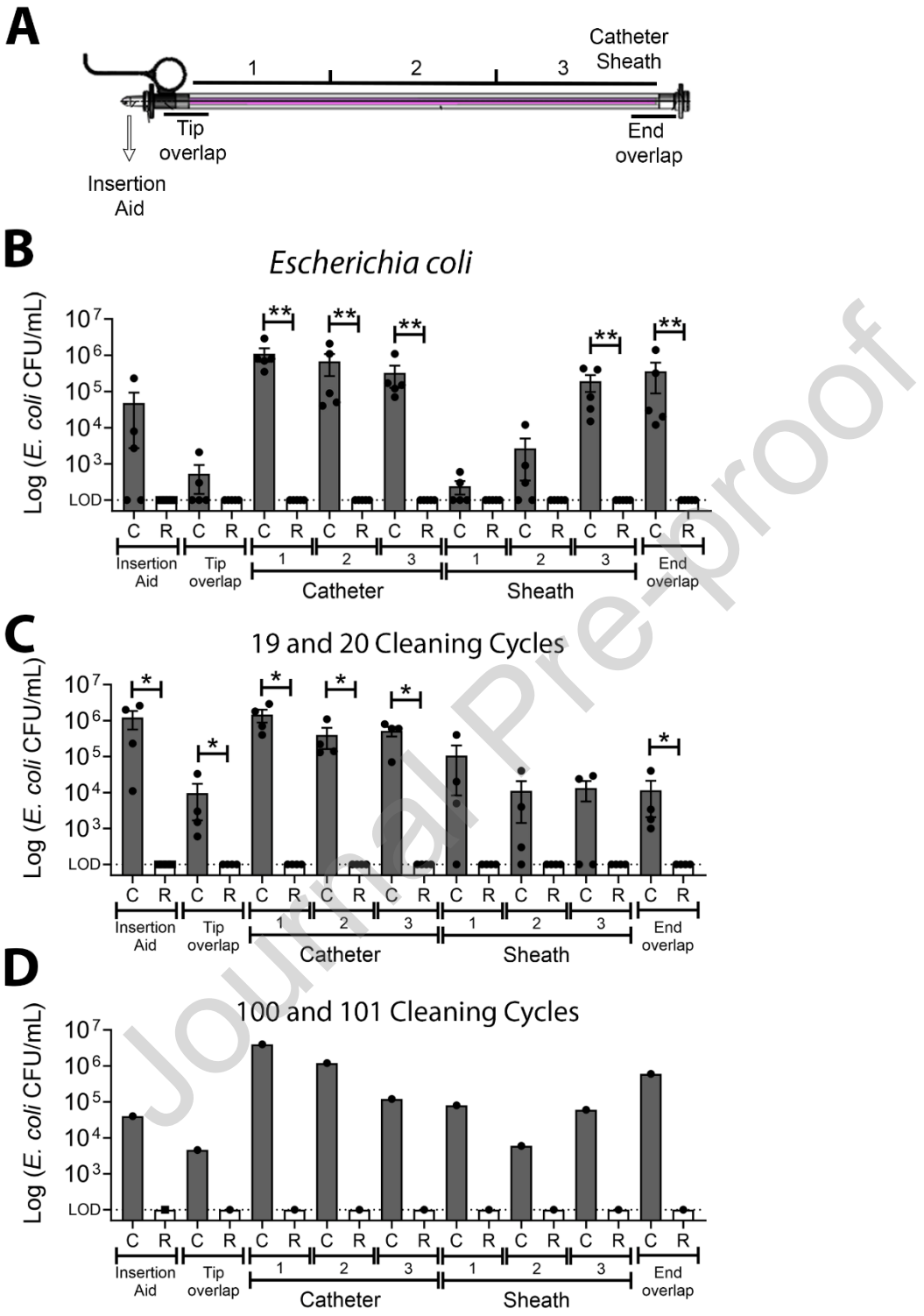

Figure 4. Reprocessor treatment eliminates bacterial burden on lubricated urinary catheters. (**A**) Schematic of an intermittent urinary catheter and the segments the catheter was

divided into for CFU assessment. (**B**) Urinary catheters (n=5) treated with lubricant B show no bacterial burden following reprocessor treatment. Following (**C**) 19 and 20 cleaning cycles (n=4) and (**D**) 91 and 101 (n=1) cleaning cycles, reprocessed catheter had no bacterial colonization on any segment of the catheter. Catheters were either inoculated (control, C) or reprocessed post-incubation (R). Control catheters (C) exhibited high levels of bacterial burden (~10^4-10^6 CFU/mL) across the different catheter segments compared to minimal burden on the reprocessed catheters (R). The control catheter in (**D**) only went through 91 cleaning cycles as opposed to 100 cleaning cycles due to tearing of the insertion sleeve. The Mann-Whitney U test; **P < 0.005. LOD: limit of detection.

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Declaration of Competing Interest

1) Dr. Ana Flores-Mireles-No Conflict

2) Ms. Alyssa La Bella -No Conflict

3) Mr. Souvik Paul, co-founder of CathBuddy- Conflict (f)

4) Dr. Daniel Wollin, co-founder of CathBuddy and paid consultant for Boston Scientific - Conflicts (b an f)

5) Mr. Alex Molesan, M.S. - No Conflict