

Assessment of the Ability of a Protective Tip to Prevent Bacterial Contamination of the Catheter

Dr Nicola Morris, Dr Richard Thompson Hollister data on file, Ref-00812, 2018

Objectives

This in vitro model was constructed or developed to assess if the protective tip prevents contamination of the catheter.

Methods

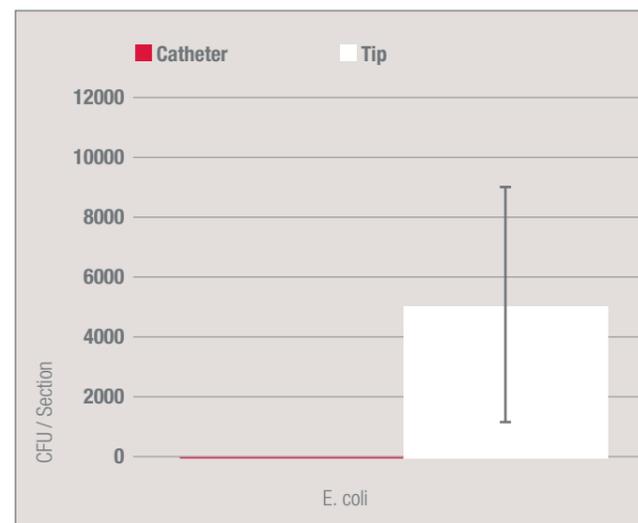
An in vitro model of the first 10 mm of the distal urethra was constructed. Prior to sterilization, a hole was drilled in the center of a petri dish and a pipette tip was placed in the hole. To simulate the contaminated urethral segment, molten agar containing Escherichia coli or Enterococcus faecalis was poured into the dish and allowed to gel. When the agar had gelled, the pipette tip was removed, yielding a bacteria-laden channel. The VaPro catheter was passed through the channel, following the instructions for use. After the catheter had passed through the petri dish the first 3 cm section of the catheter tip was cut off and the introducer tip was removed from the plate.

The catheter tip and the introducer tip were tested to see if bacteria had adhered after passing through the agar.

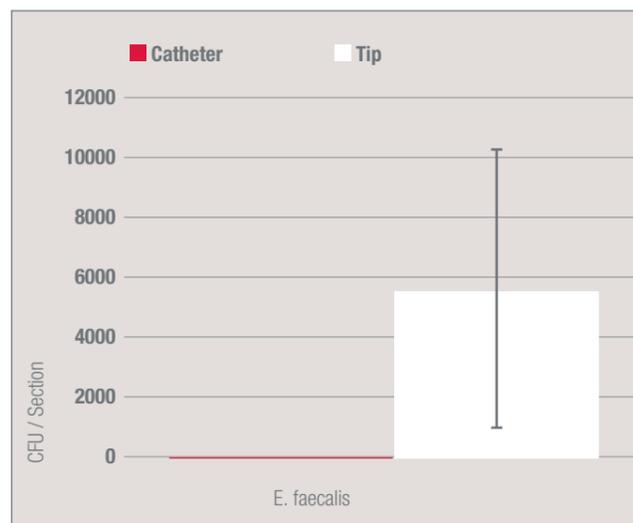
The test was carried out using suspensions of Escherichia coli and Enterococcus faecalis, which are commonly found in the urogenital area (Whiteside SA, Razwi H, Dave S, Reid G, Burton JP, 2015).

Results

No bacteria were recovered from the catheter tips when exposed to either E. coli or E. faecalis. Bacteria were recovered from the introducer tips.



Bacteria recovered from the catheter tip and the protective tip after passage through the E. coli contaminated model of the urethra. No bacteria were present on the catheter tip however bacteria was present on the protective tip. Data points represent an average of five independent experiments and error bars indicate standard deviation. Statistical difference (p= 0.019) was determined by 2 tail t-test assuming equal variances.



Bacteria recovered from the catheter tip and the protective tip after passage through the E. faecalis contaminated model of the urethra. No bacteria were present on the catheter tip however bacteria was present on the protective tip. Data points represent an average of five independent experiments and error bars indicate standard deviation. Statistical difference (p= 0.024) was determined by 2 tail t-test assuming equal variances.

CONCLUSION

In an *in vitro* model, passing a catheter through a protective tip, resulted in no contamination of the catheter tip by bacteria that were surrounding the protective tip.

IMPACT Study

Hollister data on file, TR-00453, 2021

Intermittent catheters Protective features and miCrobal Transfer

Objectives

An independent laboratory investigated the protective effects of VaPro™ No Touch intermittent catheters and how they compare directly with intermittent catheters from other manufacturers.

Methods

For optimal comparability, the researchers assessed catheters that also have a protective sleeve. Comparative intermittent catheters included SpeediCath Flex™ catheter (Coloplast), Liquick X-treme™ catheter (Teleflex) and IQ Cath™ catheter with sleeve (Manfred Sauer). All comparators have a protective sleeve, but there is none with a protective tip like VaPro catheters.

The most relevant uropathogenic microbial species were tested including Escherichia coli, Enterococcus faecium and Candida albicans (a yeast). Escherichia coli are a leading cause in urinary tract infections and have a high propensity for antimicrobial resistance. Enterococcus faecium has also been associated with multidrug resistance, including to gentamycin and vancomycin.

To simulate the touch contamination, the researchers contaminated gloves with a precisely defined concentration of each microbial strain. With these gloves, the researchers inserted the respective catheter into the urethra of an anatomical penis model. The model was also prepared by contaminating a defined quantity of microbes into the first 15mm of the distal opening to simulate real-world presence in that region. The rest of the model was sterile. Then the

researchers pushed the catheter through the model, following the instructions for use of the respective manufacturer. When it came out on the other side they cut off two pieces, each 2 inches (5 centimeters) long. Upon withdrawal of the catheter they also cut two 2 inches (5 centimeters) sections from the protective tip and sleeve. The entire cap of the VaPro catheter was also tested. The researchers counted how many bacteria or yeast adhered on the respective sections. Multiple researchers repeated this process 9 times for each bacterial and yeast strain for each catheter model.

Watch the IMPACT Study Video

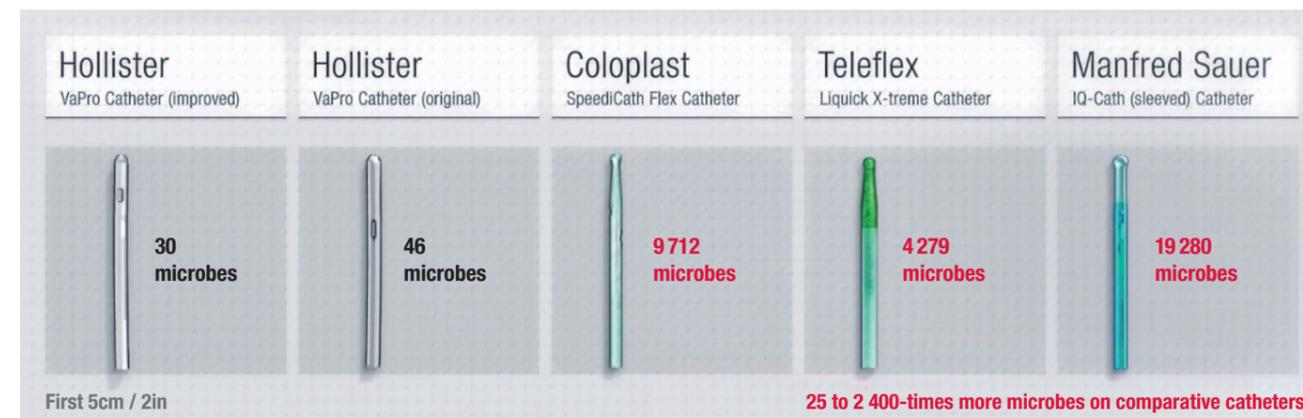


A video detailing the study methodology and results is available at www.hollister.com/VaProSuperiorProtection

The Results

VaPro catheters outperformed SpeediCath Flex catheters, Liquick X-treme catheters and IQ Cath (with sleeve) catheters in preventing touch contamination to the catheter for all three species evaluated. The VaPro catheters provide superior protection in reducing microbial contamination* to effectively zero. Comparative catheters resulted in 25 to 2400 times more microbes than on VaPro catheters (p-value of <0.05).

*of catheters included in the study using the indicated microbials



Conclusion

VaPro catheter's combination of protective tip and sleeve demonstrates the best protection against contamination when compared to other sleeved catheters without a protective tip.

Pathogen Transmission Testing of VaPro Catheter Sleeve Material

Hollister data on file, Ref-00814, 2014

Objectives

The aim of the test was to determine if the sleeve material used by VaPro hydrophilic catheters would prevent the transmission of pathogens that are associated with catheter associated UTIs (CAUTI).

Methods

An independent laboratory tested VaPro catheter sleeve material, using the ASTM F1671 'Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System', usually referred to as the Viral Penetration Test. This is a pass or fail test designed to show whether material tested protects against the transmission of bloodborne pathogens.

Figure 1 shows that viruses are significantly smaller than pathogens that commonly cause catheter associated UTIs (CAUTI). A material that stops transmission of viruses will also stop transmission of bacteria and other microorganisms, which are greater in size.

Samples of the VaPro catheter sleeve material were conditioned for a minimum of 24 hours at 21±5°C and 30 – 80% humidity (RH) and then tested for viral penetration using a virus suspension of phi X174 bacteriophage.

Parasites	Trichomonas vaginalis	~10 µm
Fungi	Candida albicans C. glabrata C. orthopsilosis C. tropicalis Clavispora lusitanae Lodderomyces elongisporus	~5 µm
Bacteria	Escherichia Klebsiella Pseudomonas Enterobacter Citrobacter Actinomyces Anaerococcus Atopobium Lactobacillus Staphylococcus Streptococcus	~1 µm
Viruses	Human papillomavirus Molluscum contagiosum virus BK and JC polyomavirus Herpesvirus 6 Anellovirus	~30 nm



Figure 1: Urinary Meatus Microbiome
(Moustafa, A., et al. (2018). "Microbial metagenome of urinary tract infection." Scientific Reports 8(1): 433)

*ASTM F1671 / F1671M-13, Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System, ASTM International, West Conshohocken, PA, 2013, www.astm.org

Results

The test result was **Pass** (Hollister data on file): viruses were not transmitted through VaPro catheter sleeve material.

CONCLUSION

The VaPro catheter sleeve material passes the ASTM F1671 test so provides assurance that it protects against pathogens that may cause catheter associated UTIs (CAUTI).

The 'No-Touch' Method of Intermittent Urinary Catheter Insertion: Can it Reduce the Risk of Bacteria Entering the Bladder?

Hudson E, and Murahata R. Spinal Cord. 2005; 43; 611-614. This study was authored by Hollister employees and funded by Hollister Incorporated

Objectives

This in vitro model was conducted to determine whether the no-touch protective sleeve affects the degree of contamination to the catheter while being prepared and inserted.

Methods

6 different types of intermittent catheters were tested in triplicate.

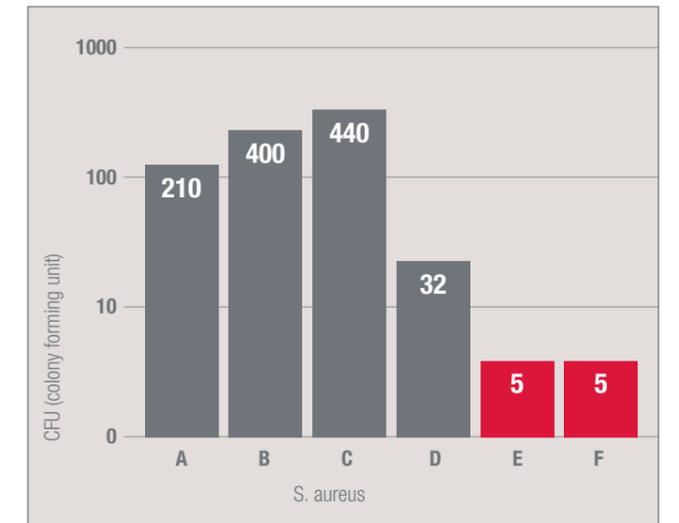
Gloved hands were contaminated with known amounts of S. aureus or E. coli and intermittent catheter preparation for insertions mimicked manufacturer's instructions.

Bacteria transferred to the catheter was quantified and validated using a validated technique. Negative controls were non-handled samples.

- Catheters A, B, C:** Standard hydrophilic catheters
- Catheter D:** Hydrophilic catheter handled through the wrapper
- Catheters E, F:** Catheters with no-touch sleeve

Results

The bacteria count on catheter E and F was significantly lower than that recovered from the traditional hydrophilic catheters (p < 0.05).



CONCLUSION

The *in vitro* model showed that intermittent catheters with the hygienic feature of a no-touch sleeve helped reduce the potential for external contamination during preparation and insertion of an intermittent catheter. This reduction may help reduce the risk of bacteria entering the bladder.

Support your Practice with Evidence-Based Research

The following summary of clinical and laboratory evidence demonstrates that a no-touch catheter with a protective tip and sleeve, has been shown to reduce the introduction of bacteria to the urinary tract. Reducing the introduction of bacteria may help reduce the risk of catheter associated UTIs (CAUTI). Intermittent catheters with a protective tip and sleeve from Hollister are **hygienic by design** – providing 100% No Touch Protection which facilitates no-touch aseptic IC.



		No-Touch Features	
		Protective Tip	Protective Sleeve
Page 3	IMPACT Study Hollister data on file, TR-00453, 2021	✓	✓
Page 4	Pathogen Transmission Testing of VaPro Catheter Sleeve Material Hollister data on file, Ref-00814, 2014		✓
Page 5	The ‘No-Touch’ Method of Intermittent Urinary Catheter Insertion: Can it Reduce the Risk of Bacteria Entering the Bladder? Hudson E, Murahata R. Spinal Cord: 43: 611-614.		✓
Page 6	Assessment of the Ability of a Protective Tip to Prevent Bacterial Contamination of the Catheter Dr Nicola Morris, Dr Richard Thompson Hollister data on file, Ref-00812, 2018	✓	
Page 7	The Effect of Urethral Introducer Tip Catheters on the Incidence of Urinary Tract Infection Outcomes in Spinal Cord Injured Patients Bennett CJ, Young MN, Raze SS, Adkins R, Diaz F, and McCrary A. J Urol 158, No. 2 (1997): 519-21.	✓	
Page 8	A New Catheter for the Female Patient O’Neil AG, Jenkins DT, and Wells JL. Aust. N.Z. J Obstet. Gynecol. 22 (1982): 151-152.	✓	

The Effect of Urethral Introducer Tip Catheters on the Incidence of Urinary Tract Infection Outcomes in Spinal Cord Injured Patients

Bennett CJ, Young MN, Razi SS, Adkins R, Diaz F, and McCrary A. J Urol 158, No. 2 (1997): 519-21:

Objectives

The aim of this study was to determine whether catheters with an introducer tip reduced urinary tract infections in spinal cord injured patients who performed self-intermittent catheterisation.

Methods

11 tetraplegic and 16 paraplegic males participated in this study. The MMG/O’Neil catheter system was used, which consists of a plastic catheter enclosed in a pre-lubricated plastic sleeve, and introducer tip which protects the catheter from the first 15 mm of distal urethra bacteria. All catheterising patients were asked to use one of two systems: The MMG/O’Neil with the introducer tip or the MMG/O’Neil with the introducer tip removed. Urodynamics, urine cultures, and urinalyses were performed and tracked.

Subjects were enrolled into 4 groups based on their ability to reflex void:

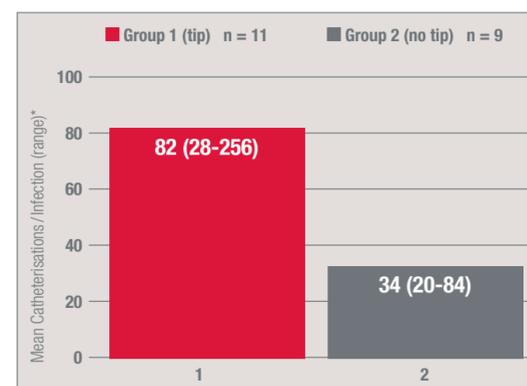
- Group 1:** Intermittent catheterisation with introducer tip catheter; not spontaneously voiding or wearing external urinary catheter
- Group 2:** Intermittent catheterisation with non-introducer tip catheter; not spontaneously voiding or wearing external urinary catheter
- Group 3:** Intermittent catheterisation with introducer tip catheter; voiding by reflex and wearing external urinary catheter
- Group 4:** Intermittent catheterisation with non-introducer tip catheter, voiding by reflex and wearing external urinary catheter

Results

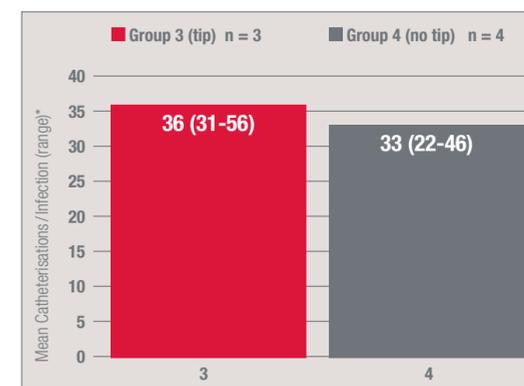
In comparable non-voiding groups, the difference between the introducer and non-introducer tips was clearly significant ($p < 0.0093$), as was the overall difference between all introducer tip catheter groups compared to all non-introducer tip catheter groups ($p < 0.01$).

Table 1 Number of Catheterisations and Significance According to Group*

Intermittent catheterisation only



Intermittent catheterisation, reflex voiding, and external urinary catheter



The above graphs show the mean number of catheterisations and range prior to an infection. Between and within all groups $p < 0.0306$. Group 3 versus group 4, and groups 1 and 2 versus groups 3 and 4 were not significant. *Actual article mentioned additional statistics.

CONCLUSION

According to this study, the MMG/O’Neil catheter with introducer tip significantly decreased urinary tract infections in hospitalised, spinal cord injured men who performed intermittent catheterisation.

A New Catheter for the Female Patient

O’Neil AG, Jenkins DT, and Wells JL. Aust. N.Z. J Obstet. Gynecol. 22 (1982): 151-152.

Objectives

The goal of this study was to determine if a new method of catheterising female patients using a new catheter with a sealed introducer tip (O’Neil) would reduce the transfer of organisms from the distal urethra to the bladder at the time of catheterisation.

Methods

132 female patients from 2 centers were enrolled in the study. Urine specimens were taken before and after intermittent catheterisation. 2 groups were formed:

- Control Group:** Used a 14 Nelaton catheter
- Experimental Group:** Used the new catheter with introducer tip

The O’Neil tip catheter and introducer tip consists of a plastic catheter enclosed in an introducer tip, with a rubber flange, which prevents the tip from being introduced beyond the first 15 mm (previous study showed potential pathogens in the distal urethra in 90% of females¹). This tip protects the catheter from the first 15 mm of distal urethra bacteria, and therefore the catheter enters the bladder without being in contact with the distal urethra.

¹ A. G. B. O’Neil, The Bacterial Content of the Female Urethra. A New Method of Study. British Journal of Urology (1981): 53; 368-270.

Results

25% of patients (17/67) who were catheterised in the Control Group developed bacteriuria as a result of the catheterisation. For those in the Experimental Group, using the O’Neil catheter with introducer tip, only 4% of patients (2/52) developed bacteriuria. This was a statistically significant result ($p < 0.005$).

Due to pre-existing bacteriuria, 13 of the 132 patients were excluded from the study.

Table 1 Urinary Infection Rates in the Experimental and Control Groups

	Total No.	Pre-existing Bacteriuria >10	Infection Rate Control Group	Infection Rate New Catheter
Glasgow	57	5	6 / 25	1 / 27
Perth	75	8	11 / 42	1 / 25
Total	132	13	17 / 67	2 / 52

Conclusion

According to this study, the O’Neil catheter introducer tip reduced the transfer of organisms from the first 15 mm of the distal urethra to the bladder, which may help reduce catheter acquired urinary tract infections (CAUTIs) in females.



With 100% No Touch Protection, whatever you touch won't touch VaPro™ catheters.

- The protective tip helps to reduce the risk of carrying bacteria into the urinary tract and helps shield the sterile catheter during insertion from bacteria located within the first 15 mm of the distal urethra
- The protective sleeve allows for the catheter to be gripped anywhere and provides a barrier to the catheter to help keep germs away

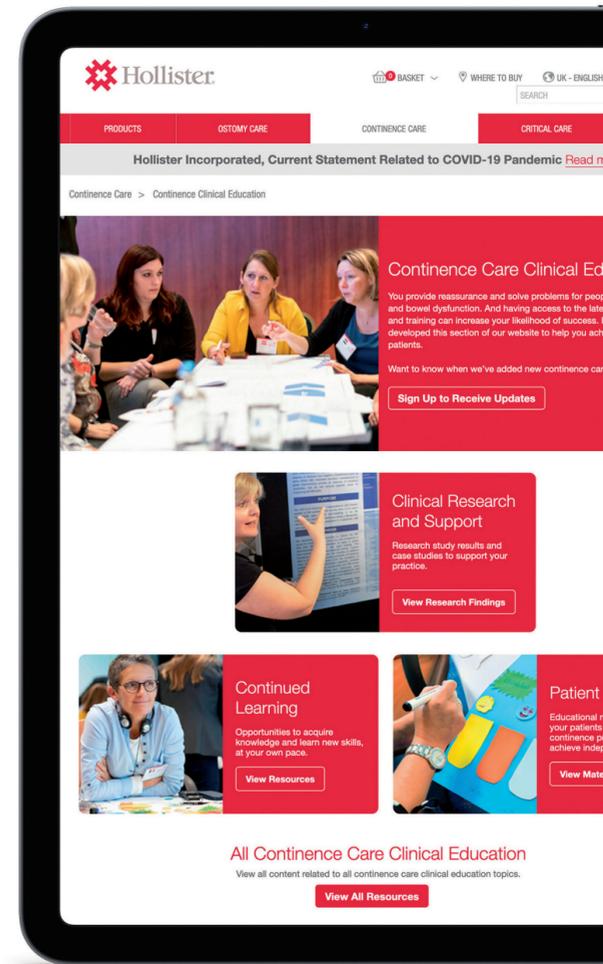
VaPro Catheter Portfolio Overview

Size	Length	System	Color Code	VaPro Catheter	VaPro Plus Catheter	VaPro Plus Pocket Catheter
8 Fr	8 in	Straight	Blue	–	–	71082-30
10 Fr	8 in	Straight	Black	–	–	71102-30
12 Fr	8 in	Straight	White	74122-30	74122-30	71122-30
14 Fr	8 in	Straight	Green	–	74142-30	71142-30
8 Fr	16 in	Straight	Blue	–	–	71084-30
10 Fr	16 in	Straight	Black	–	–	71104-30
12 Fr	16 in	Straight	White	–	74124-30	71124-30
14 Fr	16 in	Straight	Green	–	74144-30	71144-30
16 Fr	16 in	Straight	Orange	–	–	71164-30
12 Fr	16 in	Coudé	White	73124	–	–
14 Fr	16 in	Coudé	Green	73144	–	–
16 Fr	16 in	Coudé	Orange	73164	–	–

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Clinical and Laboratory Evidence

The Hygienic Benefits of a No Touch Intermittent Catheter with a Protective Tip and/or Sleeve

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 No Touch Intermittent Catheter

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