Clinical and Laboratory Evidence

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

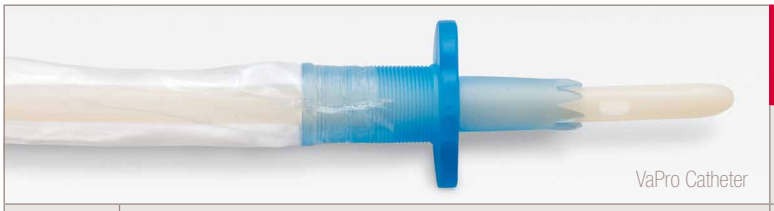
VaPro
Touch Free Hydrophilic
Intermittent Catheter

Hollister

Continence Care
People First

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.

 VaPro Catheter		No-Touch Features	
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Pathogen Transmission Testing of VaPro Sleeve Material

Hollister data on file

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 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 viruses transmitted via the blood and body fluids.

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 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 lustianiae 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 sleeve material.

Conclusion

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

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

Objectives

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

Methods

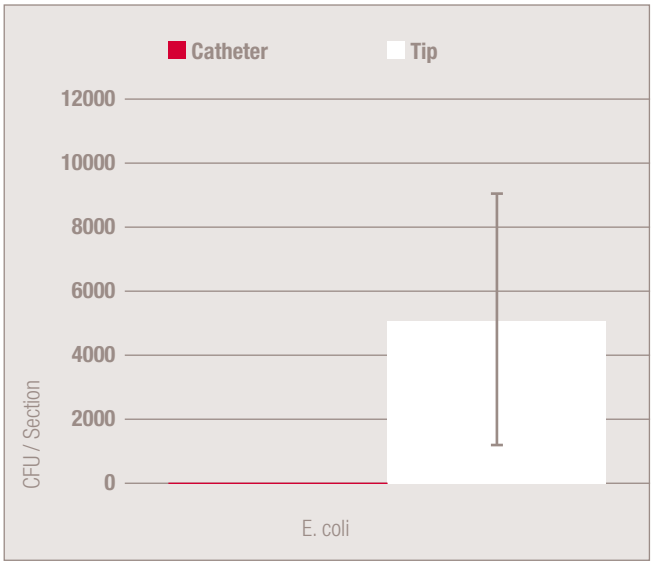
An *in vitro* model of the first 10 mm of the distal urethra was constructed. Prior to sterilization, a hole was drilled in the center of a petri dish and a pipette tip was placed in the hole. To simulate the contaminated urethral segment, molten agar containing Escherichia coli or Enterococcus faecalis 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.

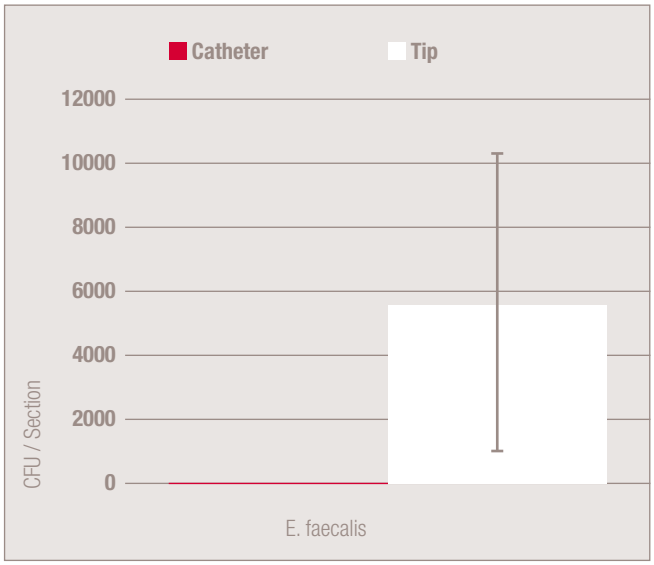
The test was carried out using suspensions of Escherichia coli and Enterococcus faecalis, which are commonly found in the urogenital area (Whiteside SA, Razwi H, Dave S, Reid G, Burton JP, 2015).

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.

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.

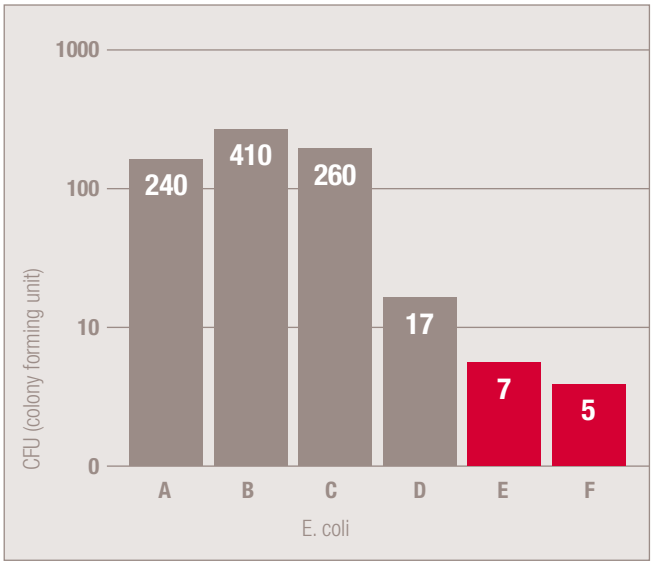
Gloved hands were contaminated with known amounts of S. aureus or E. coli and intermittent catheter preparation for insertions mimicked manufacturer's instructions.

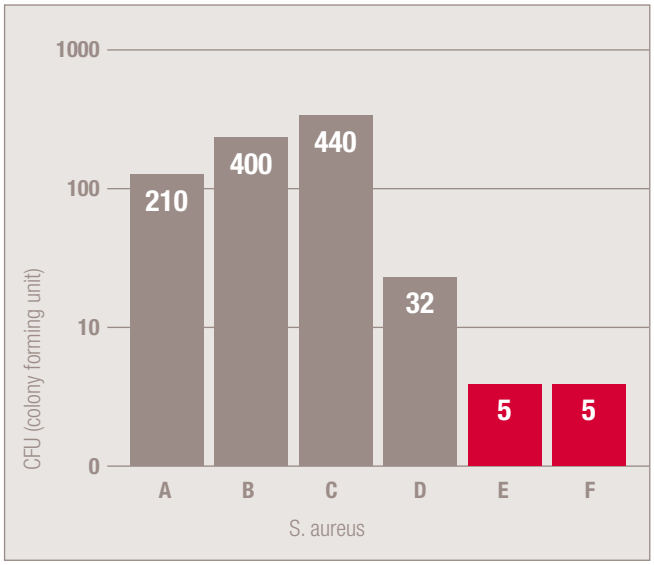
Bacteria transferred to the catheter was quantified and validated using a validated technique. Negative controls were non-handled samples.

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.

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 quadraplegic 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

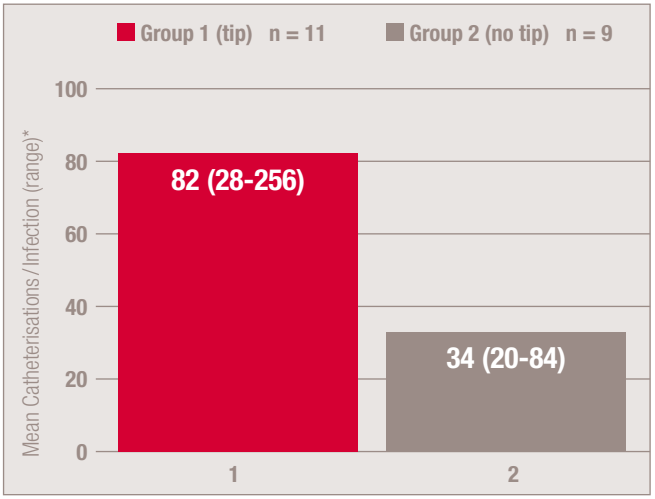
Group 4: Intermittent catheterisation with non-introducer tip catheter, voiding by reflex and wearing external urinary catheter

Results

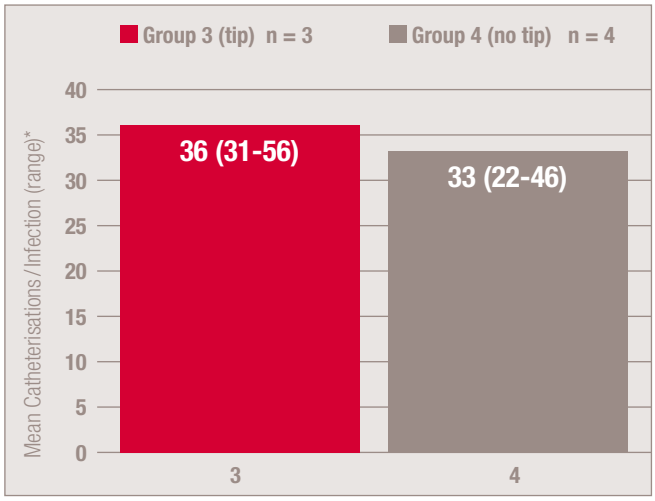
In comparable non-voiding groups, the difference between the introducer and non-introducer tips was clearly significant ($p < 0.0093$), as was the overall difference between all introducer tip catheter groups compared to all non-introducer tip catheter groups ($p < 0.01$).

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 JI.
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 females[1]). 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.

VaPro Catheters: 100% No Touch Protection

A broad portfolio for both men and women

Size	Length	System	Color Code	VaPro	VaPro F-Style	VaPro Pocket	VaPro Plus	VaPro Plus F-Style	VaPro Plus Pocket
8 Ch	20 cm	Nelaton		72082	–	–	–	–	71082
10 Ch	20 cm	Nelaton		72102	–	70102	–	–	71102
12 Ch	20 cm	Nelaton		72122	–	70122	74122	–	71122
14 Ch	20 cm	Nelaton		72142	–	70142	74142	–	71142
8 Ch	40 cm	Nelaton		72084	7600084	–	–	–	71084
10 Ch	40 cm	Nelaton		72104	7600104	70104	–	–	71104
12 Ch	40 cm	Nelaton		72124	7600124	70124	74124	7700124	71124
14 Ch	40 cm	Nelaton		72144	7600144	70144	74144	7700144	71144
16 Ch	40 cm	Nelaton		72164	7600164	70164	–	–	71164
12 Ch	40 cm	Tiemann		73124	–	–	–	–	–
14 Ch	40 cm	Tiemann		73144	–	–	–	–	–
16 Ch	40 cm	Tiemann		73164	–	–	–	–	–

WARNING: To help reduce the potential for infection and/or other complications, do not reuse.

WARNING: If discomfort or any sign of trauma occurs, discontinue use immediately and consult your healthcare practitioner.

- Ready-to-use, intermittent catheter
- Protective tip and sleeve supports no-touch insertion technique
- Easy-to-remove ring cap
- Collection bag
- Hydrophilic-coated, Phthalate-free catheter
- 2 smooth catheter eyelets
- Adhesive tab for adhering packaging to a surface
- Not made with natural rubber latex

INDICATIONS FOR USE: This intermittent catheter is a flexible tubular device that is inserted through the urethra by male, female and pediatric (paediatric) patients who need to drain urine from the bladder.

PRECAUTION: Please consult your healthcare practitioner before using this product if any of the following conditions are present:

- Severed urethra
- Pronounced stricture
- Urethritis – inflammation of the urethra
- Epididymitis – inflammation of the epididymis (testicle tube)
- Unexplained urethral bleeding
- False passage
- Prostatitis – inflammation of the prostate gland

PRECAUTION: Self-catheterization (catheterisation) should follow the plan of care and advice given by your healthcare practitioner and be carried out only in accordance with the instructions for use provided. Because catheterization (catheterisation) frequency varies by person, the recommended frequency of your catheterization (catheterisation) should be provided by your healthcare practitioner. For any other questions about your catheterization (catheterisation), please contact your healthcare practitioner.

Rx only

NOTE: Store boxes in a flat position and at normal room temperature.
This product consists of: polyurethane sleeve, thermoplastic elastomer tip, and tubing not made with DEHP.

Hollister