

Interpreting the evidence....
more than meets the eye

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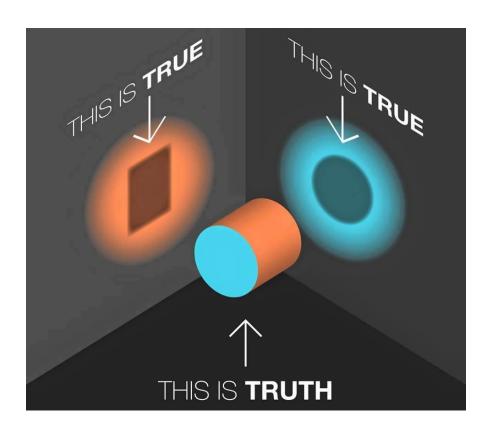
## Agenda

 The withdrawal of the 2014 Cochrane review on IC and a new recommendation

Invisible insertion difficulties



## Knowledge as a matter of perspective





# Social Science & Medicine. Part A: Medical Psychology & Medical Sociology



Volume 14, Issue 1, 1980, Pages 81-83

Research note

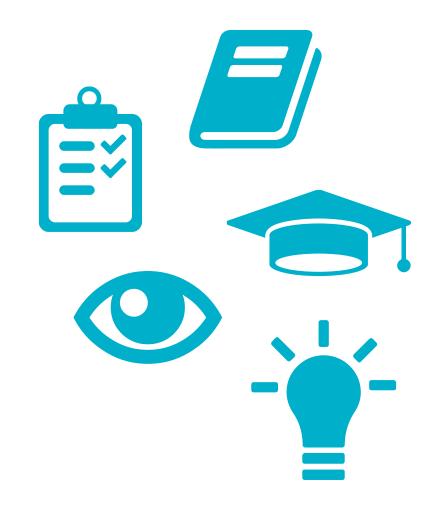
Beautiful patients are good patients: evidence for the physical attractiveness stereotype in first impressions of patients

Lena A. Nordholm

## Cognitive bias: Physicians

### How do we learn?

- We read
- We do what we have learned
- We try to teach someone
- "See One, Do One, Teach One"
- You do not see what you do not know...



### What are our educational tools?

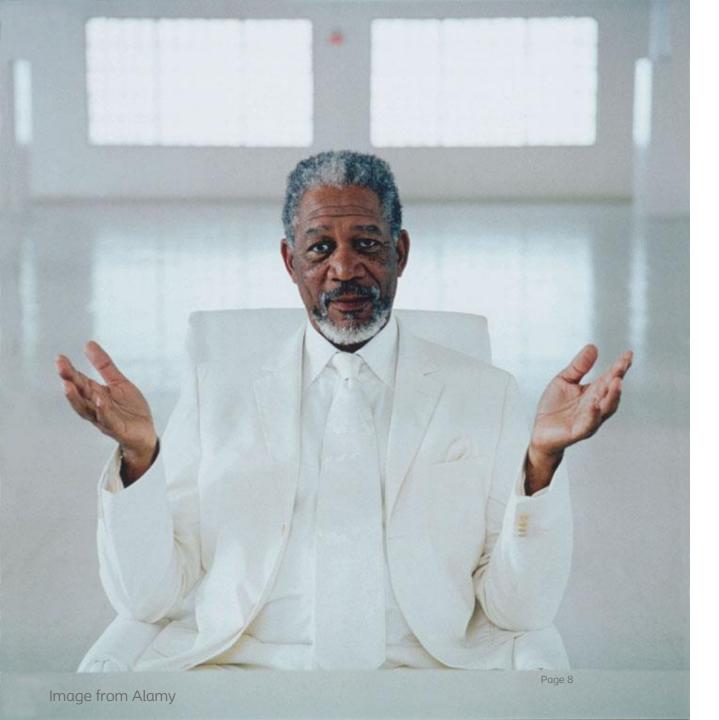


 Textbook – a book used <u>as a standard work for the study of a</u> <u>particular subject</u>



• Cochrane Reviews are systematic reviews of primary research in human healthcare and health policy, and are internationally recognized as the highest standard in evidence-based healthcare resources. They investigate the effects of interventions for prevention, treatment, and rehabilitation.

### Should we trust all literature evidence?



Scientists have discovered that people will believe anything when you claim scientists have discovered it!



Prieto J, Murphy CL, Moore KN, Fader M.

Intermittent catheterization for long term bladder management.

Cochrane Database of Systematic Reviews 2014, Issue 9.

## **Background:**

The most frequent complication of intermittent catheterization is urinary tract infection (UTI), but satisfaction, preference and ease of use are also important to users.

It is unclear which catheter designs, techniques or strategies affect the incidence of UTI, which are preferable to users and which are most cost effective.



Prieto J, Murphy CL, Moore KN, Fader M.

Intermittent catheterization for long term bladder management.

Cochrane Database of Systematic Reviews 2014, Issue 9.

### **Authors' conclusions:**

Despite a total of 31 trials, <u>there is still no convincing evidence</u> that the incidence of UTI is affected by use of aseptic or clean technique, coated or uncoated catheters, <u>single (sterile) or multiple-use (clean) catheters</u>, self-catheterisation or catheterisation by others, or by any other strategy.

### Intermittent catheterization: The devil is in the details

Christison, K; Walter, M; Wyndaele, JJ; Kennelly, M; Kessler, T; Noonan, V; Fallah, N; Krassioukov A.

J. Neurotrauma October, 2017 Accepted for publication

### 1. Data selection

Out of the 31 trials included in the 2014 Cochrane review, two were only published as conference abstracts

### 2. Data extraction

Five types of disagreements were observed:

- a. Data was mislabeled
- b. Extracted data did not match data from original trial
- c. Data was extracted in a method not consistent with convention
- d. Data was in a form that could not be used in meta-analyses
- e. Data was not originally extracted, although eligible



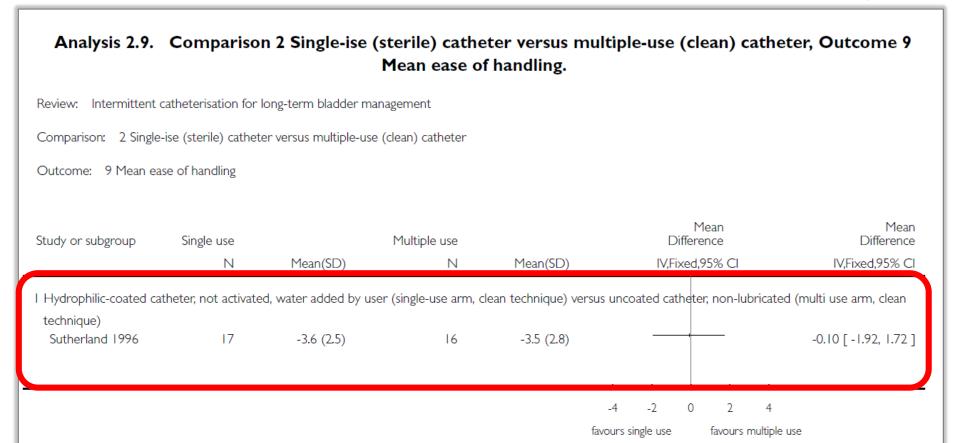
## 3. Symptomatic UTI definition

 Cochrane 2014 UTI definition - was taken from an outdated 1992 National Institute on Disability and Rehabilitation Research (NIDRR) consensus statement.

• Infectious Diseases Society of America (IDSA) 2009 consensus statement already provided the most up-to-date and comprehensive definition of UTI, which specifically covered catheter-associated UTI.

## 4. Data analysis

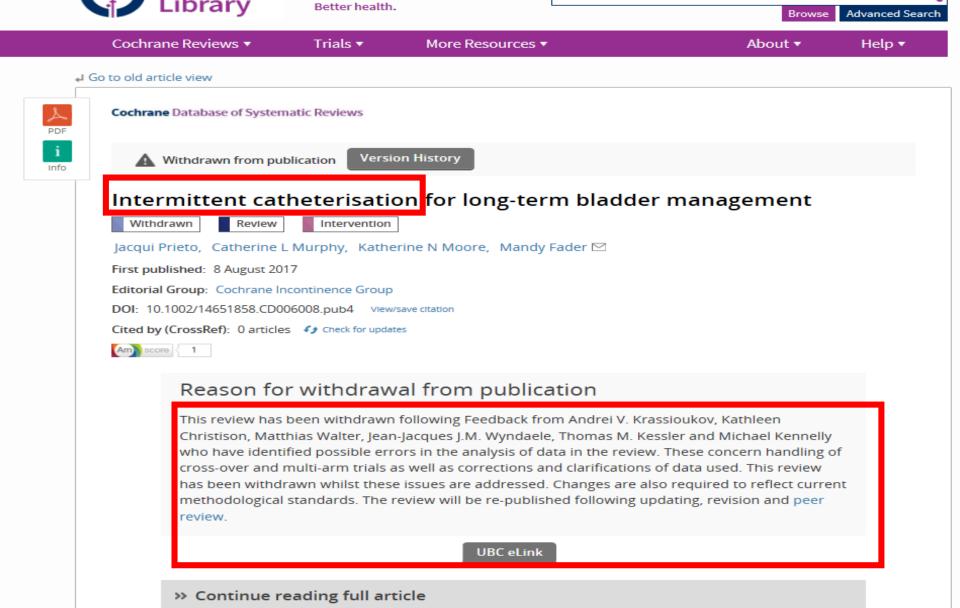
20 of all 39 analyses from the Cochrane review consisted of only one trial. However, according to the 'Cochrane Handbook for Systematic Reviews of Interventions Version' .... at least two trials are required for meta-analysis





Trusted evidence. Informed decisions. Better health.





>> Version History

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### Intermittent Catheterization: The Devil is in the Details

### Analysis of hydrophilic versus other catheters

	Hydrophilic		Other		Risk Ratio		Risk Ratio	
Trial	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI	
Cardenas 2009	12	22	14	23	20.6%	0.90 [0.54; 1.48]	<del>-  -</del>	
Sutherland 1996	1	16	1	14	1.6%	0.88 [0.06; 12.78]	<del></del>	
Pachler 1999	1	32	1	32	1.5%	1.00 [0.07; 15.30]		
De Ridder 2005	39	61	51	62	76.3%	0.78 [0.62; 0.97]	<del>•</del>	
Total (95% CI)		131		131	100.0%	0.81 [0.65; 0.99)	•	
Total events	53		67					
Heterogeneity: $l^2 = 0$	$0\%$ , $r^2 = 0$ , H	= 1.00, Q =	0.1 0.5 1 2 10					
Test for overall effec	ct: $Z = -2.02$ ,	p = 0.043	Favors hydrophilic Favors other					

### The Cochrane review definitions for UTI

<sup>\*</sup> Christison K, Walter M et al. Intermittent catheterization: The devil is in the details. Journal of Neurotrauma. DOI: 10.1089/neu.2017.5413.

### Intermittent Catheterization: The Devil is in the Details

### Analysis of single versus multiple use of catheters

	Single use		Multiple use		Risk Ratio		Risk Ratio	
Trial	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI	
Pachler 1999	1	32	1	32	14.2%	1.00 [0.07; 15.30]		
Sutherland 1996	1	16	1	14	15.1%	0.88 [0.06; 12.73]		
King 1992	3	23	5	23	70.8%	0.60 [0.16; 2.22]		
Total (95% CI)		71		69	100.0%	0.70 [0.24; 2.05)		
Total events	5		7				•	
Heterogeneity: I <sup>2</sup> =	$0\%, r^2 = 0, H$	= 1.00, Q =	0.1 0.5 1 2 10					
Test for overall effe	ct: Z = -0.66,	p = 0.512	Favors single Favors multiple					

### Applying the IDSA\* UTI definition

<sup>\*</sup> Christison K, Walter M et al. Intermittent catheterization: The devil is in the details. Journal of Neurotrauma. DOI: 10.1089/neu.2017.5413.

### **Intermittent Catheterization:** The Devil is in the Details

### Conclusion:

The experts stated that until evidence can conclusively demonstrate that multiple use is as safe as single use catheters, healthcare providers should advocate a single use of catheters in individuals with SCL\*

### Intermittent Catheterization: The Devil Is in the Details

Kathleen Christison," Matthias Water," Jean-Jacques J.M. Wyndaele," Michael Kennelly," Thomas M. Kessler, Vanessa K. Noonan<sup>k</sup> Nader Fallah<sup>k/k</sup> and Andrei V. Krassinukov<sup>1</sup>

During the last few years, the international community debated urinary tract infection and re-use of catheters when mutaging nearogenic lower urinary tract dysfunction (NLUTD) among individuals with spinal cord injury (SCI). In this respect, the 2014 Cochrane review by Prieto and colleagues. "Intermittent catheterisation for long-term bladder management," became one of the leading documents that captured the minds and attention of clinicians around the world. Although numerous countries had switched to single-use catheters for management of NLUTD following SCL the opinion that was expressed in the 2014 Cochrane review had a strong influence on healthcare providers and agencies to recommend re-use of catheters. However, many clinicians have expressed concern regarding the conclasions in the 2014 Cochrane review by Prieto and colleagues. We therefore conducted an independent appraisal of the data and analyses presented in the review. Our appraisal identified cracial discrepancies of data extraction and analyses within the review. In appraisal to that of Prieto and colleagues' review, our analysis revealed a trend to favor single over multiple use of catheters. After addressing our concerns to Cochrane's acting Editor-in-Chief, the most recent version of the 2014 Cochrane review was withdrawn from publication.

Keywords: Cochrane seview, intermittent catheterization, neurogenic lower urinary tract dysfunction, spinal cord injury. prinary tract infection

re-use of collectors during the management of neutrogenic lower. Although the authors did identify nanorous limitations and risk arinary tract dysfunction (NLUTD) arrang individuals with spinal. for bias within the trials included in their review (n.V.), they came to and injury (SCI). The most frequent complication of intermittent. the association that "there is still no constrainty evidence that the catheterization is UTL. There is no universally accepted definition incidence of UTL is affected by use of asoptic or clean technique. of UTI is individuals with NLUTD, particularly in those with SCL posted or excussed catherens, single (storile) or multiple-use (clean) While UTI is an evolving term that varies between organizations, catheters, self-catheterisation or catheterisation by others, or by in percentially devastating effect is of no organizer. UTI is corely to any other etialogy" (p.2). This has influenced effections' opinions. frequent hospitalization, sepsis, and even death.2

In this respect, the Enchance 2014 systematic notice "Intermittent cathenrication for long-term blakker management, by struction than have young, the international community has Prints and collection, became one of the leading discussion that ongoed in strong diffuses on unitary tract infection (UTD and captured the minds and situation of clinicians around the world."

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<sup>\*</sup> Christison K, Walter M et al. Intermittent catheterization: The devil is in the details. Journal of Neurotrauma. DOI: 10.1089/neu.2017.5413.

Traversational Collaboration on Reput: Discoveries (CORD), "Division of Neurology, Department of Medicine, "Division of Physical Medicine and Robobilistics, Department of Medicine, Specify of Medicine, University of British Columbia, Vancouver, British Columbia, Canada.

Department of Unitory, University of Agreesy, Agreesy, Belgium,

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<sup>&</sup>quot;G.S. Smoot Robald Station Coates, Vanciouser, British Colombia, Carada

C Katiline Christian et al. (2015). Published by Mary Ass Liebert, Inc. This Open Access article is distributed under the curse of the Crustice the original work is properly amalited

# Invisible insertion difficulties



# In America, the older population is growing...

Between 2000 and 2010, Americans 65 years and older grew at a faster rate than the total population.

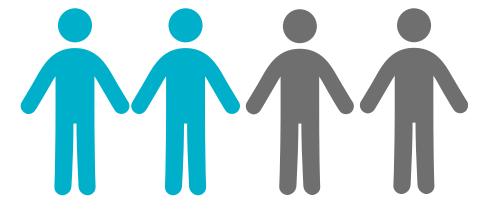
Males experienced more rapid growth than females in older ages.



Approximately 50% of all men

over 60 will have an

# enlarged prostate



- Prostate grows to a normal size in teenage years
- > Begins to grow again around the age of 50
- Hormones, diet, and genetics

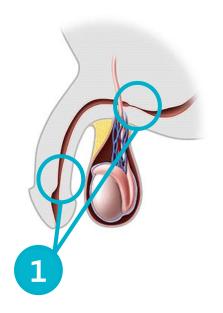


### Coudé catheter evolution

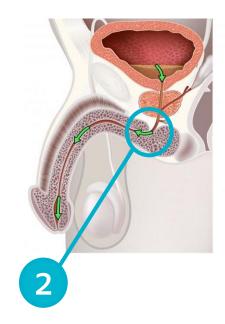




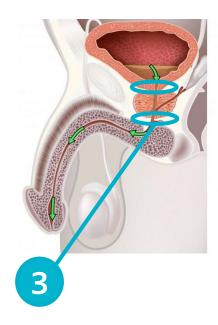
# Common anatomical challenges that can cause catheter insertion difficulties?



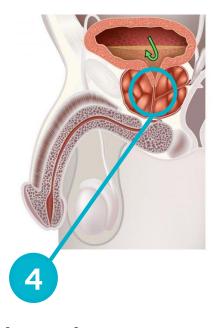
Strictures in urethra



Sharp, natural 'L' bend (pars bulbosa)



Tight internal and external sphincters

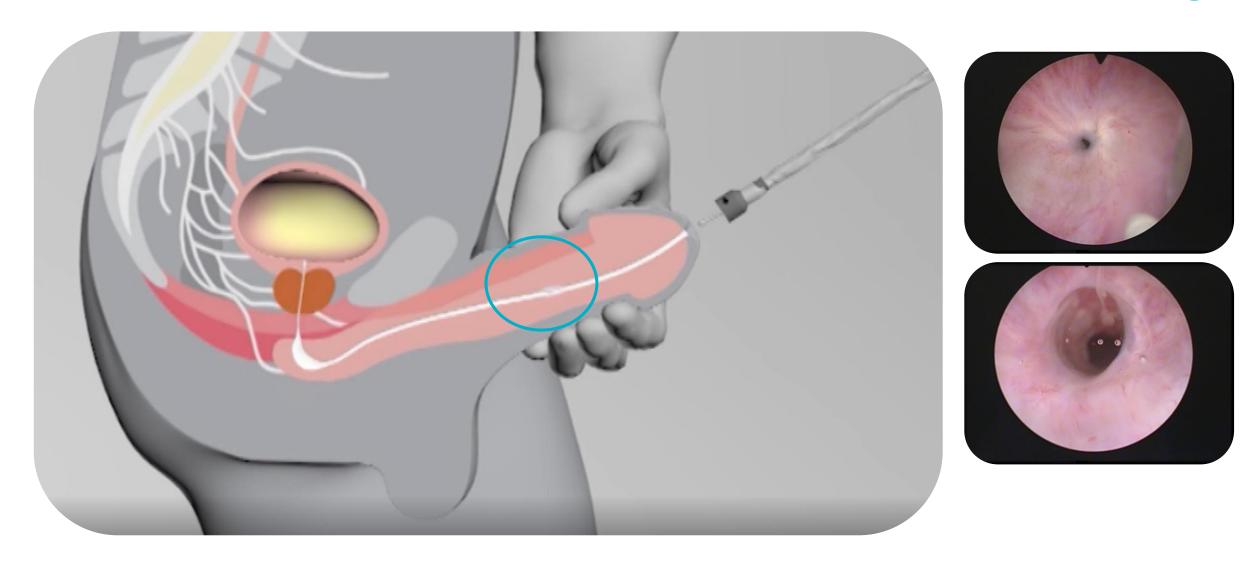


**Enlarged prostate** 

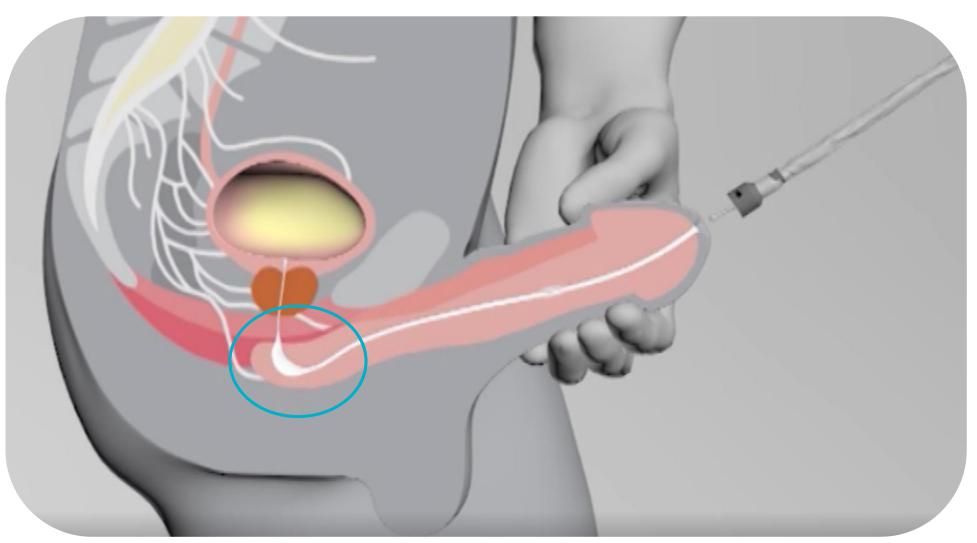


## Strictures in the urethra

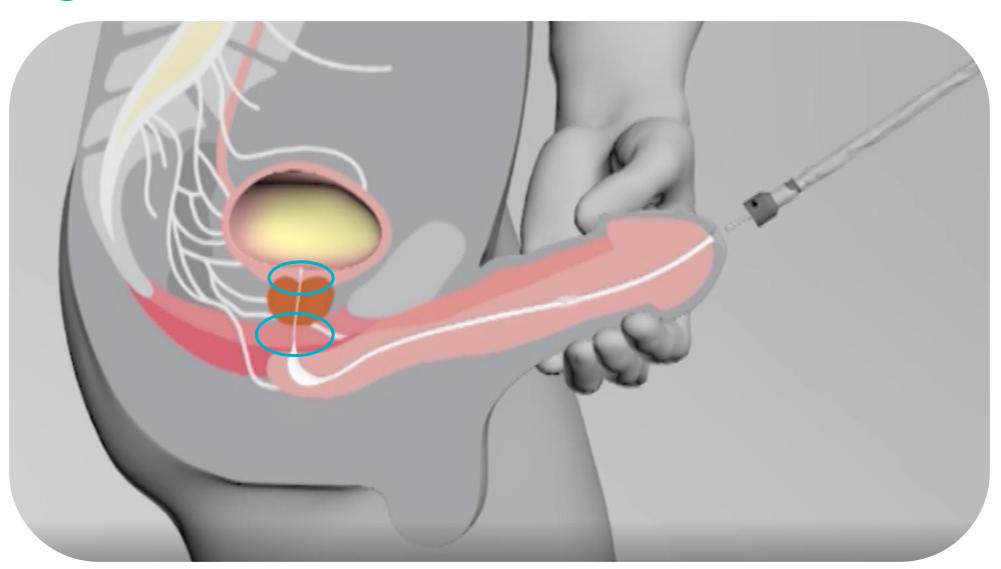




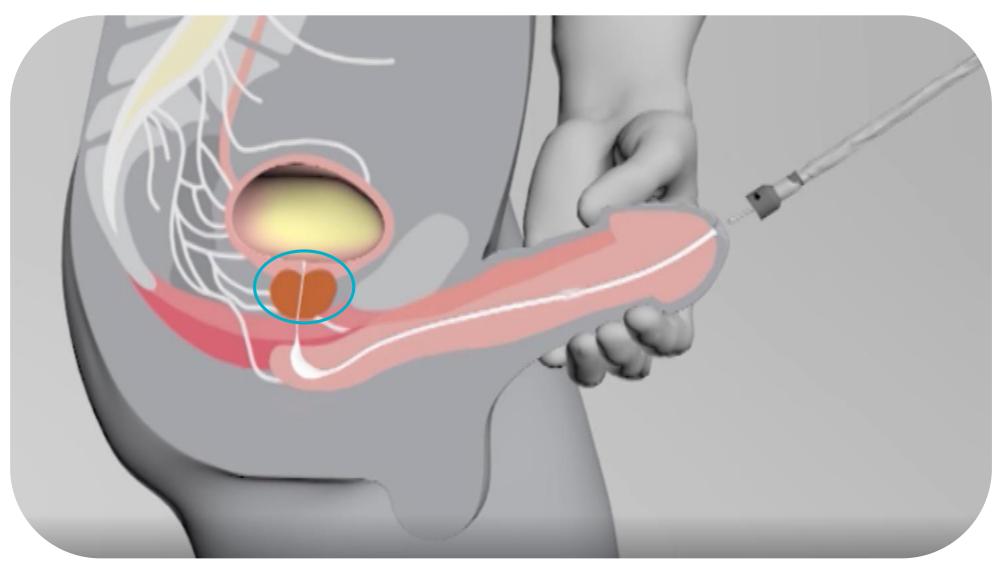
# Sharp, natural 'L' bend (pars bulbosa)

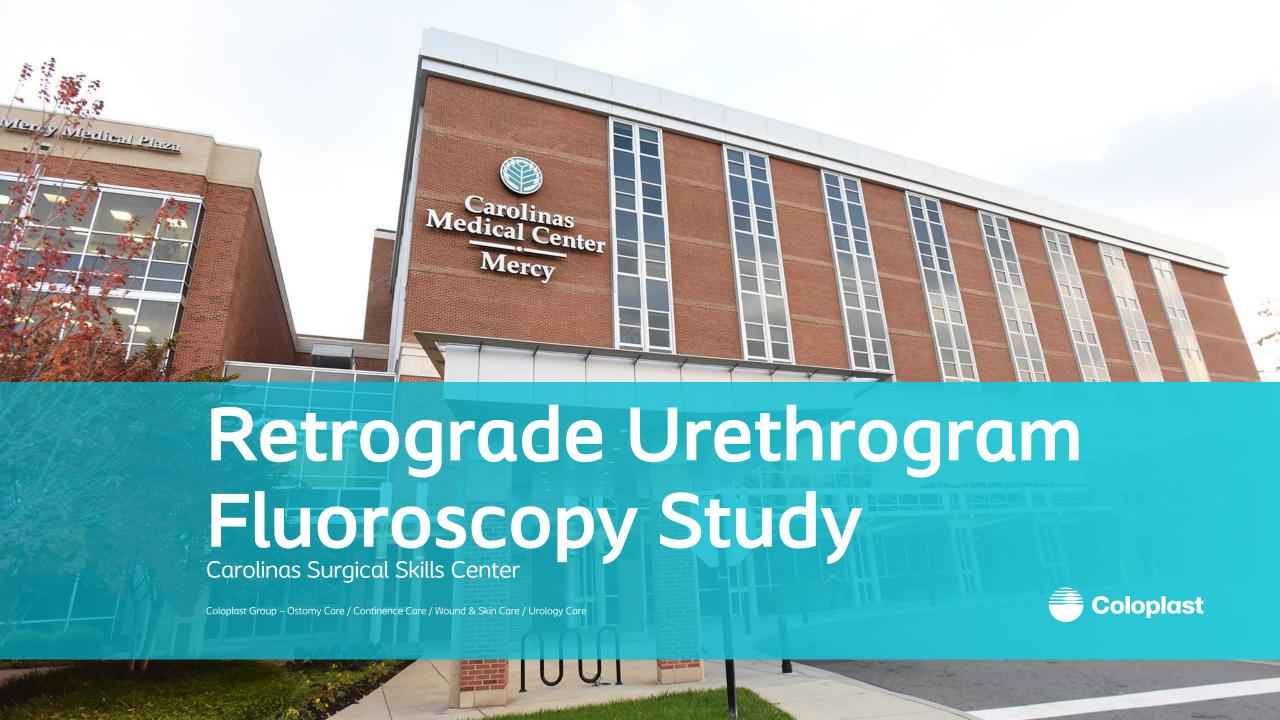


# Tight internal and external sphincters



# **Enlarged prostate**







SpeediCath® Flex Coudé launched in 2017, designed for male patients with insertion difficulties

## Investigators



Michael J. Kennelly, MD, FACS, FPMRS

Professor of Urology and Obstetrics & Gynecology Female Pelvic Medicine and Reconstructive Surgery Director, Charlotte Continence Center Co-Director, Women's Center For Pelvic Health Director of Urology, Carolinas Rehabilitation



Birte Petersen Jakobsen, MD Radiologist Global Medical Director, Coloplast

### Method

Fluoroscopy imaging technique with a cadaver



# Male urethra with x-ray contrast

Contrast media was inserted into the urethra showing the shape and anatomy of the lower urinary tract (the urethra and the bladder.)



# Catheter with and without contrast

The photo shows two catheters – one prepared with contrast media and one without (almost not visible).

Evaluated multiple different types of catheters navigating the urethra.

# Retrograde Urethrogram Fluoroscopy Study

**Objective** 

Compare clinical functionality between SpeediCath® Flex Coudé Catheter and traditional coudé catheter

**Method** 

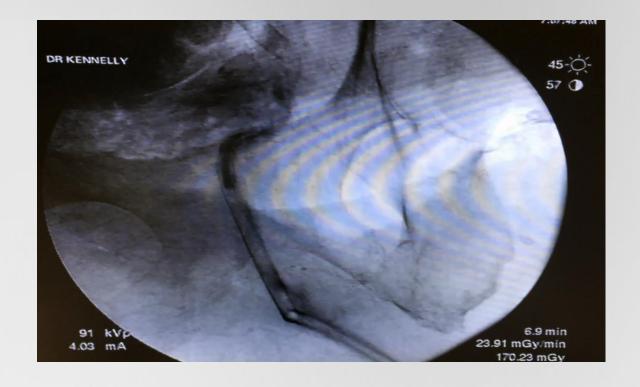
Fluoroscopy video study on male cadavers: Male with 2 strictures (55 years old)

Result

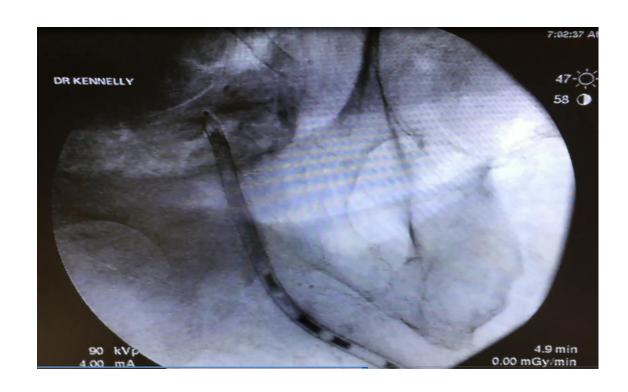
SpeediCath® Flex Coudé works for male patients with complex anatomies, including but not limited to patients with BPH



### Video 1 SpeediCath® Standard Coudé



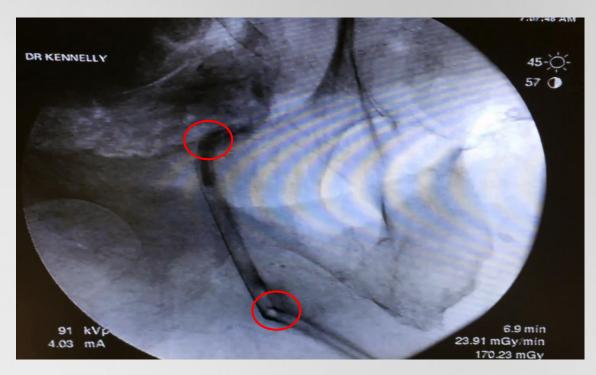
### Video 2 SpeediCath® Flex Coudé



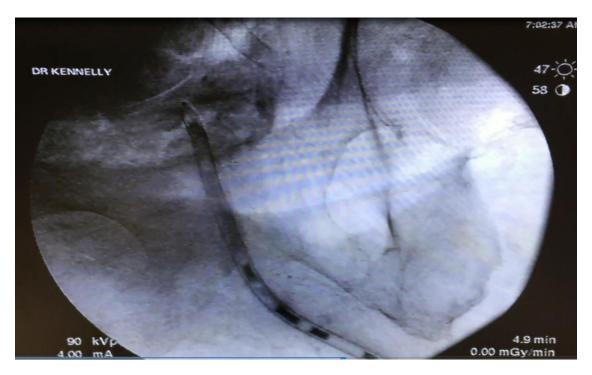
### SpeediCath® Standard Coudé

### Summary

### SpeediCath® Flex Coudé



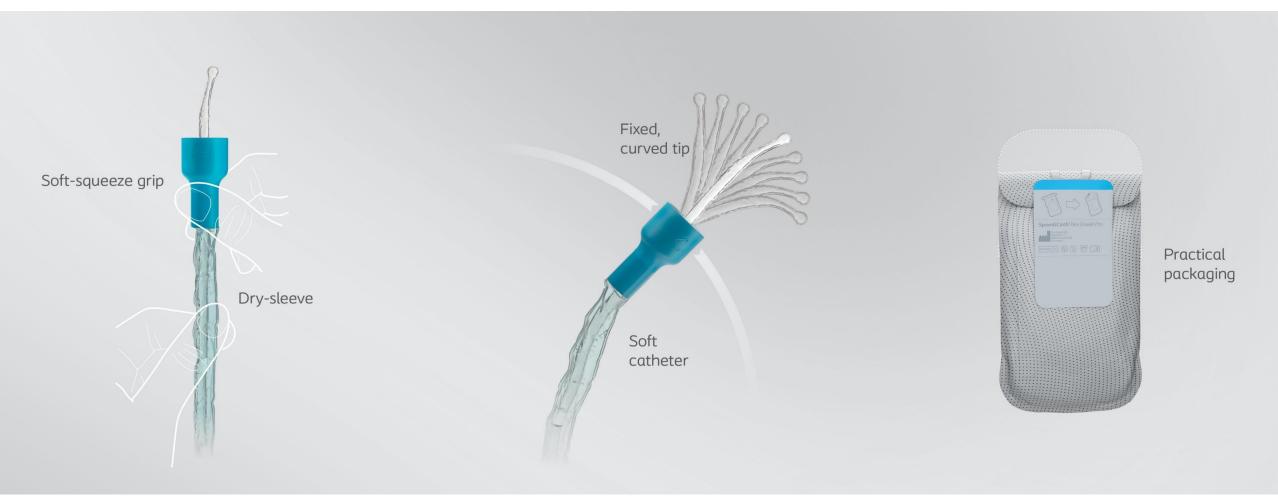
- The catheter has some difficulty following the passage of urethra curvatures
- With additional force, the catheter eventually reached the bladder



- The catheter follows the curvatures of urethra, reaching the bladder
- The catheter bypasses all obstructions smoothly, reaching the bladder successfully

### **SpeediCath**<sup>®</sup> Flex Coudé

# SpeediCath® Flex Coudé Pro launched in 2018





# Questions?



### **Our mission**

Making life easier for people with intimate healthcare needs

### **Our values**

Closeness... to better understand
Passion... to make a difference
Respect and responsibility... to guide us

### **Our vision**

Setting the global standard for listening and responding

SpeediCath® catheters are prescribed for use by patients who require bladder drainage due to urine retention or post void residual volume (PVR). Before use, carefully read all of the instructions. Call your doctor if you think you have a UTI or can't pass the catheter into the bladder. For more information regarding risks, potential complications and product support, call Coloplast Corp. at 1-866-226-6362 and/or consult the company website at www.coloplast.us.

