Introduction

Costs of Catheterization

Problems Associated with Catheterization

Urinary catheterization has been the source of a long list of complications and costs associated with patient treatment. Issues range from the blockage of urine flow and bladder spasms to more severe complications such as cystitis, blood in the urine, catheter-associated urinary tract infection (CAUTI), and in long term catheter users, an increased risk of bladder cancer. The difficulties associated with urinary catheterization have resulted in both high human and financial costs:

- Patient discomfort and suffering
- Patient death (CDC estimated 13,000 deaths attributable to CAUTI annually)\(^4,6\)
- Increased strain on doctors and nurses\(^5\)
- Increased length of hospital stays\(^5,6\)
- Unnecessary anti-microbial use\(^21,22\)
- Increased treatment costs ($0.5 billion annually for CAUTI, other costs unknown)\(^4,6,8\)

Additional costs from non-CAUTI complications are not easily quantifiable; these issues are often viewed as an inevitable consequence of catheterization and many go unreported.

CMS Policy Changes of 2008

In 2008, the Center for Medicare & Medicaid services implemented the “Hospital-Acquired Conditions Initiative” in which CMS stopped reimbursing hospitals for the treatment of Hospital Acquired Infections (HAIs) such as CAUTI. Additionally, hospitals were not able to pass the additional costs along to patients. These changes in policy have put the spotlight on generating a standard of best practices for urinary catheterization in order to limit the costs associated with CAUTI. The industry, in conjunction with the Center for Disease Control’s (CDC’s) “Guideline for Prevention of Catheter-Associated Urinary Tract Infections 2009”, has focused on the following core strategies:\(^7\)

- Insert catheters only for appropriate indications
- Leave catheters in place only as long as needed
- Only properly trained persons insert and maintain catheters
- Insert catheters using aseptic technique and sterile equipment
- Maintain a closed drainage system
- Maintain unobstructed urine flow

Additionally, research has focused on the prevention of bacteriuria (bacteria in the urine). This has been reflected not only in the emphasis of clean catheter insertion practices, but in the production and use of new silver coated Foley catheters.
The Problem

The Root of the Problem

The Need for Additional Solutions

While the industry response to the issues associated with catheter use and CAUTI has been invaluable, many of these high cost complications remain today. The root cause of these problems has not yet been addressed.

In a 2005 interview, Rabih Darouiche, MD, professor and director of the Center for Prostheses Infection at Baylor College of Medicine, put it best during a discussion on strategies to prevent CAUTIs. On bacteriuria: "Most patients with an indwelling bladder catheter will have bacteriuria. Most cases of bacteriuria will remain asymptomatic. That is very important to comprehend because the primary objective in coming up with an optimal solution for CAUTI is to prevent this infection rather than to prevent bacteriuria. In fact, you may not be able to prevent bacteriuria."

On eliminating CAUTI through work practice controls: "I think we probably have reached a point of maximum return from optimizing work habits. Therefore, we get to a point where we should look for other options that may augment those work habits."

Catheter-Associated Trauma Compromises the Bladder

Additional options are available for addressing CAUTI and other catheter-associated complications. A strong body of research exists which points to the importance of maintaining the bladder’s natural defensive mechanisms as a means to prevent infection and other complications. The bladder wall is coated in a mucinous layer made up of transitional cells capable of synthesizing glycosaminoglycan (GAG). This layer of cells is able to prevent bacterial adherence to the mucosal cells of the bladder. It is this critical defensive mechanism that is often damaged during urinary catheterization, thus limiting the bladder’s ability to combat infection and causing additional side effects such as cystitis and blood in the urine.

The cause of this trauma to the bladder is the traditional Foley catheter itself, which causes damage in two ways: the erosion and penetration of the mucosal lining and bladder wall in contact with the catheter tip, and suction aspiration damage attributable to the drainage eyes.

A proficient understanding of the bladder’s natural defenses and of the shortcomings of the Foley catheter design serve to elucidate a solution to limiting instances of complications associated with urinary catheterization.
The Bladder’s Natural Defenses

Two Mechanisms of Defense

The bladder’s immune system is comprised of two primary functions:

- The process of voiding (urination)
- The mucin (GAG) coating of the bladder wall, which acts as a barrier to bacterial attachment

The process of voiding urine removes 99.9% of bacteria from the bladder. However, the remaining bacterial population is still sufficient to cause infection. The mucosal lining of the bladder acts to prevent infection from this remaining bacteria.\textsuperscript{13, 14}

The top layer of cells shown, known as facet or umbrella cells, make up a mucinous layer that inhibits adherence of bacteria to the bladder wall. If contact is established between these cells and bacteria, receptor interactions can trigger the internalization of adherent bacteria into the facet cells where bacteria can replicate. However, attachment or invasion can result in the activation of a process of programmed cell death leading to the eventual exfoliation and clearance of infected host cells. The body is continually growing new facet cells to replace those exfoliated.\textsuperscript{9}

The bladder lining uses the exfoliation of cells in conjunction with the deactivation of bacteria to protect against infection.\textsuperscript{13, 14}
The Importance of the Mucosal Lining

Below is a sampling of clinical studies that demonstrate the importance of the bladder’s mucosal lining in fighting bacteria.

1977: Reaction of the Vesical Wall to Bacterial Penetration: Resistance to Attachment, Desquamation and Leukocytic Activity.
“To determine the contribution of the bladder wall to defense against infection, we designed a series of experiments wherein movement of the introduced bacteria and inflammatory processes (cystitis) were observed by an autoradiographic technique. As a first defense line the bladder mucosal surface showed strong resistance against bacterial attachment and penetration. Moreover, epithelial cells gripped and penetrated by bacteria were desquamated and eliminated through voiding, thus arresting deeper invasion into the bladder wall.”

1988: Host Defence Mechanisms in the Bladder: Disruption of Mucus Layer
“The urinary bladder wall is lined by a layer of mucus which is believed to provide an important barrier to bacterial invasion of the urinary tract. Abnormal function of this protective layer could therefore be a factor predisposing the host to urinary tract infection (UTI). The protective role of the mucus layer was determined by disrupting the layer immediately prior to bacterial challenge. Both ultrastructural and bacteriological analyses have shown that infection was increased in those animals where the mucus barrier was disrupted.”

1992: In Vitro Binding of Type 1-Fimbriated Escherichia Coli to Uroplakins Ia and Ib: Relation to Urinary Tract infection.
“Another possible defense mechanism involves the mucus layer that coats the urothelial surface. Defects in these defense mechanisms may lead to the adherence of E. coli.”

As these studies suggest, disruption or damage to the bladder’s mucosal lining opens the door for infection. With the presence of bacteriuria an inevitable consequence of urinary catheterization and with best clinical practices being observed by the healthcare industry, the drive to minimize complications with urinary catheterization demands that the industry’s focus must become the preservation of the bladder’s natural defenses.

With this in mind, reconsideration of the Foley catheter design becomes paramount to protecting the bladder’s defenses.
Clinical Evidence

Foley Catheters Compromise the Bladder

The Flaws of the Foley Catheter

The 75 year-old design of the Foley catheter is at odds with the goal of preserving the integrity of the bladder’s mucosal lining. Its shortcomings are two-fold:

• As the bladder drains, it collapses around the tip of the Foley catheter. Since the tip has a small surface area, most of the pressure created as the bladder pushes against the tip is focused on a small area of the bladder wall. The pressure of the tip pressed against the bladder wall, combined with the friction of motion during a drainage event, easily strips away the mucosal lining and can cause additional damage to the cells underneath.\textsuperscript{10-12}

• Once the bladder has mostly emptied, the bladder wall wraps around the catheter shaft and becomes aspirated into Foley’s exposed drainage eyes. This suction effect not only strips away the bladder’s protective lining, but causes polypoid cystitis and blocks urine from draining through the catheter.\textsuperscript{10-12}

With the advent of cystoscopy as a method of detecting abnormalities within the bladder, urologists are now able to take pictures and video of the damage done by Foley catheters. Dr. Roger Feneley, a urologist with the Bristol Urological Institute, created a truly compelling set of visual evidence when he performed cystoscopy on several supra-pubically catheterized patients:\textsuperscript{20}
Cystoscopic Evidence

Additional Visual Evidence

Roger Feneley was not alone in using cystoscopy to observe the effects of the Foley catheter on the bladder. Dr. Bruce Wiita, Chief Medical Officer of Poiesis Medical, continually noticed damage inside the bladder caused by catheters. He has accumulated his own collection of visual evidence demonstrating this trauma.

The images above exhibit the tell-tale signs of damage from the catheter tip and drainage eyes. They are particularly striking when compared to this image of a healthy bladder.

"We all know that a healthier, less traumatized tissue will probably be more able to resist clinical infection when exposed to bacteria as compared to a more diseased and less healthy tissue."  
Rabih Darouiche, MD, Baylor College of Medicine.
Clinical Evidence

Foley Clinically Tied to Bladder Trauma

Not only is the visual evidence compelling, but a large collection of clinical studies also connect bladder trauma in the bladder and associated complications with the Foley catheter.

1983: The Reversibility of Catheter-associated Polypoid Cystitis
“Cystoscopic and histologic evidence of polypoid cystitis [inflammation of the urinary bladder] was recorded in 20 hospitalized patients with indwelling urethral catheters followed by cystoscopy, biopsies and repeated urine samples before and after catheter removal. The majority of the lesions were located in the posterior wall or dome. The lesions disappeared after removal of the catheter in 13 of the 15 patients followed for up to 28 weeks despite persistent bacteriuria.”

1984: Catheter-induced Cystitis: Evaluation by Cystosonography
“The bladders of 23 patients with indwelling catheters were examined by ultrasound and cystoscopy. Twelve of the 23 showed changes consistent with bullous cystitis [a bladder infection], a catheter-induced reaction of the bladder. The lesions on the mucosa were localized on the posterior wall or were diffuse and more severe, depending on the length of catheterization.”

1988: Effects of Indwelling Catheters on Urethral Mucosa (polypoid urethritis).
“Indwelling catheters are almost invariably associated with characteristic mucosal lesions of the urinary bladder, commonly referred to as polypoid cystitis. In the present study, 20 male patients with indwelling catheters (due to benign prostatic hyperplasia) for 1-12 months were studied. The results suggest mechanical irritation and/or pressure exerted by the catheter on the mucosa is responsible for the development of polypoid urethritis.”

2008: Changes in the Urinary Bladder Caused by Short-term Permanent Catheter Insertion
“Background: Short-term urinary bladder drainage using a permanent Foley catheter is practiced frequently in hospitals. The catheter usually hurts the bladder mucosa and submucosa to various degrees. The aim of this study was to show pathological changes observed during a time period of one to 30 days of catheter treatment.

Results: The posterior wall exhibited maximal injury. There were 41 patients in the tested group, of an average age 70 years. In microscopy the mucosa was oedematous, hyperaemic with exsudate vessels and haemorrhages. Polyps were also seen, some of them haemorrhagic. Polypous cystitis was revealed in 29 cases (70%) and various mucosal defects in 12 cases (29%).

Conclusions: Polypous cystitis develops already in the first days after permanent catheter insertion. The recent polyps present an inflammation caused by the mechanical injury.”
The solution to bladder trauma is radical yet simple new design of the traditional urinary catheter.

Conventional Foley Catheters Cause Bladder Trauma:

- As the bladder drains, it collapses around the tip of the Foley catheter, causing the tip to become embedded in the bladder lining.
- Once this trauma has occurred, bladder spasms disturb the position of the anchor balloon, promoting the free flow of bacteria into the bladder.
- Trauma and the presence of bacteria increase the risk of bacterial attachment and proliferation.

The Innovative Design of the Duette™ Urinary Drainage System:

- The zero-tip, twin-balloon Duette™ urinary drainage device prevents trauma to the bladder’s mucosal lining.
- The cushioning balloon protects the antibacterial mechanisms of the surface mucin and the integrity of the cells below.
- The drainage eyes are located between the two balloons to prevent damage from aspiration of the mucosal lining.
- Duette™ is inserted and removed like a standard Foley and requires little new training of personnel.
- Duette™ maintains cost parity with current 100 percent silicone catheter models.
Meet the Duette™

Preventing Bladder Trauma

While Dr. Wiita was collecting images of bladder trauma through cystoscopy, he noticed that unlike the dome of the bladder, where the catheter tip and drainage eyes make contact with the bladder walls, the neck of the bladder, where the retention balloon of the Foley rests on the bladder walls, showed no signs of trauma to the bladder wall or to the protective mucosal layer. This led him to design a new catheter, one with a distal balloon that would subsume the catheter tip and help keep the drainage eyes from aspirating the walls of the bladder.

The result of this work is the Duette™, the world's first twin-balloon, zero-tip catheter.

How it Works

By subsuming the tip and expanding the surface area over which the bladder collapses, the Duette™'s second distal balloon prevents the tip from eroding and penetrating the bladder's mucosal lining. Additionally, the proximal and distal balloons create a standoff, preventing the bladder wall from getting close enough to the drainage eyes to sustain aspiration damage.

The Duette™ is also functionally equivalent to a standard Foley catheter, requiring only one additional step (the inflation of the distal balloon) be performed during catheterization. As a result, it requires minimal additional training for nurses and doctors to use safely and effectively.
The Solution

What Duette™ Can Do

Reducing Infection and Beyond

Duette™ is designed to reduce bladder trauma. By maintaining the integrity of the bladder’s mucosal lining and preventing trauma, the Duette™ is designed to reduce rates of CAUTI much more. Duette™ is also poised to reduce incidents of a list of complications associated with catheterization:

- Cystitis
- Chronic Irritation of the bladder, which has been shown to increase the risk of bladder cancer between 8-10 percent.
- Blockage of Urine Drainage
- Penetration and perforation of the bladder wall
- Blood in the urine
- Patient pain levels during catheterization

Healing Bladder Trauma with the Duette™

In addition to the prevention of bladder trauma, the Duette™ has already demonstrated the potential for healing previously acquired bladder damage. The following images were taken by Dr. Wiita as part of a case study exploring the healing potential of the Duette™. These photographs, which show the same area of the bladder over time, were taken from a 91 year-old patient.

![Photographs of bladder healing](image)

After 30 days with a Foley | After 30 days with a Duette™ | After 60 days with a Duette™

After just 30 days with a Foley, this newly chronic catheter user exhibited signs of damage to the mucosal lining, cystitis, and hemorrhaging. After 60 days with a Duette™, the patient has almost completely healed.
“As to diseases, make a habit of two things - to help, or at least, to do no harm.”

-Hippocrates

What it Means to You

1. Minimizing the complications that come with catheterization is an industry priority.
2. Bladder Trauma is the root cause of CAUTI and other catheter-associated complications.
3. The traditional Foley catheter causes bladder trauma with its exposed tip and drainage eyes.
4. The Duette™ urinary drainage system is designed to eliminate bladder trauma.

Following CDC guidelines on catheterization is a great way to begin combating the problems associated with urinary catheterization. However, one the root causes of these complications must be addressed: bladder trauma. With the Duette’s™ innovative twin balloon design, a new tool is available to help industry professionals create better patient care, improved care outcomes, and to lower the cost of healthcare.
Clinical References

References


2 West DA, Cummings JM, Longo WE, Virgo KS, Johnson FE, Parra RO. Department of Surgery, St. Louis Univ. School of Medicine, and the John Cochran Veterans Affairs Medical Center, Missouri, USA.


8 Infection Control Today, Expert Discusses Strategies to Prevent CAUTIs, (Interview with Rabih Darouiche,) June 1, 2005.


