Disruptive technology that is challenging the “Standards of Practice” for bladder management...

T-SPeC® Taking complications out of suprapubic cystostomy

T-SPeC® has two models based on patient size. The T7 model will accommodate patient abdomen thickness up to 7 cm, the T14 model up to 14 cm — addressing the obese and morbidly obese patient.

...enabling transition from other cystostomy options and from transurethral catheterization.

Suprapubic cystostomy (SPC) is a common method for treating acute or chronic urinary retention and urinary incontinence as an alternative to transurethral catheterization.

SPC is frequently used to provide drainage during and following common surgical procedures due to Post-Op Urinary Retention (POUR).

Over twenty years of clinical studies have proven that patients with SPC have lower rates of urinary tract infection, lower pain and improved quality of life when compared to long-term indwelling and clean intermittent urethral catheterization. In addition, SPC eliminates potential injury to urethra and bladder sphincter from catheterization.

Despite clinical advantages and patient preference, SPC has not been widely used for transurethral catheterization. This is largely due to high rates of bowel injury and mortality associated with blind percutaneous “trocar punch” cystostomy and open cystostomy - the current “standards of practice” for placing suprapubic catheters.
Current “Standards of Practice” — Procedure Risks & Complications:

THE INABILITY TO PRECISELY LOCATE THE PUBIC BONE AND CONTROL THE CORRECT ANGLE OF NEEDLE/TROCAR CONTRIBUTE TO INACCURATE PLACEMENT, PUNCTURE OF PERITONEAL CAVITY AND/OR SMALL BOWEL. 7

OPEN CYSTOSTOMY IS HIGHLY INVASIVE, REQUIRING A LARGE INCISION, LONG PROCEDURE AND EXTENDED INPATIENT RECOVERY TIME.

Clinical Procedure Outcomes

<table>
<thead>
<tr>
<th>Percutaneous Trocar Punch</th>
<th>Open Cystostomy</th>
<th>T-SPeC*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimally Invasive</td>
<td>Highly Invasive</td>
<td>Minimally Invasive</td>
</tr>
<tr>
<td>15 Minute Procedure*</td>
<td>1-2 Hour Procedure Time</td>
<td>5 Minute Procedure</td>
</tr>
<tr>
<td>Small Catheter Size (unreliable drainage)</td>
<td>Long Recovery - Post-Op Hospitalization</td>
<td>Large-bore 18 Fr. Catheter (reliable drainage)</td>
</tr>
<tr>
<td>Unpredictable Surgical Tract</td>
<td>Large Open Incision</td>
<td>Small Surgical Tract (5mm)</td>
</tr>
<tr>
<td>High Complication Rate - 45.5% 5</td>
<td>High Complication Rate - 30.3% 32</td>
<td>Low Complication Rate - 3.5% 6</td>
</tr>
<tr>
<td>High Mortality - 4.4% 10</td>
<td>High Mortality - 1.83% 32</td>
<td>No Mortality - 0% 6</td>
</tr>
</tbody>
</table>

Documented Percutaneous Trocar Punch SPC Complication Rates:

<table>
<thead>
<tr>
<th>Complication/Difficulty</th>
<th>Cases</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-operative complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaesthetic-related complications</td>
<td>1.8%</td>
<td></td>
</tr>
<tr>
<td>Bowel injury/perforation</td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>Malpositioning/expulsion</td>
<td>2.7%</td>
<td></td>
</tr>
<tr>
<td><strong>30 Day post-operative complications</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UTI</td>
<td>9.1%</td>
<td></td>
</tr>
<tr>
<td>Septicaemia secondary to UTI</td>
<td>4.6%</td>
<td></td>
</tr>
<tr>
<td>SPC exit site infection</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Exit site bleeding</td>
<td>1.8%</td>
<td></td>
</tr>
<tr>
<td>Catheter blockage</td>
<td>13.2%</td>
<td></td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>45.5%</td>
<td></td>
</tr>
<tr>
<td>Mortality (U.S. Data)</td>
<td>4.4%</td>
<td></td>
</tr>
</tbody>
</table>

*Complications directly related to SPC procedure and not associated with the concurrent surgical procedure.

Pathways bychoice of procedure: 10

- Percutaneous Trocar Punch
- Open Cystostomy

BAUS Suprapubic Catheter Guidelines 7, 8

The British Association of Urological Surgeons (BAUS) has created SPC practice guidelines based on a 2010 audit directed by the National Patient Safety Agency. The audit was initiated due to the number of adverse events and studies confirming high morbidity and mortality rates relating to percutaneous trocar puncture techniques. As a result, the guidelines recommend ultrasonography by individuals who have received specific training and are experienced with the SPC procedure. The full BAUS report can be reviewed on-line at: swanvalleymedical.com/clinical/baus.
Misplaced Trust: Transurethral “Foley” Catheter
It’s time to change the approach, not just the catheter.

Suprapubic catheterization can effectively reduce transurethral Catheter Associated Urinary Tract Infections (CAUTI) by as much as 86.6%\(^{15, 33}\).

- 80% of HAI are UTI\(^{28}\)
- 32% of all HAI are due to CAUTI (Transurethral Catheterization)\(^{28}\)
- 9,000 deaths are attributed to CAUTI each year\(^{28}\) ($1.8 billion*)
- $45 billion is spent annually in treatment of HAI\(^{29}\)
- 400% increase in multi-drug resistance to E. coli bacteria, a leading cause of UTI\(^{11}\)
- Affordable Care Act (ACA) Penalties for CAUTI events due to transurethral catheters\(^{25}\)
- ACA nonpayment for treatment cost of transurethral catheter related HA-CAUTI events\(^{25}\)
- SPC is not included in ACA CAUTI Score/Penalties\(^{25, 30}\)

<table>
<thead>
<tr>
<th>Complication/Issue</th>
<th>Urethral Catheter</th>
<th>Suprapubic Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infection Rate</td>
<td>Up to 87% Higher(^{15, 33})</td>
<td>Lower(^{26, 27, 31, 33})</td>
</tr>
<tr>
<td>Urethral Trauma - False Passage/Perforation(^{18})</td>
<td>✓</td>
<td>N/A</td>
</tr>
<tr>
<td>Urethral Lesions/Strictures (scarring)(^{20})</td>
<td>✓</td>
<td>N/A</td>
</tr>
<tr>
<td>Erosion of Urethra (^{21})</td>
<td>✓</td>
<td>N/A</td>
</tr>
<tr>
<td>Return to Normal Voiding (^{22})</td>
<td>Slow</td>
<td>Rapid</td>
</tr>
<tr>
<td>Voiding Trials - Early Discharge (^{21})</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Requires Office Visit for Catheter Change (^{9})</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Risk of Bladder Cancer (^{30})</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Nursing Costs (^{14, 24})</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Re-catheterization Rate (^{17})</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Residual Urine (^{19, 24})</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Economics - Cost of Catheterization (^{12, 13, 15})</td>
<td>Higher</td>
<td>Lower</td>
</tr>
<tr>
<td>Quality of Life - Patient Preferred</td>
<td>“Hurts like hell.” (^{16})</td>
<td>89% patient preferred(^{5})</td>
</tr>
</tbody>
</table>

86.6% CAUTI Reduction:
Prospective randomized controlled trial of urethral versus suprapubic catheterization.
“We propose that, when catheterization is required during a general surgical procedure, the suprapubic route is to be preferred.”

77.8% CAUTI Reduction:
Suprapubic or urethral catheter: what is the optimal method of bladder drainage after radical hysterectomy?
“...suprapubic catheterization is associated with a lower rate of UTI and an earlier trial of voiding...”

73% CAUTI Reduction:
Suprapubic Percutaneous Cystostomy versus Urethral Catheterisation in Abdominal Surgery: A Prospective Randomised Controlled Study.
“It allows prompt re-establishment of normal micturition, is better tolerated by the patients and has a lower risk of complications.”
Botsios, Demetriades, Goulimaris, Dadasakis. 4th Surgical Department, Aristotlean University of Thessaloniki, G. Papuanioucas General Hospital, Thessaloniki, Greece, Dig Surg 1997;14:404–408 (DOI:10.1159/000172583)

65% CAUTI Reduction:
Suprapubic Bladder Drainage in General Surgery.
“The results reported favor suprapubic over urethral catheterization in that urinary tract infections are reduced. 35% incidence of bacteriuria (100% for urethral catheters inserted an equal length of time).”
The T-SPeC® (Transurethral Suprapubic endo-Cystostomy) Clinical advantages of precise inside-to-out technology

The T-SPeC® works amazingly well and was simple to use. I found the T-SPeC® created a faster, easier, and safer tract for suprapubic cystostomy catheter placement. It required less anesthesia when compared to other cystostomy kits I have used for more than 10 years. I had a lot of optimism for the T-SPeC® device when I first heard about an ‘inside-to-out’ cystostomy kit — T-SPeC® exceeded my expectations. The device will play an important role in my practice to allow a safe and minimally invasive procedure to place a suprapubic catheter in my patients with urinary retention and incontinence. The current cystostomy kits use an ‘outside-to-in’ technique that does not always allow accurate placement of the catheter and has been shown to cause rare but serious complications such as small bowel perforation that can result in sepsis and even death. The T-SPeC® utilizes the safer and innovative passageway, ‘inside-to-out’ technique, allowing reliable catheter placement and equally important — virtually eliminates the risk of small bowel injury.

DR. BRIAN FLYNN
DIRECTOR OF FEMALE PELVIC MEDICINE AND RECONSTRUCTIVE SURGERY
ASSOCIATE PROFESSOR OF UROLOGY UNIVERSITY OF COLORADO HEALTH SCIENCE CENTER

T-SPeC® Bladder Management Applications: (Incontinence & Retention)

Neurologic Diseases/Patient Conditions
- Alzheimer’s Disease
- Cerebral Palsy
- Encephalitis
- End-stage Bladder
- Multiple Sclerosis
- Obesity
- Parkinson’s Disease
- Spinal Cord Injury
- Stroke

Post Operative Urinary Retention (POUR)
- Bladder Cancer
- Bladder Stones
- Brachytherapy
- Colorectal Surgery
- Female Surgery (Prolapse, Sling)
- General Surgery
- Hifu
- Prostate Surgery
- Urethroplasty

For more information on T-SPeC®, visit: www.swanvalleymedical.com.
1. Insert T-SPeC® Sound
The stainless steel T-SPeC® sound with embedded blade is inserted into the urethra and advanced into the bladder. The urethane tip of the sound facilitates smooth insertion. The pubic bone is detected against the inside bend of the T-SPeC® sound.

2. Attach and Adjust Positioning Arm
The T-SPeC® is equipped with a positioning arm and blade capture mechanism in alignment with the distal tip of the instrument sound. These features reliably control the location of the surgical tract.

3. Advance Blade
The blade is advanced by sliding the rear handle forward. The smooth action of the cutting mechanism ensures a precise surgical tract, created from the bladder dome to the skin surface.

4. Remove Blade
The blade and capture mechanism are removed with a simple twisting motion, leaving only the catheter bayonet connection and coil above the skin surface.

Simple and Fast T-SPeC® Technique
5 mm incision
5 minute procedure

Procedure Steps
5. Connect Catheter
The catheter is attached to the bayonet connector with a simple clockwise twisting motion.

6. Remove Positioning Arm
The positioning arm is removed by opening the latch and lifting the assembly from the handle.

7. Remove T-SpeC® and Cut Catheter
The T-SpeC® is withdrawn from the patient and the catheter is cut in the designated area between the drainage holes and the sound tip. The open end allows for use of a guidewire during Councill catheter replacement.

8. Position Catheter and Inflate Balloon
Precise surgical tract creation ensures optimal placement of the catheter balloon at the bladder dome. The 18 Fr. silicone suprapubic catheter is now properly positioned and procedure is complete.

Published Clinical Study
Prospective study of the Transurethral Suprapubic endo-Cystostomy (T-Spec®): an ‘inside-out’ approach to suprapubic catheter insertion.

<table>
<thead>
<tr>
<th>Cases</th>
<th>114</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intra-operative complication/difficulties</td>
<td></td>
</tr>
<tr>
<td>Anaesthetic-related complications</td>
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<td>0%</td>
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<tr>
<td>Malpositioning/expulsion</td>
<td>0%</td>
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<tr>
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<tr>
<td>UTI</td>
<td>0.9%</td>
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</tr>
<tr>
<td>Mortality</td>
<td>0%</td>
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</tbody>
</table>

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Clinical References


19. Selkus, Subedi. Urinary Retention in Adults: Diagnosis and Initial Management. Northeastern Ohio Universities College of Medicine, St. Elizabeth Health Center, Youngstown, Ohio.


