

**Karen McKertich**

MBBS, FRACS(Urol), is a urological surgeon, Cabrini Medical Centre and The Alfred Hospital, Melbourne, Victoria.



Urinary incontinence

Procedural and surgical treatments for women

Background

A range of surgical treatment options is available for women suffering from stress and urge urinary incontinence refractory to conservative and medical management.

Objective

This article discusses the indications for surgical treatments for stress and urge urinary incontinence in women; and the advantages, disadvantages and side effects of these treatments.

Discussion

Women who fail to respond to pelvic floor physiotherapy for stress urinary incontinence have available to them a range of variably invasive surgical treatment options including bio-injectable agents, sling surgery, colposuspension, and prostheses. Women with urge urinary incontinence refractory to the newer anticholinergic agents can be treated with minimally invasive options such as bladder injections of botulinum toxin and sacral neuromodulation, as well as more invasive major urinary tract surgery.

■ **Surgical treatments for stress urinary incontinence (SUI) include bio-injectable agents, sling surgery – using either tissue or synthetic materials, colposuspension, and prostheses such as the artificial urinary sphincter. As with any condition in which there are multiple and evolving treatment options, there is no one 'ideal' operation for all patients. The choice of procedure depends on both patient factors, and the experience of the surgeon (Table 1). Surgical treatment is indicated for women with SUI who:**

- **have failed conservative measures such as pelvic floor physiotherapy, and**
- **have symptoms of SUI that are significantly interfering with quality of life.**

Table 2 lists well established and commonly performed procedures for the treatment of SUI. While the Burch colposuspension was considered 'gold standard' management before the advent of sling operations, sling surgery, and in particular midurethral synthetic slings, is now the most common operation performed (Figure 1a–d), with most slings showing similar levels of efficacy.¹ Bio-injectable agents are generally reserved for patients at increased operative risk² (Figure 2). The female artificial urinary sphincter (Figure 3) is generally an operation of last resort in women who have failed multiple procedures with severe intrinsic sphincter deficiency refractory to fascial pubovaginal sling surgery.^{3,4}

The advantages and disadvantages of the various types of surgery are outlined in Table 3.

Risks of surgery

All surgery for SUI has specific risks, the most significant being the fine balance between undercorrection – resulting in varying degrees of persistent SUI, and overcorrection – resulting in obstruction, urinary retention and secondary bladder overactivity. Bladder overactivity, both de novo and persistent or worsened, is well recognised as a potential complication of incontinence surgery.



Table 1. Factors influencing the management of stress urinary incontinence

Patient factors	<ul style="list-style-type: none"> • Type of stress incontinence – hypermobility vs. poor urethral function (intrinsic sphincter deficiency) • Severity of incontinence • Bladder function – which affects risk of urinary retention • Neurological disorders – causing neuropathic bladder • Tissue factors such as atrophic vaginal change, prior radiation, scarring • Previous failed surgery – type and approach • Need for associated prolapse surgery • Medical comorbidity • Extent of surgery desired – minimally invasive or other • Patient preference
Surgeon factors	<ul style="list-style-type: none"> • Experience • Personal preference and skills

Table 2. Procedures for stress urinary incontinence

Procedure	Details
Burch colposuspension	<ul style="list-style-type: none"> • Open or laparoscopic elevation of the bladder neck using a suprapubic approach
Pubovaginal slings (tissue slings)	<ul style="list-style-type: none"> • Uses a sling of tissue underneath the bladder neck/proximal urethra to act as a supporting suburethral hammock • Autologous fascial slings are made from the patient's own tissue (rectus fascia or fascia lata) • Allograft slings are made of cadaveric tissues • Xenograft slings are made of tissues such as porcine dermis and small intestinal submucosa
Synthetic midurethral slings	<ul style="list-style-type: none"> • Supports the midurethra using a strip of polypropylene mesh inserted using trochars • Minimally invasive as no tissue needs to be harvested • Retropubic midurethral slings pass via the vagina into the retropubic space (eg. Tension-free Vaginal Tape™, SPARC™) • Transobturator midurethral slings pass via the vagina through the obturator foramen (eg. Monarc™, TVT-O™)
Bio-injectables/urethral bulking agents	<ul style="list-style-type: none"> • Injected cystoscopically to add bulk to urethral tissue and improve urethral mucosal co-aptation (eg. bovine collagen (Contigen™), silicone polymer (Macroplastique™), carbon coated beads (Durasphere™)
Female artificial urinary sphincter	<ul style="list-style-type: none"> • Three part biomechanical device consisting of a cuff (placed around the bladder neck), reservoir and activation device • Provides circumferential compression of the urethra
Adjustable Continence Therapy (ACT™)	<ul style="list-style-type: none"> • An inflatable silicone implant consisting of two adjustable balloons placed percutaneously at the bladder neck to produce mucosal co-aptation • Device adjustment performed via a labial skin port under local anaesthesia

Patients must be counselled pre-operatively that bladder overactivity symptoms (ie. urgency, frequency, urge urinary incontinence) may not improve after stress incontinence surgery, and that surgery is not primarily designed to correct these symptoms.

All slings made of synthetic materials have risks inherent to synthetic materials such as erosion of the material into adjacent tissues (eg. the vagina and less commonly into the bladder and urethra) and infection or rejection.⁵

Assessing the success of surgery

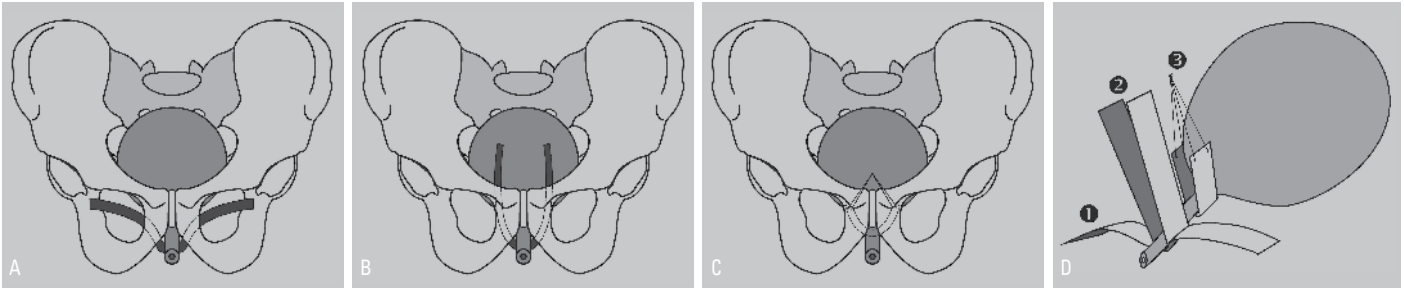
Comparing the success of treatment options for SUI is difficult

as there is no standardised definition of 'cure'.⁶ Both subjective measures such as patient satisfaction and improvement, and objective measures such as rate of stress and urge incontinence, and rate of leak (≤ 1 /week) are important, as a patient who is not completely dry may still be happy with the result of surgery.

Seventy to ninety percent of patients treated with autologous fascial slings experience a significant improvement or cure of symptoms and most synthetic midurethral slings show similar levels of efficacy for patients without intrinsic sphincter deficiency (ISD).^{1,7,8} Cure rates with bio-injectable agents are significantly lower due to their reabsorption from tissues.²



Figure 1A–D. Locations of the A) transobturator midurethral sling B) retropubic midurethral sling C) bladder neck (pubovaginal) fascial sling D) side on view of different slings: 1) transobturator 2) retropubic 3) bladder neck



Future developments in management

Future developments in the treatment of SUI include refining the indications for specific procedures and defining which procedures are best suited to which patients. Long term follow up, particularly of the synthetic sling procedures, will be important to both detect potential problems of synthetic materials in aging tissues as well as to quantify reduction in efficacy of procedures over time.

Newer variants of older techniques (eg. the TVT Secur™ variation on the TVT™ device) are largely industry driven. Unfortunately, new surgical devices for SUI are often released with minimal long term clinical data to assess safety and efficacy.^{9,10}

The most exciting new development is intraurethral injection of cultured myoblasts and fibroblasts. A biopsy is taken of the patient's arm skeletal muscle and used to create cell cultures. The patient's

Figure 2. Bio-injectable agent injected into urethra causing mucosal co-aptation

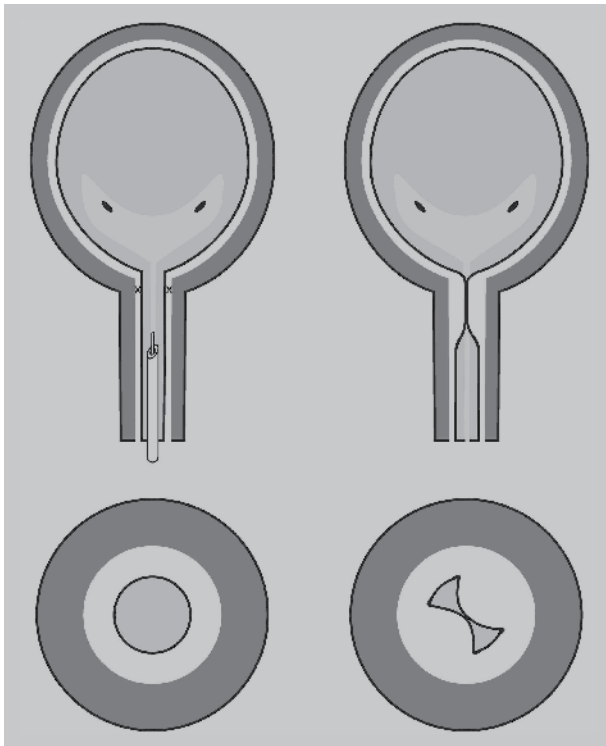


Figure 3. Female artificial urinary sphincter

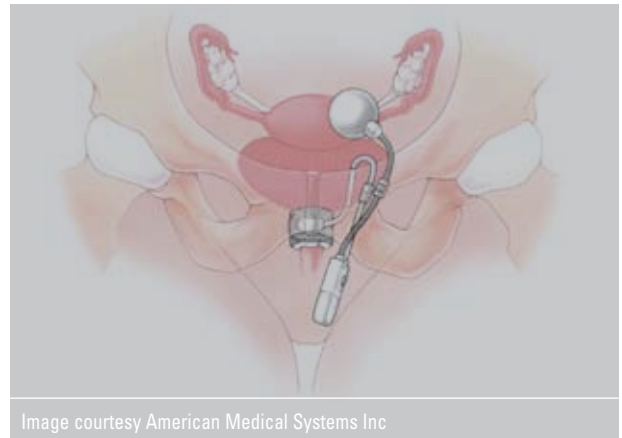


Image courtesy American Medical Systems Inc

own fibroblasts and myogenic stem cells are then injected under ultrasound guidance into the urethra and sphincter. Although this has resulted in impressive results at 2 years in one European centre, the procedure is regarded as experimental.¹¹

Surgical treatment for UUI

Urge urinary incontinence (UUI) is usually caused by detrusor overactivity, which is frequently idiopathic but can also be due to neurological disorders (eg. spinal cord injury, multiple sclerosis).

Urge urinary incontinence is often seen in combination with overactive bladder (OAB) syndrome – a clinical syndrome characterised by urgency, with or without UUI, usually associated with frequency and nocturia.¹² Urge urinary incontinence and OAB usually respond to a combination of bladder retraining, pelvic floor physiotherapy and anticholinergic medication, but some patients' symptoms remain resistant to these measures.

The following treatments are only indicated in refractory cases of detrusor overactivity causing UUI, ie. in patients who have failed maximal medical therapy with a combination of bladder retraining, pelvic floor physiotherapy and preferably at least two anticholinergic agents at full dosage. It is advisable for patients to have trialled at least one, and preferably two of the newer and better tolerated anticholinergic agents such as darifenacin (Enblex®), solifenacin (Vesicare®) and the transdermal oxybutynin patch (Oxytrol®) before they are regarded as having refractory UUI.



Table 3. Advantages and disadvantages of stress incontinence surgery

Sling procedure	Advantages	Disadvantages
Autologous fascial rectus sling (pubovaginal sling)	<ul style="list-style-type: none"> • Excellent results in long term studies • Quoted cure rates of 73–95%^{7,22–25} • Effective in the most severe types of incontinence due to intrinsic sphincter deficiency^{23–25} • Virtually no risk of rejection, infection or erosion as sling is made from patient's own tissue • Best alternative in patients at high risk of erosion (eg. postirradiation, neuropathic bladder, postreconstructive surgery) 	<ul style="list-style-type: none"> • Abdominal incision and dissection a potential source of morbidity • Longer hospital stay • Slower return to normal activity • Potentially higher rate of (transient) retention and bladder overactivity postoperatively⁷ • More technically challenging than synthetic sling surgery
Retropubic midurethral synthetic sling (eg. TVT™)	<ul style="list-style-type: none"> • Minimally invasive – no need to harvest sling • Hospital day stay or overnight • Minimal postoperative pain • Quoted cure rates of 66–91%^{8,22,23,26–28} • Long term data available with up to 7 year follow up of small numbers of patients²⁹ 	<ul style="list-style-type: none"> • Risks related to blind insertion of trocar in retropubic space include injury to bladder, bowel and major vessels • Risk of infection and rejection of synthetic material • Risk of erosion of synthetic material into vagina (less commonly urethra and bladder)^{30–32} • May not be as effective in severe SUI due to intrinsic sphincter deficiency³³
Transobturator midurethral synthetic sling (eg. Monarc™)	<ul style="list-style-type: none"> • Minimally invasive surgery • Hospital day stay or overnight • Minimal postoperative pain • Low rates of obstruction or urinary retention • Low rates of de novo urge incontinence • Excellent short term (2–3 years) results similar to TVT™⁸ • Transobturator approach minimises risk of vascular, bowel and bladder injury by avoiding retropubic space 	<ul style="list-style-type: none"> • Risk of infection and rejection of synthetic material • Limited long term results (>3 years)⁸ • Appears less effective in more severe SUI due to intrinsic sphincter deficiency³⁴ • Low rate of thigh pain related to insertion point of sling
Other procedures	Advantages	Disadvantages
Bio-injectable (eg. collagen [Contigen™])	<ul style="list-style-type: none"> • Least invasive option as injected into the urethra under cystoscopic guidance • Hospital day procedure under local (or general) anaesthesia • Can easily be repeated • Extremely unlikely to cause obstruction or bladder dysfunction • No postoperative restrictions on activity • Quoted cure rates of 30–78%^{2,26} 	<ul style="list-style-type: none"> • Efficacy inferior to slings or colposuspension • 1–4 injections are generally needed to achieve maximal improvement or cure • Results decline over time
Female artificial urinary sphincter (AMS 800™)	<ul style="list-style-type: none"> • Effective in severe intrinsic sphincter deficiency in patients who have failed other surgical measures 	<ul style="list-style-type: none"> • Compliant dexterous patient required who can operate sphincter device and deactivate cuff • More complex surgery • Mechanical problems/revision rate related to prosthesis failure/risk of device erosion and infection³
Adjustable Continence Therapy device (ACT™)	<ul style="list-style-type: none"> • Minimally invasive • Performed under cystoscopic and X-ray guidance • Device adjustment under local anaesthesia via a subcutaneous port 	<ul style="list-style-type: none"> • Minimal long term data in women • Risk of infection, device erosion and migration • Risk of device failure and urinary retention • Risk of urethral and vaginal pain³⁵

Treatment options

Treatment options for refractory UUI include:

- intradetrusor injections of botulinum toxin (eg. BOTOX™)
- sacral nerve neuromodulation
 - InterStim™
 - pudendal nerve stimulation (Bion™, MiniaturUO™)
- open surgical procedures
 - detrusor myectomy
 - augmentation cystoplasty

– urinary diversion (either incontinent diversion such as an ileal conduit or continent catheterisable diversion).

The advantages and disadvantages of these treatments are outlined in *Table 4*.

Botulinum toxin

Botulinum toxin is derived from the bacterium *Clostridium botulinum* and is the most potent naturally occurring neurotoxin known. Botulinum toxin type A (most commonly used in the urinary tract) causes muscle



paralysis by preventing the presynaptic release of the neurotransmitter acetylcholine from the nerve terminal at the neuromuscular junction. This occurs when the toxin is injected directly into skeletal muscle (eg. urethral sphincter) or into smooth muscle (eg. detrusor muscle). Neurotransmitter release of agents other than acetylcholine such as sensory or afferent neurotransmitters, are also affected and therefore botulinum toxin also appears to affect sensory pathways.^{13,14}

The effect of botulinum toxin injection into the bladder is detrusor muscle paralysis, which reduces or eradicates detrusor overactivity – the usual cause of UUI.

The main indications for use in the urinary tract are refractory cases of idiopathic or neurogenic detrusor overactivity. Botulinum toxin has also been injected into the urethral sphincter, prostate and pelvic floor for other urological disorders and pelvic pain syndromes.¹³

The BOTOX™ formulation of botulinum toxin type A is the most widely studied for urological indications. It is administered with a rigid or flexible cystoscope under either general or local anaesthesia (Figure 4). As the paralysing effects in bladder smooth muscle wear off after 6–12 months, treatment needs to be repeated. To date, no decrease in efficacy or increased drug tolerance has been seen over time.¹⁵

Complications

Local complications related to intradetrusor injection are minimal and include risk of pain, infection and haematuria. The main risk specific to intradetrusor botulinum toxin injection is a temporary increase in postvoid residual volume or urinary retention. This is due to ‘over paralysis’ of the detrusor muscle and is reversible as the effect wears off. Variable rates have been quoted for the need for intermittent self catheterisation after administration and depend on

Table 4. Advantages and disadvantages of treatments for refractory urge urinary incontinence

Procedure	Advantages	Disadvantages
Intradetrusor botulinum toxin	<ul style="list-style-type: none"> Minimally invasive day case procedure Very safe Effective in significant proportion of refractory neurogenic and idiopathic detrusor overactivity 	<ul style="list-style-type: none"> Expensive Currently limited availability in public hospitals in Australia Requires repeat treatments over time Risk of urinary retention
Sacral nerve neuromodulation (eg. InterStim™)	<ul style="list-style-type: none"> Does not cause urinary retention or need for self catheterisation Single treatment required May be more cost effective over time than multiple separate interventions such as botulinum toxin 	<ul style="list-style-type: none"> Expensive Currently limited availability in Australia outside trial settings High surgical revision rate of 33% due to complications¹⁹ Device replacement required when battery runs out
Detrusor myomectomy	<ul style="list-style-type: none"> No foreign material introduced into bladder No metabolic changes No mucus production Improvement seen in up to 63% of patients³⁶ 	<ul style="list-style-type: none"> Requires open surgery Results decline over time Less effective in neuropathic than idiopathic population Limited increase in bladder capacity³⁶
Augmentation cystoplasty	<ul style="list-style-type: none"> Patient’s native bladder retained Bladder capacity is enlarged No foreign bodies or appliances Can achieve continence rates of up to 90% in refractory patients³⁷ 	<ul style="list-style-type: none"> Major surgery Risk of rupture of augmented bladder Potential need for long term intermittent self catheterisation (14–100%³⁸) Increased rate of UTIs and calculi due to mucus production³⁷ Potential metabolic changes³⁹ Long term low risk of malignancy in augmented bladder⁴⁰
Urinary diversion (eg. ileal conduit)	<ul style="list-style-type: none"> Reliable and safe Low revision rates with surgery⁴¹ 	<ul style="list-style-type: none"> Major surgery Permanent stoma bag Increased rate of UTI and calculi
Continent urinary diversion	<ul style="list-style-type: none"> Patient is free of appliances on the abdomen Continent stoma is discreet/difficult to see on the abdomen Improved patient self image 	<ul style="list-style-type: none"> Major surgery Patient must self catheterise High surgical revision rates reported due to problems with continence mechanism^{42,43} Similar risks to augmentation cystoplasty



the dose administered and underlying condition treated (eg. many patients with neurogenic bladders already perform intermittent self catheterisation). In the nonneuropathic population, rates of intermittent self catheterisation of up to 16% have been reported.¹⁶

Systemic side effects from distal migration of the toxin away from the detrusor, such as transient muscle weakness elsewhere, are rare. Rare cases of antibody formation to the toxin with reduced efficacy have been reported.¹³

Contraindications

Contraindications are few and include pre-existing abnormalities of the neuromuscular junction (eg. myasthenia gravis), bladder cancer, coagulopathy and pregnancy. Inability or unwillingness to perform intermittent self catheterisation in the case of urinary retention is generally regarded as a relative contraindication.

Outcomes

All published series support the use of botulinum toxin type A in refractory neurogenic detrusor overactivity with improvements in symptoms, continence, key urodynamic parameters and quality of life.¹⁶ Most studies in idiopathic detrusor overactivity causing UUI and OAB have shown it to be effective and without significant side effects except for the potential for urinary retention. Overall, botulinum toxin improves continence with 50–90% of patients with both neurogenic and idiopathic detrusor overactivity regaining complete continence and quality of life.¹⁷

Availability

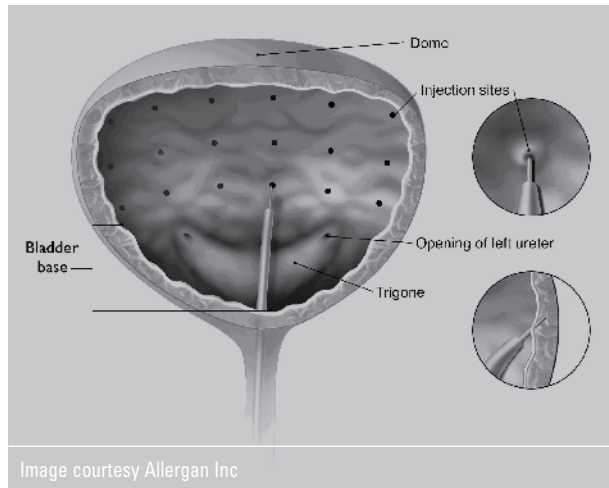
Botulinum toxin is not yet approved by the Australian Therapeutic Goods Administration or the USA Federal Drugs Administration regulatory authorities for use in the urinary tract. As such, availability in the public hospital system is limited and coverage by private health funds is variable. The BOTOX™ formulation of botulinum toxin costs \$500–1500 when used in the urinary tract depending on dosage.

Sacral neuromodulation

Sacral neuromodulation involves chronic electrical stimulation of the S3 or S4 nerve root via an electrode which modulates abnormal reflexes between the bladder, urethral sphincter and pelvic floor muscles. It is thought to work by alteration of the micturition and other voiding reflexes as well as by relaxation of the pelvic floor muscles.¹⁸ The InterStim™ device is the most widely used and studied form of sacral neuromodulation in the urinary tract and is effectively a bladder ‘pacemaker’ using technology similar to cardiac pacemakers (Figure 5).

Neuromodulation using the InterStim™ device is a two stage procedure with a first stage peripheral nerve evaluation using a temporary percutaneously inserted lead implant to determine efficacy of the device. If the patient experiences a favourable response (at least 50% reduction in symptoms on bladder diary), a permanent neurostimulator and lead can be implanted. The device is programmed

Figure 4. BOTOX™ injection into the bladder



externally – similar to a pacemaker. Battery life of the device is 6–10 years at which time the pacemaker part of the device needs to be replaced. High surgical revision rates of up to 33% before battery replacement have been reported.¹⁹ The permanent device costs approximately \$17 000.

Indications

The InterStim™ device has been approved since 1998 by the USA Federal Drugs Administration for the following urinary tract indications:

- symptoms of overactive bladder including UUI and OAB, and
- nonobstructive urinary retention.

In general, patients for sacral neuromodulation are overtly neurologically normal and have no structural abnormalities of the bladder.

InterStim™ is available in Australia but has only been funded for use in faecal incontinence. Applications are underway to fund the above urinary tract indications and are anticipated to be approved in 2008.

Efficacy

About 60–70% of patients respond to the initial test stimulation.¹⁸ Randomised controlled trials and case series show that 67–80% of patients will achieve continence or a greater than 50% improvement in symptoms after permanent implantation.¹⁹ It should be remembered that these results apply to a challenging group of patients whose UUI is refractory to medical management.

Contraindications

Contraindications include the need for regular or future magnetic resonance imaging (MRI) and pregnancy. Patients with defined neuropathology, eg. spinal cord lesions, multiple sclerosis, and myelodysplasia have poorer results.^{18,19}

Open surgical procedures

Open surgical procedures such as detrusor myomectomy, augmentation cystoplasty and urinary diversion with an ileal conduit are rarely used for refractory detrusor overactivity. Patients



with neurogenic bladders and unfavourable urodynamics where bladder dysfunction risks renal damage are the main candidates for these surgeries.

Figure 5. InterStim™ device showing device implanted in buttock with lead stimulating sacral nerve

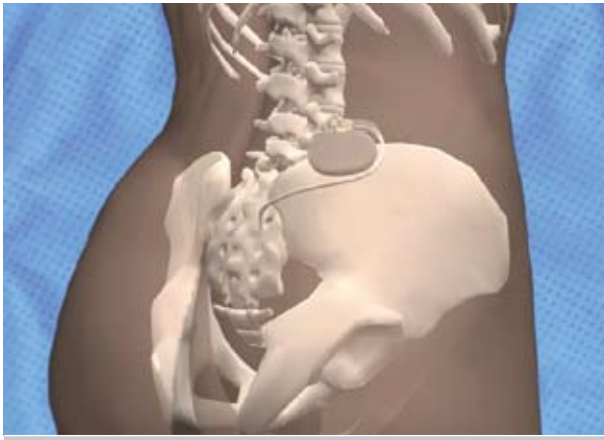


Image courtesy Medtronic Inc

In detrusor myomectomy the detrusor muscle is stripped and a bladder diverticulum created, thereby increasing bladder compliance and capacity. In augmentation cystoplasty the bladder is enlarged by implanting an isolated strip of the patient's own small bowel into the bladder. Ileal conduit urinary diversion creates a permanent urinary stoma out of a nonfunctioning segment of ileum connected to the ureters. Continent urinary diversions do not drain out of a stoma and require the patient to self catheterise a small abdominal stoma with an inbuilt continence valve.

Future developments in management

The advent of newer anticholinergic medications as well as more minimally invasive and effective treatment options such as botulinum toxin and sacral neuromodulation have revolutionised the management of patients with UUI, who in the past, would often suffer with their symptoms rather than resort to major surgery.

The future of tissue engineering with the use of stem cells and growth factors in reconstructive urology is an exciting and expanding field with the potential for bladder wall regeneration.²⁰ Tissue engineered bladder augmentation has already been described using patients' own cells generated from a bladder biopsy in a small series of children with severely damaged neuropathic bladders due to spina bifida.²¹

Conclusion

The future is bright with a greater range and more minimally invasive treatment options available for both SUI and UUI refractory to conservative and medical management. Patients must be appropriately counselled regarding their options while weighing up the risks, benefits and personal preference. Significant improvements can be achieved in both continence and quality of life.

Conflict of interest: none declared.

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