

**Recent developments in technology for the assessment and management of  
incontinence**

Christopher J. Hillary<sup>1</sup>, Martin Slovak<sup>2,3</sup>, Avril McCarthy<sup>2,3</sup>, Hashim Hashim<sup>2,4</sup>,  
Christopher R. Chapple<sup>1,2</sup>

<sup>1</sup> Department of Urology, Sheffield Teaching Hospitals NHS Foundation Trust, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF.

<sup>2</sup> NIHR Devices for Dignity Healthcare Technology Co-operative, Sheffield Teaching Hospitals NHS Foundation Trust, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF

<sup>3</sup> Medical Physics and Clinical Engineering, Sheffield Teaching Hospitals NHS Foundation Trust, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF

<sup>4</sup> Bristol Urological Institute, Southmead Hospital, Bristol, BS10 5NB.

C. Hillary – [c.hillary@sheffield.ac.uk](mailto:c.hillary@sheffield.ac.uk)

M. Slovak – [m.slovak@sheffield.ac.uk](mailto:m.slovak@sheffield.ac.uk)

A. McCarthy – [avril.mccarthy@sth.nhs.uk](mailto:avril.mccarthy@sth.nhs.uk)

H. Hashim – [h.hashim@gmail.com](mailto:h.hashim@gmail.com)

C. Chapple – [c.r.chapple@sheffield.ac.uk](mailto:c.r.chapple@sheffield.ac.uk)

**Corresponding Author**

Mr C J Hillary

Clinical Research Fellow in Urology

Department of Urology Research

J Floor

Royal Hallamshire Hospital

Glossop Road

Sheffield

UK

S10 2JF

## **Abstract**

Urinary incontinence, the leakage of urine, is a common condition, which can have a significant impact on a patient's quality of life. Incontinence may arise as a consequence of a weakness of the urinary sphincter or bladder dysfunction, usually overactivity.

Incontinence therapies occupy a large proportion of the healthcare budget. As no single device to manage incontinence is appropriate for all situations, a diverse range of products are available on the market and the development of improved products based on fundamental designs has been slow.

This review highlights some of the key issues of continence care, describes the current technology and recent developments involved in the diagnosis, assessment and treatment of incontinence, along with the strengths and limitations of these methods. These issues are imperative to address if improved technology is to be developed.

## **Key words**

Catheter; continence management; devices for dignity; incontinence; stress urinary incontinence; tissue engineering

## 1. Introduction

Urinary incontinence, the leakage of urine, is a common condition and is set to become an increasing healthcare problem with a greater ageing population. Incontinence can have a significant impact on a patient's physical, social and psychological wellbeing, and it is estimated that between 17% and 40% of both male and female patients collectively suffer from urinary incontinence with the elderly being more frequently affected [1].

Urinary incontinence is defined by the International Continence Society as 'the complaint of any involuntary loss of urine' [2] and can result from a variety of mechanisms in both males and females (figure 1). Incontinence more frequently affects the elderly and in post-menopausal and multi-parous females is commonly due to stress urinary incontinence (SUI), which is defined as the 'involuntary leakage of urine that occurs on effort or exertion' [2]. Incontinence may occur in the context of the overactive bladder symptom complex (OAB), which is a bladder storage problem encompassing the symptoms of urinary frequency, nocturia (waking up at night to void), urinary urgency and/or urgency urinary incontinence (UUI). Mixed urinary incontinence (MUI) is a combination of both SUI and UUI.

Urinary incontinence affecting males can occur in association with voiding lower urinary tract symptoms (LUTS), for example hesitancy to void and poor urinary flow, which is often seen in the context of benign enlargement of the prostate (BPE), leading to bladder outlet obstruction (BOO). SUI in males is less common than females and can occur following prostate operations both for benign or malignant disease.

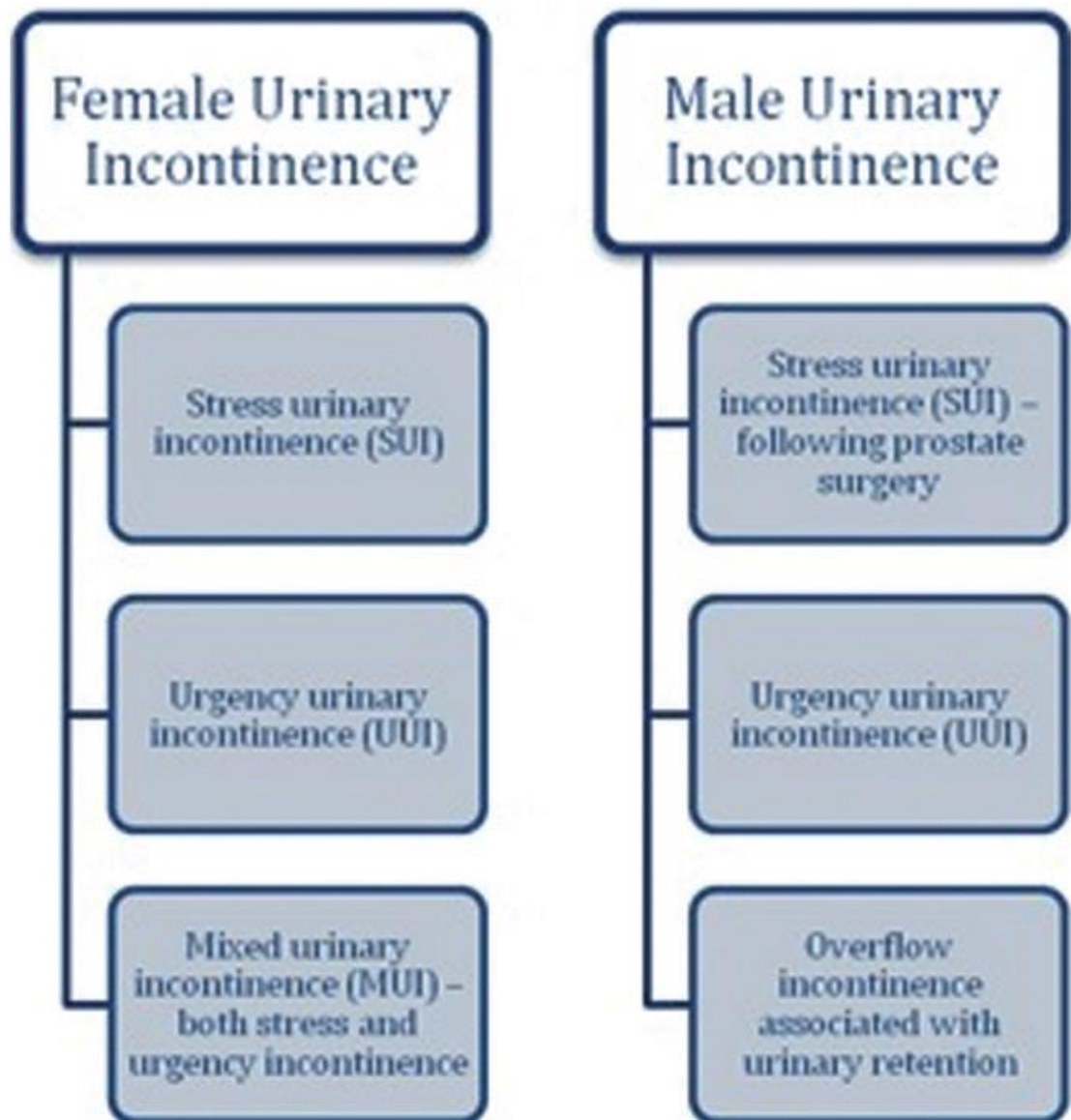


Figure 1. Common types of urinary incontinence by gender.

Diagnosis of the cause of both storage symptoms and incontinence is important in order to direct specific therapies. Following an initial assessment of symptoms and a detailed clinical examination, important initial investigations include checking the urine to exclude infection and the presence of white or red cells and the use of a bladder diary or frequency/volume chart. Additional investigations include pad weight testing, which provides an objective measurement of leakage; and invasive measurements, such as pressure-flow studies (urodynamic assessment).

Urodynamics can identify involuntary bladder contractions associated with over-activity; demonstrate SUI during straining and can provide information on the function of the urinary sphincter.

Urinary incontinence is commonly associated with significant impairment of quality of life in studies [3]. The management of this problem and associated symptomatic disorders such as OAB was responsible for 1.1% of the NHS healthcare budget and an estimated annual cost the NHS of £536million in 2004 [4]. Patients have often undergone a multitude of treatment modalities, including medical and/or surgical management and may suffer side effects as a result of such therapies.

Whilst there are advancements in the field of pharmacotherapy, clearly there is a need for improved diagnostic, monitoring and treatment strategies for incontinent patients. They are often elderly and are frequently either unwilling or too unfit to undergo invasive intervention and suffer side effects with medications often related to interaction with co-existing medication.

## **2. Recent advances in incontinence diagnosis**

The diagnosis of a particular cause for urinary incontinence is essential to allow appropriate management to be offered to a patient. It is important not only to define the clinical problem, and for the clinician to assess the response to the treatment, but also to provide a degree of 'biofeedback' to the patient based on their response to therapy. The most objective tool to achieve this aim is a frequency-volume chart (or bladder diary), which enables the quantification of volume of urine voided, urinary frequency, leakage, degree of nocturia and whether a patient produces an increased proportion of the 24 hour urinary output at night

(nocturnal polyuria), which is a separate clinical entity. Despite this, only a minority of patients who present with incontinence are routinely assessed using this tool [5]. This is likely to be due to the time-consuming interpretation of paper versions of a bladder diary during often time-limited clinical assessments and lack of knowledge about the importance of this assessment and its accurate interpretation in non-specialised hands in both primary and secondary care. Furthermore, the data are often incompletely or inadequately completed by the patient. Initial data from the development of a standardized diary has recently been published [6] and electronic versions of the bladder diary are available, even in the form of 'apps' on smart phones, which may encourage patients to complete these assessments more accurately [7]. Despite these advances however, electronic versions of the diary present inherent challenges, such as training and mechanical issues and the benefits of these devices are yet to be fully evaluated.

### **3. Recent advances in alternative treatment pathways**

Urgency urinary incontinence (UUI), which is the leakage of urine that is preceded by urgency can occur in the context of OAB or neurological disorders. Behavioural therapies, such as bladder training (which is facilitated by the use of a bladder diary) are offered as a first-line treatment, followed by anti-muscarinic drug therapy. However, many patients suffer from side effects using these medications and more recently a beta-three agonist with fewer side effects has been introduced. Consequently, the investigation of other minimally invasive treatments, such as using electrical stimulation therapy has been advocated [8]. The most commonly used technique involves electrical stimulation of the posterior tibial nerve. A

commercially available device, Urgent PC uses stimulation of the posterior tibial nerve (PTNS) at the ankle using electrodes, however this technique is invasive and requires regular patient clinic visits, which may be impractical for those who live long distances from the clinic [9]. There are limited randomised controlled data in the literature to confirm long-term efficacy for this therapy beyond three months [10]. The technique can be effective in 55% of patients [10], but involves weekly attendance at a clinic and therefore inevitably is associated with significant cost.

The Devices for Dignity healthcare technology co-operative (<http://www.devicesfordignity.org.uk>) is investigating the possibility of self-administering the treatment of PTNS by the patient at home using a non-invasive and lower-cost approach through self-adhesive conducting pads.

#### **4. Recent advances in incontinence surgery**

As SUI is associated with a degree of pelvic floor weakness, supervised pelvic floor exercises (PFE) for at least three months are recommended as a first-line treatment option for patients affected by SUI. However, poor compliance and an inability to do the exercises has led to the development of several electrical stimulation devices that use vaginal probes for administration. Large-scale use of these devices is limited due to patient discomfort, whereas recent products that rely upon the use of electrical stimulation through a disposable intra-vaginal device have been developed [11] and investigators report improved compliance and effectiveness. The evidence base relating to the therapeutic efficacy of electrical stimulation does not justify its use in the treatment of SUI as a direct therapeutic modality although it is often useful in demonstrating specific muscle groups when

educating patients about the use of exercises. Motivational tools such as the 'squeezing app' have successfully been designed in order to improve the compliance of patients performing pelvic floor exercises [12]. Unfortunately however, the evidence base for such devices is also lacking in the literature.

Following the failure to respond to physiotherapy, current surgical treatment of SUI largely relies upon either the use of a vaginally implanted sling formed of autologous fascia (AFS), harvested from patient's own tissues or synthetic non-biodegradable polypropylene mesh. Alternatively, vaginal plication or abdominal surgery is usually reserved for cases where there is a significant degree of pelvic organ prolapse. While AFS is associated with high success rates, there is more potential morbidity and a longer recovery phase, leading to the more widespread use of polypropylene mesh as a repair material.

Following an escalation in the number of complications reported to the US Manufacturer and User Facility Device Experience (MAUDE) database in 2008, the US Food and Drug Administration (FDA) began to issue notifications to inform patients of the risks associated with the 'kits' used for SUI surgery and the mesh implants themselves. Current reports of mesh related complications are likely to underestimate the true extent of the long-term complication rate, since erosions of this synthetic material can take years to occur and the surgical follow-up is short in many publications, which often assess a limited number of patients.

Mesh erosion and exposure, where the material extrudes through the patient's tissues has been reported to occur in approximately 4% of patients undergoing a transvaginal tape (TVT) procedure for SUI [13]. This complication often requires mesh removal and significant debility can occur as a result of this [14]. In



recognition of this growing problem, patient groups have begun to arrange websites and online forums, for example <http://www.tvt-messed-up-mesh.org.uk>.

Recent technological advances in the field of tissue engineering and the development of new materials have led to the investigation of degradable synthetic materials in order to produce remodelling of the pelvic floor tissues without the development of a chronic inflammatory response and the persistence of a strong and rigid implanted material. The FDA approved biodegradable polymer, poly-L-lactic acid has been shown to have desirable mechanical properties for use in pelvic floor reconstruction and also supports cell proliferation *in vitro* [15] and demonstrates cellular infiltration following acute implantation in rabbit models [16]. Such materials do show some promise for use as an alternative support material, however experimental results are currently at an early stage and are not yet available from clinical studies.

There has previously been interest in the use of regenerative medicine based approaches for the treatment of SUI, with sphincteric cell injection therapies for the treatment of intrinsic sphincter deficiency. These techniques can potentially be performed under a local anaesthetic as a day case procedure. Carr et al [17], reported the results of injecting muscle-derived stem cells (MDSC) peri-urethrally in 8 women, 5 of whom symptomatically improved following injection without any adverse events reported. The effects of such therapies in the long-term however are poorly sustained.

The artificial urinary sphincter (AUS) has been used to treat severe SUI in both females with intrinsic sphincter deficiency and SUI in males resulting from prostate surgery. The AUS has been used for over 40 years with only minor changes to the original design of the implant, which consists of an inflatable cuff implanted to surround the bulbar urethra, a reservoir and control pump (AMS800™ American Medical Systems, Minnetonka, MN, USA). In a recent systematic review including 17 studies of AUS implantation in women with SUI, Chartier-Kastler *et al* [18] revealed overall continence rates of between 64% and 100% with rates of infection between 0% and 46% and erosion experienced in between 0% and 67% of patients. This wide range of complications is likely to be related to patient selection in particular if these were primary or re-operative cases and other factors such as the expertise of the surgical team. For male SUI, a recent systematic review has demonstrated infection/erosion rates with the AUS of 8.5% and mechanical failure occurring in an average of 6.2% of patients [19]. More recently, male slings have been introduced, which are offered as an alternative to the AUS and are claimed to be safe and effective. However, their long-term outcomes are unclear [20] and the risk of urinary retention means that some patients would be required to intermittently self-catheterise to empty the bladder on a long-term basis. There have been recent reports of exposure of the mesh in men requiring urethroplasty following removal of the mesh, which would also add to the overall costs.

## **5. Recent advances in incontinence management**

Whilst awaiting definitive therapy as well as in patients who have declined more invasive therapy or where there is a failure of therapy or where for whatever reason

it is not possible, several devices are available. These aim to improve patient confidence, comfort and reduce complications. Pads or liners are generally used for patients with light to moderate leakage, whereas catheters are used for severe incontinence or in those with significant mobility issues to divert urine away from areas of pressure sores. Other non-invasive methods of continence management, including external urethral collection devices such as penile sheaths in male patients are useful for patients with severe incontinence but who have sufficient dexterity to operate them, while toileting aids, such as urinals and collectors can be used for patients with UUI, who struggle to reach the toilet without leaking.

### *5.1. Absorbent products*

These devices are essential for many patients with incontinence to enable them to confidently carry out routine activities of daily living. Advances in material design have led to a variety of superabsorbent polymers in order to increase absorbency and reduce material bulk. Recently, pull-ups and T-shape diapers have been introduced in order to facilitate ease of change, whilst maintaining dignity. Products are generally available as disposable or reusable and clinical trials have demonstrated that women in the community with moderate to heavy leakage prefer the disposable pull-up variety over other designs [21]. Reusable devices have high initial costs, however are cheaper than disposable varieties over time and perform well in patients with light incontinence.

Incontinence associated dermatitis is an issue for pad wearers due to persistent exposure to moisture and the urea in urine. A device that has an absorbent anterior portion that prevents the backflow of urine to the perineum has

been developed, which demonstrates significant improvements in rates of incontinence associated dermatitis as compared to standard absorbent products (43.3% versus 13.3% subjective improvements for modified devices and standard pads respectively) [22].

### *5.2. Female devices*

For female patients with SUI, there has been interest in the use of mechanical devices that aim to restore the position of the proximal urethra to above the level of the pelvic floor. This improves the transmission of pressure to the proximal urethra and allows it to close. These intra-vaginal devices include tampons and pessaries, which may already be familiar to patients. A recent design demonstrated by Ziv *et al* [23] utilizes a design, which specifically aims to provide support to the urethra, while being composed of a flexible material that allows the passage of natural vaginal secretions. Urethral plugs, which aim to simply block the leakage of urine from the urethral meatus, have been described but are uncomfortable and in the long-term injure the urethra [24]. Recent systematic reviews have suggested that the simplest and most familiar devices to women, tampons (albeit those designed for continence), are as effective as more formal mechanical devices [25]. Furthermore, they are disposable and relatively cheap.

### *5.3. Male devices*

Condom sheaths allow the continuous channelling of urine into a suitable collecting bag. They are particularly useful for wheelchair users who experience moderate to severe urinary incontinence and wish to avoid using a pad or catheter. Previously,

sheaths were made of latex and were secured to the penile skin using adhesive tapes or fixation devices. There are reports of such fixation devices leading to ischaemia and gangrene of the glans penis [26]. Newer sheaths with an integral adhesive obviate the need for such tapes, and latex has since been largely replaced by silicone materials. Complications such as skin ulceration and urinary tract infection (UTI) are well documented, albeit less so than in association with indwelling catheters.

Self-adhesive sheaths are generally well tolerated [27] and those that are strongly adhesive to the penile skin result in fewer reported leakages, despite being difficult to remove, whereas the opposite is true of weakly adhesive sheaths.

Penile compression devices have been available for decades, however because they are often uncomfortable and can injure the penis and urethra [28], these were replaced by the AUS and male sling, which demonstrate high success rates [29]. Recently however, there has been renewed interest in these devices and studies have found that the penile compression device, Dribblestop™ (Rennich Industries, Ltd., Calgary, Canada), is easy to use, safe and results in significant improvements in incontinence episodes [30]. However, appropriate assessment of the patient is important before using penile clamps because in high pressure, poorly compliant bladders, they can be dangerous to use resulting in renal failure and back-pressure on the kidneys.

#### *5.4. Catheters*

The standard catheter type in practice is known as the Foley catheter and has been in use with an essentially unchanged mechanical design for 70 years [31]. Although innovative approaches with regard to different coatings are still the subject of

ongoing research in order to reduce infections and the formation of a biofilm, a more fundamental change for innovative catheter design is needed [32]. At the same time the standardization of the catheters used in practice is difficult due to their availability, diversity and patient choice.

Trauma to the urethra can result when the catheter is removed as a result of a 'cuff' of material forming at the site of the deflated balloon, due to hysteresis within the material. Solutions to this problem of 'cuffing' are currently under investigation by the Devices for Dignity team to prevent patient discomfort associated with routine catheter changes. A major problem with all catheters, which is also influenced by patient related factors are the problems of biofilm formation, recurrent infection and associated encrustation of catheters.

#### *5.5. Catheter devices and bags*

Owing to the significant incidence of infection, several urinary catheter adjuncts have been developed. In order to prevent the spillage of urine and potential contamination that could occur during changing catheter bags, several polypropylene valves have been developed to lock-out urinary flow [33]. At present, however there are no clinical data available to support the routine use of these devices over standard catheter tubing. Although some patients would prefer a smaller discreet valve, those with dexterity problems find larger valves easier to operate [34]. In order to improve the discreetness of catheters and aid patient comfort, a leg-bag catheter tubing with a smaller diameter is currently being investigated by Devices for Dignity. Recent data suggests that kinks in catheter tubing are less likely to occur with smaller diameter tubes but urinary stasis, due to

slower drainage, can be associated with urinary tract infection [35]. Tubing with anti-kinking features, such as corrugated tubing or a spiral shaped design can prevent occlusion of the catheter tube if kinking does occur, however these devices are purportedly difficult to keep clean and are therefore not widely supported by continence advisors. Furthermore, in order to reduce the audible noise and visual ballooning associated with conventional catheter bags, companies have developed catheter bags with an improved chamber design [36].

### *5.6. Clothing*

For female patients with light incontinence, reusable pants incorporating a pad are ergonomically acceptable, however they demonstrate a poor leakage performance [37]. These products are generally more cost effective than disposable pads, although issues relating to odour control, skin care and the frequency with which they may need to be changed are commonly reported by patients.

More recently, clothing items that facilitate improved access for patients to change pads, for example trousers with an extended zipper have been developed (<http://www.continenceproductadvisor.org/products/clothingodourcontrolandskinare/clothing>), while pads that inhibit urinary tract infections, aid skin care and prevent odours are available [38]. At present there are no large-scale clinical trial data available to compare the cost effectiveness of these devices.

### *5.7. Commodes and urinals*

The basic design of commodes has changed little since their invention. Issues such as the device's appearance, comfort and smell remain a problem, particularly in

ward-based environments and in the community. Patient safety with regards to transfer onto the commode is a common problem, with a significant proportion of nursing home related falls occurring as a result of commode use (estimated 22.2% of falls) [39]. Methods to alleviate this include commode designs with improved brakes or static commodes, however it is likely that the transfer process itself of patient to commode is implicated in the vast majority of fall episodes. The Devices for Dignity “Dignity” commode has been designed specifically for those who have a carer and incorporates a bidet system with a dryer along with static feet for safer transfer and use. Commode cleanliness and associated infections continue to be a problem, however a report from the Design Bugs Out programme has demonstrated that commodes with fewer removable parts are reportedly easier to clean by staff and patients [40].

A variety of urinal designs are available to those who have difficulty in accessing toilets due to mobility impairment. These devices are largely re-usable and can be utilized either in a sitting, supine or standing position in order to collect urine for later disposal. Some devices incorporate a handle design for patients who can void in the sitting position, for example in a wheelchair, however female urinals have difficulties with placement in a suitable position, discomfort of material used or a feeling that the urinal might leak [41].



## **6. Conclusions**

Urinary incontinence is a common and distressing clinical condition to manage for both patients and their carers, particularly in the community. Despite this, the problem is under reported, under recognised, and poorly resourced with many patients buying absorbent products over the counter instead of consulting a doctor or the continence service. There have been recent advances in many aspects of continence care in response to the challenges faces with current products and devices, as shown in Table 1.

The rates of surgical cure of urinary incontinence in both men and women is high, however surgical treatments are associated with significant complications. Despite promising advances in the field of tissue engineering addressed at reducing these surgical complications, the results of novel synthetic materials are at an early stage. Therefore, many patients opt for management to simply contain their incontinence instead of cure it.

The design of products, including absorbent materials, external devices and catheters have only progressed marginally from their original designs. While disposable absorbent products are preferred by patients with mild to moderate urinary leakage, techniques to improve reusable materials would be more cost effective and reduce the disposal burden.

	Standard options available	Recent Development	Issues still to be addressed
<b>Diagnosis</b>			
Objective assessment of symptoms	Bladder diary	Electronic bladder diary [7]	The widespread implementation of bladder diaries into general use.
UTIs in pad users	Dipstick test	Self-adhesive pad device [42]	Sensitivity of the UTI test. Appropriateness of treating colonised urine in asymptomatic patients.
<b>Treatment</b>			
Incontinence surgery	Autologous fascia sling and Synthetic non-degradable mid-urethral tape	Degradable materials for implantation [16]. Injectable sphincteric approaches [17]	Long-term safety using clinical trials.
SUI – pelvic floor exercise	Pelvic floor muscle training	Motivational app [12]	The widespread implementation of pelvic floor muscle training in patients with SUI.
Electrical stimulation Stress urinary incontinence	TENS vaginal probes devices	Disposable tampon like device [11]	Effectiveness and comfort assessed in large scale trials.
Electrical stimulation Urge urinary incontinence	Sacral neuromodulation	Percutaneous peripheral nerve stimulation [9]	Effectiveness and comfort assessed in large scale trials.
<b>Management</b>			
Absorbent products	Wide range of disposable pads	Pads that prevent urine back flow [22]	Pad disposal costs and acceptability.
Mechanical devices - SUI	Internal vaginal devices	flexible devices [23]	Comfort, acceptability of disposable and non-disposable varieties. Disposal costs.
	Penile Compression devices	Renewed interest [30]	Discreteness of device, comfort, ease of use, complications of device.
Intermittent catheters	Single use catheter	Discrete compact set [43]	Assessment of cost effectiveness, reusable single patient use catheter.
Indwelling catheters	Foley catheters	Infection/biofilm reduction Designs to prevent ‘cuffing’	Improve antimicrobial properties, improve mechanical design – prevent cuffing / balloon failure.
Catheter leg bags	Catheter leg bags	Discrete bag design, noise reduction during movement [44]	Poor aesthetic performance.
Sheaths	Variety of sheaths devices	End of glans devices for a retracted penis	Poor leakage control, skin sores.

Body-worn urinals	Female and male urinals	No recent developments	Poor leakage control, discomfort and poor aesthetic performance.
Handheld urinals	Female urinals	Pulp product (VernaFem)	Discomfort with reusable products, fear of spillage, disposal costs.
Commodes	Male urinals	Urine directors	Discreteness of product, disposal costs.
	Static and mobile commodes	Dignity commode, easier to clean	Risk of falls.
Bedpans	Disposable and non-disposable bedpans	No recent developments	Difficult to use, do not permit appropriate posture.
Clothing	Reusable pants with pad	Clothing with improved access	Odour, poorly absorbent.

Table 1. Key summary of the current continence products, the challenges faced and possible solutions.



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