Summary of clinical evidence for use of urinary sheaths

Coloplast

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1. Introduction

Urinary incontinence can affect any man. A frequent consequence of prostatic disorders, it occurs more commonly with age. Left unmanaged, incontinence can have a major impact on a person's well-being – interrupting daily activities and even preventing people from going out for fear of experiencing leakage in public.

Without a suitable solution for their incontinence, some men feel unable to do the things they used to enjoy; both social and family relationships can breakdown; and many men often experience negative emotions including, embarrassment, loneliness, and shame. For these reasons, many are reluctant or unable to talk about incontinence and try to conceal their symptoms. This lack of communication can be a major barrier to starting successful treatment or cause men to 'make-do' with ineffective remedies.

That is why recommending an appropriate, reliable, and discreet solution for incontinence is so important for patient's quality of life.

You can make the difference. As a provider of continence care, you have the potential to make a huge difference to your patient's quality of life. Finding an incontinence solution that is both effective and compatible with each patients' needs is a central part of this role.

Today, many healthcare professionals recommend absorbent pads for men with urinary incontinence, but pads need to be changed frequently to avoid issues such as odour and skin rashes. To give the best level of care, patients should be made aware of all the options available to them, so that they can be empowered to manage the problem for themselves. As part of a urine collecting system, sheaths offer a discreet and reliable solution to male urinary incontinence. However, they need to be used correctly to ensure they can perform at their best.

This booklet provides a summary of some of the evidence available to support a sheath collecting system, how they can improve a patient's quality of life, how they can be used and managed effectively, and illustrates the impact they can have on real men's lives.

2. Urinary incontinence and quality of life

Urinary incontinence is a problem that affects men worldwide – 11% aged 60-64 and 30% of those over 85 (Shamliyan et al, 2009; Anger et al, 2006). It has a considerable impact on a person's condition, limiting their ability to live everyday life.

In order to allow this group of men to return to some level of normality, effective and discreet management of urinary incontinence is key. How well continence products perform promotes either confidence or anxiety and therefore, influences a person's preference towards a specific type of management option.

In terms of overall patient comfort and hygiene, many consider urinary sheaths to be the preferred method of management. But with a lack of clinical evidence to support this theory, many remain sceptical as to their advantages over absorbent products, or pads. Without this, a clear recommendation cannot be made and the relative effectiveness of each method cannot be established (Chartier-Kastler et al, 2011).

In this section, two articles point towards one management system, describing a preferred method and its impact on quality of life for the end-user, and ease of use for the professional.

Randomized cross-over study evaluating impact on quality of life and patient preference of urinary sheaths versus diapers in incontinent men

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Introduction & Objectives

To evaluate the impact of urisheaths versus absorbent products on quality of life (QoL) in incontinent men.

Study design

- A randomised, controlled, crossover trial in 61 outpatient adult men with stable, moderate to heavy urinary incontinence
- Conducted from June 2007 to February 2009 in 14 urology centres
- Participants tested Conveen Optima urisheaths (Coloplast A/S, Denmark) and their usual absorbent product for 2 week periods each in random order (Figure 1)

Outcome measures

- Impact on QoL was measured with the King's Health Questionnaire (KHQ) and the SF-12 Acute questionnaire
- Patient preference was recorded. A 10-item patient questionnaire was used
- A 72-hour leakage diary was used to record the number and severity of leaks and daily product consumption
- Safety was measured as the number of local adverse events

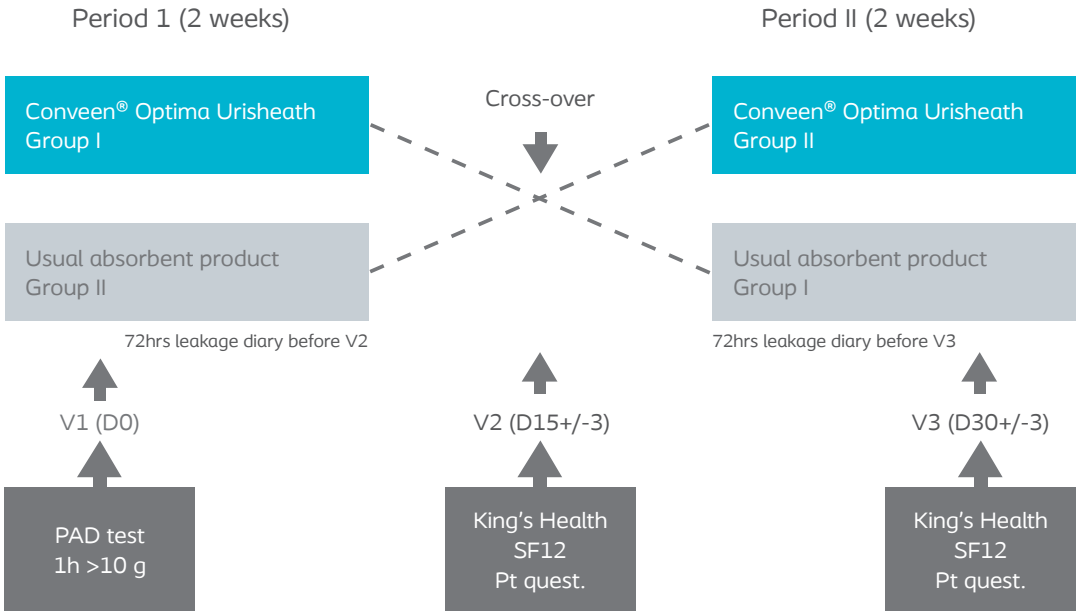

Figure 1. Study design
V=visit, D=day, Pt quest=10-item patient questionnaire

Results

- All dimensions of the KHQ scored lower with urisheaths, indicating an improvement in QoL, especially for "limitations of daily activities" (-10.24 ± 3.99, p=0.01) and "impact of incontinence" (-7.05 ± 3.45, p<0.05) (Figure 2)
- The majority (69%) of patients preferred urisheaths to their usual absorbent product (p=0.002) (Figure 3)
- Urisheaths scored significantly higher for all parameters (efficacy, self-image, odour management, discretion, skin integrity) other than ease of use

Safety

- Safety was considered to be good
- Adverse events that were judged to be possibly related to the urisheaths were reported in 5 patients (8.3%); 4 cases of skin irritation (resolved with improved hygiene) and 1 case of maculopapular rash (resulted in discontinuation)
- Three urinary tract infections (two on absorbent product, one on urisheath) were reported for two patients but were not considered product related

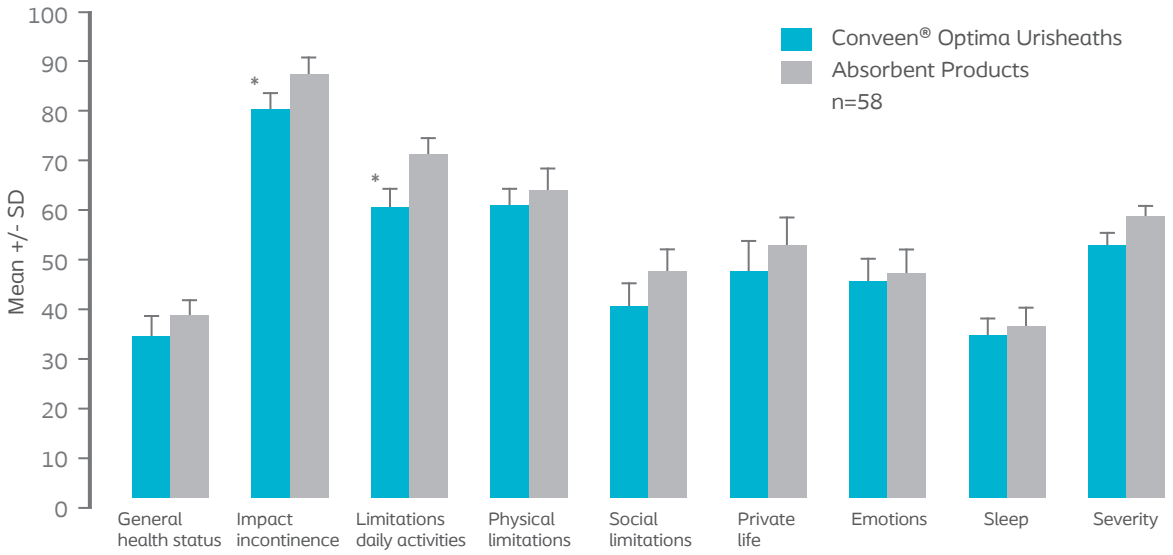

Figure 2. KHQ scores
The lower the score the higher the quality of life. *Significant difference (p<0.05).

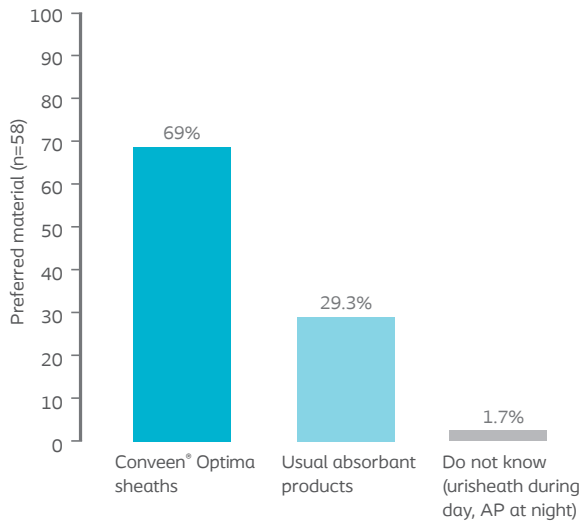

Figure 3. Patient preference

Conclusions

- Conveen Optima urisheaths showed a positive impact on QoL (according to the KHQ results) in moderate/heavily incontinent men who were long-term users of absorbent products
- Participants largely preferred the Conveen Optima urisheaths
- In view of these results, urisheaths (Conveen Optima) may be recommended in preference to absorbent products in incontinent men

A comparative study of two types of urinary sheath: a randomised, prospective, crossover clinical study

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Introduction and objectives

To compare the new Conveen® Optima urinary sheath with the established Clear Advantage® urinary sheath with regard to patient satisfaction and preference. The primary endpoint was urinary sheath product preference, and secondary endpoints were handling, application, comfort, leakage and skin reactions.

Study design

This randomised, prospective, open, crossover study at seven centres in the UK included males at least 18 years of age and using at least one one-piece urinary sheath a day. Exclusion criteria were mental health problems and participation in other clinical studies. Each participant tested 10 urinary sheaths of each product Conveen Optima and Clear Advantage. Participants were randomised according to a block randomisation list.

In order to calculate a 95% confidence interval for the expected preference for each product of 50% and an estimated error of 15% the number of subjects needed was 43, thus, it was planned to include 50 patients to compensate for dropouts.

Data regarding demographics and nurse/helper evaluation was reported descriptively. 95% confidence intervals were calculated for the product preference results. Secondary parameters were analysed using the Wilcoxon test and the Sign test where appropriate.

Results

Of the 53 men included in the study, 44 fulfilled the evaluability criteria and were included in the analyses. Eighty-one percent of the participants reported having a preference (Figure 1).

With Conveen Optima more participants found that:

- It was easier to open and remove the sheath from the individual packaging
- They did not experience wrinkles or bubbles when applying the sheath
- They felt safe immediately after application of the sheath
- The sheath was comfortable to wear
- The drainage from the sheath into the urine bag was satisfactory
- The individual packaging of the urinary sheath enabled them to easily carry it around with them
- It was easier to connect and subsequently disconnect the sheath from the urine bag

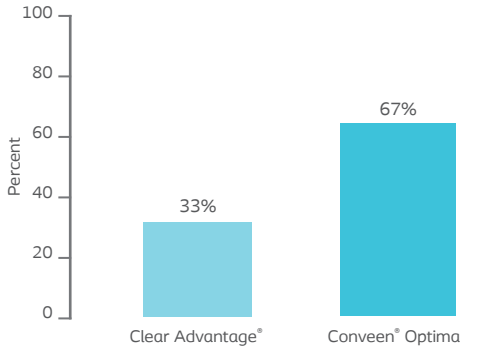
The scores for these results are shown in Table 1.

- Participants felt more secure when using the Conveen Optima (scale ranged from 0=very insecure to 10=very secure; P=0.029, Wilcoxon test).
- Where nurses applied the urinary sheaths wearing gloves, more nurses found Conveen Optima easy to apply
- For all other questions asked, there was no statistically significant difference between the Conveen Optima and the Clear Advantage urinary sheaths

Interpretation of results

This study shows that the Conveen Optima urinary sheath provides a higher feeling of security. Furthermore, the Conveen Optima sheath was found to be easier to handle and apply in some of the aspects studied and importantly, it was found to be at least as user-friendly as the Clear Advantage sheath in all the other aspects studied.

The study showed that 67% preferred the Conveen Optima urinary sheath over Clear Advantage, which was previously shown to perform significantly better than other self-adhesive urinary sheaths on the UK market at that time. 60% of the participants were using Clear Advantage before entering the study and must therefore be expected to favour Clear Advantage. It is thus interesting to note that such a large proportion preferred Conveen Optima. This large preference may be due to the improved feeling of security, the improved comfort and improved packaging of the product.



67% (95% confidence interval 52% to 82%) preferred Conveen® Optima

33% (95% confidence interval 18% to 48%) preferred Clear Advantage®

Figure 1. Product preference

Conclusion

This is one of the first randomised clinical trials aimed at providing evidence for healthcare professionals in order to assist them and their patients in making informed choices concerning a urinary sheath product. The study shows that the newly developed Conveen Optima urinary sheath provides a higher feeling of security than the well-established product, Clear Advantage. Furthermore, Conveen Optima was found to be easier to handle and apply as well as more comfortable to wear. Finally, the overall product preference for Conveen Optima was 67%, indicating that it is more acceptable than the well-established product.

Parameter	Issues	Clear Advantage	Conveen Optima	P value
Application	Ease of opening individual packaging	3.30	4.32	<0.001
	Ease of removal from individual packaging	3.66	4.39	<0.001
	No wrinkles/bubbles on sheath when applied	3.57	3.86	0.036
	Confidence when wearing the sheath	3.36	3.69	0.043
Overall wear	Comfortable to wear	3.79	4.02	0.018
	Drainage of urine into bag during use	3.89	4.14	0.033
Connection to urine bag	Ease of connecting sheath to urine bag	3.80	4.14	0.018
	Ease of disconnection of urine bag from sheath	3.82	4.32	<0.001
Packaging	Ease of carrying sheath around	3.21	4.30	<0.001

Issues were stated as questions and answered on the following scale:
1 strongly disagree; 2 disagree; 3 neither agree or disagree; 4 agree; 5 strongly agree.
The differences between the products were all statistically significant at 5% (Wilcoxon test).

Table 1. Handling, application, comfort, and packaging

3. Management of urinary sheaths

Urinary sheaths are a good treatment option for the management of male urinary incontinence, but unfortunately their use is not widespread. They can be used to manage a variety of continence problems and with correct management, they can be very effective (Brodie, 2006)

In this section, an outline of the assessment process is presented, with the view that it should be followed before selecting and fitting a sheath. The challenges linked to promoting continence in men are explored alongside an illustration of how urinary sheaths can offer an appropriate management option for urinary incontinence. Practical tips for applying a sheath and coping with problems are also offered to improve the effectiveness of this management option.

A guide to the management of one-piece urinary sheaths

Brodie, A. (2006): Nursing Times; 102: 9, 49-51

Introduction

Urinary sheaths can be used to manage a wide variety of continence problems. The groups of patients for whom they can be used include those with the following problems:

- Sphincter damage following prostatectomy
- Spinal cord injury
- Neurological pathology e.g. Parkinson's disease, multiple sclerosis, spina bifida
- Functional incontinence: people with this problem include those with poor mobility dementia, impaired vision, or for whom getting to a toilet poses a safety issue
- Poor skin integrity – a urinary sheath will allow drainage of urine away from the skin surface

Assessment

A thorough assessment is required to determine the cause of urinary incontinence. Only following this should possible treatment options be discussed and decided upon. Urine should be fully tested for any signs of infection and any residual volume assessed appropriately, so to rule out other issues such as incomplete emptying. Patients must then be given accurate information about the product that is to be used and application method should be explained thoroughly. The manufacturer's guidelines for use should also be followed for the safe and correct use of the product.

Phillips (1992) identified that healthcare professionals need to be confident and familiar with a product in order to be able to explain its application to a patient or carer. A step-by-step guide to the fitting of a one–piece urinary sheath is presented in Box 1 (overleaf).

A step-by-step guide to applying a urinary sheath

- A full explanation of why a sheath has been chosen, what it is and how it works should be given to the patients and carers/next of kin. Check if the patient has used a sheath before. This will guide selection of an appropriate product
- Check if the patient has any allergies
- Examine and document the condition of the patient's skin before applying the sheath
- Ensure that the penis is dry and free from cream or powder, and trim any pubic hair if necessary
- If skin problems are anticipated, recommend the use of a barrier wipe before applying the sheath
- Use a sheath-measuring guide to measure the shaft of the penis at the widest point (the guide supplied by the manufacturer for the sheath selected must be used)
- If the patient is able to walk around, re-measure his penis when he is standing up to check any differences in size
- Use professional judgement and experience as well as the assessment findings to select the most appropriate sheath
- Ask the patient to sit on the edge of the bed/chair, or to stand if it is safe for him to do so
- Use a hair shield or a paper towel with a hole
  cut out in the middle to help keep the pubic hair away from the penis. Patients/carers may choose to trim the hair
- Apply the sheath according to the manufacturer's instructions. All sheaths must be unrolled along the penis
- Teach the patient/carer to use their dominant hand to unroll the sheath and the other hand to hold the end of it at the penis tip, using gentle traction to pull the penis outwards
- Using a urinary sheath with a pull-tab may be preferred, especially if a carer is applying the sheath for a patient, as it requires a non-touch technique
- Select and attach a non-sterile leg bag
  Bags with adjustable tubes are useful, as the tubing can be cut to the appropriate length making drainage more efficient
- Consider using securing devices, such as a G-strap
- Leave written instructions for carers with regard to sheath changing and removal
- Ensure patients/carers are aware of how they will receive further supplies
- Re-assess the patient in 24–48 hours

Box 1.

Troubleshooting

Sometimes urinary sheaths fail owing to variations in the method of application, temperature, storage and anatomical changes (Foxley, 2005). Here are some methods to solve common problems:

The sheath sometimes falls off

- First check the size, as this can alter according to temperature changes, age, weight loss or gain, or position;
- Use a measuring guide that is specific to the make of urinary sheath that is being used;
- Measure the patient in the position he is normally when the urinary sheath falls off; This may mean that he needs a different size sheath; alternatively, a skin adhesive could be used under the sheath;
- Try a shorter length urinary sheath in the same size if a patient has a retraction of his penis when he is in certain positions;
- Check that the patient is not using creams, talcum powder or moisturisers that may affect the adhesive properties of the sheath;
- Check that the patient has not secured the drainage bag too tightly, as this will pull on the sheath. It may be useful to use a G-strap to add extra security;
- Check that there is a small gap between the end of the penis and the drainage port of the urinary sheath. If there is not enough room for the urine to drain, it will flow backwards and cause the sheath to fall off.

Sore skin

- Check the condition of a patient's skin before applying a sheath so that any allergic reactions to the material in the sheath can be identified;
- Do not use a sheath until any broken skin has healed, as this could cause further skin breakdown and infection;
- Use a skin barrier before applying a sheath; this would include wipes and sprays;
- Try an alternative sheath if a patient has an allergic reaction after its application, particularly if a latex sheath has been used;
- Check for any infection under the foreskin that may need to be treated before a sheath is applied;
- Check the size of the sheath and penis, as the sheath may be too tight;
- Change sheaths every 24 hours according to the manufacturer's guidelines. If possible, allow the skin to breathe for short periods in between sheath changes;
- Check how the patient/carer is removing the sheath. It must be removed with warm, soapy water every time; pulling it off will cause trauma.

No urine draining from sheath to drainage bag

- Check if the sheath has become dislodged;
- Check that the tubing of the drainage bag is not occluded;
- Check that drainage is not being prevented by a vacuum that has developed in the end of the sheath. If this is the case, disconnect the drainage bag briefly, which will release the vacuum and allow the urine to drain;
- Check that the sheath is not too tight, as this may compress the urethra and obstruct the flow of urine;
- Check that the sheath is not twisted at its end, as this may obstruct urine drainage.

No urine draining from sheath to drainage bag

- Check the size of the sheath, as it may be too tight;
- If necessary, an adhesive remover can be used.

Conclusion

Currently, urinary sheaths are used ineffectively to manage male urinary incontinence. Information on the products and the process for effective management needs to be more widely available, alongside further training for nurses assessing for and applying urinary sheaths. Nurses need to accept their responsibility to offer this as a management option for patients, and education on urinary sheaths should supplement Nurses knowledge to facilitate their ability to respond to the patient's needs

Use of urinary sheaths in male incontinence

Williams, D., & Moran, S. (2006): Nursing Times; 102: 47, 42-45.

Introduction

Getting men engaged with solving their incontinence issues is a major difficulty. It remains common in men, and this is despite incomprehensive data as a result of their reluctance to reveal any issues. Many men would rather isolate themselves and deal with the problem on their own. If the patient reaches assessment stage, the health professional should recognise the psychological impact and choose an appropriate management option accordingly.

Urinary sheaths

A large proportion of negativity surrounding sheaths relates to poor and/or incorrect assessment. There are many types of sheaths available, each manufacturer recommends its own sizing guide, and one-piece versions are most commonly used (Brodie, 2006).

Successful outcomes are more likely with patients who are willing to work with the health professional to solve their problem. In those who manage incorrectly, or those with cognitive impairment, penile trauma may occur – a carer or family member may help to maintain the system (Pomfret, 2003).

Penis retraction

The size of the penis can be affected by temperature, integrity of blood supply, and related neurological conditions. Mild retraction does not mean that a urinary sheath system cannot be used – short-length sheaths have been successful with this group of patients (Pemberton et al, 2006). A recent trial offered significant support for the use of urinary sheaths; noting less urinary tract infection and death over the indwelling catheters (Saint et al, 2006). Adverse outcomes can be reduced if health professionals optimise alternative strategies to long-term indwelling catheters.

Sheaths following prostate surgery

Sheaths are a good non-invasive solution following Prostate surgery. Patterson (2004) highlighted that many men do not receive information about post-operative urinary incontinence, nor are they appropriately referred. Management with a long-term indwelling catheter may expose the patient to complications, including infection (Bissett, 2005; Pemberton et al, 2006). An active continence management strategy for these patients can include the use of a urinary sheath system during pelvic floor exercise programmes and bladder retraining regimens (see case study two).

Functional impairment

They are also a good option for men with functional problems – urine stored in a bag can be especially useful for those in a care programme where they spend time alone between support visits. Despite the technology used to produce modern absorbent pads, removal of the urine away from the body may help prevent skin breakdown.

Neurological impairment

Urinary incontinence needs appropriate management following conditions such as a stroke. It is estimated that up to 52% experience a combination of urge and functional incontinence (Brittain, 2002). It is also a characteristic of other neurological conditions such as multiple sclerosis, Parkinson's disease and spina bifida. The most common bladder dysfunction experienced by clients with these conditions is neurogenic detrusor overactivity (Haslam, 2005).

The associated loss of urinary function that accompanies these conditions can have an intense impact on quality of life. Many are managed with long-term catheters but this may not be the most appropriate option. In the case of male clients, urinary sheaths offer a containment system.

Conclusion

Penile sheaths are successful in the management of moderate to severe urinary incontinence and can provide a suitable alternative to disposable products. However, incorrect size and fitting can also cause anxiety and discomfort. Patients need to be confident in the knowledge that the sheath system is reliable, can be removed and changed easily, is discreet and will cause them no harm.

Case study one

Mr Taylor was referred to the community continence promotion team with symptoms of urgency, frequency, penile pain and incontinence when he stood up. He had type 2 diabetes and had a past urological history of bilateral renal stones, ureterscopy and pyeloplasty and renal impairment.

He had refused further investigations, including urodynamic studies and flexible cystoscopy examination, and previous treatments to manage his bladder symptoms, including anticholinergic therapy, had not been effective. An ultrasound bladder scan excluded overflow incontinence.

Containment represented the most appropriate strategy for the management of his urinary incontinence and the choice was limited to disposable products and urinary sheath systems.

A trial period with a sheath was commenced but the patient experienced excoriation of the penile shaft due to poor technique on removal and sheath detachment when he passed urine. These problems were having a negative effect on the patient's quality of life leading to social isolation, low self-esteem, anxiety and disturbed sleep.

The patient was feeling negative about continuing with the sheath system and reported some disruption in his relationship with his wife and family members.

Changes were made to the management regimen which included the use of a skin protection barrier film to the penile shaft. However, Mr Taylor continued to report problems and requested a change to body-worn absorbent pads.

This case study shows that, despite thorough assessment, patient education and support, a urinary sheath system may not be suitable for all men. Each client must be assessed objectively and individually, with treatment and management planned accordingly.

Case study two

Mr Jefferies is aged 69 and was recently discharged from hospital following a transurethral resection of prostate. He attended the continence clinic one month after his surgery with urinary urgency and nocturnal enuresis. He had no other health problems and before his prostate problem enjoyed regular holidays with his wife.

He reported that he was distressed and embarrassed by his urinary incontinence which had caused him to move in to a separate bedroom at night. Although he was using continence pads purchased by his wife he was not happy wearing them. Mr Jefferies was also worried his children and grandchildren might be able to smell urine when they visited.

A bladder ultrasound scan confirmed that no significant residual urine was present in the bladder and routine urinalysis showed no sign of urinary tract infection. Mr Jefferies reported a regular bowel pattern with no strain and a daily fluid intake of approximately 1200ml, consisting of tea, juices and two mugs of coffee each day.

Mr Jefferies requested a management plan to enable him to resume his activities outside his home and help him with urinary leakage at night.

He was measured for a short-length silicone urinary sheath (Conveen Optima) as he felt it was the easiest to apply. This was attached to a 500ml anti-kink leg bag and supported with a catheter retention strap and leg bag retention sleeve. Correct measurement of the leg bag outlet tube length is vital to achieve optimum positioning for emptying the bag. It was also emphasised that the leg bag must remain securely in place on the leg when a night drainage bag is attached for use in bed. Failure to follow this advice may result in the sheath becoming detached during the night.

Following a period of initial adjustment and after starting a pelvic floor exercise programme, Mr Jefferies was able to adopt the urinary sheath system and stop using continence pads. At his review he reported he had returned to sharing a bed with his wife and he was considering booking a holiday.

After six months he reported a significant improvement in his bladder function and was only using the urinary sheath at night and during long journeys. The use of a urinary sheath system significantly improved Mr Jefferies quality of life and enabled him to manage his urinary incontinence with greater confidence.

4. Living a normal life

If you have urinary incontinence, you know it's not just a health issue. It can be a social issue too. Incontinence can interrupt daily life and even keep you from going out for fear of leakage.

In this section, the benefits of a reliable and discreet solution for men are documented. The testimonies point toward a system which meets the end-user's needs and enables them to get back to living a normal life, despite their urinary incontinence. The solution consists of a Conveen Optima urinary sheath and a Conveen Active leg bag.

Denis Fernandez, 65

When Denis Fernandez was treated for a prostate cancer, he wondered whether he'd ever return to the active life he'd always enjoyed. Between his work life, his family and the many activities and hobbies he enjoys, Denis Fernandez has led a very active life. "I've had all sorts of jobs – bookseller, optician, accountant, and I also worked in the public administration. The same goes for my hobbies," says the 65-year-old.

Denis has plenty of interests, but nothing has meant more to him over the years than sport. "It's been a big part of my life," he says. "I'd been in all sorts of competitions, and was even being paid for it. But a lot of it had to end when I got sick." The progress of the disease and the operation itself meant that Denis could no longer control when he had to urinate. That put a lot of his favourite activities out of reach. "There are a lot of situations where you can't just run off to the loo every 10 seconds," he explains.

"Now I'm able to live an active life again!"

Eventually, Denis discovered Conveen Active. "It was an amazing discovery," he says. "I just put this little bag on the inside of my thigh, and it has enough capacity for me to be able to do whatever I want."

For Denis, "whatever I want" amounts to quite a list: "Well, I train at least every other day, either rollerblading or triathlon sports. I also cycle a lot, and I've even started doing Nordic walking." When asked about the difference Conveen Active has made, Denis pauses for a moment before concluding: "Today, I'm resuming activities I did before and who knows, I might even get back to ballroom dancing."

Bernard Reilly, 51

Bernard Reilly is enjoying his return to a more normal life after discovering Conveen® Active and Conveen® Optima. Bernard feels he has a lot to be thankful for. He and his wife Brenda recently celebrated their silver wedding anniversary, and he's back to living a normal life after several months of uncertainty.

Bernard and Brenda like spending their spare time together, often taking walks in the local parks. In October 2010, however, Bernard was diagnosed with prostate cancer and had his prostate gland removed. "After the operation," Bernard says, "the next challenge then was trying to live with the incontinence."

Bernard tried different solutions – starting with pads. But these didn't work for him, and he gradually lost his confidence because of the incontinence: "It stopped me doing a lot of things which I took for granted like actually just getting out the front door of my home and trying to lead a normal life."

All that changed, however, when a Conveen Active brochure arrived with the post. "When I showed my continence nurse the brochure, she made a couple of phone calls and had sample products delivered to myself and to the clinic," he recalls.

"I tried the new bag, got on great with it, it was a huge improvement. It's given me lots and lots of confidence now not to even think twice about going out and about."

Now, after several months of using Conveen Active and Conveen Optima, Bernard can reflect on how it has affected his life: "The biggest impact that it's had on my life is that it's changed my life. My wife Brenda and son Steven have got the old Bernard back, thankfully, and I went from never, ever thinking I'd get back to work and seeing my old colleagues to actually getting back to work, doing my old job and back to normal."

"I could tell he was feeling a lot, lot better when he started to plan for next year and that we are going to go on holiday"

Brenda Reilly

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The Coloplast story began back in 1954. Elise Sørensen is a nurse. Her sister Thora has just had an ostomy operation and is afraid to go out, fearing that her stoma might leak in public. Listening to her sister's problems, Elise creates the world's first adhesive ostomy bag. A bag that does not leak, giving Thora – and thousands of people like her – the chance to return to their normal life.

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