CONFERENCE PROGRAM

ABSTRACTS

Innovating for Continence:
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TAMSULOSIN ("FLOMAX") USE FOR WOMEN WITH BLADDER OUTLET OBSTRUCTION IN THE NURSING HOME: DEMONSTRATIVE CASES AND EXAMPLES OF THE BENEFIT OF COLLABORATIVE WORK BETWEEN GERIATRICIANS, NURSES AND A CONSULTING UROGYNECOLOGY NURSE PRACTITIONER

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Introduction: Incontinence is present in more than half of all nursing residents. It is associated with falls, urinary tract infections, pressure ulcers and dermatitis. Tamsulosin ("Flomax"), an alpha blocking agent commonly used in men with benign prostatic hyperplasia, has been used in women with functional or anatomical bladder outlet obstruction, but its use is controversial, because there are few high quality studies documenting its efficacy in women. The use of this agent has been rarely described in the literature in female residents of long-term care facilities. The following are two examples of its use in nursing homes.

Case 1: 74 year old woman with moderate dementia admitted from home because of need for increased supervision. During her admission at the nursing home she developed more frequent episodes of urinary incontinence. She was diagnosed and treated for two urinary tract infections. About nine months after admission, a urogynecology nurse was consulted. The patient complained of urinary obstructive symptoms and was started on a regimen of treatment including tamsulosin. In addition geriatrics staff reviewed the case and recommended stopping nortriptyline, which the patient was taking for depression. The tamsulosin was well-tolerated, and the patient had decreased daytime incontinence and the patient felt she was able to void more easily.

Case 2: 84 year old woman with a history of weight loss, urinary incontinence, constipation, and groin discomfort, was referred for evaluation to a urogynecology nurse. The patient was found to have a posterior pelvic mass associated with urinary retention. The urogynecology nurse recommended interventions including a pelvic ultrasound, a bowel regimen and tamsulosin. The patient was found to have a pelvic mass which was likely a malignancy; she and her family decided to pursue palliative management. On a bowel regimen and alpha blocker the urinary retention and constipation improved. The patient expired, but staff and the patient’s family felt her quality of life had improved with amelioration of her bladder obstruction.

Discussion: Tamsulosin ("Flomax") is an alpha-blocker, thought to function at the bladder neck, leading to improved urine flow. Its use is controversial in women: there are few high quality studies involving women and many geriatricians have concerns about the potential side effects (e.g., orthostatic hypotension, increased congestive heart failure incidence). Tamsulosin has been recommended by many urologists in certain women with functional or anatomical bladder outlet obstruction, but its use has been rarely described in older women in nursing facilities.

Conclusion: In these two cases, tamsulosin was used as part of a multidisciplinary intervention led by a urogynecology nurse practitioner involving a search for causes (including constipation and an anatomical obstruction), behavioral modifications, and medication adjustment. These cases demonstrate how an aggressive and complete investigation of incontinence can lead to an appropriate management plan and improved quality of life.

Urinary incontinence in female nursing home residents should not be accepted as inevitable and untreatable, but should merit a full evaluation. Geriatricians should familiarize themselves with the medical management of women with incontinence, and consider the use of alpha blockers such as tamsulosin in women with bladder outlet obstruction, after optimization of other risk factors.

Conflicts of interest: None
SYNCHRONIZATION OF BILATERAL NEUROMODULATION IN BLADDER CONTROL

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Introduction: InterStim® Therapy, usually uses unilateral electrical stimulation of the sacral spinal nerve (SN, S3), to relieve symptoms of urge incontinence and increased frequency. Using the rat bladder rhythmic contraction (BRC) model, we characterized the effectiveness of three stimulation modalities: 1) bilateral stimulation with phase-matched individual pulses, 2) bilateral stimulation with phase-mismatched pulses, and 3) unilateral stimulation of a single SN root sequentially with stimulation of the alternate side.

Methods: In anesthetized female rats (urethane, i.p. 1.2g/kg), two wire electrodes were placed under the L6 SN roots. A cannula was placed into the bladder via the urethra and the urethra was ligated, resulting in an isovolumetric bladder preparation. Saline infusion induced the BRC reflex. Effect of SN stimulation on the BRC was evaluated.

Results: There was no significant change in BRC during a 45 min recording if electrical stimulation was not applied (n=21). Unpaired Student’s t-test analysis demonstrates that a significant inhibition of BRC frequency is produced by all forms of neuromodulation at motor threshold intensity, 10 Hz for 10 mins (pulse width: 0.1 ms, p<0.05, vs. control, n=21, figure). Effect to bilateral stimulation using phase mismatched pulses induced bladder quieting responses was significantly greater than those induced by unilateral SN stimulation alone (p<0.05). However, there were no significant differences in responses to bilateral phase matched stimulation and bilateral phase mismatch stimulation (p>0.05).

Conclusions: We demonstrate in a preclinical model that bilateral stimulation produces a stronger inhibition of the bladder micturition reflex than sequentially unilateral stimulation. The increased effectiveness of bilateral stimulation does not require precise pulse locking of stimulation (e.g., on each lateral SN). Potential applications of bilateral stimulation should be further evaluated further in a clinical setting.

Source of funding: Medtronic, Inc.

Conflict of interest: Authors are employees of Medtronic, Inc.
INTRAVESICAL DRUG DELIVERY FOR OAB / URGE INCONTINENCE

Daniel Yachia, Innoventions Ltd., Or Akiva, Israel

**Problem definition:** Anticholinergics/antimuscarinics are effective in about 50% of OAB patients. 13-73% of the patients develop systemic side effects (i.e., mouth dryness, constipation) driving to treatment discontinuation.

**Background:** Intravesical application of these drugs is successful for preventing these side-effects, with the main drawback of repeated catheterization. The possibility of retaining these drugs alone or in combination with other drugs, in relatively high local doses for extended periods on the urothelium without risking their systemic toxicity level may have great therapeutic advantages.

**Design description:** The PharmaSphere™ is a novel proprietary intravesical floating system for sustained drug delivery. It has a reservoir/core containing a drug or a combination of drugs in a matrix for sustained release. It will be left in the bladder until the treatment cycle is completed or the drug is depleted. Then it will be removed or replaced with a new one.

**Design validation:** The smooth and floating balloon-like PharmaSphere™ with no sharp edges, the special syringe for filling the reservoir with solid and/or liquid substances, and the insertion and retrieval devices have been developed. Its engineering prevents direct contact between the bladder mucosa and the matrix containing the drug for preventing irritation by the drug.

**Results:** Bench trials with the PharmaSphere™, the special syringe, the insertion and retrieval devices and proof-of-principle for sustained-release were successfully conducted. A series of in-vitro studies for choosing the suitable matrices for short (days) and long-term (weeks-months) sustained-release, for dose and eluting time optimization is on-going.

**Conclusions:** The encouraging results suggest that further development for clinical evaluation for this intravesical drug carrier is justified.

**Source of funding:** Partially funded by the Office of the Chief Scientist of Israel

**Conflict of interest:** The Author is the President, CSO and shareholder of Innoventions Ltd.
AN INTRAVESICAL DEVICE FOR PATIENTS WHO FAILED SUI SURGERY

Daniel Yachia, Innoventions Ltd., Or Akiva, Israel

**Problem definition:** About 30% of patients after stress urinary incontinence (SUI) surgery may need re-treatment within 5 to 7 years. Diapers, vaginal pessaries, bulking injections or intraurethral plugs can be used for managing recurrent SUI.

**Background:** Although intraurethral plug-like devices can block the leaking, the need for removing and reinserting them at each voiding and the high rates of ascending infections made them less acceptable. Innoventions developed a proprietary balloon shaped intravesical sealing device (*ContiSphere™*) for managing such cases.

**Design description:** The *ContiSphere™* has a metal core and using a pad containing a small magnet, the balloon is pulled toward the bladder outlet (BO) to seal it. For urinating, the magnetic pad is removed, allowing the balloon to float, and open the bladder outlet (BO) for voiding. Then the pad is returned to its perineal position.

**Design validation:** The *ContiSphere™* has been validated in simulated bladder models, ex-vivo animal bladders under high intravesical pressures (up to 100 cm H2O). The device could seal the BO completely in all experiments. Its sealing position was secured with the pad and released by removing the pad. Then in animals and in a group of 20 treatment failed patients.

**Results:** Indwelling time was up to 29 days. In 86.3% of the patients the pad weight test was 0 to 3 gr., in 13.6% the use of pads reduced from 4-7/day to 1-2/ day (failures). 20% could not tolerate the feeling of a foreign body in their bladder. Advanced cystocele prevented the device to shape itself to the deformed BO and seal it.

**Conclusions:** This completely intravesical *ContiSphere™* is able stop or significantly reduce incontinence in surgical failure patients having a preserved BO.

**Source of funding:** Self funded

**Conflict of interest:** The Author is the President, CSO and shareholder of Innoventions Ltd.
COMPARATIVE IMPACT OF CONTINENCE PROMOTION INTERVENTIONS TARGETING OLDER WOMEN RELUCTANT TO SEEK CARE FOR URINARY INCONTINENCE

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**Context:** Surveys suggest that only 13% to 50% of older women with urinary incontinence (UI) talk to a health care practitioner about their condition or implement evidence-based treatment\(^1\). Continence awareness programs exist, but their effectiveness remains unknown\(^2\).

**Objective:** To determine the comparative impact of a constructivist learning workshop on UI, an evidence-based self-management tool for UI, or both, compared to the effects of a sham workshop, on incontinent women's perceived improvement in their UI condition.

**Methods:** 2x2 factorial open-label cluster randomized controlled trial testing. The cluster (unit of randomization) is at the level of each local community senior's group, where participants are recruited for the workshops. One of four interventions (3 experimental and 1 sham intervention) is randomly assigned to each community group. Randomization is achieved by computer-generated random digits, balanced in block groups of four.

**Study population:** Eligible participants are community-dwelling, UK women, 60+ years of age, not sought medical advice for incontinence symptoms in the last 5 years experiencing UI with a frequency no less than once weekly.

**Outcomes:** One outcome for the trial is an improvement in UI at three months post-intervention, measured by a rating of improvement on the Patient’s Global Impression of Improvement questionnaire.

**Results:** Six hundred and eighty-seven women attended the workshops. 259 (mean age 71 + 7 years) met eligibility criteria and recruited to the trial. At 3-month follow-up, 24.6% of the combined group reported that their UI condition was very much or much better, compared to 24.5% of the constructivist workshop group alone, 21.4% of the self-management group, and 7.2% of the sham control group (\(p=0.013\)). Less than 5% of participants were lost to follow-up.

**Conclusion:** Interim analysis suggest that a continence promotion intervention combining constructivist learning theory and the use of a self-management tool, has the greatest impact on improvements in UI in older women with incontinence.

**References:**

**Source of funding:** The research reported on this poster was jointly supported by the Canadian Institutes of Health Research and the Economic and Social Research Council of the United Kingdom as part of the Canada-UK Aging Initiative (Grant number 200909CUK-212417, agreement number 00912-001).

**Conflicts of interest:** None. The Investigators retained full independence in the conduct of this research.
ASSESSING THE STIGMA CONTENT OF URINARY INCONTINENCE INTERVENTION OUTCOME MEASURES

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Introduction: The purpose of this study was to assess urinary incontinence intervention outcome measures for stigma content. Individuals are stigmatized when they possess, or are thought to possess, an attribute or characteristic that conveys a social identity that is devalued in a particular social context (Crocker, Major and Steele, 1998). People with continence difficulties are sometimes perceived to be old, dependent and of reduced intellect. Fears of being stereotyped prevent some individuals with continence difficulties from seeking healthcare solutions. Stigma may also serve as a barrier to the use of recommended treatments, products and services.

Methods: A literature review was conducted to identify urinary incontinence intervention outcome measurement tools. Measures were assessed for stigma content using three constructs: perceived-stigma, self-stigma, and enacted-stigma.

Results: Eleven intervention outcome measures were identified. Analyses revealed that more than half of the measures do not have any stigma content. Four measures addressed perceived-stigma, and six measures addressed self-stigma, while one measure addressed enacted-stigma.

Discussion: A representative model is proposed that depicts landmarks and moderators of urinary incontinence stigma, as well as interactions between the individual who has the condition, healthcare and from society at large.

Acknowledgements: This study was funded by a CIHR Canada-UK New Dynamics of Aging grant on “Psychosocial impacts of assistive technology for incontinence” (reference number 200809CUK-193463 – J.W. Jutai - PI)

Conflicts of interest: None
QUALITY OF LIFE SURVEY OF INDIVIDUALS WITH URINARY INCONTINENCE WHO VISIT A SELF-HELP WEBSITE: IMPLICATIONS FOR THOSE SEEKING HEALTHCARE INFORMATION

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Introduction: Urinary Incontinence (UI) affects 200 million people worldwide with annual direct costs in the US alone estimated at $16.3 billion. Those with UI have reported a decrease in general quality of life with symptoms of depression, anxiety, low self-esteem, poor body image, and social stigmatization. The purpose of this study was to examine the feasibility of collecting self-reported quality of life data in a self-selected sample of individuals who visited a website providing information, education, and management suggestions regarding UI.

Method: Participants included 374 individuals with UI who responded to a solicitation for enrollment in a “Continence Comprehensive Health and Life Assessment” survey posted on The Simon Foundation for Continence website (www.simonfoundation.org). Types of problems and events associated with UI, including social connectivity and quality of life, are discussed along with limitations of the study and implications for future research.

Results and conclusions: Given that 13.01% of respondents had not spoken to a healthcare provider about their UI symptoms, 24.73% had never seen a healthcare professional who “specializes in bladder problems,” and 75% said they were not currently using any active approach to managing symptoms, use of such information is discussed in terms of how to better construct internet healthcare information to maximize seeking appropriate healthcare services and preparing internet-based information regarding incontinence diagnosis and treatment.

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Conflicts of interest: None
A PERSON-CENTERED CARE FOR INCONTINENCE MANAGEMENT

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Introduction: Immediate notification that an incontinence article has been insulted with body excreta such as urine or feces and must be changed is an unmet challenge. One of the first-line therapies recommended for an active person with light or moderate incontinence is to provide biofeedback and to manage their symptoms. Analysis of volatile organic compounds (VOCs) from biological samples has gained considerable interest particularly for clinical evaluation and diagnosis. This poster presents the design and clinical evaluation of an electronic nose (e-nose) for insult detection and incontinence management providing real-time biofeedback using personal-communication devices such as a smart phone.

Methods and results: An array of VOC gas sensors that can measure sulfides, aldehydes and ammonia has been designed for ambulatory use. A clinical study was conducted to evaluate the sensors for the real-time detection of insults in absorbent articles. Figure 1 shows the real-time insult detection and the incontinence management system presented in this paper. The sensor responses are read using a mobile device configured to an ad hoc network.

Conclusions: A controlled study conducted with the real-time insult detection system has recorded 55 incidents with wirelessly transmitted data for further analysis. A plethora of options exist for connectivity and annunciation of incontinent or odor events. Clinical services for incontinence management by staff are well described. These systems are complex and specialized for clinical environments. This paper proposes that VOC detection be combined with ubiquitous mobile devices to create a system that is discrete, personal, simple, and mobile to take the place of a friend or family member’s surrogate nose.

Source of funding: Internal

Conflict of Interest: The authors are employees of Kimberly-Clark Corporation.

Figure 1. Real-time insult detection and incontinence management system
DON'T WEE-PELVIC FLOOR EXERCISER
Eleanor van den Heuvel, Felicity Jowitt, Edward Varney, Brunel University, Uxbridge, UK

Problem definition: Urinary incontinence (UI) is known to affect 10-40% of adult women and prevalence increases with age. UI due to weak pelvic floor muscles, stress UI, is the most prevalent condition accounting for 37% of all UI. Weak pelvic floor muscles also contribute to mixed UI which accounts for a further 33% of UI in women. Pelvic floor muscle training (PFMT) has been shown to be effective for treating UI in women of all ages but only 15-20% of women comply with PFMT exercises. Reasons for this lack of compliance include finding the exercises boring, lack of motivation and being uncertain about correct performance.

Background: The device is an improvement over currently available exercise methods and technologies because it addresses the key reasons for non compliance (boredom, lack of motivation and uncertainty about correct performance). Currently available devices (including intra vaginal weights, numerous devices to insert and squeeze, or functional electrical stimulation devices) offer little in the way of feedback to show that exercises are being performed correctly or rewards that would motivate continued performance.

Design validation: We will develop a simple computer game that is controlled by a vaginal interface, where the user is encouraged to squeeze appropriately, to make things happen on a screen. The game will be aesthetically pleasing and will reward users by responding to correct pelvic floor performance. During this short project we will develop the game in collaboration with potential users. User focussed design will be used to develop initial interfaces, employing focus group techniques.

Conclusions: The results from this short project will be used to either commercialise directly, or to develop a more comprehensive research project.


Source of funding: £10,000 Devices for Dignity (D4D) competition winner

Conflicts of interests: None
THE CONTINENCE PRODUCT ADVISOR – A NEW WEBSITE FOR THE SELECTION AND USE OF CONTINENCE PRODUCTS

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Introduction: Appropriate continence product selection can radically affect the quality of life of people with incontinence who are unable to be fully cured, are awaiting treatment or elect not to pursue treatment options. The wide range of available products, the requirement for patient choice and economic pressures mean that careful product selection is increasingly important. The use of available evidence to support decision-making by health care professionals and product users will help to ensure products are matched to need thereby maximising quality of life while avoiding costly purchasing mistakes and adverse effects.

Limitations of existing information sources: Evidence relating to continence products is reviewed and published every four years by the International Consultation on Incontinence (Abrams et al, 2009). Although efforts have been made to improve its user friendliness, it remains in a format aimed at health care professionals. Web-based information often fails to be generic and long-lasting when brand or country specific.

The Continence Product Advisor website (CPA)

This new website provides information which is:

- **INDEPENDENT:** written and reviewed by continence health professionals and users of continence products.
- **EVIDENCE-BASED:** where possible content is based on evidence (or expert opinion if evidence is lacking) with references to sources.
- **GENERIC:** focuses on product designs and types without reference to branded products except when essential.
- **NOT-FOR-PROFIT:** no advertising is displayed, the development and maintenance of the website is funded through educational grants.
- **INTERNATIONAL:** linked to information in different countries for local advice on product availability, guidelines and regulations.

The CPA is an ICI/ICS collaboration; the website has been developed by the Continence & Skin Technology Group (UCL & University of Southampton, on behalf of the ICI) and the IT department of the International Continence Society. The website will be launched in 2013.


Notes: There is no formal funding for this project. We are very grateful to the ICS and their web team for their time and expertise in building the website and to the ICI for providing the content.

Conflicts of Interest: None
A TRIAL OF DEVICES FOR INTRACTABLE URINARY INCONTINENCE FOLLOWING TREATMENT FOR PROSTATE CANCER

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Introduction: Intractable urinary incontinence affects 10-15% of men following radical prostatectomy⁴⁵ and is usually managed using absorbent pads. Male specific devices (sheath (condom catheter), body-worn urinal (BWU), penile compression device (clamp)) are much less commonly used and there is little published research about them. Anecdotal evidence suggests that health care professionals (HCP) lack confidence in recommending and fitting these devices and men have limited opportunity to try devices which they may prefer either instead of or in combination with pads.

Aims: To identify men’s preferences for single or combinations of product designs (devices ± pads)
1. To compare designs with respect to cost to the health service of continence product provision, and out-of-pocket expenses incurred by users
2. To determine if provision of these devices improves the quality of life of such men

Methods: Design: Randomized cross-over trial where 80 men test each device design for three weeks.
Inclusion criteria: History of prostate cancer followed by urinary incontinence managed with pads for ≥12 months.
Exclusion criteria: Known latex sensitivity or faecal incontinence.

Results: Seventy-four men were recruited; 17 withdrew from the study. Preliminary results are presented below (see chart). Full results will be presented at the conference.
At recruitment, 48 men depended solely on pads and eight men also used a sheath (none used a BWU or clamp, although some men had previous unsuccessful experiences of these devices). Three months after testing all devices, although pads remained important for containment, men were opting to use a range of devices to suit their circumstances. For day use when at home, at recruitment only 5 (9%) men were using a combination of pad plus a device; after testing, 40 (71%) men were using a combination of products.

Conclusion: Incontinent men should be offered the full range of containment devices as, with expert fitting, many prefer this to pads only. Initial data show that men use devices discriminately to allow them greater choice and freedom to do desired activities.


Funding: This study is funded by the Prostate Cancer Charity, UK.
Conflicts of Interest: None
IMPACT OF A TELEMONITORING SYSTEM FOR URINARY INCONTINENCE MANAGEMENT FOR RESIDENTS IN LONG TERM CARE

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Introduction: This abstract presents research findings regarding the evaluation of a telemonitoring system for urinary incontinence assessment on care plans and continence outcomes for nursing home patients/resident. Incontinence is a significant and costly condition that impacts the health and quality of life of the individual patients/residents, their families including support networks, and the environment. Current manual incontinence assessment approaches, including the manual checking and charting of bladder patterns, tend to result in poor individual estimation of continence status and as such, a lack of care. The study addressed this gap in current urinary incontinence care by exploring the possibilities for more effective management based on the inputs of a telemonitoring system.

Method: Voiding patterns of 32 patients/residents living in a 120 bed Australian nursing home were measured during a 72-hour urinary incontinence assessment at two different time points. Care plans were generated from the initial telemonitoring assessment (example figure 1). The second assessment (example figure 2) was conducted 2 to 5 weeks after the initial care plan was implemented to allow evaluation of the implemented care plan compared to the base level of care.

Results: The statistically significant outcomes following the implementation of the care plan based on the telemonitoring assessment were: reduction in the volume of urine voided into continence aids, reduction in the frequency of prescribed toileting visits, increased number of actual toilet visits and successful toileting events and an increased level of adherence to the number of toilet visits prescribed in care plans.

Conclusions: An instrumented electronic incontinence assessment tool has the potential to improve continence care outcomes, and related health impacts. The accurate nature of the assessment, as well as the increased interest in effective continence care, were two factors identified in delivering the improvement in outcomes.

Source of funding: Simavita Pty Ltd provided funding for the University of Wollongong to undertake the research study.

Conflict of interest: None

Figure 1: Initial incontinence assessment patient Mr. X

Figure 2: Second incontinence assessment patient Mr. X
CATHETER LENGTH PREFERENCE IN MALES WHO USE A WHEELCHAIR AND PERFORM CLEAN INTERMITTENT SELF-CATHETERIZATION

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Introduction: This study investigates the overall preference and ease of use characteristics of two different lengths of intermittent catheters for males.

Aims/Methods: The primary objective of this study was to assess user preference between intermittent catheters of two different lengths (30 cm and 40 cm) and otherwise identical construction. Secondary outcomes included assessments of including ease of insertion and removal, ease of controlling the catheter when inserting into the urethra, ability of the catheter to drain the bladder and ease of draining into a urine receptacle.

One response indicating preferred catheter length (30 cm or 40 cm) was reported by each participant, along with all associated reasons for that preference. Responses to ease of use questions were reported on a five point Likert scale (“Very Easy” to “Very Difficult”) and the analysis was limited to the last catheterization for each test product. The percentage of positive responses for each catheter type was calculated using the Pearson chi-square test for association (α=0.05, two-tailed).

Results: Approximately 91% preferred the longer catheter (CI: 91.4±0.6), with the top three reasons cited for such preference as ‘More satisfactory length for me’, ‘Drained bladder more completely’, and ‘Easier to drain into a receptacle’. The longer catheter also had significantly higher percentages of positive responses to all five secondary ease of use characteristics assessed (p<0.05).

Conclusions: Male patients who use a wheelchair prefer to perform clean intermittent catheterization with the standard 40cm catheter length when compared to a shorter 30cm length in an otherwise identical catheter. One of the most frequently reported reasons for preference of the longer catheter was that it ‘drained bladder more completely.’

Source of funding: This study has been funded by Hollister Incorporated

Conflict of interest: Melissa Menier is an employee of Hollister Incorporated. Dr. Joseph Costa has received research support from Hollister Incorporated.
LAPAROSCOPIC IMPLANTATION OF NEUROMODULATORS FOR TREATING BLADDER AND LOWER LIMB SPASTICITY AND PROMOTING MICTURITION IN SPINAL CORD INJURED PATIENTS – CASE REPORT

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Introduction: Pelvic organ autonomic disorders and lower limb spasticity and atrophy are among the most important factors affecting morbidity and quality of life of thoracic spinal cord injured patients.¹ Recently, the laparoscopic implantation of neuroprosthesis (LION) is figuring as a possibly more specific and selective treatment for these affections.²

Objective: Evaluate the effect of the LION procedure on bladder and rectal function and lower limb spasticity and contractility, to promote an alternative locomotion to thoracic spinal cord injured patients.

Methods: We report our first case of a LION procedure. The patient is a 29 year-old man, with C7-Th1 (neurological Th3) automobilistic spinal cord injury since age 18 years, classified as grade B (ASIA), only due to rudimentary anal sensitiveness. Electrodes were implanted justaneurally to the pudendal, sciatic and femoral nerves.

Results: At one month follow-up bladder spasticity was completely resolved and bladder capacity doubled (190mL pre-op to 380mL post-op). Moreover, the patient was able to extend the knee from postoperative day one. Thirty-two days after surgery, the right femoral nerve electrode was misplaced, requiring a reintervention and postponed the standing up training. At two-months follow-up thighs circumference increased from 38.5cm (right) and 42cm(left) to 40cm(right) and 42cm(left). He is showing some voluntary pelvic floor contraction, sensitivity improved on Th4 to Th11 and L2 to S4 dermatomes with the stimulator turned on, and on Th4 and Th5 with it turned off. The stand up and walking training is planned to start at post-operative three months, in January.

Conclusion: The LION procedure offers new target nerves for modulation and is a promising method for motoric and urologic rehabilitation in spinal cord injured patients.


Acknowledgements: This study is approved under the Ethics in Research Board of the Federal University of São Paulo, under the protocol 19626.

Conflicts of interest: None

Figure: Electrodes Placement: A – left femoral nerve; B – left sciatic and pudendal nerves; C – right femoral nerve; D – right sciatic and pudendal nerves (PM – Psoas Muscle; IS – Ischial Spine; SN – Sciatic Nerve; SSL – Sacrospinous Ligament)
THE ECONOMICS OF MENALIND PROFESSIONAL SKIN CARE PRODUCTS

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**Aim:** To evaluate the economic benefits of Menalind professional skin care products compared to current practices for skin care for residents with incontinence in aged care residential facilities.

**Background:** More than 50% of nursing home residents are incontinent of urine and/or faeces. A consistent approach to skin care for residents with incontinence is deemed essential for the prevention of incontinence-associated dermatitis (IAD). The use of a pH balanced cleanser, protection cream, and moisturising body lotion can also reduce the incidence of pressure ulcers and skin tears associated with incontinence and at-risk skin. Lewis-Byers and Thayer noted that costs of care escalate when additional caregiver time and supplies are required to care for damaged skin.

**Method:** 19 residential care staff completed a product evaluation of the Menalind products at nine residential care institutions in NSW. Detailed data regarding current practice was collected, a cost model was developed to quantify resource utilization and calculate the cost of different approaches to skin and incontinence care, and a literature review was undertaken.

**Results:** 19 caregivers from 9 residential care institutions trialled the Menalind products and completed an evaluation form. 47% of caregivers saved an average of 4 minutes per cleanse using the Menalind cleanser compared to soap and water. There was general consensus regarding an improvement in skin condition with the Menalind protection cream compared to Sorbolene.

**Summary:** Menalind products are an economic alternative to traditional soap and water skin care regimes as well as to current practice protocols using more advanced products. Even where the purchase price of products is significantly higher, the additional cost of products is more than offset by the cost savings associated with caregiver time and face washer laundering associated with using Menalind.

In addition to this, the cost saving of implementing Menalind professional skin care products protocol will be even greater if the professional products and standardised protocol can reduce skin damage such as IAD, pressure injuries or skin tears.

**References:**

**Conflict of interest:** Ms. Sue John was commissioned as a health economist, by HARTMANN to conduct this study.
TOWARDS MODERN USER-RELEVANT ASSESSMENT OF INCONTINENCE PRODUCTS: WSP 354.1 (11)

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Introduction: Incontinence sufferers benefit from industry initiatives which improve performance testing of absorbent products.

Development: EDANA with member companies support the ISO 16021 position that freedom from leakage is the most important factor when evaluating incontinence products for use. Freedom from leakage depends on product-, user- and usage related factors together, as described in ISO 15621. The need for product capacity will depend on all factors, therefore e.g., circumstances of the user situation should also form part of any assessment - elements which are not reflected in the current ISO 11948 standard.

The industry has developed a new user like laboratory method taking into account features known to have an effect on product leakage, measuring the capacity of incontinence products, and replacing the previous "one-dimensional" absorbency measurements. The new ‘Absorption before leakage’ (ABL) test method measures capacity of incontinence products for moderate and severe incontinence for non-ambulatory patients.

The ABL test method is a laboratory test method for product capacity, designed to give results as close as possible to in-use-reality and was validated with in-use in nursing homes.

Products covered: The new test can be applied to all-in-one type of briefs (from XS to XL) and to two-piece products (pads together with a fixation pant), but it does not include pull-on pants.

Benefits: The new test differentiates product capacities of products as a result of both the absorption and the product design features.

With this ABL test method, healthcare professionals will have a foundation to select and prescribe a product targeted to meet the individual’s capacity needs in care settings (non-ambulatory wearers).

Next step: EDANA is also developing lab test methods for products designed for mobile users. A project targeting people living in their own homes is already on-going with a user-trial and initial laboratory work.

Source of funding: EDANA, the International Association for Nonwovens and Related Industries, and its member companies

Conflicts of interest: None
MEASURING THE ABSORPTION PROPERTIES OF SUPERABSORBENT----- POLYMERS USING A MODIFIED ABSORPTION AGAINST PRESSURE METHOD

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Background: Superabsorbent polymers (SAPs) can absorb and retain under pressure large quantities of fluid, making them the ideal component for absorbent products. In order to model the behaviour of SAP in the core of such pads, there is a need to determine their swelling kinetics and other parameters such as porosity\(^1\). The work described here aims to develop a suitable methodology for understanding SAPs’ behaviour.

Methods and materials: The method chosen was based on a standard EDANA\(^2\) method used to measure the fluid uptake by demand by a SAP – absorption against pressure (AAP). The AAP setup (Fig. 1) consists of a cylinder with a mesh on the bottom on which the SAP is spread. A uniform pressure is applied to the test portion (0psi, 0.2psi or 0.5psi). After an absorption contact time of 1 hour, the cylinder is removed and weighed to determine the amount of fluid absorbed. Methodology was developed by modifying it to also determine for SAP volume and porosity. Firstly, the experiment was stopped after predetermined times (2 to 120min). The SAP mass was recorded and then the excess saline was removed by placing the apparatus repeatedly on paper towels until the SAP turned white (dry). SAP mass (excluding interstitial saline) was recorded again. The SAP was then placed in a measuring cylinder and liquid pycnometric measurements were used to determine the volume of SAP.

Results and discussions: Results on E2444 SAP are reported. The mass of SAP varies with time and pressure as expected and the volume of SAP varies accordingly. The porosity of the SAP shows an initial sudden increase followed by a slower decrease for higher values of time. The porosity varies with pressure, with approximately 40% decrease from 0psi to all other pressures.

Conclusions: The methodology developed provides information that may be used to interpret the polymer’s absorption capacity and under conditions where the porosity of the swollen gel and the pressure applied are controlling factors.


Source of funding: This project is fully funded by BASF, Germany.

Conflict of interest: None

Fig.1 Absorption against pressure experimental setup.
AN EXPERIMENTAL VALIDATION OF A THEORETICAL MODEL FOR FRICTION BETWEEN NONWOVEN FABRICS AND SKIN

Vasileios Asimakopoulos, University College London, London, UK

Introduction: Incontinence is a very common problem among the British population. Pad wearers often get sore skin due to abrasion damage from friction. Cottenden (2009) have developed a theoretical model for explaining the friction between skin and the pad fabric that goes against the skin which is made from nonwoven fabrics.

Aim: The aim of this project is to validate this theoretical model through a series of experiments, divided in three different strands, which advance successively the work to more complicated stages.

Methods and results: This poster focuses on the first strand, which involved experimenting on rigid cones that is the shape that approximates better on portions of the human body. I chose rigid cones to isolate the factor of geometry allowing the study of just this factor. The experimental procedure is presented in Figure 1. If the model is correct, data from different pathways over different cones should all fall on the same linear plot, for which the gradient is defined by the coefficient of friction between the cones and the fabric. As I present in the poster, the results of the three cones do have very similar gradients that correspond to practically the same coefficient of friction, validating in this way the model.

Conclusion: Until now I validated the model for the rigid cones, showing results produced by the model are not affected by different geometrical shapes. The second strand involves conducting friction experiments on compliant arms that are made of foam which simulates better the behaviour of soft tissues. Finally, the next step is to perform friction experiments on real human skin in vivo on a number of volunteers.

Source of funding: The researcher funds this work using mainly his own resources.

Conflict of interest: None

Figure 1: The setup of a friction experiment on rigid cones. The yellow lines show the fabric pathway.
ADOLESCENT PELVIC HEALTH EDUCATION: PREPARING YOUNG WOMEN FOR LIFECOURSE EXPERIENCES WITH CREDIBLE MEDICAL ACCESSIBLE GUIDANCE

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Background: With health care providers and the public becoming more aware of female pelvic floor disorders (PFD), (e.g., urinary incontinence, pelvic pain, pelvic organ prolapse) as public health concerns due to their cost and impact on women’s quality of life, most women are unsure of basic pelvic anatomy and muscular/organ function, or when it is appropriate to seek care. Life events including menarche, sexual activity, pregnancy, childbirth, and menopause can have an impact on pelvic health. While the number and severity of PFDs increase with age, pelvic conditions can appear in adolescence as constipation, menstrual-related conditions, urinary tract, yeast, and sexually transmitted infections. Basic pelvic health education, currently nonexistent, may prepare young women to prevent PFDs and/or improve healthcare seeking.

Purpose: This study explored the effectiveness of adolescent females’ knowledge, perceptions and behaviors related to pelvic health (i.e., bladder, bowel, uterine, vaginal health and pelvic muscles/structures) through a school-based six-week curriculum.

Methods: A multisite, pre-post staged-intervention study design assessed baseline knowledge, perceptions and behaviors and post intervention change among female adolescents at three geographically-diverse urban schools with a curriculum adapted from a community-based women’s health promotion program and tailored for cultural relevancy. See Figure 1.

Results: Baseline data suggests participants had little knowledge of their bodies, pelvic function nor pelvic conditions. Statistically significant post-intervention improvements were made in the intervention versus the delayed-intervention group for all knowledge and most behavior questions. Survey results suggest experience with pelvic dysfunction with a surprising 63% reporting some level of stress urinary incontinence (SUI), leaking urine with laughing, coughing and sneezing; and a large percentage, almost 70%, reporting nocturia or waking up at night to urinate.

Conclusions: Short-term pelvic health education may be effective at building knowledge in adolescent girls with which to navigate lifecourse events, prevent future PFDs, and establish healthy behaviors toward overall pelvic health.

Acknowledgements: This research was supported by a Pfizer Investigator Initiated Research Grant (WS805964).

Conflicts of interest: None

FIGURE 1: SIX DAY ADOLESCENT PELVIC HEALTH EDUCATIONAL CURRICULUM

<table>
<thead>
<tr>
<th>Day</th>
<th>Content</th>
<th>Name of Learning Module</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cultural Views of the Female Pelvis</td>
<td>Back To Basics</td>
</tr>
<tr>
<td></td>
<td>Importance of Pelvic Health</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Physiology: Pelvic Anatomy and Organ Function</td>
<td>My Goodies</td>
</tr>
<tr>
<td>3</td>
<td>Introduction to Pelvic Muscles and Structures</td>
<td>The Power Of The Pelvis</td>
</tr>
<tr>
<td>4</td>
<td>Lifecourse Events (e.g., menstruation, ovulation, pregnancy)</td>
<td>More Than You Could Ever Imagine</td>
</tr>
<tr>
<td>5</td>
<td>Symptomatology and When to Seek Care</td>
<td>Taking Care Of U</td>
</tr>
<tr>
<td>6</td>
<td>Review and Why Pelvic Health Matters</td>
<td>Putting It All Together</td>
</tr>
</tbody>
</table>
THE CRYPTIC DAMAGE OF CLOSET INCONTINENCE: SHIFTING RECOGNITION TO SHRINK STIGMA

Sherrie Palm and Lynn Gunn, Association for Pelvic Organ Prolapse Support, Mukwonago, WI, USA

**Problem:** For decades the medical community treating and the individuals experiencing continence concerns have been cognizant of its existence; incontinence has multiple causal factors and impacts the lives of hundreds of millions of people worldwide. Despite its commonality, significant stigma still exists. In the past decade, a multitude of continence pharmaceuticals and products have been marketed, but little has shifted regarding stigma. Our goal is to examine the intimate impact of incontinence and find pathways to reduce stigma.

**Background:** APOPS mission is to establish recognition and understanding of pelvic organ prolapse as well as assist, support, and encourage women as they navigate the diverse physical, emotional, social, and sexual impact of POP. Women experiencing POP must address multiple symptoms that involve impactful personal and social stigma including but not limited to incontinence concerns. APOPS has initiated multiple avenues to encourage women to come out of the closet and participate in open dialogue and share how embarrassing symptoms have disrupted their lives. By introducing topics on our Facebook Chatroom that seldom get discussed openly, we encourage dialogue which evolves into substantial support between members, a valuable step toward the comfort zone. Other channels APOPS engages in to evolve open exchange include addressing incontinence and aspects of impact during call in radio programs, television opportunities, and introducing targeted layers in magazine articles.

**Design description:** Initiating a targeted campaign to focus on educating the general population rather than patients currently recognizing and being treated for incontinence could facilitate recognition of the multitude of incontinence concerns kept behind closed doors. Dialogue and educational display in multiple avenues of media, radio, TV, and magazines must incorporate discussion related to explicit aspects of intimate impact to establish recognition and soften the stigma, similar to campaigns utilized for erectile dysfunction.

Live media interviews that include targeted questions related to impact to sexual intimacy, impact to employment, and impact to fitness regimens may introduce recognition of causal factors that can and should be acknowledged and addressed as well as initiate a domino effect related to open dialogue about awkward topics. Magazine ad campaigns that are compact, concise, impactful, can establish recognition of commonality and soften the stigma. Introducing stigma related topics in the APOPS Facebook Chatroom on a continual basis creates a comfort zone for women once shy about but now comfortable with sharing personal information. As media becomes more open about including these topics during prime time slots and they are discussed openly, the potential increases for those suffering in silence to recognize they are not alone. Repetitive discussion about embarrassing topics softens stigma and enables individuals to admit to incontinence concerns.

**Design validation:** Detection of common denominators of incontinence in the average person’s life will establish recognition of the value of treatment intervention as opposed to simply living with continence concerns because of fear or embarrassment. As media opportunities increase, influx of those seeking guidance will substantiate whether or not there is value in encouraging those who currently have little voice to openly acknowledge incontinence. Tracking flow of incoming individuals looking for guidance post media events will validate whether there is value in this direction.

**Conclusion:** Establishing the connection between aspects of our lives most people experience and the commonality of incontinence may enable people to speak more freely about it and shift understanding and stigma.

**Source of funding:** None

**Conflict of interest:** None
THE IMPACT OF MESH IMPLANTATION ON VAGINAL SMOOTH MUSCLE INNERVATION AND CONTRACTION

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Introduction: To improve anatomical outcomes, mesh is increasingly used in the surgical repair of pelvic organ prolapse (POP). However, the use of mesh is limited by mesh related complications, including vaginal erosion. With the vagina being a central component of pelvic support, and vaginal smooth muscles playing a major role in the ability of the vagina to perform this function, we sought to evaluate the impact of mesh on vaginal smooth muscle; hypothesizing that the new generation of large pore, lightweight, low stiffness meshes would provide a more protective effect.

Methods: The study included 28 parous non-human primates (Rhesus Macaques) that were randomly selected for Sham (N=7) or mesh implantation with stiffer mesh Gynemesh™ PS (27.5±2.7 N/mm, N=7) vs two lower stiffness meshes, UltraPro® (0.009±0.0016 N/mm, N=7) and SmartMesh™ (0.18±0.026 N/mm; N=7). Mesh was implanted via an abdominal sacrocolpopexy procedure, and the mesh-tissue complex was harvested 3 months later. Each complex was evaluated to determine smooth muscle function after depolarization with KCl, in addition to histological evaluations of overall tissue morphology and peripheral nerve density. Results were statistically compared using One-way ANOVA and Dunnett’s test (post-hoc).

Results: The mean nerve density following Gynemesh PS implantation was .004%, which amounted to an 80% decrease relative to Sham (P=0.038). Comparisons of the same regions for SmartMesh and UltraPro showed no significant difference. Gynemesh PS also had the greatest negative impact on vaginal contractility, with a force generated that was decreased by 80% relative to Sham (P = 0.001). SmartMesh also decreased, but by a lesser degree (48%, P = 0.016). No significant differences were observed with UltraPro (P = 0.16).

Conclusions: Implantation with the stiffest mesh, Gynemesh PS, led to the greatest decrease in smooth muscle innervations and contraction, while implantation with the lower stiffness meshes had less of an impact.

Source of funding: NIH R01 HD061811
Conflicts of interest: None
EVALUATION OF LONG TERM PERFORMANCE UTILIZING A HIGHLY ABSORBENT INCONTINENCE PRODUCT IN A LONG TERM CARE SETTING AND ITS IMPACT ON OVERALL SKIN HEALTH

Karen Lou Kennedy-Evans, KL Kennedy, LLC, Tucson, AZ, USA

Background: A high Trans Epidermal Water Loss (TEWL) rate is indicative of a greater chance of skin breakdown due to exposure of the effects of urine and stool resulting in a higher moisture level on the skin. A lower average reading indicates a lesser likelihood of skin breakdown and other related complications. A previous study on TEWL indicated many currently used incontinence products on the market today have a TEWL rate 3-5 times greater than the highly absorbent brand in this study (Tranquility Brand products manufactured by Principle Business Enterprises, Inc.). These findings suggest incontinence, as a contributing factor in pressure ulcer development, which can result in a delay in healing of skin challenges, may be positively impacted by the reduction of the amount of moisture (urine and stool) which is coming in direct contact with the skin.

Question/Purpose/Aim/Objective: “Can the skin under the highly absorbent incontinent brief be as dry after 8 hours of urine incontinence as that of a resident/patient’s skin being changed every two hours with the “house brief”? To determine the effects of diaper selection utilizing TEWL rates in elderly institutionalized adults and monitoring those changes while in the study’s with highly absorbent briefs (using Tranquility Brand) compares to used to capacity or up to 8 hours whichever comes first. The final TEWL readings will determine if a lower average TEWL rate may be maintained while wearing the studies highly absorbent brief (Tranquility Briefs) for longer periods of time then standard changing protocol every 2 hours, resulting in both medical and fiscal efficacy.

Brief review of salient literature: Akin’s (1997) work suggests that urinary containment products with the same materials but with different construction methods can impact skin barrier function.

Methods: 20 elderly institutionalized subjects (EIS) underwent TEWL readings with their usual & incontinence management product (UIM) and measurements were taken using a vapometer device manufactured by Delfin. Subjects were acclimated to a superabsorbent gelling incontinence brief (SGB). Subjects underwent repeated TEWL measurements for 14 days. Ten of the study subjects were monitored up to 8 consecutive hours in a single brief, TEWL readings were measured and recorded approximately every 2 hours on same residents per the facility schedule for checking and monitoring residents. The patients returned to UIM/ house product at the conclusion of the study. Clinical observations of skin health were also recorded. Data was collected by independently contracted nurse researchers.

Measurement instruments: TEWL readings were taken using a Vapometer (Delfin Instruments, Kuopio, Finland). The device is a non-invasive closed chamber system which calculates the evaporation rate from the increase of relative humidity in the measurement chamber. Ambient air flows do not disturb the measurement. Measurements are not affected by the angle at which the device is held. The device has been used in a number of published studies and has shown clinical accuracy in both low and high evaporation states.

Results: Initial TEWL readings with UIH Briefs revealed 13 residents with readings greater than 200 gm/m². One of the residents had a reading greater than 675 gm/m². These initial readings indicate an extremely high moisture level against the skin of these residents. Mean baseline TEWL readings prior to the SGB were 265.82 gm/m². SGB mean baseline TEWL readings decreased to less than 100 gm/m² within 24 hours after changing to the SGB with mean readings of 42.74 gm/m² making this statistically significant. Residents participating in the “8 hour” study achieved an average 622% reduction in the TEWL moisture level readings upon conversion to the highly absorbent brief.

Statistical analysis: There is statistical significance at P<0.05


Funding source: Funding was provided by Principle Business Enterprises, Inc.

Conflict of interest: The author is a member of Principle Business Enterprises Technical Advisory Board.
IMPROVING POTENTIAL FOR POSITIVE OUTCOMES
BY UTILIZING INDIVIDUALIZED CONTINENCE CARE ASSESSMENTS
OF RESIDENTS IN CANADA AND THE UNITED STATES

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PROJECT LEADER: Laura Gunter²
CONTRIBUTING AUTHOR: Diane K. Newman⁴

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Introduction: Assessment tools for incontinence management utilized by healthcare professionals
across care settings generally do not fully define the characteristics to be considered when providing
best care, since they are mostly limited to a collection of numerical data values that only partially describe
the real-world needs of the individual. Without full understanding of an incontinent individual’s needs,
care interventions may be limited or not as effective, leading to resident and family dissatisfaction and
frustration with the care process as well as interference with support staff job satisfaction. TENA Portraits™,
developed by SCA, was created to help more holistically meet the assessment needs of staff so they may
anticipate steps for provision of best continence care.

Method: The TENA Portraits™ system was validated across over 400 care homes in the long-term
care setting with a companion taxonomy utilizing ADLs and other insights to define the needs for each
resident. Over 15,000 residents were evaluated through the TENA Portraits™ process to formulate a more
comprehensive individualized care assessment for those experiencing incontinence. Illustrative Case:
Mr. A was identified as a “Charlie” with certain parameters that could be optimized. Recommendations
for improving his quality of life were identified and implemented, with improvements realized in level of
continence, overall mood, and socialization.

Results: As tested, the TENA Portraits™ process complemented the MDS assessment process,
providing more comprehensive evaluations to improve understanding of the individualized needs of each
resident. This data was then reviewed with staff to assist in forming recommendations to generate more
complete and effective plans for continence care, promote more appropriate product selection, and
identify opportunities for restorative toileting programs to improve quality of life.

Conclusions: Across the continuum of care, individuals who experience incontinence face the risk of
being inaccurately assessed and not receiving the most effective care plan to support greater dignity
and independence. The TENA Portraits™ process provided additional understanding of the base and
contributing factors for this condition, leading to heightened awareness among care staff. This helped
influence staff understanding of how to complete more comprehensive assessments and care plans for
improving the quality of care. This process warrants further study in the long-term care setting to look for
similar results across more centers. Additional studies are also needed in other care settings such as
home care and acute care, since it may support similar improvements and potentially reduce risk during
care transitions.

Source of funding: Developed and funded by SCA Personal Care, Inc.
Conflict of interest: Authors are employees of SCA Personal Care, Inc. Diane K. Newman,
DNP FAAN BCB-PMD is a consultant to SCA.
REVIEW OF BEDWETTING TREATMENT PRACTICES IN CHILDREN USING THE BELL AND PAD TREATMENT WITHIN HOSPITALS, COMMUNITY CONTINENCE CLINICS AND A PRIVATE PRACTICE

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²Ramsey Coote Instruments, Melbourne, Australia
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⁴Royal Children’s Hospital, Melbourne, Australia

Introduction: Bedwetting (or Nocturnal Enuresis - NE) is a widespread and distressing condition that can have an impact on the child/young person’s behaviour and on their emotional or social life. This abstract will present interim results that evaluate the use of the bell and pad treatment for children with Nocturnal Enuresis (NE) between the ages of 6-15 years and eleven months old. Although the enuresis alarm is reported as treatment of choice in children with NE, no distinction is made between the body worn alarm and the bell and pad alarm and in terms of their effectiveness.

Methods: Information from clinical records will be collected to evaluate the use and success of bell and pad treatment. We will collect this information from hospitals, community continence clinics and private practice.

Results: The interim results will provide evidence to the success rate of the bell and pad treatment. It will provide up to date guidelines and practical tools on the use of the bell and pad treatment.

Conclusions: This will provide a valuable community resource to help the treatment of children with a bedwetting problem get cured as supported by the evidence of use of the bell and pad system, as first line treatment for NE.

Source of funding: Dr. Esther Apos has a financial interest and is paid to do this research by Ramsey Coote Instruments. Ramsey Coote Instruments has provided an unconditional educational grant for coordination of this collaborative project. There are no restrictions imposed by Ramsey Coote Instruments on the analysis of the data or on publication and use of the results. This project has also been awarded a voucher grant from the Victorian Government Department of Business and Innovation, Australia.

Conflicts of interest: None
“FIBRE FOOTPRINTS” OF NONWOVEN FABRICS USED IN ABSORBENT INCONTINENCE PRODUCTS

Sabrina Falloon, Alan Cottenden, University College London, London, UK

Introduction: A nonwoven fabric is the top sheet of an incontinence pad or diaper. With long-term use of absorbent products, a combination of mechanical (friction) and biochemical (urine) interaction can lead to some form of skin damage. The aim of this project is to better understand the mechanism(s) by which this friction occurs and to improve nonwovens so that they are kinder to the skin. It is known that less than 1% of the nominal contact area of a topsheet is actually in contact with the skin\(^1\), and it is this real area that mediates friction. The real area is referred to as the fibre footprint and was investigated for a range of nonwovens under a range of pressures.

Methods: Images of contact between pieces of nonwoven and glass slides (a skin surrogate) are collected under the microscope under different pressures, focusing the microscope at the surface of the slide so that only those fibres touching it are in focus. Total contact length data are obtained from the micrographs using various image processing techniques.

Results: Below is a figure to show how a digital image of a nonwoven is processed to yield an image displaying only fibres in contact.

Conclusions: Each nonwoven has displayed characteristic fibre footprints, with varying contact lengths. It is not yet clear how they relate to friction force, but this will be investigated in the near future. This work should lead to a deeper understanding of the relationship between friction force and contact area for a human skin-nonwoven interface. It is anticipated that the work will also reveal useful information about the nonwovens, leading to an improvement in their design, making them more skin friendly.


Funding: This work is funded jointly by University College London (UK) and SCA Hygiene Products AB (Sweden).

Conflict of interest: None

Table 1: Example data set for one nonwoven - values corresponding to final image output

<table>
<thead>
<tr>
<th>Pressure/ kPa</th>
<th>Total contact length per square millimetre of nominal contact area [µm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.078</td>
<td>7895</td>
</tr>
<tr>
<td>0.58</td>
<td>13094</td>
</tr>
<tr>
<td>1.58</td>
<td>17190</td>
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</tbody>
</table>

Figure 1: A piece of nonwoven under the microscope (left); micrograph enhanced using MATLAB (centre) and further processed using special software (right)
NONWOVEN FABRICS AND SKIN: HOW DOES FRICTIONAL INTERACTION LEAD TO SKIN DAMAGE?

Sabrina Falloon, Alan Cottenden, University College London, London, UK

**Introduction:** Long term use of disposable pads or diapers can lead to skin irritation. It is thought that if the effects of the friction between the skin and nonwoven coverstock fabrics could be reduced, the skin damage would also be reduced, making pad-wearing more comfortable for incontinent people. This poster will report recent work to characterise and understand the interface between nonwoven materials and human skin, describing how friction forces vary with interfacial pressure, speed of movement, and nonwoven type.

**Methods:** Friction was measured by pulling strips of 13 different nonwoven fabrics across the volar forearm of a young female, under three different loads (see Figure 1) to measure coefficients of friction. All measurements were carried out in an environmentally controlled room.

**Results:** Under the highest applied load (0.99N), deformation of the skin (rucking and indentation) was observed with all nonwovens, but mostly this did not affect the force-displacement curves. Graphs of friction force against applied load were linear for all 13 nonwovens, suggesting that Amontons’ Law held for them all (i.e., coefficient of friction was independent of applied load).

**Conclusions:** Four representative nonwoven fabrics from the 13 will now be used in further testing, under a wider range of loads and on a large group of volunteers. This will account for the larger range of conditions and skin types against which nonwovens interact in real circumstances, ultimately resulting in a more reliable set of data.

**Funding:** This work is funded jointly by University College London (UK) and SCA Hygiene Products AB (Sweden).

**Conflict of interest:** None

**Figure 1:** Strip of nonwoven fabric is pulled across volar forearm by tensometer; dead weight at end of strip applies load.
OnabotulinumtoxinA TREATMENT PROVIDES SIGNIFICANT IMPROVEMENTS OVER PLACEBO FOR ALL OVERACTIVE BLADDER SYMPTOMS, INCLUDING NOCTURIA

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Introduction: Pharmacologic treatment of overactive bladder (OAB) syndrome with anticholinergics is often limited by inadequate efficacy and side-effects. OnabotulinumtoxinA was evaluated in OAB patients with urinary incontinence (UI) who were inadequately managed with anticholinergics in a large phase 3 pivotal trial.

Methods: OAB patients with ≥3 urgency UI episodes in 3 days and ≥8 micturitions/day were randomized 1:1 to 20 cystoscopic intradetrusor injections (0.5 ml/injection) of onabotulinumtoxinA 100U or placebo, sparing the trigone. Co-primary endpoints were changed from baseline at week 12 in UI episodes/day and proportion of patients with a positive response (greatly improved and improved) on the treatment benefit scale (TBS). Daily average frequencies of nocturia, micturition, and urgency episodes, volume voided/micturition, health-related quality of life (HRQOL) and adverse events (AEs) were evaluated.

Results: At week 12, UI episodes/day was significantly reduced from baseline with onabotulinumtoxinA versus placebo (−2.65 vs. −0.87; P<0.001), and more patients reported a positive response on the TBS (60.8% vs. 29.2%; P<0.001). Reductions from baseline with onabotulinumtoxinA versus placebo were observed in the daily average frequency of nocturia (−0.45 vs. −0.24; P<0.05), micturition (−2.15 vs. −0.91; P<0.001) and urgency episodes (−2.93 vs. −1.21; P<0.001), which corresponded to large, clinically relevant differences between onabotulinumtoxinA and placebo in the percentage change from baseline in episodes of UI (−47.9% vs. −12.5%), nocturia (−20.2% vs. +0.2%), micturition (−16.9% vs. +4.1%) and urgency (−31.6% vs. −10.0%). Volume voided/micturition increased with onabotulinumtoxinA versus placebo (41.1 vs. 9.7 ml; P<0.001). OnabotulinumtoxinA improved patients' HRQOL across multiple measures (P<0.001). AEs were localized to the bladder; uncomplicated urinary tract infections were most common. A low rate of urinary retention (5.4%) was observed; study discontinuation rate due to AEs was low (1.8%).

Conclusion: OnabotulinumtoxinA 100U was well-tolerated and demonstrated clinically relevant improvements in OAB symptoms, including nocturia, in patients who were inadequately managed by anticholinergics.

Source of funding: This study was funded by Allergan.

Conflicts of interest: Dr. Sand is a consultant/lecturer for Allergan, Astellas, Ferring, Pfizer, Watson and Merck. Dr. Nitti is a consultant/Investigator/Lecturer for Allergan. He is also a consultant for Medtronic, Uroplasty and Serenity, and is a consultant/investigator for American Medical Systems, Astellas and Coloplast. He is a stockholder/investor in Serenity. Dr. Dmochowski is a consultant for Allergan, Merck, Johnson and Johnson and Ferring. Dr. Thompson is an employee of Allergan, Ltd; UK. Dr. Zhou is an employee of Allergan, Inc; USA. Dr. Herschorn is a clinical trial investigator and a consultant for Allergan, Pfizer and Astellas and is a consultant for American Medical Systems.
DEFINING COMFORT FOR HEAVILY-INCONTINENT PATIENTS ASSISTED BY ABSORBENT PRODUCTS IN SEVERAL CONTEXTS

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Background: As part of a person-centred care (PCC) approach to sustainably delivering healthcare, increased focus is on the more functional characteristics of healthcare product performance, that is, particularly as perceived by the end-user. Patients themselves have already indicated that comfort issues in the contexts of psychosocial and environmental effects are of prime concern to them, particularly how well they can perform important tasks without discomfort. Also, certain tasks of Activities of Daily Living (ADL) are recognised as instrumental to a person’s independence. Current national and international product standards arguably are not structured to present measures and methods for the most essential user related factors according to ISO 15621, thereby potentially hindering innovation towards new, better performing and cost effective solutions for incontinence care.

Result: Novel system approach to Comfort In defining comfort as perceived by heavily-incontinent patients, major steps are:

- System definition: What are the tasks where use of a better incontinence product will have most impact on the comfort of heavily-incontinent patients? A combination of aetiological and background studies have been made.
- Defining the construct “comfort” as an essential quality characteristic.
- New measurement methodology: How does one measure the impact of tasks on patient comfort? The usual tools for measurement data analysis do not always work with multivariate, qualitative measurements and ordinal scales.

Future work: Ultimately the results of this research will be exploited in better methods for classification and ranking of specific incontinence products and related impact analysis; future standards; the development and improved use of incontinence healthcare products; and above all better healthcare.


Conflicts of interest: None

Figure 1. The system: User-Pad-Task and their mutual interactions in given environment (disc)
CLINICAL UTILITY OF LUNG-GENERATED PRESSURES IN DETERMINING VALSALVA LEAK POINT PRESSURE IN PATIENTS UNDERGOING URODYNAMIC STUDIES

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Introduction: Our previous study established initial correlation between lung-generated pressures measured by the Plung device and urodynamic pressures measured by traditional catheterization methods1. In this follow-up investigation, the clinical utility of the Plung device in measuring Valsalva leak point pressure (VLPP) during urodynamic studies (UDS) with patients complaining of stress urinary incontinence (SUI) is examined.

Methods: 27 patients complaining of lower urinary tract symptoms including SUI underwent conventional UDS and were asked to reproduce their symptoms concurrently using the Plung device. Patients locked their lips around the mouthpiece and performed a minimum of three Valsalva maneuvers during filling cystometry. Any significant leakage was detected by a uroflowmetry transducer or manually noted by the clinician.

Results: In this cohort, 21 patients with reputable data were included, with a mean age of 61.5 years (43 - 83) and 86% female (18/21). Six studies were excluded due to significant artifact, rectal contractions, or inability to generate Plung pressures above 30cmH20. A strong correlation between Pabd and Plung was observed (r=0.79 ± 7.97) and the average equation of this association was Pabd=1.09(Plung) + 29.74 (+/- 9.62). The sensitivity of the Plung test was 50%, however decreased compliance and stress-induced DO was demonstrated during UDS in two patients who were considered false-negatives, confounding the result. The specificity of the Plung test was 71%. Those patients who demonstrated leakage only upon cough were excluded from these calculations as the mechanism of this provocative maneuver is not directly comparable to a Valslava.

Conclusion: The Plung technique provides a non-invasive and rapid obtainment of VLPP in classifying SUI without the obstructive effect of a catheter. The estimated Plung pressure can potentially be used as a referral tool for urodynamic studies as well as in treatment tracking. We recommend future investigations include only those with pure SUI as urgency was a confounding factor in this study.

References:

Conflicts of Interest: Ing Goping, Adele Campbell, and Christar Heng are employees of Laborie Medical Technologies Canada ULC.

Figure 1. Male patient performing the Plung maneuver during filling cystometry (pump volume = 75mL) with evidence of stress urinary incontinence visible on the Flow and Volume channels respectively. [Pves (black), Pabd (medium grey), Plung (light grey)].
The ICIQ PADPROM Project: Developing a Questionnaire to Measure Quality of Life of Men and Women Who Use Absorbent Pads to Manage Urinary Incontinence

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Introduction: Patient Reported Outcome Measures (PROM) provides a way to gain an understanding into the impact of interventions on quality of life (QoL) from the patients’ perspectives. Existing PROMs are not designed to measure QoL associated with better containment of urinary incontinence (UI) where symptoms remain unchanged.

Aim: To develop a robust psychometrically sound PROM for absorbent pad users.

Methods: A rigorous process for instrument development based on the International Consultation on Incontinence questionnaire (ICIQ) development protocol is being followed:

• Interviews with pad users (N=8 women + 11 men) were carried out to supplement interviews from a previous study (N= 20 women). A total of 39 interviews were recorded, transcribed, coded and analysed (using constant comparative methods) to identify the key issues which impact on QoL of pad users. These key concepts were used to generate items and formulate questions on the developing ICIQ-PADPROM.

• Cognitive debriefing interviews were conducted with further pad users (N=30) to establish content validity and refine questions.

• A modified Delphi was conducted with continence nurse specialists (N=6).

Results: Interviews revealed that there are important gender differences relating to pad use which impact on QoL. For example, men expressed greater concerns about the designs of pads and commonly reported modifying pads to meet their needs. Changing and disposing of used pads in public toilets and anxiety about security checks whilst traveling or at public events were particular issues which affected men. Questions which reflect these concerns have been included in the draft questionnaire which will be tested further by postal distribution.

Conclusions: Work on the development of the PADPROM is continuing and the draft questionnaire reflects concerns of men and women of different ages, with both light and moderate to heavy incontinence. It is anticipated that the final PADPROM will facilitate clinicians’ decision-making and assist researchers in evaluation and development of new product designs.

Funding: The development of the PADPROM is funded by SCA through a PhD studentship at the University of Southampton.

Conflicts of interest: None
DEVELOPMENT OF A QUALITY OF LIFE TOOL FOR LONG-TERM CATHETER-USERS

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Introduction: Long-term urinary catheters are commonly used to manage urinary retention and incontinence but can be difficult for people to manage and are frequently problematic with many complications including infection, blockage and leakage.

Aims: The aim of this study was to develop a tool for clinical use - so that current catheter systems can be optimised for individual patients, and for research use - to enable measurement of the benefits of improved systems and technical innovations.

Methods and results: We followed the rigorous process for tool development based on the International Consultation on Incontinence questionnaire development protocol.

- Semi-structured interviews with catheter users (N=27 + 4 carers) were recorded, transcribed, coded and analysed (using constant comparative methods) to illicit the concerns and needs of catheter users together with factors that affected users’ quality of life. This data was used to derive questions for the draft quality of life long-term catheter questionnaire (LTCQ).
- Cognitive de-briefing interviews were carried out with further catheter users (N=31) to establish content validity refine questions and remove/add questions to the LTCQ.
- The questionnaire (44 items) was posted to 703 patients from 64 primary care surgeries to enable psychometric validation (370 patients completed and 108 of these patients completed it a second time for re-test purposes) from which the short (16 items) LTCQ was derived.
- The short LTCQ was posted to a further 398 catheter-users (215 patients completed) for evaluation of the response system in a different population and to make final refinements (1 question added).

Conclusions: The final questionnaire (LTCQ) comprises two domains (i) catheter function and concerns, ii) and lifestyle impact, and four stand-alone questions (pad use, pain, spasm and sexual activity) and represents the first patient-derived psychometrically tested tool to measure the quality of life of long-term catheter users. Use of this tool should benefit long-term catheter users by allowing for identification and targeting of catheter-associated problems and by facilitating research into new catheter technologies.

Funding: Action Medical Research UK

Conflicts of interest: None
EXTRA CORPOREAL MAGNET INNERVATION - NEOCONTROL

Michael Jordan, Urological Private Practice, CEO and Owner of Magic Race LLC, Munich, Germany

My experience over 13 years and more than 3500 treated patients:
ExMI™ produces a highly focused time varying magnetic field which penetrates deep into the perineum, activating the pelvic floor muscles by stimulating all branches of the pudendal and splanchnic nerves. The EXMI can both treat bladder stress incontinence and OAB, feces incontinence and incontinence after radical prostatectomy and also pelvic pain. It also can prevent incontinence if applied 4 weeks after delivery. There are more than 100 published articles regarding the EXMI.

Own experience:
1. I asked a gynecologist friend to allow 10 women that already made a TVT appointment 6 months later to be treated with the EXMI. All 10 of them having stress incontinence with no OAB components completed the treated 3 times / week for 20 sessions of each 20 minutes. 6 out of the 10 cancelled the TVT appointment.
2. A patient that came at the age of 15 with a bladder sphincter dyssynergia, having 800 ml vesicle residue, monthly infections, using 12-15 pads / day, depressed, with school and social problems because of his disability. His mother did not want to approve a sphincter section that was offered by a couple of clinics. I treated him with the EXMI, fatiguing his sphincter by contracting it 50X / second for 15 minutes without breaks. After only 8 sessions done every other day, the bladder emptied completely.
3. I have treated this young man now for over 7 years. He studies film directory, has a girl friend, and has an almost normal sexual and social life. He continues to get 2-3 treatments every 3-4 months. Many patients with OAB after only 6-8 sessions can drop even 40-60% of their OAB medication. Many of these patients had important side effects from the medication and still could not get a better QoL.

Conflict of interest: The author owns since 2009 the company which markets ExMI™.
**Introduction:** The SUmiT Trial was a double-blind, randomized, sham-controlled trial demonstrating the efficacy of PTNS in treating OAB. The purpose of this secondary analysis was to evaluate treatment efficacy based on demographic and baseline health factors, and to analyze the treatment effect after 6 and 12 interventions.

**Methods:** 208 out of 220 enrolled in the study were included in this analysis. Differences in treatment efficacy were evaluated by age (<65 years vs. ≥65 years), gender, history of OAB medication use, and baseline urge urinary incontinence (UUI). The effect of therapy after 6 and 12 interventions was also explored. Validated questionnaires and 3-day voiding diaries were used to analyze treatment efficacy.

**Results:** Among the 208, 79% were women, 48% were ≥65 years, 31% had previous OAB medication use, and 79% reported baseline UUI. While men and women experienced similar improvement in OAB symptoms in the PTNS group (68% vs. 56%), the rate of improvement differed in men and women in the sham group (5% vs. 26%). Also, those with baseline UUI tended to have greater reductions in moderate/severe urgency than patients without baseline UUI (p=0.07). No differences in efficacy were detected when results were stratified by age or history of OAB medication use. The percent of participants reporting ≥50% improvement in moderate to severe urgency after 12 interventions was 46% and 28% for the PTNS and Sham groups, respectively (p=0.007). No significant improvements were reported after 6 interventions. However, overall OAB symptoms significantly improved from the 6th to 12th intervention in the PTNS group (p<0.001), but not in the sham group (p=0.13).

**Conclusion:** PTNS therapy is an effective OAB treatment in both men and women, regardless of age and prior use of OAB medications. Twelve weekly PTNS treatments are needed to realize the full treatment efficacy for those suffering with OAB.

**Source of funding:** Uroplasty, Inc.

**Conflict of interest:** Authors are clinical or marketing affairs employees of Uroplasty, Inc.
Introduction: The goal of the iDry project was to better understand and manage urinary incontinence (UI) and improve the quality of life of people with UI, through an innovative iPhone app.

Background: Thirteen million people in the US suffer from UI, greatly affecting their daily physical and social activities and quality of life. While many UI related interventions are available for patients, few quantitative measures or applications effectively monitor the effects of and progress resulting from these interventions. Generally, UI patients are asked to record their events using a paper-and-pencil “incontinence log”. Such a practice is laborious for the patients and creates difficulty in data interpretation for clinicians. Attempts to use electronic devices for data collection have focused more on data collection than overall management. Our goal was to make this process much easier and more efficient, and also to help patients actively manage their conditions and monitor their progress.

We believe the data collected from the users of this app can be a valuable asset for clinicians and researchers to investigate and understand UI. Our data can be a useful resource complementary to the data used in conventional observational studies.

Method: We designed and developed an iPhone app that tracks UI events, charts progress, reports results, and provides reminders and information about interventions. The app also collects data that can be mined by UI researchers. We released the app in the Apple App Store for free access by the public. We also conducted a field trial and an online beta test.

Results and conclusions: The feedback we received from test subjects and beta testers was very positive regarding the app’s features, its benefits in UI management, and the usefulness of the data for research. The app has been available since mid-November 2012 and has received positive reviews.

Funding: This project was funded by a Small Business Innovation Research (SBIR) grant from the National Institute on Aging (NIA), of the National Institutes of Health (NIH).

Conflict of interest: The author is the owner of Three Ten LLC.
CONTINUOUS BLADDER VOLUME MEASUREMENT USING URINE CONDUCTANCE

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**Problem Definition:** Conventional cystometry is limited in its ability to reproduce natural symptoms of incontinence. Catheterless, ambulatory monitors could take measurements during a patient’s natural activities. By monitoring bladder function during symptomatic episodes, physicians could improve diagnostic accuracy. Such a device must detect intravesical pressure and urine volume. However, no methods currently exist to continuously and wirelessly measure volume from within the bladder.

**Background:** Ambulatory bladder monitors can measure pressure continuously. However, continuous volume measurement is also necessary for cystometric analysis. Ultrasound probes placed outside the body are infeasible for continuous, portable use. Implantable ultrasound sensors have prohibitive power requirements and are fixed to bladder tissue. Conductance-based volume measurement, which requires little power, is used extensively in cardiovascular applications and could be optimized for use in the bladder. However, previous studies show the maximum detectable volume is limited by electrode configuration and excitation parameters.

**Design description:** The proposed device uses two silver electrodes on the surface of a silicone sphere to generate an excitation current on the order of 100 kHz and two to measure the resultant voltage. Leads connect to an instrumentation circuit at the core of the sphere. Because both urine volume and concentration affect conductance, a coaxial electrode sensor adjusts for the dynamic conductivity of urine. The design goal is to detect volumes in 50 mL increments from 0-500 mL. It will be integrated with a piezoelectric pressure sensor, battery, and EEPROM for data storage. The device is intended to be used for 48 hours.

**Design verification methods:** The design will be tested on balloons filled with synthetic urine at varying concentrations and on excised porcine bladders. Once the design is optimized, the device will be tested on human volunteers already receiving traditional cystometric tests.

**Conclusions:** While early in the development process, the proposed solution could improve diagnostic accuracy for urinary incontinence using natural, ambulatory cystometry.

**Acknowledgments:** The authors would like to thank Dr. Margot Damaser for lending her expertise, Dr. Robert Linsenmeier for editing, and Ms. Cheryle Gartley and Mr. Al Maslov for their guidance.

**Source of funding:** Biomedical Engineering Department, Northwestern University

**Conflicts of interest:** None
The Duette™ – A SOLUTION TO THE DAMAGING EFFECTS OF FOLEY CATHETERIZATION

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

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

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

The solution: The solution to bladder trauma is an innovative yet simple redesign of the Foley catheter. One with a distal balloon that would subsume the catheter tip and help keep the drainage eyes from aspirating the walls of the bladder.

How it works: By subsuming the tip and expanding the surface area over which the bladder collapses, the Duette’s™ second distal balloon prevents the tip from eroding and penetrating the bladder’s mucosal lining. Additionally the proximal and distal balloons act as a standoff, to prevent the bladder wall from being damaged through aspiration into the drainage eyes.

By maintaining the integrity of the bladder’s mucosal lining and preventing trauma, the Duette™ is designed to reduce the adverse effects of traditional Foley catheterization, including:

- Cystitis (inflammation of the bladder lining)
- Chronic irritation of the bladder, which has been shown to increase the risk of bladder cancer between 8-10 percent
- CAUTI
- Blockage of urine drainage
- Penetration and perforation of the bladder wall
- Hematuria (blood in the urine)
- Patient pain levels during catheterization

Conflict of interest: Poiesis Medical is the developer, owner and marketer of the Duette™ Dual Balloon Bladder Care Catheter.
TARGETED DELIVERY OF MYOBLASTS WITH TIPS MICROSPHERES TO INJURED MUSCLE RINGS: A PROSPECTIVE TREATMENT FOR FAECAL INCONTINENCE

Nina Parmar & Richard Day, Applied Biomedical Engineering Group, Division of Medicine, University College London, London, UK

Introduction: Obstetric trauma is a common cause of faecal incontinence (FI) in women. FI is often attributed to injury of anal sphincter muscles and new treatments are sought. Cell therapy is an emerging therapeutic option for this condition but has been unsuccessful in the few studies reported to date. We report on our preliminary findings on the delivery of muscle cells using a novel microcarrier device combined with a pioneering bioengineered three dimensional (3D) model of the injured external anal sphincter.

Method & Results: To evaluate the use of the cell-microcarrier device for repair of torn anal sphincter muscle, rings of skeletal muscle measuring 5 mm Æ were grown by seeding myoblasts into collagen gels. After 7 days culture the rings were formed, exhibiting a syncytium of muscle and contractile properties. A transverse incision was created in the rings to simulate sphincter tearing sustained during childbirth. Optimal conditions were identified for attachment of labelled myoblasts to the surface of poly(lactide-co-glycolide) TIPS microcarriers and delivered to the injured muscle rings. After one week of culture, cells had migrated from the microcarriers and formed new muscle fibres that integrated with injured muscle ring. Preliminary studies demonstrated myoblasts transplanted with the microcarrier system integrated with tibialis anterior muscle of mice. The transplanted cells migrated from the microcarriers and formed new fibres in the host muscle verifying the observations made with the muscle ring model.

Conclusion: We have demonstrated the feasibility of delivering muscle cells to damaged sphincter muscle using an innovative microcarrier system. This approach has the potential to improve the efficiency of cell delivery and integration with damaged sphincter compared with conventional cell therapy methods. Furthermore, development of an in vitro model of sphincter muscle injury provides a valuable and robust tool for investigating this and other new treatments for incontinence.

Sources of funding: Sir Halley Stewart Trust, Wellcome Trust, UCL Grand Challenges

Conflicts of interest: None
SMOOTH MUSCLE CELLS LOADED WITH SUPERPARAMAGNETIC IRON OXIDE NANOPARTICLES FOR USE IN THE TREATMENT OF INCONTINENCE

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**Introduction:** Faecal incontinence (FI) is a debilitating disorder that affects a significant portion of the population. Cell therapy is an attractive treatment option but there is a need for improved techniques to enable cell tracking with this approach.

**Aims & Methods:** The aim of this study was to investigate the feasibility of loading smooth muscle cells (SMC) with superparamagnetic iron oxide nanoparticles (SPION) to facilitate visualization of implanted cells. The effect of incubating human rectal smooth muscle (HRSMC) with different concentrations of SPION (0, 31.25, 250 and 1000µg/ml) for 24 hrs. was investigated, along with the ability to visualize loaded cells in a bioengineered sphincter.

**Results:** Transmission electron microscopy revealed that SPION were endocytosed by cells and became concentrated inside endosomes. Superconducting quantum interference device measurements showed the majority of SPION loading occurred within 1hr of exposure. Flow cytometry analysis based on cell granularity revealed the amount of SPION was not constant for all of the cultured cells. SPION-loaded cells showed no difference in their metabolic activity compared with control cells; however an increase in cell proliferation (P<0.0001) occurred in direct correlation with the concentration of SPION in the medium. This observation corresponded with increased gene expression of markers of synthetic SMC phenotype (vimentin [p<0.01], caldesmon [p<0.05]) and inhibition of contractile SMC phenotype marker calponin (p<0.05) following loading with SPION and subsequent incubation in differentiation medium for 7 days. The presence of SPION-loaded SMC in a bioengineered sphincter was clearly visible using pre-clinical magnetic resonance imaging.

**Conclusion:** These data demonstrate that loading smooth muscle cells with SPION is a feasible technique for visualizing cells in sphincter muscle. Furthermore, the proliferative effects caused by loading SMC with SPION may offer additional benefits for the use of cell therapy in the treatment of FI.

**Conflicts of interest:** None
DEVELOPMENT OF A CULTURALLY COMPLIANT UROFLOW TOILET

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**Problem definition:** Currently available toilets for uroflow diagnostic testing are designed for sitting during urination, but not squatting. Because of this, it is not possible to accurately perform urodynamics on women from cultures accustomed to squatting.

**Background:** Obstetric fistula is a common pathology in many developing nations. While the primary issue of fistula closure can be achieved with great success, many of these women continue to suffer from urinary incontinence. Accurate diagnosis of their type of urinary incontinence by urodynamics is hampered because current uroflow toilets accommodate women who sit during urination. When a woman accustomed to squatting during urination attempts uroflow while seated, the resulting data does not represent her normal urination.

**Design description:** Our goal was to create a toilet which allows women accustomed to squatting during urination to complete the uroflow portion of a urodynamics examination as accurately as possible. Additionally, the design must be durable, lightweight, and easily packed for transport to remote clinics which treat obstetric fistulas.

**Design validation:** Our design was created in SolidWorks CAD software (Dassault Systemes, Waltham, MA) and tested to ensure sufficient weight bearing capacity using Abaqus FEA software (Dassault Systemes). All materials were selected for a combination of strength, durability, corrosion and temperature resistance. Field testing is planned for the spring of 2013 when our design will be implemented at a leading fistula repair hospital in Niger.

**Conclusions:** We believe our design meets a key need in the treatment of obstetric fistula patients in developing nations. The ability to perform urodynamics on these patients opens many possibilities for treatment and research in these populations.
OAB PATIENT ADVOCACY ROUNDTABLE

Claire Saxton and Alaina Willing, Urology Care Foundation, Linthicum, MD, USA

And also with much help from the organizations participating in the Roundtable, which included:

- Alliance for Aging Research
- American Geriatrics Society’s Foundation for Health in Aging
- American Urological Association
- Astellas Pharma US, Inc.
- Blue Thong Society
- Chesapeake Urology Associates
- Interstitial Cystitis Association
- National Association For Continence
- National Family Caregivers Association
- National MS Society
- Red Hot Mamas
- Simon Foundation for Continence
- Society for Women’s Health Research
- United Spinal Association
- Urology Care Foundation
- Women’s Health Foundation

Purpose: The purpose of our Roundtable was to assess the needs and gaps in Overactive Bladder patient advocacy – especially in terms of public awareness, patient education, services to patients, doctor/patient dialogue, and political advocacy. We also wanted to identify patient advocates’ highest priority needs and those that their organizations were most likely to work on in collaboration with other advocacy organizations.

Methodology: We brought together a wide range of patient advocacy groups who provide education, patient services, or political advocacy efforts on behalf of people living with overactive bladder. At a Roundtable meeting held in Linthicum, Maryland on December 5, 2012, each attendee presented the services their organization provided as well as their perspective on the unmet needs of people living with overactive bladder. After the Roundtable, each group voted to show their organization’s priorities for the needs and gaps identified as well as which issues their organization would be most likely to work on in collaboration with other organizations.

Results: Overwhelmingly, the patient advocacy organizations’ representatives thought that the highest need for collective action was in the public policy arena. Sixty percent of the votes prioritized advocacy efforts on topics such as access and coverage to treatment and supplies, raising politicians’ awareness of overactive bladder as a medical condition that significantly affects quality of life, and ensuring that research studies look at impact on quality of life and not just symptom reduction. Twenty-six percent of the votes prioritized working collaboratively on patient education efforts. Fourteen percent of the votes prioritized working in collaboration to provide education and discussion tools to health care providers to improve their discussions about overactive bladder with patients.

Conclusion: There is great need for public policy advocacy on behalf of those living with overactive bladder and great willingness to partner together on these public policy issues. There are also opportunities for groups to work together on overactive bladder education to the general public, already diagnosed patients, and health care providers.

Source of funding: The OAB Patient Advocacy Roundtable is part of the “It’s Time To Talk About OAB” campaign of the Urology Care Foundation. This campaign was made possible with generous support from Astellas. The salaries of the authors of this paper were partially underwritten by this educational grant from Astellas.
The Simon Foundation for Continence is dedicated to bringing the topic of incontinence out into the open, removing the stigma surrounding incontinence, and providing help and hope for people with incontinence, their families, and the health professionals who provide their care.

www.simonfoundation.org
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www.continencecentral.org