The Poster Session at Innovating for Continence: The Engineering Challenge 2017 was made possible by an educational grant from LABORIE
DEVELOPMENT OF INFECTION-RESPONSIVE SURFACE COATINGS FOR DIAGNOSIS AND TREATMENT OF CATHETER-ASSOCIATED URINARY TRACT INFECTIONS

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Introduction / Aims of the Study: Intrinsic design problems of the standard Foley catheter introduce vulnerability to infection, and facilitate colonization by the crystalline biofilms of Proteus mirabilis. Production of a potent urease enzyme by Proteus mirabilis causes elevation of urinary pH, owing to the catalyzed hydrolysis of urea within the bladder. This induces the precipitation of struvite and apatite crystalline solids, which may cause blockage and obstruction of the catheter lumen. The aim of this study was to create novel, infection-responsive coatings for urinary catheters in order to both detect impending catheter blockage (resulting in a urinary color change) and treat the P. mirabilis infection in situ (preventing blockage entirely) using controlled release of a self-quenching dye and bacteriophage, respectively. Bacteriophage (phage) are naturally occurring viruses, which attach to bacterial cells with the purpose of infection, and ultimately, the destruction of the cell. Phage provide an elegant and effective alternative to chemical antibiotics, active against bacterial biofilms and planktonic cultures alike.

Study Design, Materials and Methods: This study investigates the delivery (by responsive polymeric films) of molecular and biological cargos for the detection and treatment of catheter colonization. Triggered release using a dual-layered polymeric architecture employs an upper layer of pH-responsive polymer poly(methyl methacrylate-co-methacrylic acid) (Eudragit S100), capping a lower ‘reservoir’ layer of poly(vinyl alcohol). Elevation of urinary pH (>pH 7) dissolves the Eudragit layer, releasing the cargo into the artificial urine media. Infection detection is achieved via the encapsulation of the self-quenching dye 5(6)-carboxyflurescein (1), and infection treatment by lytic bacteriophage (Figure 1). Use of an in vitro catheterized bladder model system allows testing of such coatings under clinically relevant conditions. The model replicates a fully sterile closed-drainage system, as used in clinical practice. Prototype coatings were applied directly to the top 1cm of silicone catheters (directly above the retention balloon), so that the coating may sit within the pool of residual urine contained within the glass ‘bladder’. Blockage of catheters and release of cargo were readily identified in the model system by monitoring the flow of urine.

Results: Evaluation of prototype coatings demonstrated that coatings loaded with dye provided up to 12 hours advanced warning of blockage, and are stable both in the absence of infection, and in the presence of non-urease-producing species. (Figures 2(a) and (b)) Triggered release of therapeutic species displayed eradication of P. mirabilis biofilms after 24 hours exposure (Figure 2(c)).
Interpretation of Results: When considered in the clinical context, the 10-12 hour advanced warning of blockage is sufficient to permit intervention before the occurrence of serious complications. This coating system performs at least as well as other sensor systems currently reported, although the implementation of this approach provides considerable manufacturing and practical advantages. Research focusing on the triggered release of bacteriophage in particular may lead to new treatment options for infections of this nature, showing response exclusively to successful colonization of *P. mirabilis*. Unlike traditional treatments, bacteriophage therapy bypasses the issues associated with antibiotic resistance, representing a significant advancement in bacterial control systems.

Conclusion: In conclusion, this project has described the successful incorporation and pH-triggered release of various molecular and biological cargos from a dual-layered polymeric architecture for the diagnosis and treatment of CAUTI caused by biofilm communities of *P. mirabilis*. Collectively, this work provides sound proof-of-concept for this infection-responsive technology and a firm foundation for its further optimization and development. Both diagnostic and therapeutic aspects of this work have potential to significantly improve patient welfare and reduce the cost of care through the prevention of catheter blockage and associated complications.

Reference:

Ethical Approval: None.

Funding Sources: The Annett Charitable Trust, EPSRC Healthcare Partnership Grant (# EP/027602/1), European commission’s 7th Framework programme EC-FP7 project number 245500 Bacteriosafe. Also Dunhill Medical Trust (R394/1114 awarded to BVJ) and the QVH Charitable Trust.
IN VITRO AND HUMAN HAPTIC ASSESSMENTS FOR PRE-CLINICAL EVALUATION OF CATHETER COATING PROPERTIES

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Introduction: Intermittent urinary catheters have been coated with hydrophilic polymers to lubricate the surface and reduce discomfort upon catheter implantation (1). Many currently available coatings, however, dry out too rapidly and possess insufficient durability to withstand typical frictional forces encountered during the catheterization process, resulting in loss of coating from the surface and potential urethral trauma (1). In the development of more durable coatings with improved lubricity properties, in vitro test systems play an important pre-clinical screening and evaluation role. This testing facilitates identification and optimization of lead candidates before the performance of more highly regulated and costly in vivo studies (2). The aim of this study was to characterize surface properties of a range of developmental coating formulations, including wettability, dehydration kinetics and friction properties, by in vitro quantitative methods and compare these findings to the more subjective feeling of lubricity, as assessed haptically.

Materials and Methods: Poly(vinyl pyrrolidone) (PVP) and poly(vinyl chloride) (PVC) films were provided by BASF Chemical Corporation (Germany) and Goodfellow Ltd. (UK) respectively. Propan-2-ol and ethanol were obtained from Sigma-Aldrich (UK) and J.T. Baker (Netherlands) respectively. PVP homopolymers, and 1%, 5% and 10% w/w amphiphilic block copolymer (ABC)/PVP sIPNs were synthesized by addition of the respective mass of PVP (10 g, 9.9 g, 9.5 g and 9.0 g) and ABC (0.0 g, 0.1 g, 0.5 g and 1.0 g respectively) to a solution (100 mL) of propan-2-ol and dH2O (1:1) with stirring. Surfaces of PVC samples were dipped in the respective formulations and dried overnight at 40°C. Differences in surface wettability, water retention ability and lubricity of coated PVC samples were characterized by in vitro determination of sessile contact angles, kinetics of dehydration studies, and determination of coefficient of friction values respectively. Human haptic assessments were performed by asking participants to mark on a four-point Likert scale the extent to which they found material B (ABC/PVP sIPN-coated samples) to differ in terms of slipperiness to material A (PVP control) after touching the hydrated surfaces. Rank scores were generated for each formulation (a lot less slippery: 1; slightly less slippery: 2; slightly more slippery: 3; a lot more slippery: 4).

Results: All ABC-containing sIPN-coated surfaces exhibited significantly lower contact angles relative to the 100% PVP control, and the extent of reductions in static and dynamic coefficient of friction values were up to 40% for sIPNs with a 5% w/w content of ABC (Table 1). Furthermore, no statistical differences in the weight percentage water contents between the ABC/PVP sIPNs and the 100% PVP control were observed during the initial 50 min of drying (Figure 1). Upon prolonged drying (post-50 min), however, water contents of both the 1% and 5% w/w ABC-containing sIPNs were significantly higher than the 100% PVP control.

Table 1. Contact Angles and Coefficient of Friction Values.

<table>
<thead>
<tr>
<th>Formulation (% w/w of ABC)</th>
<th>Contact Angle (°) (Mean ± SD)</th>
<th>Static coefficient of friction (μs) (Mean ± SD)</th>
<th>Dynamic coefficient of friction (μd) (Mean ± SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>54.1 ± 6.7</td>
<td>0.215 ± 0.035</td>
<td>0.202 ± 0.053</td>
</tr>
<tr>
<td>1</td>
<td>35.5 ± 3.3</td>
<td>0.162 ± 0.050</td>
<td>0.160 ± 0.038</td>
</tr>
<tr>
<td>5</td>
<td>25.3 ± 2.8</td>
<td>0.131 ± 0.051</td>
<td>0.122 ± 0.044</td>
</tr>
<tr>
<td>10</td>
<td>33.3 ± 1.2</td>
<td>0.149 ± 0.033</td>
<td>0.168 ± 0.051</td>
</tr>
</tbody>
</table>

Figure 1. Time-dependent dehydration kinetics.
The number of participants within each category of the Likert scale following haptic assessment is displayed in Figure 2. No significant differences between the percentage of participants within any of the four categories of the Likert scale were observed when the 1% w/w, 5% w/w or 10% w/w ABC-containing sIPN coatings were haptically assessed in comparison to the 100% PVP control.

**Figure 2. Haptic assessment responses.**

**Interpretation of Results:** The agreement between *in vitro* contact angle measurements and coefficient of friction values was expected based on the assumption that the higher water contents of more hydrophilic surfaces would lead to lower frictional forces. Furthermore, the longer retention of water by the 5% w/w ABC/95% w/w PVP sIPNs was again expected on account of their significantly more hydrophilic surfaces. The significant differences in surface contact angles and coefficient of friction values observed between the ABC-containing sIPNs and the 100% PVP control were not, however, reflected during human haptic assessments of the catheters immediately post-hydration. These differences between the findings of the organoleptic study and the *in vitro* laboratory tests may be related to the high variability of human tissue, which acts as the countersurface in haptic assessments (3).

**Conclusion:** We may conclude that the subjective feeling of lubricity is multifactorial and the *in vitro* and haptic assessments of surface properties as performed herein require optimization to more reliably predict patient preference and coating performance *in vivo*.

**References:**

**Ethical Approval:** Ethical approval for human organoleptic studies was obtained from the Ethics Committee at the School of Pharmacy, Queen’s University Belfast. Written informed consent was obtained from all volunteers prior to the study and confidentiality assured.

**Funding Sources:** Department for Employment and Learning, Northern Ireland; Invest Northern Ireland; Royal Academy of Engineering.

**Conflict of Interest:** The authors declare no potential conflicts of interest.
EVALUATION OF FLOURISH®, A SINGLE USE DISPOSABLE INTRAVAGINAL DEVICE FOR MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE

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Aims of the Study: The primary objective of this study was to demonstrate that the Flourish intravaginal device provides effective management of stress urinary incontinence symptoms for female subjects as evidenced by a significant reduction in the rate of incontinence episodes and pad weight after 30 days of daily use compared to a baseline of 7 days of no use.

Study Design, Materials and Methods: Women with stress urinary incontinence and no significant urge incontinence and no more than 1st degree pelvic organ prolapse kept a voiding diary and determined pad weight gain for 7 baseline days. Those exceeding an average of 1.5 incontinence episodes daily then used the Flourish intravaginal device on a daily basis for 30 days during which a voiding diary was kept and pad weight gain was determined. Post void residual volumes were also tested, with and without the vaginal device.

Results: 20 women completed the Intervention Phase of the study. Approximately half were postmenopausal. They had an average of 3.1 stress incontinence episodes per day during the Baseline week, and the average pad weight gain was 8.6 g/day. The number of incontinence episodes in the final week of the Intervention Phase of the study was reduced by 100% in 35% of women. Over 90% reduction was seen in 55% of the study group, and at least a 70% reduction was seen in 90% of the study group. Overall, the number of incontinence episodes was reduced by 87% and pad weight gain was reduced by 78%. There was no difference in post void residual volumes with and without the device.

Conclusion: These results confirm that the Flourish intravaginal device effectively manages stress urinary incontinence in a non-obstructive way that does not impede normal voiding.

Discussion: The only OTC intravaginal product currently marketed for management of stress urinary incontinence is Poise Impressa®. Additionally, the Always/Tampax® Bladder Support has received FDA approval, but is not yet on the market. The Flourish device was designed to support the urethra in a different fashion than those two products, both of which share a generally hourglass shape and place a bulk of support in the lower vagina underneath the urethra. As compared with Poise Impressa, Flourish is lighter, has less surface area contacting the vaginal wall and has less material in the lower vagina. The current trial confirms that the Flourish approach is effective. Head to head trials will be required to determine whether it is significantly more effective, as suggested by the current results.

Conflict of Interest: Dr. Spitz has a financial interest in Contine.

Funding Source: Corporate (Contine Corporation)
BLADDER DIARY INTEGRATION: A LOOK AT PERITRACK

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Problem Definition: A bladder diary can be used by clinicians to help assess urinary incontinence (UI) symptoms in patients, as well as help patients understand behavioural influences causing their UI. Over time, the bladder diary tracks UI symptom changes as a result of treatment programs, and assists in managing patient expectations of progress. There are some challenges faced by the clinician in collecting this data however, such as forgotten entries, lost records and the inconvenience for both patient and clinician.

From the perspective of the UI sufferer, a bladder diary can highlight important behaviours and habits. Through documenting various key indicators, it establishes a baseline of activity against which progress can be monitored. Additionally, it reinforces the multifaceted approach to UI, as well as keeping a realistic and reliable record of change.

To be useful, a bladder diary must be easy to access and use, convenient and reliable.

Background: A study published in Neurology and Urodynamics assessed patients’ and clinicians’ preferences in a pilot crossover study of two different electronic voiding diaries against a standard paper diary, and results showed that the majority of patients (82%) preferred the e-diary, while slightly more clinicians (9%) preferred the electronic report over the paper diary. The PeriCoach is a take home biofeedback system consisting of a sensor, smartphone app and information Portals. Through a clinician-accessed Portal, a patient may share their PeriCoach data with their treating clinician. New to the PeriCoach app is the PeriTrack: Bladder Diary. This Bladder Diary (BD) monitors fluid intake, voids and leaks, pads usage, and an occasional question of “How’s your PF strength?” It also incorporates a check box for menstruating, which gets added to their activity calendar. The PeriTrack interface is user friendly, and being on their Smartphone is easily accessible and offers a quick way for them to make entries on the go or at the end of the day. The results are available to the user in the app as well as in their Portal, which can also be seen by their connected clinician.

Muscle strength data is collected by the PeriCoach sensor from each exercise session completed. Combined with the BD information, this opens up the possibility of comparing the muscle data with symptomatic change.

Results & Conclusion: Looking at de-identified data in the PeriCloud, User0D36 was identified as being a regular user of the BD as well as consistently using the PeriCoach over a period of 12 weeks. Her first exercise session using PeriCoach was Day 1, and her first BD entry was Day 2. Daily entries were made during the first 7 days, almost daily for Week 2, and then no entry for Week 3. Week 4 was back to almost daily entries, dropping off again over a couple of weeks. Week 12 contained 3 days of entries for the week. The exercise sessions averaged 5 sessions per week over the 12 weeks. Diary entries did not always coincide with exercise sessions, and so this indicates that the user felt motivated to make entries even when not prompted by the PeriCoach exercise activity.

When comparing some of the key items from first week BD entries to the final week under review, the following results were observed: Week 1: Pad use → 1 Super, 1 Plus, 8 Normal; Leaks (volume estimation for the week) → 3,700mL. Week 12: Pad use → 2 Ultra Thin; Leaks → 400mL. This shows significant decrease in both reported leaks and pad usage.

Looking at the squeeze strength measured by the PeriCoach sensor – a calculation of both max squeeze force and length of hold - over the 12 weeks, the user has shown a 13.5% improvement from initial session, which supports the improvement in symptoms as self-reported by the user.

These results support the ease-of-use, accessibility and convenience of the PeriTrack: Bladder Diary as encouraging users to engage in this self-reporting, as well as being able to observe a correlation between change in squeeze strength and symptoms.

Funding Source: Internal.
Conflict of Interest: The author is an employee of Analytica Ltd.

1(Altif Mangera, 2013)
HOW MUCH IS ENOUGH? A REVIEW OF PELVIC FLOOR MUSCLE TRAINING DOSAGE USING PERICOACH

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Problem Definition: Pelvic floor muscle training (PFMT) has been thoroughly documented to be an effective first-line treatment for urinary incontinence, and strengthening the pelvic floor muscles can have many other benefits. There are varying schools of thought, however, on “how much is enough”, and many clinicians are unsure of the best dosage for maximum effect for busy women. Doing too few exercises will not challenge the muscles sufficiently; too many can lead to fatigue and possible muscle spasm. The dose also needs to be sustainable for women leading active lives – a viable program is one that the woman can continue long-term to ensure continued good muscle strength.

Background: The PeriCoach® System includes a data management system, which stores de-identified exercise data for all PeriCoach users. Each exercise session is recorded with a time stamp and sensor information, which informs of the user muscle strength for that session. Analysing this data with regards to squeeze strength and frequency over time will give insight into appropriate dosage for muscle strength improvement with use of PeriCoach. Calculation of squeeze strength incorporates both max squeeze force and endurance (how long the squeeze is held) throughout an exercise session. Users that have been exercising for at least 6 weeks will be included, and only a single orientation will be analysed – the orientation that represents the most number of users for the time period. The percentage change in squeeze strength at the 6-week mark will be assessed in comparison to the initial “baseline” measurement.

Results: Looking at the users’ first 10 weeks of using the PeriCoach the data indicates more patients used the PeriCoach lying down. Users who were recalibrating their sensor too frequently (at least 5 data points were needed between recalibrations) were excluded in order to be able to create a reliable estimate of percentage change. Out of the 168 patients included, 39 were using less than 3 times per week; 41 were using 3-4.9 times per week; 36 were using 5-9 times per week; 35 were using 9 to 14.9 times per week; 5 were using 15-19.9 times per week and 12 were using more than 20 times per week, whether self-selected or on clinician instruction.

When assessing squeeze strength improvements, the group exercising over 20 times per week improved the most (56%), with 15-19.9 numbers per week showing a decline of 16.45%. This reflected the smallest number of participants, however, so one user’s results can have a significant impact on the average result. The group that showed the second-best result was 5-9, although all groups under the 15 times per week limit showed similar rates of improvement.

Conclusion: The majority of users are completing 15 sessions per week or less, with the group categories under that number all fairly evenly distributed. This indicates the maintainability for users of twice per day sessions being almost as likely as under three times per week. However, above this number, the participation drops off significantly. The squeeze strength results demonstrate a notable increase in strength for the over 20 times per week as compared to all other groups. When looking at both participation numbers and dosage however, 15 sessions per week or less is both the most populated – indicating the most sustainable - and most effective in increasing squeeze strength.

Funding Source: Internal.
Conflict of Interest: The author is an employee of Analytica Ltd.

Some users may be using both orientations concurrently
DEVELOPING SERIOUS GAMES FOR EDUCATING NURSING HOME STAFF ABOUT INCONTINENCE ASSOCIATED SKIN DAMAGE

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Introduction: Incontinence associated skin damage (IASD), an inflammatory type of damage of the skin barrier, is the most common physical complication of incontinence. Nearly 50% of nursing home residents are incontinent, placing them at risk for developing IASD. Education of nursing home staff about IASD is essential. Because turnover among nursing home staff is high, educational training is an ongoing need. Interactive web-based modules using designs and techniques of entertainment video games are an innovative and versatile way of delivering serious educational content to health care staff but few have been targeted to nursing home staff.

Purpose: To develop and conduct a pilot evaluation of interactive, web-based, simulation (“serious”) games for educating nursing home staff about the assessment and risk factors of IASD

Materials and Methods: Research and practice literature was reviewed for current evidenced-based and best practice knowledge about IASD. A script (including dialogue, plot, and suggestions for scenes) and assessment questions and answers based on this knowledge and clinical experience was developed by the investigator, and two clinical experts, an advanced practice nurse specializing in wound and continence nursing (APRN-WC) and a nursing assistant registrant (NAR). The artistic design and technical programming team of a software development company consulted with these content experts using AGILE methods and real-life photographs to create the simulation games (including look and manner of avatars, graphics of skin damage, and interactive gaming exercises). Responses of the first set of users to an optional, short evaluation survey were summarized.

Results: Two twenty-minute simulation games set in a nursing home, featuring three nursing avatars (an APRN-WC, NAR and staff RN), and a variety of interactive exercises and opportunities for scoring points were developed. Both modules adopted a case approach with voice-over dialog by professional actors and 3D color graphics. One module highlighted IASD risk factors, the other focused on IASD assessment incorporating the approach of a valid and reliable instrument, (the Incontinence Associated Skin Damage Severity Instrument.D.2), and both modules emphasized a respectful communication and a team approach to care. The modules were created with Unity3D, a best-in-class multi-platform physics engine with graphical pipelines to DirectX and OpenGL. Unity3D is widely considered a gold standard platform for entertainment games and educational simulations. An initial pilot group of 14/14 users (100%) completed the evaluation. On a five-point Likert scale (strongly agree to strongly disagree), 79% (n=11) of respondents indicated “strongly agree” to each of two process questions--that playing the simulation games was enjoyable and that they were an effective way of learning. The remaining 21% responded “agree” to these process questions. In terms of achieving four learning objectives after completing the modules, 69-79% of respondents rated their ability as excellent and the remainder selected very good, using a five point scale (Excellent to Poor).

Interpretation of Results: This project successfully completed the development of an interactive, web-bases serious game to instruct nursing home staff about IASD and its severity, assessment and risk factors. Initial evaluations are positive.

Next Steps: Availability of the educational games has been made known to a national set of nursing home staff during a webinar about IASD offered by McKnight's Long-Term Care News / Senior Living and at the 2016 WOCN Society conference. Next steps are to continue to increase publicity about the games and to encourage their use on various computer systems and further evaluation in terms of learning and practice support.

Conclusion: Serious gaming technology offers a stimulating, engaging, and efficient way to educate nursing home staff about important clinical problems such as IASD.

Funding Source: Vitals Sims LLC and Hartmann.
SURFACE ELECTRICAL MUSCLE STIMULATION FOR TREATMENT OF STRESS URINARY INCONTINENCE

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Background and Aims: Electrical stimulation of the pelvic floor muscles (PFM) through use of intravaginal probes has been demonstrated as an effective tool in treating women with stress urinary incontinence (SUI). Unfortunately, many women opt-out of treatment with intravaginal probes for various physiological and psychological reasons, allowing incontinence symptoms to gradually worsen. Elidha is developing an alternative means of delivering PFM stimulation aimed at improving treatment adoption and compliance. The technology applies electrical muscle stimulation through surface electrodes applied proximate the perineal tissue. This approach has shown promise when administered in a clinical setting [1][2] and Elidha now looks to deliver it in a manner acceptable for home use. The first aim of the study was to demonstrate that the device was easy for a layperson to apply and operate, comfortable to wear, and capable of stimulating the PFM. The second aim investigated differences between candidate stimulation waveforms using patient reported contraction strength and comfort measures. Results from these single session evaluations are intended to inform study design of future multi-week efficacy studies.

Study Design: The study utilized Elidah’s SUI therapeutic device which comprises a disposable electrode and a stimulator. The electrode has an hourglass shape with four conductive regions and a central egress. The electrode utilizes conductive ink technology in lieu of conventional wires. The stimulator, provided in a compact wearable form factor, houses the waveform generator, rechargeable battery and user control interface. An internal microcontroller allows preprogramming of the device with candidate stimulation waveforms. Subjects applied the device per written and pictorial instruction. Additionally, an oscilloscope and multimeter were connected via patient cables to allow direct measurement of electrical parameters including applied voltage and current. The output voltage intensity was incrementally increased while the subjects commented on the strength and comfort of the PFM stimulation. This was repeated with various waveforms and subjects provided comparative assessments. An adaptive approach eliminated poorly performing waveforms from further consideration and allowed additional evaluation of waveform derivatives of the highly performing waveforms. At the end of the study the subjects completed a questionnaire.

All waveforms were delivered at a stimulation frequency of 50 Hz and provided alternating 6 second periods of contraction and relaxation with 1 second of ramping. Waveforms were broadly classified as one of three types:
• Traditional Intravaginal – Single pulse bi-phasic square wave
• Burst Mode Alternating Current (BMAC) – Repeating bi-phasic square wave profile with 30-50% duty cycle
• Modulated – Repeating bi-phasic square wave with sinusoidal amplitude modulation
Results: Eight subjects completed the study. There was no specific target demographic in this pilot evaluation, so potentially relevant factors varied widely including age (25-70), BMI (16-27), prior births (0-3) and incontinence symptoms (none-moderate). All subjects were able to apply, wear (~1 hour) and remove the device without difficulty or discomfort, even in the presence of pubic hair. All subjects were able to identify intensity levels corresponding to an initial sensation, a notable tightening of the PFM, and a point of discomfort (i.e. discomfort for 20 minutes of continuous use).

The traditional intravaginal waveform failed to provide notable stimulation and was quickly eliminated from ongoing consideration. Subjects reported that BMAC and modulated waveforms provided similar levels of PFM contraction and that modulated waveforms provided the highest degree of comfort during stimulation. Further, the modulated waveforms allowed the highest tolerable current level (Irms), but the difference was not statistically different from the BMAC waveforms.

Discussion: The outcome satisfied the first study aim, effectively demonstrating the feasibility of a surface electrode, patient-applied SUI treatment device. This work also supports use of waveforms different from those typically used with intravaginal devices. The positive response to the modulated waveform was consistent with findings from application of a similar waveform to the quadriceps [3]. Future work will move from single-session assessments to multi-week trials designed to show clinical efficacy in reducing incontinence systems. Based on pelvic floor therapy literature, successful treatment regimens are likely to comprise daily 20 minutes treatment sessions, with measurable improvement after 6-8 weeks. This promising technology, which aims to deliver an efficacious alternative to intravaginal SUI devices, will potentially lead to greater adoption and compliance rates among the 1 in 3 women affected by urinary incontinence.

References:

Ethical Approval: Human subjects provided a statement of informed consent approved by Western IRB (#20162650).

Funding Source: Portions of this work were funded through an SBIR Phase 2 grant from the National Science Foundation (award #1630203).

Conflict of Interest: The authors are employees of Elidah, the manufacturer of the study device.
DEVELOPMENT AND EVALUATION OF A CONTINENCE PRODUCT DECISION AID FOR PATIENTS, CARERS AND CLINICIANS

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Introduction and Aim of the Study: For patients with long-term bladder or bowel incontinence effective containment of leakage is fundamental to health and quality of life. There is a wide range of absorbent products and devices available, but patients, carers and clinicians are frequently unaware of the suitability of available options. Sub-optimal use of products can negatively impact on health and quality of life. Aim: To develop and evaluate the acceptability and usability of a continence product decision aid (PDA) to support patients, carers and clinicians to choose continence products.

Study Design and Methods: Underpinned by the International Patient Decision Aids Standard quality framework and the Ottawa Decision Support Framework, development and evaluation of the PDA was undertaken in 4 phases.

I. Systematic search of the continence product literature and synthesis of evidence.

II. Evidence-based set of 24 prototype PDAs developed with iterative feedback from continence specialists (n=7) and other clinicians.

III. Acceptability testing:
   a. The PDA and a feedback questionnaire were provided to patients (n=10) with incontinence experience to assess content and format.
   b. Following revisions, acceptability was assessed via semi-structured interviews with patients/carers (n=10) and clinicians (specialist and non-specialist) (n=11).

IV. Usability Testing: Feasibility randomised controlled trial with men post-radical prostatectomy recruited at removal of catheter (n=40 with 21 recruited so far). Control Arm = usual care, Intervention Arm = usual care, plus PDA.

Results: An algorithm was developed to differentiate patient groups using characteristics that influence continence product choice (gender, mobility, carer dependency, cognitive impairment, type and level of leakage) leading to 24 patient groups (12 female/12 male) (Figure 1). For each group, a ‘traffic light’ option grid (green = recommended for most people, amber = consider, red = not recommended for most people) guides appropriate patient choice (Figure 2). The majority of patients and carers and all clinicians interviewed stated that the PDA provides a useful guide for supporting optimum product choice, but it was highlighted that some patients will need support to use it effectively. Specialist clinicians identified the benefits of using the tool for training non-specialist clinicians to assess patients. A usability trial is underway (n=21 recruited) and findings will be available for the conference.

Conclusion: This tool provides the first evidence based, systematically developed aid to choosing continence products. The development process highlighted the complexity of choosing the optimal continence management products and provided insight into the important factors that influence choice of continence products that need to be considered. The tool...
has the potential to substantially improve patients’ quality of life by supporting self-selection and optimal product choice.

**Ethical Approval:** Ethical approval was received from the NHS Health Research Authority.

**Funding Source:** Movember Foundation in partnership with Prostate Cancer UK as part of True NTH programme.

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**Figure 2: Men’s Algorithm**

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[Diagram of the Men’s Algorithm showing steps and options for product selection based on user preferences.]
EVALUATION OF A NEW WEBSITE FOR MEN MANAGING INCONTINENCE ASSOCIATED WITH PROSTATE CANCER

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Background to the Study: Long-term urinary incontinence (UI) is a frequent consequence of prostate cancer treatment that can have very damaging effects on quality of life. Research evidence shows that men lack information about incontinence and containment products -- particularly unbiased, evidence-based information – such as how to obtain the best products for particular needs. To fill the information gap, and as collaborators on the TrueNTH continence management programme, we have worked with men who are incontinent after prostate cancer treatment to build a dedicated website which is specific to the needs of men having prostate cancer surgery and other prostate cancer treatments that cause urinary and/or faecal incontinence.

The new prostate cancer continence website is hosted by the Continence Product Advisor website (CPA, www.continenceproductadvisor.org). The CPA provides generic and independent evidence-based product advice for consumers and professionals. The prostate cancer continence website builds on the CPA evidence base and provides information specifically for men preparing for, or coping with, incontinence post treatment and includes:

- **New and updated content** based on interviews with men who have experienced incontinence post treatment.
- **Men’s reports on what they need** to prepare for and manage a urinary catheter and incontinence.
- **Links between the website and Prostate Cancer UK (PCUK) and other key websites** for specific information as appropriate.
- **New materials** - user videos, quotes and downloadable information sheets.
- **A suppliers’ database** so men can easily make product purchases.
- **Mobile First** platform to enable viewing of the website using all device types i.e. PC, tablet, phone.

The next step in the website development is to evaluate the content with men who are experienced in managing incontinence after prostate cancer treatment to ensure that the resource meets the needs of as many men worldwide as possible.

Aims of the Study: To evaluate the value and utility to men of the new prostate cancer continence website and to identify areas for further improvement and/or development.

Objectives:

- Describe and evaluate men’s views about the microsite
- Evaluate the comprehensiveness of the website and identify any gaps
- Test the functionality of the website (on a PC) i.e. ease of navigation through the site and new functions e.g. suppliers’ database.
- Identify further opportunities to improve the information and functionality.

Methods: This is a qualitative study using semi-structured interviews, user questionnaires and observation of website use. Website navigation by participants will be observed by a researcher and recorded using personal capture software (Echo 360 http://echo360.com) which will provide a visual record, with commentary, of any difficulties men have when moving around the site, in particular, if they get ‘stuck’ and are unable to navigate to the next step.

Participants: Sixteen men who have experienced incontinence after radical prostatectomy or other treatment for prostate cancer (different time points post treatment <3 months, 3-12 months, >12 months) and who use the internet will be recruited. Men who have been involved in the development of the website will
be excluded. Men will be recruited through urology clinics, prostate cancer organisations and as previous participants in other related studies who have expressed an interest in taking part in other research.

**Results:** The study will commence in the New Year and results will be reported at Innovating for Continence in April 2017.

**Conclusion:** Recuperating from prostate cancer treatment is complicated when urinary incontinence persists over several months or longer and it is well documented that men require support during this time. Not only will the prostate cancer continence website provide evidence-based product information but it will also include video clips from men who have or are experiencing incontinence and in which personal support and coping strategies are suggested. These honest real life opinions and helpful suggestions may go far to aid men in their journey to recovery.

**Ethics Approval:** We are awaiting ethics approval.

**Funding Source:** This work was funded by the Movember Foundation in partnership with Prostate Cancer UK as part of TrueNTH programme.

**Conflicts of Interest:** Alan Cottenden discloses: Astellas: Lecturing honoraria (current, SCA: Consultancy (current), Biomedical Engineering Association: Member of board (current), Simon Foundation for Continence: Member advisory board (current). Other authors had no disclosures to make.
DEVELOPMENT OF AN EFFECTIVE WASHABLE NIGHT-TIME ABSORBENT GARMENT FOR MEN: EVALUATION OF EXISTING PRODUCTS

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Introduction: A proportion of men treated for prostate cancer will experience urinary incontinence. For some men this is transient and is quickly resolved; for others it can be life-long, with wide-reaching effects on lifestyle and quality of life. Absorbent products tend to be selected by most men as part of their continence management but as previous research has demonstrated many of these products are more suited to women and are not particularly effective for men, especially for those who experience heavy incontinence at night. We know that men tend to leak more urine at night than women and that leakage often occurs at the sides of the pad¹ yet very few products have been developed specifically to address these problem. In a study for the UK Health Technology Assessment Programme in 2008² we discovered that the most effective absorbent product for men was a square of toweling cotton folded like a babies’ nappy and worn with waterproof plastic pants. However, whilst it contained urine effectively it was considered by many of the men who took part to be difficult to use and aesthetically unaccepteable to wear. Working in collaboration with a group of men who experience night-time incontinence we secured funding to investigate the advances that have taken place in the development of reusable absorbent products. Our aim was also to identify the design features that could improve these products. If no suitable products could be found to fulfill this need a second phase of the study would be to develop a new product based on the findings.

Aims of the Study:
- To review all existing absorbent and waterproof products for heavy night-time incontinence;
- To identify strengths and limitations of a selection of these products;
- To identify products which are better – in at least some aspects – than the folded toweling cotton square with waterproof pants, in terms of effectiveness (better at containing leakage), comfort, aesthetic acceptability and other key performance characteristics.

Study Design: We conducted a search of all the products manufactured for moderate/heavy urinary incontinence and procured a sample of those which were available to purchase in the UK. In collaboration with a panel of users we identified four of the most promising garments, based on our knowledge and experience of fabrics and design features and visual acceptability. In addition to these, we included the cotton toweling square worn with waterproof pants as a reference product based on its performance in previous studies. The following products were selected for the study: a) Boxer shorts with waterproof inserts worn over one of two products which required a separate waterproof layer (b & c). Products d) & e) were designed with an integral waterproof layer. We recruited sixteen men who had pre-existing heavy night-time urinary incontinence. Each man (participant) initially used the reference product for a minimum of two nights then, using a randomised crossover design, all the men used each product in a different order for up to two weeks at night at home. The men were asked to weigh the product every night and morning to determine the amount of urine it contained and to state whether or not it had leaked. We used questionnaires to compare each product with the reference product (the toweling cotton square and waterproof pants) and to enable the men to identify strengths and weaknesses of each product. Finally the men were asked to rank the products against each other for various attributes.

a) Waterproof-lined boxer shorts  b) towelling cotton pull-ups  c) All-in-one bamboo diaper  d) All-in-one diaper  e) Bamboo diaper with loose waterproof layer
**Results:** From our initial product search and selection procedure we identified four garments to go forward for clinical evaluation and comparison with the reference garment. These comprised:

- A pull-up pant worn with waterproof-lined boxer shorts
- A Velcro-fastening diaper worn with the same waterproof-lined boxer short
- An all-in-one Velcro-fastening diaper with integrated waterproof layer
- An all-in-one Velcro-fastening diaper made from bamboo fabric with a loose waterproof layer.

We recruited 16 men to the study, yielding 12 datasets. Each man gave written consent to take part in the study. The mean amount of urine leaked onto each weighed garment was 428ml, with leakage rates increasing across all garments as the amount of urine increased. None of the garments was rated as being better than the reference product for containing leakage, but all scored better for visual aesthetics, ease of putting on and wet comfort. We identified a particular problem of leakage around the legs and waist of some products which was associated with poor fit and insufficient placement of absorbent fabrics at the side of the garments. Unacceptably long drying times were associated with all the garments except for the one with the loose waterproof backing. The reference product was also rated as the easiest for washing.

**Interpretation of Results:** From these findings we have identified that there is a lack of effective and acceptable washable absorbent continence garments designed for men with heavy night-time urinary incontinence. It appears that a cotton toweling square and waterproof pants remains the most effective product despite its aesthetic shortcomings. Newer products are available which address some of these issues but we have been unable to find a product as effective as the reference product but which is acceptable to the group of men who need to use it. Through this research we have been able to identify particular design features and materials which may contribute towards a better-designed product that is not only effective, but is also aesthetically acceptable for men to wear.

**Conclusion:** This study has demonstrated that there is a need for an improved washable night time product to improve the lives of men who live with long-term urinary incontinence. In Phase 2 of this study we will continue to work with men to develop a better product.

**References:**

**Ethical Approval:** Ethical approval was obtained for this study by Hampshire B Research Ethics Committee, UK.

**Funding Source:** Movember Foundation in partnership with Prostate Cancer UK as part of True NTH programme.

**Conflicts of Interest:** Alan Cottenden discloses: Astellas: Lecturing honoraria (current), SCA: Consultancy (current), Biomedical Engineering Association: Member of board (current), Simon Foundation for Continence: Member advisory board (current). No other authors had disclosures.
ADAPTING ORIGAMI PRINCIPLES TO IMPROVE DISPOSABLE INCONTINENCE PRODUCT PERFORMANCE

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Introduction: Origami, traditionally known as the art of paper folding, is not limited solely to paper media. The concepts used in folding paper also apply to more pliable materials such as fabric. As with paper, different fabric origami designs exhibit properties such as shape compliance, increased surface area per unit volume, and selective stiffness. This study explores selected fold patterns using diaper fabrics, aiming to increase organic shape conformance, increase fluid wicking distance, and reduce sag due to saturation.

Methods: The fabrics chosen for this study are Zorb®, cotton knit terry, athletic wicking jersey, spandex, and polyurethane laminate (PUL). Patterns will be folded and then imprinted on the fabrics using a heating iron. Testing of each of the three properties on these fabrics will proceed as follows:

1) Shape conformance: All materials will be tested. Organic origami design principles will be adapted to create different pliable shapes which resemble current disposable incontinence products. The allowable change in curvature along the three cardinal axes will then be measured for each design on each of the materials.

2) Wicking: Only the wicking jersey will be tested. A range of pleat patterns will be chosen and formed on each fabric. Using dyed water, the linear distance and the rate of travel will be measured, both horizontally and vertically (against gravity).

3) Stiffness: All materials will be tested. Known selectively stiff patterns will be altered, then made in each material. The stiffness will be quantified using a measurement of deflection. The vertical sagging distance upon saturation (addition of 300mL dyed water) will also be measured.

Results: Complete results will be available for the conference. Preliminary research and testing suggest supportive evidence of the study objective. Work has shown that acute angles in single-layer pleated patterns increase both wicking distance and rate in all three absorbent materials. Despite the fabrics’ increased flexibility compared to paper, they retain their shape well under both dry and wet conditions, using the technique described.

Conclusion: Adapting these three origami principles to disposable incontinence products could be a revolutionary approach to solving the relevant issues, and is a real possibility. Doing so would increase both user comfort and product efficiency in an innovative way. The patterns and approaches tested here are not exhaustive, and others could certainly be examined. Further exploration needs to be done of integration of these concepts into current disposable incontinence product design.

References:


Funding Source: National Science Foundation
Conflict of Interest: None
Ethical Approval: None
INHIBITION OF EFFLUX SYSTEMS WITH COMMONLY USED DRUGS CAN CONTROL INFECTION AND BLOCKAGE OF URINARY CATHETERS BY PROTEUS MIRABILIS

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Introduction: Indwelling urethral catheters (IUC) are widely used for long-term bladder and urinary incontinence management in elderly individuals. However, bacterial infections associated with long-term IUC use constitute a major cause of morbidity and mortality. Proteus mirabilis is a particular problem in this regard, and forms extensive crystalline biofilms on catheter surfaces that obstruct urine flow and lead to serious complications such as pyelonephritis, septicemia and shock. Currently, no truly effective countermeasures are available to combat these infections. Efflux pump systems are significant means by which bacteria can evade the effect of selected antimicrobial agents, and their functions in bacterial infection and biofilm formation are now emerging. Suppression of these systems using efflux pump inhibitors (EPIs) can be an effective strategy to combat P. mirabilis IUC-related infections, and several drugs already in use are potential EPIs, such as selective serotonin reuptake inhibitors (SSRIs), thioxanthenes, and phenothiazines. Here we evaluate the potential for existing drugs to act as EPIs, and test the potential for these to prevent catheter blockage in P. mirabilis infections.

Materials and Methods: A range of potential EPIs including SSRIs, thioxanthenes, and phenothiazines, were selected, and EPI activities were assessed by measuring fluorescent accumulation of ethidium bromide (EtBr) in cells exposed to sub-MIC levels of EPIs. Representative in vitro models of the catheterised urinary tract, simulating a complete closed drainage system as used in clinical practice and utilizing sterilized urine medium, were employed to evaluate the performance of selected EPIs in preventing catheter blockage. The impact on time taken for catheters to block, as well as levels of crystalline biofilm formation and other traits relevant to virulence, were measured.

Results: Efflux pump activities were demonstrated in P. mirabilis for thioridazine, fluoxetine, sertraline, paroxetine, escitalopram and perphenazine. Fluoxetine and thioridazine were investigated further for their effect on P. mirabilis virulence characteristics and catheter blockage. Both compounds induced changes in P. mirabilis motility on agar plate with significant decreases in swimming and swarming abilities as compared to those in untreated medium controls. Treatments with fluoxetine and thioridazine significantly increased time taken for catheters to block (2 to 3-fold), at 128 and 200 μg/mL, respectively, compared to untreated controls. Treatments in time limited bladder model settings followed by imaging and quantification of biofilms directly on catheter surfaces, demonstrated significant reduction of crystalline biofilm formation, but without significant reduction in levels of planktonic cells in the residual “bladder” urine.

Conclusion: These results show that commonly used drugs have EPI activities in P. mirabilis, and can inhibit crystalline biofilm formation. Therefore, repurposing of existing drugs could be a promising approach to prevention of catheter blockage. However, methods to deliver these compounds in adequate doses and within a key therapeutic window and at the right stage of UTI will be important to their successful application. The focus of our ongoing studies is on deployment of clinically relevant concentrations of EPIs at local sites within the urinary tract.

Funding Source: The Dunhill Medical Trust (Grant R394/1114 awarded to BVJ).
CORRELATION OF SACRAL NERVE LEAD TARGETING AND UROLOGICAL EFFICACY: MOTOR MAPPING, ELECTRODE POSITION, AND STIMULATION AMPLITUDE

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Introduction: Sacral neuromodulation (SNM) is a clinically used therapy for refractory urge frequency and incontinent patients. A recent sheep model has focused on quantifying objective responses to SNM in order to examine questions of efficacy and durability. One simple hypothesis is that lead placement is critical for effective therapy delivery. This preclinical study retrospectively evaluated the relationship between implanted sacral lead locations, motor threshold values, motor mapping, and acute urological efficacy to determine if acute location and physiological measurements are correlated.

Methods: Twelve female polypay sheep were implanted with bilateral InterStim® devices (Model 3058) connected to quadripolar leads (model 3889) placed in the S2-4 foramina with S3 as the ideal target as per Brink et al. 2015. CT scans at post-op and ≥ 12 months post-implantation were used for 3D rendering performed using MedCAD points placed on the sacrum and lead contacts to compare coordinates across animals’ anatomy. Acute cystometry was performed to test responses to SNM (0.21ms pulse-width, 10Hz) at maximum tolerable amplitude (MTA). Motor threshold (MT) values were obtained by visual identification of the first motor response and the motor reflex was mapped to an anatomical map.

Results: Sheep were categorized as responders (n=6; 50%) or non-responders (n=6; 50%) based on ≥50% increase in bladder capacity to acute SNM. There was a significant difference in motor mapping areas between responders (peri-anal contactctions) and non-responders (activation of leg) (Figure 1: chi-square; p<0.05). Secondly, higher MTA values correlated with larger bladder capacity increases (Pearson correlation; p<0.05). Finally, contact position correlated with urological response (ANOVA; p<0.05). A generalized Procrustes analysis on the 17 leads in S3 (remainder in S2 or S4) showed the variability of distributions was higher in distal contacts (0 & 1, mean distance to center 7.3 ± 1.8 mm for left & 6.8 ± 1.3 mm for right) than at proximal contacts (2 & 3, mean distance to center 5.8 ± 0.86 mm for left & 4.3 ± 0.35 mm for right (ANOVA; alpha = 0.05; F(3, 64) = 20.55; p< 0.0001).

Figure 1. Motor mapping of first motor response to SNM. Motor threshold responses were mapped to one or more of 8 bilaterally symmetric regions (color coded at left to match bar graphs at right). Right panel shows the sum of motor responses in the peri-anal areas (upper panel, blue and gold columns) of non-responders (NR; left two columns) and responders (Resp; right two columns) and the other leg areas (lower panel) of NR (left 6 columns) and Resp

Figure 2. Distance of each contact from best fit center on Procrustes-transformed 3D coordinate system. Error bars = standard deviation. Asterisks denote significance using Tukey’s multiple comparisons post-hoc analysis: ** = p < 0.001; **** = p < 0.0001.
**Discussion:** 1. Responder sheep showed motor responses in peri-anal areas significantly more often than non-responders. 2. MTA weakly correlated with increased bladder capacity. 3. Activation of lead contacts proximal to the sacral foramen produced more reliable urological results than did activation of distal contacts. These results suggest a well-positioned lead will elicit specific motor responses that could be essential to effective SNM therapy. Future work will characterize changes in lead location over time to provide a temporal correlation of this relationship.

**Ethical Approval:** All animal procedures and events were approved by the Medtronic Physiological Research Laboratories IACUC.

**Funding Source:** Funding was provided by Medtronic, Inc.

**Conflict of Interest:** All authors with the exception of JW are employees of Medtronic, Inc.
EVALUATION OF PENILE COMPRESSION DEVICES
FOR PHYSIOLOGICAL IMPACT AND USER ACCEPTABILITY

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Introduction: Penile compression devices (clamps) are applied to the shaft of the penis to compress
the urethra thereby preventing incontinence in male following prostatectomy. Clamps are significantly
more secure and less likely to leak than pads or other devices allowing men to participate in short vigor-
ous activities, such as swimming or dancing (1). However, they are significantly more painful than other
devices, affect penile blood flow (2) and are not currently recommended by the National Institute for
Health and Care Excellence (NICE).

Clamp designs vary widely and further investigation is needed to assess the comparative efficacy and
the strengths and limitations of each design. In addition, the impact of clamps on penile circulation and
skin integrity will inevitably contribute to their success in use. The objective of the present study was to
evaluate existing clamps for physiological impact, efficacy and user acceptability.

Study Design: Hampshire ethical committee approval (REC South Central – Hampshire B, 05.09.14)
was obtained to invite a cohort of 12 men to review 16 existing clamps, 5 designs of which were select-
ed for further investigation. The performance of the chosen clamps (Weisner, Dribblestop, Cunningham,
Uriclak and Cook) were assessed in the laboratory using measurements of circulatory impedance (Dop-
pler flow), applied interface pressure and inflammatory response when worn by 6 men. Physiological im-
pact of clamping with the Dribblestop and Weisner was assessed via MRI scanning. Finally the clamps
were tested in a home-based usability study. Informed consent was obtained from all participants.

Results: When first applied, interface pressures of around 150 mmHg were generally recorded.
However in the case of one commonly used clamp (Cunningham) pressures in excess of 300mmHg
were achieved, values which were associated with a substantial decrease in the blood perfusion flux in
the penis distal to the clamp location. On clamp removal, perfusion levels were restored back to
unloaded levels.

Pressures generally decreased with time of wearing. In practice, this requires adjustment of the clamp
by the participants to maintain continence. No single clamp design proved ideal for all users with varying
opinion amongst participants as to their preferred clamps. Nonetheless, the Weisner was acceptable
to most participants and the most effective at preventing leakage. However, it was the only clamp also
associated with hematuria and elicited the highest pain score. MRI scanning of the penis identified sub-
stantial deformation compared to the unloaded morphology (Figure 1 and 2) under clamping pressure
from the Dribblestop (Figure 3) and Weisner (Figure 4). The structures, corpus cavernosum and corpus
spongiosum, could be seen to flatten in cross-sectional images. Tissues external to the Buck fascia,
including blood vessels and skin were displaced laterally to areas outside of the clamp pads. Urine
was contained within the urethra proximal to the clamp site.

No single clamp design proved ideal for all users and each clamp had its proponent. The Weisner was
acceptable to most participants and was the most effective at preventing leakage. However, it was the
only clamp associated with hematuria and elicited the highest pain score.

Conclusion: Clamps are useful devices favoured by some men who suffer from incontinence follow-
ing prostatectomy. This study demonstrates that no currently available clamp has an acceptable level
of impact on blood flow, and is effective and acceptable to users. Based on the current findings, future
work will develop a new clamp with acceptable and appropriate features. The design will benefit from
the introduction of a computational model (FEBio) of the penis, with morphological features and dimen-
sions provided from the MRI images also being presented at conference (abstract submitted).
References:

Conflicts of Interest: None

Funding Source: This work was funded by the Movember Foundation in partnership with Prostate Cancer UK as part of the True NTH programme. (Grant: 250-10)

Acknowledgement: Thank you to Chris Everitt for the MRI radiography

Figure 1: MRI T2 space image taken on the mid-sagittal plane of the penis without a clamp.

Figure 2: Image taken 11.2mm distant from Figure 1.

Figure 3: Dribblestop clamp compressed penis with a square edged profile. Occluded urine (yellow) is present in the urethra. Occluded blood is present in the dorsal vein (red). Corpus cavernosum (purple) and corpus spongiosum (blue).

Figure 4: Weisner clamp compressed penis with a smoother edged profile.
THE INFLUENCE OF PENILE CLAMP DESIGNS ON THE INTERNAL MECHANICAL STATE OF SOFT TISSUES

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Introduction: Penile clamps are one option to minimize urine leakage after prostate cancer surgery. However, such devices may cause soft tissue damage. To minimize this damage while maintaining device functionality, we have adopted a combined computational and experimental approach to establish optimum device design criteria.

Methods: ScanIP® module [1] was used to segment and mesh a geometrical anatomical penile model including skin, fat, tunica albuginea (TA), corpus cavernosum and corpus spongiosum (CS). 3D orthotropic material properties were assigned to skin and TA, while all other tissues were considered to be linearly elastic [2]. In the Preview module [3], uniform circumferential pressure was initially applied to simulate a soft cuff-type clamp. 12 model variants were developed, representing 5 generic clamp designs and interface materials. Opposite vertical displacements were assigned to top and bottom surfaces of every clamp to compress mid-shaft. (Figure 1) We examined effective and maximal shear strain and stress distributions during 50% urethral occlusion and determined device skin-interface conditions and physiological responses of soft tissues. (Figure 2) Estimated parameters included interface pressures, blood flow using Laser Doppler imaging, and pro-inflammatory cytokine release.

Results: The model yields effective strain and stress distributions in an axial cut through the penis. Stresses in skin, fat and TA regularly exceeded 10 kPa (75mmHg) with corresponding maximum effective

Figure 1: Computational finite element modeling of the penis and penile compression clamps; (a) A three-dimensional (3D) model of the penis. (b) An axial cut through the penis, showing the skin (S), fat (F), tunica albuginea (TA), corpus cavernosum (CC), corpus spongiosum (CS), and urethra (U), and (c) The flat, angled, contoured, and contoured with knurl clamps.

Figure 2: Distributions of effective tissue stresses in an axial cut through the penis while using different penile clamps, at 50% closure of the urethra. The clamp interface materials are given different elastic moduli of 25, 50, and 100 kPa.
strains of between 14-18%. Maximal deformations were found in the CS around the urethra. Our preliminary findings indicate many clamp designs occlude soft tissue blood flow.

**Conclusion:** Penile clamps may cause discomfort and soft tissue damage. Soft tissues are particularly vulnerable to irreversible damage if loaded for prolonged periods, as could be the case of penile clamp wear. Our goal is to identify design characteristics, which will provide the safest mechanical conditions in penile soft tissues and thus minimize risk of tissue damage while effectively managing incontinence. In the next stage of this study, the model will be used to assess prototype clamps.

**References:**

**Funding Source:** This work was funded by the Movember Foundation in partnership with Prostate Cancer UK as part of True NTH programme.

**Conflicts of Interest:** None.
A COMBINATION OF SINGLE-USE AND RE-USE OF INTERMITTENT CATHETERS – SUSTAINABLE SOLUTION OR RISKY AND BURDENSOME STRATEGY?

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Introduction and Aims of the Study: Although the benefits of intermittent catheterization (IC) use are clear, urinary tract infection (UTI) remains a common problem despite innovations in catheter design and materials. To overcome the issues associated with IC and particularly UTI, research has focused on single use catheters and the development of catheter coatings, pre-lubrication and compact catheter designs. However, a recent Cochrane review concluded that there is no convincing evidence that one catheter design or method is better than another in terms of UTI¹, and more robust research is needed. Catheter re-use is usual practice in many centres. However, it has gained little attention from researchers or industry, even though single-use catheters may not be the most environmentally friendly or cost effective strategy. A combination of reuse and single use IC may be a reasonable compromise for cost and convenience. In this study, we wished to explore the views of IC users regarding advantages and disadvantages of combining single use and re-use of catheters for an individual using ongoing IC and living in the community.

Study Design: The study incorporated a review of the literature and qualitative interviews with IC users. The literature review was conducted using the search engines CINAHL, AMED, MEDLINE, EMBASE and Cochrane Reviews and included papers published from the year 2000 onwards. In addition, further papers were found through hand searching references and from previous searches. Semi-structured interviews were conducted with a convenience sample of 39 IC users, 24 men and 15 women aged 23-86 years; 4 participants re-used their catheters. All interviews were conducted in participants' own homes using a semi-structured interview schedule; informed consent was gained from all participants. All interview transcripts were analysed thematically using NVivo 10 (QSR International).

Results: Both the literature review and qualitative interviews revealed similar issues regarding re-use. The top priority was safety; the majority of IC users wanted robust evidence that re-use was safe in terms of UTI risk. The practicalities of the cleaning method were also crucial. One participant wondered 'how much labour would be to get it back to the required state of sterility……..to be reusable'. IC users would be willing to re-use depending on the burden involved in the cleaning method and the amount of extra products and time. One felt that 'if there is too much preparation time then I wouldn’t be interested'. Several were concerned about the environmental impact and cost of single use catheters; this was considered an advantage of re-use. In some cases, participants felt guilty about the waste involved with single use catheters. This was also a finding from the literature². A further concern raised was the issue of running out; one participant felt that being able to re-use their catheter would mean ‘you’d know you’ve always got one.’

The interviews and literature review both highlight different advantages and disadvantages of single use and re-use; an advantage of one was often seen as a disadvantage of the other. Some raised the need to take many single use catheters on holiday as a disadvantage, but the need to take fewer when re-using was an advantage. Others in this study, and in a recent study³, would find re-use more difficult when away from home. Therefore, a flexible approach where IC users could use a mixture of single-use and re-use in their daily routine (at home, work, or holiday) might be an option. This allows care to be individualized for each IC user.

Interpretation of Results: The qualitative interviews revealed that if shown to be safe with a practical cleaning method, many IC users would find re-use an acceptable option. The literature review revealed that there is little attention given to re-use. The findings also endorse the view that a mixed package could
be an option and that many IC users have concerns regarding the environmental issues and costs related to single use.

**Next Steps:** This study highlights the need for a clinical trial to determine whether re-use of IC catheters is safe in terms of UTI risk, to test the cleaning method and to clarify the advantages and disadvantages of single use and re-use. Some of the disadvantages raised by participants in relation to re-use are not modifiable. However, if re-use is shown to be safe and acceptable to IC users, several could be addressed through developments in design and innovation such as cleaning, preparation and equipment and the design and coating of the catheter. This raises the possibility of a new market for industry.

**Conclusion:** To provide both high quality and cost effective care, it is the responsibility of all associated with research and development in IC to consider methods that are evidence based as well as sustainable in terms of both environmental impact and burden of cost. If IC users would consider re-use as an option, then there is the need for a clinical trial to properly test this.

**References:**


**Ethical Approval:** Ethical permission was granted from an NHS Research Ethics Committee.

**Funding Source:** National Institute for Health Research Programme Grants for Applied Research programme.
INTERMITTENT CATHETER USERS’ SYMPTOM IDENTIFICATION, DESCRIPTION, AND MANAGEMENT OF URINARY TRACT INFECTION: A QUALITATIVE STUDY

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Introduction and Aims of the Study: Urinary tract infection (UTI) is the most frequently reported complication among IC users. However, the typical signs and symptoms may not be experienced or described by individuals using IC. Predicting and diagnosing UTI in IC users can, therefore, be more difficult than in the general population. While symptom presentation and identification have important implications for the diagnosis and management of UTI, little research has been conducted to understand how IC users themselves identify and describe UTI symptoms. The aim of this study was to report IC users’ own description of UTI symptoms and experiences of UTI, including their strategies for prevention, identification, and management.

Study Design: A convenience sample of IC users aged >18 who had been using IC for > 3 months was recruited from GP surgeries in Hampshire and Dorset, UK. Semi-structured interviews were completed. Informed consent was gained from all participants. The interviews were transcribed and thematic analysis was conducted using NVivo 10.

Results: 139 IC users were invited to take part and 74 (53%) responded of whom 42 were willing to participate. Of those, 3 participants were found ineligible. Furthermore, 9 participants were excluded from this study as they had never experienced UTI since starting IC. The total number of participants was therefore 30, including 19 men and 11 women, mean age 66 years (range 23-86), using IC for approximately 10 years (range 9 months – 31 years). The frequency of IC ranged from 1-10 catheterisations a day (mean 4/day). Reasons for IC included chronic urinary retention (N=15), neurological impairment (N=10) and other factors such as post surgery or post chemotherapy (N=5). When comparing to typical textbook UTI signs and symptoms (1,2), IC users tended to use more informal terms such as ‘not feeling well’ and ‘don’t feel comfortable’ rather than ‘malaise’ and ‘lethargy’, and not to localize pain and discomfort unless specifically asked. They often found it hard to know whether their symptoms were caused by a UTI or their underlying condition or from co-morbidities and age-related problems. The most commonly reported signs by the participants were cloudy and malodourous urine. Whereas some IC users acted on their initial symptoms alone and visited the General Practitioner (GP), others described how they would first attempt to self-manage and monitor for the further development of symptoms before visiting the GP. Coping strategies included drinking more fluids, increased attention to personal hygiene, or self-medicating with antibiotics without confirmation of UTI. Uncertainties were expressed about the causes of UTI, commonly attributed by IC users to poor hygiene and lifestyle behaviours. Some developed and followed their own strict routines in order to prevent UTI, avoiding outings and never using public toilets.

Interpretation of Results: Our results demonstrate the complexity among IC users that exists about understanding the signs and symptoms of UTI. The language of IC users to describe their symptoms differs from typical textbook signs and symptoms. Some indicate difficulty separating possible UTI symptoms from other more general symptoms. The way in which IC users act on perceived UTI signs and symptoms varies depending on (i) their perception of symptoms, (ii) their level of confidence in the effectiveness of self-help strategies, and (iii) their previous experience of UTI and its management by the GP.

Next Steps: In order to help both clinicians and IC users determine the most appropriate course of action regarding UTI, there is a need to develop a more patient-based UTI symptom question list as well as an evidence-based algorithm for self-care and help seeking. Some coping strategies described by IC users may lack evidence. Further exploration of the subjective descriptions of UTI symptoms and matching
these with laboratory confirmation may aid both the IC user and the clinician in providing best care. There may be a need for simple evidence-based education tools for this population to assist in self-management and appropriate antibiotic use.

**Conclusion:** IC users’ description of UTI symptoms often do not conform to textbook UTI symptoms, and can lack precision, owing in part to the presence of underlying health conditions. This, together with differing perceptions about the need to act or seek help, presents challenges for the role of clinicians in the diagnosis and management of UTI in this group.

**References:**

**Ethical Approval:** NRES committee London Hampstead; REC reference 13/LO/1511; approval letter dated 2 October 2013.

**Funding Source:** National Institute for Health Research Programme Grants for Applied Research programme.

**Conflicts of Interest:** None
THE CONTINENCE PRODUCT ADVISOR WEBSITE: TWO YEARS ON!

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Introduction: The Continence Product Advisor (CPA, www.continenceproductadvisor.org) is a website launched in June 2013 to provide independent, evidence-based advice to people with incontinence and caregivers wanting to select the most suitable containment products and use them effectively. The CPA is a joint venture of the University of Southampton (UoS) and University College London (UCL) in England, the International Consultation on Incontinence and the International Continence Society (ICS). The site is hosted by the ICS. Staff at these organisations are conducting a rolling program to develop the site, drawing on comments from its users. This poster will provide an update from Innovating 2015 of the website’s main features, recent developments and innovations planned for the future.

Major recent improvements include:

- **Accessibility for all device types** - a major rewrite of the website using “mobile first” principles allowing content to dynamically reconfigure itself according to the size of the browser. This allows the website to be viewed across a diverse range of devices from smartphones (Figure 1) and tablets through to large retina displays (PCs).
- **Engagement with users** – user interaction provided by the continence community in the tips system gives the new website the widest reach and broadest possible engagement with our target audience.
- **Access to products** – each product page now contains links to suppliers of that product group so users can more easily access purchasing information.

A major research project at UoS and UCL on urine containment products for men post-prostatectomy, has been funded by Prostate Cancer UK (Movember). This has enabled us to build a new prostate cancer continence website, hosted by the CPA, with information specific to the needs of men managing incontinence as a consequence of prostate cancer treatment. Throughout this project we have worked with groups of men who have described their experiences and needs on which we have based the content and structure of the new site. An evaluation of this will be presented at conference (abstract submitted). Within that project we have also:

- **Reviewed the CPA content** and made it gender-specific where appropriate
- **Added new and improved video clips** of how to use products and user experiences
- **Added downloadable information sheets** e.g. on catheter care
- **Developed a patient decision aid** (PDA) for better self-selection of products (abstract submitted); this tool will be integrated into the website - replacing the current product selector tool – and will enable users and caregivers to more easily and confidently identify one or more product to suit their needs.

Website Activity: Traffic on the CPA has grown steadily and has now reached in excess of 3500 per week, giving – through Google Analytics – lots of useful information on which sections users are finding the most helpful and yielding a steady stream of requests for information and suggestions for improvement. We have received 400+ queries from visitors to the site - product users, caregivers and industry personnel – and each of these receives a personalised response from a clinical expert. We have over 160 user tips submitted - these are moderated by the editorial team and incorporated into the relevant product page. They are then rated by other users thereby demonstrating the relative benefit of each.

Next Steps: We have continued to improve the CPA for the benefit of people managing incontinence. We have incorporated new functions and new/revised content notably in response to the needs of men with prostate cancer based on their self-reported experiences and needs. This disease-specific model may, in the future, be used for other groups e.g. Multiple sclerosis or spinal cord injury. In addition, we would like to
provide information specific to the needs of children/young people/parents/caregivers. The recent ICI update will enable us to further improve the website content with current research evidence. Following this, it is still our intention to have material translated into other languages as the site content remains available only in English.

**Ethics Approval:** Approval not required.

**Funding Source:** The Movember Foundation in partnership with Prostate Cancer UK as part of the TrueNTH programme.

**Conflicts of Interest:** Alan Cottenden discloses: Astellas: Lecturing honoraria (current), SCA: Consultancy (current), Biomedical Engineering Association: Member of board (current), Simon Foundation for Continence: Member advisory board (current). No other authors had disclosures.
SAFE REUSE OF INTERMITTENT CATHETERS: DEVELOPMENT OF AN EFFECTIVE AND ACCEPTABLE CLEANING METHOD

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Hypothesis / Aims of the Study: Catheters for intermittent catheterisation (IC) are single-use only in the UK and while reuse is commonplace in other countries, there is no evidence-based, recommended cleaning method. Where users reuse, catheters are often washed in soap and water and stored in a convenient container. Concerns raised about urinary tract infection rates with multiple use catheters are not supported by a 2014 Cochrane review (1). If individuals do reuse their catheters, it is critical that they and clinicians are confident in the cleaning method. There has been no systematic evaluation of cleaning method options. The purpose of this study was twofold: 1) to identify and test potential cleaning methods for use with uncoated PVC catheters, 2) to conduct clinical testing with IC users in their own homes.

Study Design/Materials and Methods:
Identification and laboratory testing of cleaning methods:
Six methods were selected as suitable for cleaning uncoated PVC catheters: steam sterilisation, boiling, ultrasonic, vinegar, soap and water, Milton fluid soak (a commercial form of sodium hypochlorite used to sterilise babies bottles) and were compared against control treatment of tap water rinse. Sections of uncoated PVC catheters (2 cm portions of tip, shaft, funnel) were exposed to known concentrations of a range of bacterial uropathogens in an artificial urine medium over time periods of 0, 3, 6, 24 h. Each method was assessed for effectiveness via culture. Episcopic differential interference contrast microscopy (EDIC-M) was used to show any evidence of biofilm development and to provide visual assessment of any surface changes.

Clinical testing of the most effective cleaning methods:
Following laboratory testing, the most effective cleaning methods were presented to a panel of IC users. This enabled selection of the most effective and acceptable methods. These were then tested by three IC user panels (total of 16 men; 13 women) at home using three self-selected catheter brands. Detailed cleaning instructions and training were provided by a registered nurse expert in IC. Catheters were cleaned and reused in a step-wise manner, from one clean and reuse up to a maximum of 28 cycles. Catheter urine specimens were taken at baseline and prior to each increment in number of cycles. Culture analysis on selective chromogenic agar provided quantification of the culturable population and species identification. EDIC-M was also used to examine sections of catheters for biofilm development.

Results / Expectations: Laboratory testing showed Milton soak, steam sterilisation and boiling to be most effective at cleaning the catheter sections following exposure to uropathogens. EDIC-M clearly showed attachment of bacteria in the control (tap water rinse) samples. However, examination of catheters following the heat-based cleaning treatments showed surface damage and evidence of increased bacterial attachment on the PVC catheters. In addition, these were less acceptable methods to catheter users and were therefore excluded. Two methods: i) soap and water, and ii) soap and water plus Milton soak (Milton Method) were therefore selected as the most effective and acceptable methods for clinical testing. Home-based testing of cleaning treatments by IC users showed that simple cleaning with soap and water alone was less effective than when followed by a Milton soak. The Milton Method was therefore adopted for subsequent testing (Table 1). The effectiveness of the Milton Method continued with up to 28 re-uses (Table 1). EDIC-M analysis found no evidence of bacterial attachment or biofilm development.
No. times catheter reprocessed | Cleaning method tested | Total samples tested* (from men and women) | No. (%) samples with culturable bacteria |
--- | --- | --- | --- |
1 - 7 | Soap & water only | 225 (m =117; w =108) | 58 (26) |
 & Milton Method | 678 (m = 306; w = 378) | 21 (3) |
8 - 14 | Milton Method | 84 (m = 36; w = 48) | 0 (0) |
15 - 27 | Milton Method | 24 (m = 6; w = 2) | 1 (4) |
28+ | Milton Method | 63 (m = 27; w = 36) | 0 (0) |

*A total of three samples were taken from each catheter.

Table 1. No. of culturable bacteria on 2 cm lengths of catheters following different reprocessing frequencies

Interpretation of Results: Data from laboratory testing showed the relative effectiveness of cleaning methods and provided data for subsequent clinical testing. Cleaned catheter samples from IC users confirmed that soap & water followed by a 15 minute Milton soak was effective for catheters reused up to 28 times; users also reported that the method was acceptable (practical, easy to use at home and away).

Next Steps: Users agreed that catheter reuse was a possible option for IC users in the future with advantages which complemented those of single use catheters. The safety and acceptability must now be tested in a multi-centre trial.

Conclusion: The use of the Milton Method was effective and acceptable to IC users at home and could be the foundation of a mixed package of multi and single use.

Reference:

Conflicts of Interest: None

Ethical Approval: Approval given by South Central-Hampshire REC (REC ref: 13/SC/0282).

Funding Source: NIHR-funded Programme Grant for Applied Research programme (PGFAR Rp-PG-1610-10078).
Introduction and Aims of the Study: Neurogenic Bladder (NGB) patients are at an increased risk of developing upper urinary tract complications due to high bladder storage pressure. Urodynamics is currently used to diagnose and assess treatment efficacy in NGB patients. At present, there is no practical method to obtain at-home measurements with patients, thus periodic urodynamic evaluations are necessary. These routine visits may be challenging for caregivers and NGB patients due to their condition. The Peritron+ was originally designed to assess the strength and endurance of the pelvic floor muscles (Peritron Perineometer). The addition of tubing (Air-Trap Tubing) allows the device to assess intravesical pressure (Pves) for home or clinic use. Two studies were conducted to assess if the Peritron+ can be used to assess bladder pressure. The first study compared intravesical pressure (Pves) measurements from the Peritron+ to urodynamic readings. The second study assessed the ease of use and usability of the Peritron+ when used in a home setting.

Study Design: Ethics board approval was obtained prior to both studies and all parents and patients completed informed consent/assent (unless under the age of assent). The first study, assessing accuracy, enrolled adult patients (18 or older) who were indicated for urodynamics. The Peritron+ was connected to an external water transducer, urodynamic tubing and an urodynamic catheter. All patients had simultaneous urodynamics and Peritron+ measurements at 50 ml, 100 ml, and 200 ml fill volumes, and post-void in sitting and supine positions. Two values from Peritron+ and the urodynamic system were analyzed to see if the difference was within 3 cm H2O. The second study, assessing usability, enrolled pediatric patients (2 to 18 years old) who regularly performed clean intermittent catheterization (CIC). For the second study, staff and patients/caregivers were asked to measure Pves in the clinic and at home (Figure 1). Two questionnaires, one for the study staff and one for patients/caregivers, which asked the user to score ease of use and other usability aspects of the Peritron+ using a variety targeted questions and a mix of scales (i.e. Very Easy to Very Confusing and Straight Forward to I Couldn’t Follow Them).

Results: Ten female patients aged 31 to 73 years old were enrolled in the first study assessing the accuracy of the device. In all events, infused volume 50 ml, 100 ml, 200 ml, and post-void, the difference in Pves was ≤3 cm H2O. Three males and 2 females age 3 to 15 years old were enrolled in the second study, that assessed the usability of the device. The study staff rated the Peritron+ a cumulative score of 97% for ease of use/usability. During the home visits there were 14 issues reported, 11 related to the patient’s catheter, 1 related to the fluctuation of Peritron+ readings, and 2 related to the patient (patient menses and bowel movement observed). The patients/caregivers rated the Peritron+ a cumulative score of 86.6% for ease of use/usability. There was no adverse events or device deficiencies that occurred during either study.

Next Steps: Future studies should be conducted to assess the Peritron+ in larger patient populations and to assess the clinical utility in managing treatment options.

Conclusion: The Peritron+ can easily be set-up and operated in the clinic or at home to accurately assess intravesical pressure. This novel device can be used to monitor subjects for safe bladder pressure and evaluate the efficacy of the treatment.

Ethical Approval: Ethic Board Approval was obtained prior to enrolling patients.

Conflicts of Interest: Ing Goping and Stephanie Bitzos are employees of Laborie Medical Technologies. Sidney Radomski is on the advisory board for Pfizer, Allergan, and Astellas. Sidney Radomski conducts research for Allergan, Pfizer, Laborie, and Astellas.

Funding Source: The study was funded by Laborie Medical Technologies, Mississauga, Canada.
Figure 1. Peritron+ connected to Air-Trap Tubing.
The free luer spot is used to connect either a luer-catheter adaptor or a luer fitted CIC.
COMPARISON OF COUGHS USING AIR-CHARGED AND WATER-FILLED URODYNAMIC PRESSURE MEASUREMENTS

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³ Drexel University of Medicine, Philadelphia, PA, USA

Introduction and Aims of the Study: Urodynamic studies involve the measurement of bladder pressures to objectively characterize incontinence. Previous studies have shown that air-charged catheters behave as over-damped systems and attenuate signals above 3Hz while water-filled catheters act as under-damped systems with a frequency cut-off over 19Hz (1). The effect of attenuation could mean that the pressure measurements of high frequency events such as coughs are not identical between the two technologies indicating that the two types of catheters are not interchangeable for urodynamic investigations. The purpose of this study was to examine the frequencies detected using air-charged and water-filled catheters during patient coughs measured during urodynamic investigations.

Study Design: The Institutional Review Board (IRB) approved COWACC study (Comparison of Water and Air Charged Catheters) enrolled 50 women who gave informed consent. A commercially available 7FDR TDOC® Air-charged catheter was utilized to form a dual pressure catheter. The pump was stopped at various fill volumes and the water filling channel was redirected to a water pressure transducer. This allowed simultaneous water pressures measurements to be obtained within the bladder while the air-charged balloon provided the equivalent air-charged pressure measurement. For this exploratory endpoint, a subset of 10 patients were analyzed specially for cough measurements. The tracings selected for cough analysis had sampled urodynamic pressure measurements at 50 Hz (standard testing was conducted at 10 Hz), allowing for frequency measurements of up to 25 Hz. After filling the bladder with 200 cc of saline, patients were asked to bear down 3 times, then cough 3 times before UPP measurements were completed. The strongest cough of the 3 was selected and resulted in 1280 paired measurements which were normalized and fed through standard Fast Fourier Transform (FFT) algorithms for representation in the frequency domain. The difference in measurements in the time and frequency domain were compared for each of the ten women.

Results: Both the air-charged and water-perfused pressure measurements produced similar looking coughs on the tracings in the time domain. Figure 1 shows the strongest, single-peak cough analyzed. The duration of the cough lasted 0.52s. The maximum pressure measurement was registered as 113 cmH₂O for the water-perfused measurement and 112.6 for the air-charged measurement. The air-charged measurement showed a delay of 0.02 seconds before reaching the maximum pressure. The largest difference in measurements of 31.3 cmH₂O was noted at 0.22s after the maximum pressure was registered with the water-pressure line. This was due to the rapid drop and then oscillation of the water-pressure measurement on the completion of the cough. A similar pattern showing the water-pressure measurement decreasing sooner than the air-charged measurement was seen on each patient analyzed. The average difference in peak measurements for all 10 coughs (air-charged measurement – water-filled measurement) was 5.4 cmH₂O with a range of (4.7 cm H₂O to -28.6 cmH₂O) with 9 out of ten coughs showing peak pressures within 10 cmH₂O. The patient that produced a difference in measurements of -28.6 cmH₂O was a cough with two peaks that exceeded 100 cmH₂O. The frequency analysis of the pressure measurements showed that both measurement types are similar. Below 1 Hz, the air-charged pressure measurements captured more data than the water-perfused line. However, from 1.5 to 2.7 Hz, the reverse was true (Figure 1 shows representative data).
Figure 1. Time and frequency information on pressure measurements of single patient during a cough after filling bladder to 200 cc.

**Interpretation of Results:** Peak cough pressures are used to assess causes for stress incontinence.Leaks that occur above 90-100 cmH₂O are likely caused by hypermobility of the urethra, while leaks that occur at pressures of 60 cmH₂O or below suggest intrinsic sphincter deficiency (2). All peak pressures from the air and water pressure measurements examined for these patients would have indicated the same diagnosis. A slight delay of peak pressure (all 60 ms or below) as well as differences in pressures after the peak as the signal returns to the baseline would not be clinically relevant as these parameters are not used for making clinical decisions. These results are in line with the data found previously showing that 83-97% of the spectral power density of bladder pressures during a cough are at 3Hz and below (3). The differences in signals found during this study are likely to have low clinical impact.

**Conclusion:** The vesical pressure measurements recorded by air-charged and water-filled catheters during coughs performed during urodynamic evaluations produce similar peak pressures and provide the same clinical information.

**References:**

**Ethical Approval:** Study received IRB approval and informed consent was obtained from all patients prior to Urodynamics evaluation.

**Funding Source:** Supplies were provided by Laborie Medical Technologies.

**Conflicts of Interest:** Veronica Ciolfi, Bruna Couri, Stephanie Bitzos, and Ing Goping are employees of Laborie Medical Technologies. Timothy McKinney is a consultant for Laborie Medical Technologies.
Background and Objectives: Intermittent catheterization (IC) is a common therapy for individuals with lower urinary tract dysfunction (LUTD) [1]. Catheter practice differs between regions and there is a lack of quality evidence regarding whether catheter reuse is as safe as single-use catheterization [2]. The objectives of this study were to explore real life data on patient safety, satisfaction and quality of life of reuse vs. single-use catheters for IC.

Study Design and Methods: This was a prospective, multi-center, clinical trial. The study included patients who currently practiced catheter reuse, and who agreed to prospectively try out and evaluate single-use hydrophilic-coated catheters for 4 weeks. Patient reported outcomes and the validated Intermittent Self-Catheterization Questionnaire (ISC-Q) were used to study satisfaction and quality of life. Safety measures included bacteria contamination of reused catheters and urethral complications. The study was approved by applicable ethics committees/institutional review boards at each site before study initiation and all participants gave their informed consent before taking part. The clinical study is registered in clinicaltrial.gov with the identifier NCT02129738.

Results: Of the 21 reused catheter samples collected and analyzed by culturing and Scanning Electron Microscope (SEM), 19 were found to be contaminated by bacteria (90%). Culturing verified presence of 1-3 bacteria species in 17 samples of varying concentration (mean = 2.0 x 10^6, SD = 5.1 x 10^6 CFU). In 6 of the samples a mature/early phase continuous bacteria layer (biofilm) could be seen with SEM. The most common reported species were Enterococcus fecalis, Staphylococcus epidermidis/aureus, Pseudomonas and Klebsiella pneumoniae. At the start of the study, 62% of the patients reported to have experienced urological complications the last 12 months, mainly urinary tract infections (UTI). A total of 19 patients completed the prospective test period. During this period, 79% did not experience any urological complications. For 3 patients with previous reported complications, new events were detected (2 UTIs and 1 bleeding and pain). In one patient, who was previously without any urological complications, events of UTI and bleeding were reported during the test period. Among those who completed the prospective test, 95% were satisfied with the hydrophilic-coated catheters as compared to 43% with the reuse catheter (p = 0.0008). More patients found catheterization comfortable or without any discomfort during the prospective test period with hydrophilic-coated catheters as compared to the reuse catheter (68% vs. 48%, p = 0.0361). Quality of life measured with the ISC-Q score increased by 20% (p = 0.0204) when patients switched to the single-use catheters.

Interpretation of Results: The results from the current study suggest that reusing a catheter for multiple catheterizations poses a potential safety risk for concerned patients. In this study, almost every collected reused catheter was found to be contaminated by bacteria. The study results furthermore suggest that if single-use of hydrophilic-coated catheters can be secured in clinical practice, higher satisfaction and better quality of life can be fulfilled for people practicing IC.

Next Steps: This study adds clinical evidence of safety differences between reuse/single-use catheters and it also provides support for patient preference of single-use catheters for IC. While awaiting further evidence, it is recommended to implement these results into clinical practice and ensure single-use hydrophilic-coated catheters as the first and standard choice for those who are prescribed IC.

Conclusion: In the US, the practice of reusing catheters for IC has changed over the past 10 years and most patients needing IC are prescribed with single-use catheters [1]. The results from this study support this change as safety concerns are identified in patients reusing catheters. Patients reported experiencing higher satisfaction and improved quality of life with single-use hydrophilic-coated catheters.
References:

Ethical Approval: University of Pennsylvania IRB #820448
Funding Source: Wellspect HealthCare, DENTSPLY IH, Sweden
UROLOGICAL HEALTH IN WOMEN ACROSS THE LIFESPAN: AN INTERDISCIPLINARY RESEARCH NETWORK

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Society for Women’s Health Research, Washington, DC, USA

Introduction: Urologic and kidney problems are common in women across the lifespan and significantly impact their daily life. Urological health in women is still understudied and in particular, urinary incontinence (UI) remains a large issue. UI affects approximately 24% of 18-44 year old women and nearly 50% of community-dwelling women over the age of 65 [1]. The stigma of UI prevents the overwhelming majority of women with UI from discussing symptoms with their healthcare provider and over 50% of patients with a serious illness rate bowel and bladder incontinence a fate worse than death [1, 2].

The Society for Women’s Health Research (SWHR®) recognized the need to have researchers and clinicians work collaboratively to define the current state of knowledge, the gaps, and the recommendations for future research directions in urological health in women. To form this Interdisciplinary Network and promote this style of collaboration required careful selection of members across various disciplines and their commitment to frequent meetings over several years. The Urological Health in Women Across the Lifespan Interdisciplinary Network aims to raise awareness of the impact of bladder health on women’s well-being across the lifespan. In accordance with the mission, the Network has published a set of recommendations in a peer reviewed journal as well as launched public outreach campaigns to raise awareness of prevalent issues like UI. Over the next three years the Network will continue to promote education of UI and other urological issues among women, girls, healthcare providers, and educators. We will present the mission and organizational structure of the Network as well as accomplishments to date, projects in progress, and future plans.

References

Ethical Approval: None

Funding Sources: Amphora Medical, Inc.; Astellas Pharma US, Inc.; Allergan, Plc; Cook Medical; Kimberly-Clark Corp.; Medtronic.
INTRODUCING A NOVEL ELECTRONIC TRANSANAL IRRIGATION SYSTEM, NAVINA™ SYSTEMS

Jan Hörling, Mattias Gränfors, and Sofi Sigvardsson
Wellspect Healthcare, Molndal, Sweden

Introduction: Transanal irrigation (TAI) is considered a successful therapy for bowel continence, most commonly in patients with neurogenic bowel disorder but also in some cases of severe functional bowel (1,2). TAI is designed to assist the evacuation of feces from the bowel by sealing the anal canal with a balloon and subsequent instillation of water. However, there remain opportunities to improve accessibility to all patients, and both initial uptake and long-term adherence (3). The Navina™ Systems were created to alleviate these issues.

Expectations: Navina Smart is the first available electronic transanal irrigation device. Both balloon inflation and water instillation are managed by an electronic pump, as opposed to previously available manual TAI-device. The electronic pump with fixed settings and push controls is invented to make handling easier for patients with poor hand function. The user may not need to rely on a caregiver during TAI, which can create a greater independence for the patients.

The Navina™ Smart app is created to improve the initial and long-term adherence by increasing the possibility for healthcare professionals to follow-up with patients during start-up phase. Also, to gather information for the healthcare professionals to study the patients as a group to help evaluate which patients are better helped by TAI.

Poor adherence is also related to balloon bursts during irrigation. This can be a traumatic experience for the patient and have in a few cases led to severe complications such as bowel perforation. The electronic device in Navina™ Smart monitors the balloon size and water volume. Therefore, the balloon cannot become too big and burst due to over-inflating. Also, both Navina™ catheters (Regular and Small) are more durable than the catheters from the most widely used manual TAI-system (Peristeen™) Table 1.

Conclusion/Next Step: With the new electronic transanal irrigation system, Navina™ Systems, our ambition is to improve previous issues with manual TAI-systems such as adherence, accessibility and safety. One specific example of the latter is to verify a more durable catheter balloon. However, clinical evidence is needed to show the effect of current improvements.

References:

Table 1. The catheter balloon was tested in air and in a rigid plastic tube with a diameter of 46 mm and the balloon was inflated with an electronic pump. Differences in mean between catheter balloons were statistically tested using the 2 sample Student’s t-test

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Navina™ regular (n=30) Mean (SD)</th>
<th>Peristeen™ regular (n=30) Mean (SD)</th>
<th>p-values</th>
<th>Navina™ Small (n=30) Mean (SD)</th>
<th>Peristeen™ Small (n=30) Mean (SD)</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diameter at burst in air (mm)</td>
<td>80.9 (2.1)</td>
<td>72.1 (0.7)</td>
<td>&lt;0.001</td>
<td>72.5 (1.1)</td>
<td>66.6 (0.6)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time to burst in air (sec)</td>
<td>27.4 (3.0)</td>
<td>17.9 (0.6)</td>
<td>&lt;0.001</td>
<td>19.4 (1.3)</td>
<td>10.1 (0.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pressure at burst in air (mbar)</td>
<td>388 (32)</td>
<td>231 (4.2)</td>
<td>&lt;0.001</td>
<td>493 (20)</td>
<td>243 (4.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Length at burst in tube (cm)</td>
<td>10.6 (0.5)</td>
<td>10.2 (0.3)</td>
<td>&lt;0.001</td>
<td>8.4 (0.3)</td>
<td>7.0 (0.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Time to burst in tube (sec)</td>
<td>13.5 (1.7)</td>
<td>10.2 (0.5)</td>
<td>&lt;0.001</td>
<td>13.3 (1.3)</td>
<td>7.2 (0.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Pressure at burst in tube (mbar)</td>
<td>504 (64)</td>
<td>356 (28)</td>
<td>&lt;0.001</td>
<td>687 (58)</td>
<td>377 (16)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Ethical Approval: NA
Funding Source: All Authors
TEST-RETEST AND RELIABILITY ANALYSIS OF A WATER LOAD PROTOCOL AS A TOOL TO ACHIEVE A FIXED DIURESIS RATE FOR INVESTIGATION INTO BLADDER SENSATION

Douglas Tincello and Hayser Medina Lucena
University of Leicester UK

Introduction and Aims of the Study: A forced diuresis protocol has been developed to evaluate bladder sensation during filling. The original protocol required consumption of 250-300 ml water every 15 minutes to achieve a steady diuresis rate, but the reliability of this protocol to produce a stable and predictable diuresis remains unproven. In recent work, we found the rate of diuresis to have a high variability, in some cases more than 5 ml/minute between test in the same participant. This study was designed to calculate and compare diuresis rates within cycles of each test, and between cycles and to confirm the consistency of voided volume between cycles to optimize the reproducibility of voided volume.

Study Design: This study was the first of four parts of an observational and experimental study. Twelve volunteers were asked to undergo a previously designed diuresis and bladder sensation protocol (1). The protocol allowed the visual recording of bladder sensation by the patient marking sensations on a 10 point visual analogue scale every 5 minutes while drinking an excess of water continually for the duration of the test. Following ethical approval, informed consent was obtained from participants before obtaining serum to measure glomerular filtration rate to exclude undiagnosed kidney disease. Participants were asked to refrain from vigorous exercises on the day before the test session and not to have caffeine or a meal 2 hours before, and alcohol 12 hours before the beginning of the test. A biomedical impedance test was performed prior to the diuresis test to determine the participant’s fluid status, to know if the participant was overhydrated or dehydrated. The volume drunk during the test was adjusted from 250ml to 300 ml based on the impedance to avoid any risk of water intoxication. Participants were asked to drink 250 ml of water every 15 minutes 1 hour before the test. If participants were overhydrated (+500ml) on bioimpedance result they were asked to continue to drink 250 ml every 15 minute, but if they were under-hydrated this volume was increased to 300 ml. Participants were given a data-logging sheet to record their bladder sensations. No verbal cues were given other than to concentrate on the sensation in their bladder and to mark on the data-logging sheet the intensity of this sensation. When they reached the strongest sensation they could bear they were asked to hold on for up to 5 minutes and to remember this as their maximum sensation, marking it as a 10 on their sheet. They were then asked to void and this volume measured (V1). Immediately post void they recorded this as the minimal sensation. Participants continued to drink and recorded bladder sensation for another entire filling cycle, where the voided volume was measured (V2) and for at least 30 minutes of the next cycle (voided volume V3). The first cycle allowed participants to fix the maximum and minimum sensations in their minds; cycle two was the core part of the experiment where analyses were done, and cycle three was used to confirm a steady diuresis rate has been achieved during cycles two and three (i.e. V2/t2 = V3/t3). This test was performed twice within 14 days apart. The same instructions were read to participants at the beginning of each test. Data were presented as median (range) and compared by Wilcoxon signed rank test or Mann Whitney U test for paired and unpaired data.

Results: 12 women were recruited. Median age was 26 years (19-37 years), median BMI 29.1 Kg/m² (21.0 -42.4 kg/m²). Nine were British, two Turkish and one from South East Asia. 11 out of 12 had the two tests within 14 days. One person withdrew after first test due to vomiting. All participants had a normal sodium level and glomerular filtration rate >60ml/min. On the first test 11 out of 12 had a preload of 1000ml (one had drank 1250ml). Seven drank 250 ml every 15 min and 5 drank 300ml. Overall, there was no difference in median first void (V1) (735ml (386-1218ml) and median second void (V2) (678ml (420-1064ml) (p=0.433). The median diuresis rate of V2 was 12.1 ml/min (8.94-17.18) and 14.4 for V3 (8.13-20.0) (p=0.136), indicated a fixed diuresis rate was achieved during the test protocol. The diuresis rates during cycle 2 and cycle 3 achieved after drinking either 250 or 300 ml every 15 minutes were compared.
The median differences were 2.36 ml/min (0.01-6.30) with 250 ml/15 min and 3.03 ml/min (1.64-4.63) after 300 ml (p=0.639). Because the variability of the calculated difference was less, we performed the second test with participants all drinking 300 ml/15 minutes. During second test all participants had a preload of 1000 ml. Median first void (V1) was 618 ml (482-1042 ml) and median second void (VS) was 617 ml (490-1026 ml) (p=0.533). The median diuresis rate of V2 was 13.7 ml/min (8.90-16.36) and 13.5 for V3 (9.16-16.33) (p=0.477). The difference between diuresis rate in cycle 2 and cycle 3 where all participants drank 300 ml/15 mins was 0.53 ml/min (0.12-2.31).

**Interpretation of Results:** The maximum bladder sensation was achieved at similar bladder volumes within cycles and between cycles, demonstrating that this test was reproducible. There was more variability in the diuresis rate when participants had drunk 250 ml/15 min than when they had drunk higher volumes (300 ml). The difference in the median diuresis rate in the second test was smaller with less variability than in the first cycle, where ingested volumes varied. This was probably due to the larger volume providing a greater preload to the kidneys and helping to achieve a fixed diuresis rate. However, median diuresis rates were more similar in the second test experiment, suggesting a degree of “learning” was affecting the repeat test. After analysing the data of participants who drank 300 ml every 15 min, the median of the diuresis rate was 3.03, which means that variability of the diuresis rate between cycles should not be more than this value and anything above this will be rejected as invalid.

**Conclusion:** The water load protocol achieves a constant high diuresis with rapid, non-invasive bladder filling. The results from this study have validated previous work and allowed us to define the expected range of within test variability of diuresis rate. Variability is reduced with a water load of 300 ml/15 minutes and we recommend rejection of any test where the variation in diuresis rate between the two test cycles exceeds 0.53 ml/min.

**References:**
1. McCarthy A, Harvey J, Finney S, Gillespie J. Bladder awareness during filling and changes in sensation associated with the decision to void. (unpublished)

**Ethical Approval:** Ethical committee approval from Coventry and Warwickshire Research Ethics Committee (15/WM/0399)

**Funding Source:** None
CHANGES IN DEMOGRAPHICS AND TYPE OF PROCEDURE AMONG WOMEN UNDERGOING SURGERY FOR PELVIC FLOOR DYSFUNCTION

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Introduction and Aims of the Study: Uterovaginal prolapse surgery is common and frequently requires surgical correction. It is well recognised that obstetric pelvic floor trauma is a significant risk factor for the later development of pelvic organ prolapse. In the last three years, we had noticed an increasing number of younger woman being referred to our tertiary level clinic for management of prolapse, and it seemed that the severity of these prolapses was increasing. Thus we undertook this retrospective study to determine whether there had been a change in time in the demographics of woman attending our service, and whether there had been a change in surgical procedures performed.

Study Design: This was a retrospective chart review of all patients listed for prolapse surgery under the care of a single UK urogynaecologist. Ethical committee approval was not required because this was a study of routinely collected clinical data. Data were collected from theatre diaries; all cases of uterovaginal prolapse repair were included from two three-year windows: 2006-08 and 2013-15. Demographic details (age, ethnicity) of the patient were collected and the procedure listed was categorised by compartment of prolapse to be repaired. These were apical (sacrocolpopexy, hysteropexy or sacrospinous fixation), anterior (standard fascial repair, anterior mesh procedures), posterior (standard fascial repair, posterior mesh procedures), perineum (perineal repair or perineorrhaphy). The intention to perform hysterectomy or not was also recorded. Some patients had surgery planned for more than one compartment and these were counted for each compartment separately. The median age and type of procedure planned were compared between year cohorts using appropriate non-parametric tests. The relationship between age (linear and by different cut-offs), type of procedure and year cohort was examined using two by two tables, non-parametric tests, Chi square test, and odds ratio (OR) with 95% confidence intervals (95% CI).

Results: 365 women were included, 164 (45%) from 2006-08 (“old” cohort) and 201 (55%) from 2013-15 (“recent” cohort). The median age of women in the recent cohort was lower (60.0 years vs 62.5, p = 0.014). The recent cohort had more younger women by each age cut-off applied (Table 1a).

<table>
<thead>
<tr>
<th>Age (median)</th>
<th>2006-08 (n=164) “old” cohort</th>
<th>2013-15 (n=201) “recent” cohort</th>
<th>OR (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>age &lt;50 (n%)</td>
<td>25 [15.2]</td>
<td>55 [27.4]</td>
<td>1.88 (1.20, 2.93)</td>
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<tr>
<td>age &lt;45 (n,%)</td>
<td>15 [9.1]</td>
<td>37 [18.4]</td>
<td>0.012</td>
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<tr>
<td>age &lt;40 (n,%)</td>
<td>4 [2.4]</td>
<td>16 [8.0]</td>
<td>0.022</td>
<td></td>
</tr>
</tbody>
</table>

Table 2

<table>
<thead>
<tr>
<th>Age cut-off (%)</th>
<th>p</th>
<th>Age cut-off (%)</th>
<th>p</th>
<th>Age cut-off (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apical procedures</td>
<td>22.5% vs 37.9%</td>
<td>0.01</td>
<td>17.3% vs 37.4%</td>
<td>0.003</td>
<td>20.0% vs 35.4%</td>
</tr>
<tr>
<td>Perineorrhaphy</td>
<td>41.3% vs 19.6%</td>
<td>&lt;0.001</td>
<td>50.0% vs 20.1%</td>
<td>&lt;0.001</td>
<td>80.0% vs 21.2%</td>
</tr>
<tr>
<td>Posterior procedures</td>
<td>47.5% vs 41.1%</td>
<td>0.303</td>
<td>57.7% vs 39.9%</td>
<td>0.016</td>
<td>75.0% vs 40.6%</td>
</tr>
</tbody>
</table>
Apical procedures (OR 1.88) and perineorrhaphy (OR 29.31) were more frequent among the recent cohort while anterior operations were less common (OR 0.55) (Table 1). Apical procedures were less common in younger women by all age cut offs: < 50: 22.5% vs 37.9% (p=0.01); <45: 17.3% vs 37.4% (p=0.005); <40: 20.0% vs 35.4% (p=0.16). Perineorrhaphy was more common in younger women: < 50: 41.3% vs 19.6% (p<0.001); <45: 50.0% vs 20.1% (p<0.001); <40: 80.0% vs 21.2% (p<0.001). Posterior procedures were more common in younger women: <45: 57.7% vs 39.9% (p=0.016); <40: 75.0% vs 40.6% (p=0.002); <35: 84.6% vs 40.9% (p=0.002).

**Interpretation of Results:** This study confirmed the impression that in recent years women undergoing uterovaginal prolapse surgery were significantly younger. Apical and perineal procedures were substantially more common in the recent cohort. Posterior vaginal and perineal procedures were much more common in younger women. It is not possible to be certain how much of the change was due to changing presentations, and how much due to evolution of surgical decision making. The two cohorts are from before and after the media awareness of mesh complications, so the change in surgical procedure may partly represent a move away from vaginal surgical mesh repair of apical compartment prolapse. However, the high rate of posterior and perineal procedures among young women is worrying and may related to the changes in midwifery practice in terms of both “hands on” versus “hands off”, and also the move to rapidly absorbable polyglactin sutures for perineal repair[1].

**Conclusion:** There has been a change in the demographics of women attending with pelvic organ prolapse with apical and perineal procedures performed substantially more often in the recent cohort. These finding must be confirmed in other centres and longitudinal studies are needed to explore factors mediating this phenomenon.

**Ethical Approval:** Not required as retrospective chart review

**Funding Source:** None
EVALUATION OF INCOSTRESS DEVICE FOR URINARY INCONTINENCE: A FEASIBILITY STUDY AND PILOT RANDOMISED CONTROLLED TRIAL

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² University of Cardiff, UK

**Aims of the Study:** IncoStress is an intravaginal device for management of urinary incontinence. This was a feasibility study for an RCT of the IncoStress device to assess methods/procedures for a large trial of its clinical effectiveness.

**Study Design:** Women attending continence services were invited to participate and gave fully informed consent, before randomisation to usual care (the control group) or usual care plus use of the IncoStress device (the intervention group). Randomisation was computer generated, using sealed envelopes and undertaken in blocks of 9 (2:1 intervention/control ratio). Process outcomes of recruitment, retention and compliance with treatments were recorded plus primary outcomes of IQOL and ICIQ-FLUTS questionnaires at baseline and follow-up (three months and six months). Data were analysed using SPSSv22, and descriptive statistics provided. A sub sample of participants were invited to take part in a qualitative interview to better understand frequency and ease of use of the device as well as, overall satisfaction, and recommendations for changes to the research processes which could be incorporated into a future large multi-centre trial.

**Results:** 80 women (51 intervention: 29 control) were recruited. Median age was 45 years (27-70 years), median BMI was 26.4 Kg/m² (16.5-43.8kg/m²). Follow-up responses were obtained from 34 intervention group patients (66.7%) and 17 (58.6%) controls. Women used the device for a median three days a week (0-7); seven hours a day (0-12). 22 patients (n%) reported no vaginal discomfort, 18 found it easy to use and 21 were satisfied with the device. Median IQOL score in the intervention group improved from a baseline of 42.4 (0-94) to 68.2 (5-98) at follow-up and in the control group from baseline 45.5 (0-88) to 53.0 (0-94). Median ICIQ-FLUTS score in the intervention group improved from 14.5 (6-35) to 12.5 (4-26) and in the control group from 15.0 (5-35) to 14.0 (6-38).

Twelve interviews were carried out with women between the ages of 33-78 years. Ten of the women had used the device to some extent. Regarding frequency and ease of use and cleaning, most participants found the device easy to use and clean. Two reported difficulties with the device falling out, so they used it more during the night. Most participants reported that they would be prepared to pay around £30 for the device as it had improved their quality of life. Eight would recommend the device to others suggesting it would prevent further invasive treatment.

**Interpretation of Results:** The improvements in both outcome measures were greater in the intervention group than in the control group, suggesting that the IncoStress device is effective. Most of the patients used the device during the day finding it acceptable, some found it quite uncomfortable but overall easy to use and 41% of those who used it were satisfied with it. The small qualitative study of interviews with users allowed us to assess women’s experiences of using the device and to identify the extent of compliance and reasons for non-compliance, in addition we were able to assess the support and information needs required to facilitate compliance as well as treatment fidelity to ensure reliability and validity. The interviews indicate that the device is acceptable to women and could be used within a large multi-centre RCT.

**Conclusion:** Recruitment was feasible and randomisation processes were robust. Symptom response was significant but loss to follow up could be improved using a retention strategy in a better-resourced larger study. This pilot demonstrates the potential value of IncoStress and confirms the feasibility of a larger RCT of the effectiveness of vaginal devices for urinary incontinence.

**Ethical Approval:** Ethical approval was obtained from the National Research Ethics Service in London – Stanmore (11/LO/0485)

**Funding Source:** None
UNDERSTANDING FEMALE PATIENTS WITH ACCIDENTAL BOWEL LEAKAGE

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Objectives: To support development of the Eclipse System, a non-surgical vaginal insert for female fecal incontinence, Pelvalon sought demographic and clinical background information on the intended patient. The objective of this study was to develop a deeper understanding of female patients with Fecal Incontinence (FI) in order to best educate them on their condition and the Eclipse System. Sequential qualitative and quantitative efforts were pursued to understand the average patient’s demographics, thought process, and experiences when seeking a solution to their condition.

Methods: Data was collected both through sequential qualitative and quantitative phases: patient interviews and an online survey. In the first phase, 20 female patients were interviewed by phone. They were recruited to participate via Google AdWords as they searched for more information on their symptoms. A total of 99 patients responded, 13 were excluded due to not having FI or being male, and 20 of the remaining 86 chose to participate in the phone survey.

In the quantitative phase, 302 US patients participated in an online survey fielded in September 2013. Participants were 18+ years old, community-based patients, who had experienced FI for at least 6 months, with at least one episode per month. Quotas were used for patient ages to ensure that each age group (18-39, 40-49, 50-59, 60-69, 70+) had at least 50 patients. Participants were recruited by Harris Interactive, Inc.

Results: Of the 20 female patients interviewed by phone, all but 1 were Caucasian and were scattered across the United States, with an average age of 64. 65% reported to be in good or excellent health while 30% reported “fair” and only 5% (one patient reported poor health. 14 of the 20 had episodes of bowel leakage multiple times a week. Only 50% of the patients had previously mentioned their FI to a doctor. Out of these 20 patients; 15 had tried some sort of incontinence pad, 9 tried fiber, 9 modified their diet, 5 used medication, and 3 tried pelvic floor exercises.

Of the 302 patients who participated in the online survey, the majority again were Caucasian (86%), with African American (6%) being the second largest group observed. 18% were 39 or younger, 16% were in their 40’s, 21% were in their 50’s, and 21% were 70 or older. When describing their condition, “accidental bowel leakage” (41%) and “bowel control problems” (33%) were the preferred terms, while “bowel incontinence” (18%) and “fecal incontinence” (9%) were not as popular.

When asked how much their condition bothered them, 72% said moderately to greatly, while 26% were slightly bothered. Only 1% said they were not at all bothered by their condition. 52% experienced bowel leakage for 1-5 years, 10% for 5-10 years, 13% for over 10 years, and 26% had experienced symptoms for under a year but at least for 6 months. Sixty eight percent (68%) of patients reported they had no way to predict when leakage would occur, while 23% would use their first bowel movement of the morning or their diet to predict episodes of soiling. Similar to the interview respondents, 63% of patients experienced episodes at least once a week. Of the 302 patients surveyed, 182 (60%) had previously discussed their symptoms with their doctor or planned to discuss symptoms at a scheduled appointment.

Interpretation of Results: These results indicate that female FI patients are in relatively good health, and do not uniformly seek treatment. Most of these patients are also moderately to severely bothered by their symptoms, and have experienced them for at least 1-5 years. One finding that provides insight into the significant impact on quality of life is that most patients are unaware of when their next episode of leakage will occur. Even patients with less frequent episodes may therefore be unable to enjoy the freedom of accident-free days.

Most surveyed patients prefer the term accidental bowel leakage (ABL) for their condition. This may be because Fecal Incontinence isn’t as descriptive, and can represent a variety of symptoms. Per a study by Dr. Madhulika Varma, M.D., “bowel dysfunction, including frequency, fecal urgency, stool consistency, and
evacuation symptoms, contributes to fecal incontinence". Our findings aligned with a 2012 cohort study by Brown et al. This study examined care-seeking behavior, and concluded that only 29% of female ABL sufferers tell their doctor about their symptoms. This study also observed that the preferred term by patients for this condition was Accidental Bowel Leakage as opposed to the medical term, Fecal Incontinence. The population surveyed by Brown et al had a similarly over-representation from Caucasian respondents, perhaps a reflection on the survey methodology.

**Conclusion:** These findings have implications for the design and introduction of new therapies for ABL. Due to bother level and unpredictability of ABL episodes, new solutions should prioritize delivering a reliable and consistent improvement in bowel control. However, additional features may be important to patients. Features that enable user control over the therapy may be beneficial for those patients who have episodic or fluctuating incontinence. The reluctance of patients to discuss the condition with their physicians may indicate an ambivalence about the perceived solutions that physicians can offer. For that reason, patients may be attracted to non-invasive therapies that can be tried with low risk, versus surgeries or more invasive or permanent therapies. Additionally, due to the stigma of the condition, product design should focus on discretion to improve the experience for patients who are reluctant to reveal their condition. These user insights were incorporated into the design of the Eclipse System.

**References:**

**Ethical Approval:** Not applicable
**Funding Source:** Pelvalon
**Conflicts of Interest:** C. Holtshouse, R. Muldoon, and S. Herbowy work for Pelvalon and are involved in development and marketing of the Eclipse System.
IS SUBMUCOSAL WIRELESS PRESSURE SENSING FEASIBLE: OBSERVATIONS FROM INITIAL IMPLANTATION STUDIES

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\textsuperscript{1} Department of Biomedical Engineering, Lerner Research Institute, Cleveland Clinic, Cleveland, OH, USA
\textsuperscript{2} Department of Biomedical Engineering, Case Western Reserve University, Cleveland, OH, USA
\textsuperscript{3} Advanced Platform Technology Center of Excellence, Louis Stokes Cleveland Veterans Affairs Medical Center, Cleveland, OH, USA
\textsuperscript{4} Glickman Urological and Kidney Institute, Cleveland Clinic, Cleveland, OH, USA

Introduction: There has been recent interest in placing pressure sensing elements beneath the bladder mucosa to facilitate chronic vesicular pressure monitoring. Wired submucosal sensors using a trans-detrusor cable have been demonstrated in vivo, with limited chronic retention, potentially due to the cable tethering the detrusor. We have developed a wireless pressure monitor and surgical technique for complete submucosal implantation. We expected to sense vesical pressure through the urothelium, and that the device would heal within the submucosal plane for chronic use. This study reports our findings from an initial chronic implantation study in large animals.

Methods: Pressure monitors were implanted (n=7) in female calf models (n=5). Two animals received two serial device implantations separated by a two-week healing period. One device was implanted suprapubically to test device retention with an intact mucosa. Five devices were implanted cystoscopically with a 25-Fr rigid cystoscope. Pressure monitors were delivered into submucosal pockets posterior to the trigone. Barbed sutures were attached to the device surfaces to facilitate initial retention. Drainage catheters were placed for two weeks after implantation to compress the detrusor around the implant during healing. Ambulatory device recordings were attempted over a 30-day period per animal. Weekly anesthetized procedures allowed for imaging via fluoroscopy and cystoscopy, as well as cystometry simultaneous with wireless device recording.

Results: Wireless recordings during anesthetized cystometry correlated with the reference pressure sensor and manual bladder compressions were captured in real time (Fig. 1). Manual abdominal compressions indicated an attenuation factor between submucosal and vesical pressure. Individual analysis of normalized compressions (n=12) indicated high correlation (r=0.85-0.94) between submucosal and vesical pressure. Post-implant calibration confirmed proper pressure monitor function, indicating that the observed effect was due to biomechanics of the implant location.

Healing response was robust over 4 weeks. Mucosal erosion occurring 2-4 weeks after implant, leading to device migration into the bladder lumen and expulsion during urination. Cystoscopically implanted devices were gradually pushed from the pocket by a “zipper” effect, while the suprapubic device eroded into the lumen suddenly after 3 weeks.

Figure 1. Simultaneous reference catheter and wireless implanted device recordings during cystometry showed correlation (A). Attenuation in the data may (B) be attributable to the submucosal device implant location.
**Conclusions:** The pressure monitor may be successfully placed in a suburothelial position. Submucosal pressures are correlated with vesical pressure, but may differ due to biomechanical forces pressing on an implanted sensor. Fully wireless devices implanted beneath the mucosa has a risk of erosion through the mucosa, potentially caused by disruption of blood flow to the urothelium, or an as-yet unstudied mechanism of submucosal regrowth. Further investigation into device miniaturization, anchoring methods, and understanding of submucosal pressure biomechanics will enable chronic submucosal pressure monitoring.

**Ethical Approval:** All procedures involving animals were outlined in a protocol which was reviewed and approved by the Cleveland Clinic Institutional Animal Care and Use Committee (IACUC) prior to project initiation.

**Funding Sources:** State of Ohio 3rd Frontier Grant TECG20150781 and VA RR&D Merit Review, Grant F7422-R
Introduction: Female pelvic disorders, such as urinary incontinence, pelvic pain, and pelvic organ prolapse are common; yet many women remain uninformed about basic female anatomy, muscular and organ function related to their own pelvis. Insufficient knowledge leaves women ill-prepared for common pelvic-related life events – menarche, sexual activity, pregnancy, childbirth, menopause and aging. Because the risk of pelvic disorders increases with age, knowledge is needed at a young age to influence health perceptions, access and treatment preferences.

Aim: This study assessed the effectiveness of an early educational intervention to improve adolescent females’ knowledge, perceptions and behavior of pelvic health -conceived as bladder, bowel, uterine, vaginal health and pelvic muscles/structures- through an interactive curriculum delivered within the school-setting.

Study Design: Pelvic health education classes were delivered in six weekly one-hour classes by three pelvic health teachers. A comparison control group received the normal curriculum delivered in that class (gym or science). Pre-post survey research methodology was used to discern baseline knowledge, perceptions and behavior of pelvic health; and to assess knowledge acquisition and adoption of healthy behaviors post intervention.

Consent: The Western Institutional Review Board (WIRB) approved this interventional, educational research that was conducted at three Chicago schools in geographically disparate areas of the city. Female adolescents were eligible to participate if they were English-speaking and enrolled in the identified seventh, eighth, ninth or tenth grade classes. The Principal Investigator and research coordinator attended parent-teacher conferences at all participating schools to meet parents, introduce the study, and answer questions about the study. Students in classes identified for participation received an introductory visit from the Principal Investigator and research coordinator to explain the consent process. At two of the schools, parents received an introductory letter via mail, description of the study and contact information for the Principal Investigator and a copy of the consent form. The third school opted out of mailed letters to adhere to their school-parent web-based communication protocol. Written parental consent and student assent were collected for all participants. Standard socio-demographic data was collected to describe the study population.

Results: One hundred sixty-eight students with a mean age of mean age 14.1 (SD=0.1) (13-17 years of age) participated in the study (Intervention: 103, Control: 65). The majority (69%) of participants self-reported race as African-American; 23.8% reported Hispanic ethnicity. Knowledge of pelvic anatomy and function at baseline was minimal. Anatomical knowledge was very low with few participants in both groups correctly identifying that urine exits the body through the urethra or that there are three openings in a woman’s pelvic region. After the educational intervention, anatomical knowledge improved significantly and we detected a significant increase in awareness of pelvic floor muscles in the control and intervention group (20% vs. 89%, p <.001), the benefit of pelvic floor muscle exercise (31% vs. 78.0%, p<.001) and knowledge that urine loss was abnormal (25.4% vs. 60%, p<001). More participants were able to correctly
identify the vagina (21.5% vs. 51.5%, p<0.001), pelvic floor muscles (16.9% vs. 57.3%, p<.001), and the bladder (12.3% vs 42.7, p < .001).

**Interpretation of Results:** Although not designed as a prevalence study, it was notable that 46% of the students were currently experiencing symptoms of pelvic floor dysfunction, be it OAB, SUI, chronic constipation or pelvic pain. Further research could look at contributing factors, such as diet, exercise and family/cultural predispositions.

**Conclusions:** Short-term pelvic health education interventions may be effective at building knowledge and information in young women with which to navigate life course events. Empowered young women may be able to prevent future pelvic floor disorder and establish and sustain healthy behaviors toward overall pelvic health.

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

### Percent Correct by Knowledge Question by Research Group

<table>
<thead>
<tr>
<th>Questions</th>
<th>Pre-Test</th>
<th>Post-Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All n=168</td>
<td>Control n=65</td>
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<tr>
<td>Do you know what the pelvic floor muscles are?</td>
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<td>9.2</td>
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<tr>
<td>Are pelvic floor muscle exercise good for your overall health?</td>
<td>19.4</td>
<td>23.4</td>
</tr>
<tr>
<td>Is it normal to leak urine?</td>
<td>29.8</td>
<td>35.4</td>
</tr>
<tr>
<td>Wiping from front to back prevents bacteria from anus from getting in vagina?</td>
<td>43.5</td>
<td>49.2</td>
</tr>
<tr>
<td>Where does urine exit the body?</td>
<td>18.0</td>
<td>19.0</td>
</tr>
<tr>
<td>How many openings does a woman have in her pelvic region?</td>
<td>37.4</td>
<td>41.3</td>
</tr>
</tbody>
</table>

### Percent Correct by Organ, Muscle, Structure by Research Group

<table>
<thead>
<tr>
<th>Organ</th>
<th>Pre-Test</th>
<th>Post-Test</th>
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<td></td>
<td>All n=168</td>
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THE EFFECT OF EMG BIOFEEDBACK ASSISTED PELVIC FLOOR MUSCLE THERAPY WITH THE MAPLe ON WOMEN WITH THE OVERACTIVE BLADDER SYNDROME

Jeroen Voorham\(^1\), Stefan De Wachter\(^2\), Tine van den Bos\(^1\), Hein Putter\(^3\), Guus Lycklama a Nijeholt\(^4\), Petra Voorham-van der Zalm\(^5\)

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Introduction: The overactive bladder syndrome (OAB) is defined as urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence. Pelvic Floor Muscle Therapy (PFMT) attempts to suppress urgency, control incontinence and restore a normal voiding interval, and aid bladder emptying through increasing awareness of the function and coordination of the muscles, so as to gain muscle identification, control, and strength and to decrease bladder overactivity.

Methods and Aims: We investigated whether there is an effect of Biofeedback Assisted PFMT (BAPFMT) as an urge suppression technique on symptom reduction, Quality of Life and EMG signals on different sides and layers of the pelvic floor muscles in women with OAB for tone at rest and maximal voluntary contraction measured with the MAPLe before and after treatment and after one-year follow-up.

Results and Conclusions: Results show that EMG BAPFMT with the MAPLe is effective in the OAB syndrome in women after nine weeks of treatment and after one year follow-up. Validated questionnaires showed a significant reduction in symptoms and complaints of OAB and an increase Quality of Life for patients. Significant changes were seen in EMG activity before and after treatment, nearest to specific muscle layers and sides for tone at rest, MVC and endurance. This indicates that in the diagnosis and treatment of OAB should focus more on the individual muscle sides and layers of the pelvic floor, instead of the conventional average EMG of all muscles sides and layers combined.

Ethical Approval: The study was approved by the medical ethical committee of the Leiden University Medical Center and all patients signed an informed consent.

Funding Source: The study was given an unrestricted grant by Novuqare BV.

Conflict of Interest: Jeroen Voorham is a shareholder in Novuqare BV.
DESIGN OF A SENSOR TO MEASURE BLADDER VOLUME USING ELECTRICAL CONDUCTANCE

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Introduction: Laboratory-based urodynamics testing is useful for diagnosing lower urinary tract (LUT) dysfunction. However, it suffers from a number of pitfalls, including poor sensitivity, specificity, and measurement reproducibility, as well as patient physical and emotional discomfort. Ambulatory urodynamics systems have been identified as a possible alternative to more reliably diagnose LUT disorders while reducing patient distress and allowing for normal physiologic bladder activity. However, currently studied ambulatory systems still rely on catheters. Furthermore, none of these ambulatory urodynamics systems includes a method for measuring bladder volume, a crucial property of bladder functioning that would enable calculation of bladder compliance. Previous methods of measuring bladder volume have been attempted, but suffered a number of drawbacks including poor accuracy, requiring externally worn transducers or surgically implanted sensors, and high power consumption. Electrical conductance has been trialed previously, but has the key limitation of being sensitive to the concentration of the solution media.

Purpose: To develop a sensor capable of providing a catheter-free method of measuring bladder volume to be implemented as part of a catheter-free ambulatory urodynamics system.

Study Design: A sensor was designed based on preliminary experimentation which combined a conductance probe (volume-sensitive) and conductivity probe (volume-independent). The sensor was then printed on a circuit board. Testing was performed in both in vitro (latex balloon) and in vivo settings (a bladder in an anesthetized calf). In each experiment, the sensor was inserted into the balloon or bladder, which was filled with three concentrations of normal saline (0.45%, 0.9%, and 1.8% NaCl) in 100mL increments to a total volume of 500mL, with three measurements at each volume. Measurement results are presented in graphs of measured conductance vs. volume saline, with error bars representing one standard deviation. A mathematical equation was developed to convert sensor measurements to bladder volume. The form of the equation was empirically derived assuming spherical bladder shape, and the equation was fit to the data from the latex balloon and calf bladder using a least residuals algorithm (MatLab). Goodness of fit between the equation and the data was measured as average error between predicted volume and actual volume (mean ± standard deviation) as well as coefficient of determination ($r^2$).

Results: In both the latex balloon and calf bladder, measurements using the conductance probe increased initially at low volumes, and asymptotically approached a maximum at higher volumes. Magnitudes of measurements made using both the conductance and conductivity probes increased with greater concentration of saline. The equation was fit to the 0.9% NaCl data for the latex balloon ($r^2 = 0.836$). For the latex balloon, average error between the volume predicted using the equation and the actual volume for 0.45%, 0.9%, and 1.8% NaCl were $317 \pm 148$, $50.3 \pm 28.5$, and $56.6 \pm 36.4$ mL respectively. The fit was repeated using the 0.9% NaCl data from the anesthetized calf ($r^2 = 0.802$). Average error for 0.45%, 0.9%, and 1.8% NaCl in the calf bladder were $1562 \pm 380$, $85.0 \pm 42.8$, and $50.2 \pm 38.7$ mL respectively.

Interpretation of Results: Studies in latex balloons and the bladder of an anesthetized calf have demonstrated an average accuracy within 100 mL for 0.9% and 1.8% NaCl. However, lower concentration saline had the least accuracy. Potential sources of error include progressive changes in the sensor with continued testing (waterlogging of circuit board, sensor corrosion), and for the calf test, indeterminate sensor position within the bladder and faultiness of the spherical bladder assumption.
**Next Steps:** The described volume sensor is in the process of being implemented onto an intravesical device that is being developed as an ambulatory urodynamics system. Further *in vivo* studies are being planned for 2017.

**Conclusions:** This study describes a sensor that could potentially be used to measure bladder volume as part of an ambulatory urodynamics system. Unlike previous methods for measuring bladder volume, this sensor does not require surgical implantation or externally worn elements. Additionally, a mathematical equation is described which converts the sensor measurements into bladder volumes.

**Ethical Approval:** All procedures involving animals were outlined in a protocol which was reviewed and approved by the Cleveland Clinic Institutional Animal Care and Use Committee (IACUC) prior to project initiation.

**Funding Sources:** State of Ohio 3rd Frontier Grant TECG20150781 and VA RR&D Merit Review, Grant F7422-R
**Polymer Brush Functionalised Catheter Surfaces**

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**Introduction:** Over the past decade efforts have been made to optimise catheter surfaces in an attempt to reduce the occurrence of urinary tract infection and encrustation [1]. Organic and inorganic materials have been mooted as potential methods of reducing bio-film formation and increasing lubricity. Hydrogel coatings (i.e. networks of cross-linked polymer chains in an aqueous solvent) are available and effective in reducing bio-film formation, trauma and encrustation due to their hydrophilic nature [2,3]. However pain during insertion and infections with these technologies is still common.  
Zwitterionic polymer brush technologies, consisting of a layer (~100 nm) of bio-inspired phospholipid polymers with one end chemically grafted to the surface, have received much research over the past decade [4]. Polymer brush modified surface have been shown to reduce bio-film formation and friction for vascular applications [5] with enhanced surface properties when compared to their hydrogel counterparts. However polymer brush technologies are yet to be considered for urinary catheters. This paper aims to identify the feasibility of functionalising catheter surfaces with zwitterionic polymer brush technologies for the reduction of urethral trauma and infection for indwelling and self-catheterisation devices.

**Methodology:** Polymer grafted surfaces have been prepared using a UV initiated free-radical polymerization process. Planar polydimethylsiloxane and Silicone catheter (Foley catheters, Coloplast) surfaces were immersed in piranha solution to produce an OH- terminated surface and immersed in an ethanol solution containing 5% 3-methacryloxypropyl trimethoxysilane (MPSi), 1% succinic acid, and 0.1% 2-Hydroxy-1-[4-(2-hydroxyethoxy) phenyl]-2-methyl-propan-1-one (D9295) overnight for salinization of the trimethoxysilane group. Functionalised surfaces were then immersed in 0.5 Mol/L of 2-methacryloyloxyethyl phosphorylcholine or 2-(Methacryloyloxy) ethyl(dimethyl-(3-sulfopropyl)ammonium hydroxide prepared using degassed DI water. UV irradiation was used to initiate the atom-transfer radical-polymerization process. Surfaces were characterised using a variety of methods. Contact angle assessment was carried out to quantify the extent of hydrophobicity. Fourier transform infrared (FTIR) has been conducted to identify the surface chemistry under environmental conditions. The friction of surfaces was assessed using a micro-tribometer. The tribological properties were assessed under a variety of loads and sliding distances, lubricated in DI water and synthetic Urine.

**Results and Discussion:** Preliminary results have indicated the successfully grafting of polymer macro-molecules to the silicone surfaces. A decrease in water contact angle from ~ 80° to ~ 10-14° was observed demonstrating a significant reduction in hydrophobicity. A significant reduction in friction was observed due to the creation of a hydrophilic surface and formation of water rich layers at the interface. Further work will look at the antifouling capabilities of these surfaces using novel scaling testing facilitating flow and there interaction with urethral tissues.

**References:**


**Ethical Approval:** Not relevant.

**Funding Source:** This research has received support from UK NIHR-EPSRC IMPRESS Network: (EP/M000109/1 and EP/N027345/1).
IMPRESS: ENGINEERING IMPROVEMENTS FOR CONTINENCE

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2 Applied Biomedical Engineering Group, University College London, London, UK

Introduction: Many clinical challenges persist in the field of both faecal and urinary incontinence. Applied research from the engineering sciences has significant potential to directly address these and so improve healthcare provision for patient benefit. However, incontinence encompasses an array of interrelated causative factors, involves a complex area of the anatomy and is shrouded in taboo and social stigma. Consequently, the area has seen limited research activity and innovation.

IMPRESS (Incontinence Management and PRevention through Engineering and ScienceS) is a research network with the aim to encourage more engineers and scientists to work on the clinical and social challenges raised by incontinence. Our belief is that increased engagement of this community will bring patient benefit through the translation of existing strategies from other fields and the development of new innovative technologies.

Methods: Our approach has been to work closely with patients and patient-groups, healthcare professionals, allied networks, the scientific community and industry partners, through events including public workshops, technical symposiums, conferences, clinical placements and online media, to build a multi-disciplinary community and disseminate incontinence challenges to an engineering science audience. In conjunction with these activities we have launched targeted funding calls for innovative research needing to demonstrate proof-of-principle to secure longer-term funding toward commercialisation and clinical utility.

Results: We have distilled the knowledge and experience from our network into a working ‘roadmap’ intended to help inform, guide and stimulate technology research in the critical area of incontinence healthcare. An excerpt is shown in figure 1. The roadmap considers incontinence from the viewpoint of multiple stakeholders; with clinical considerations (i.e. spanning assessment, intervention and long-term management), a patient perspective on desired health outcomes and finally how these relate to technological research challenges. We have then illustrated how our pilot research projects map onto this roadmap and report their achievements to date.

Conclusion: By looking past the taboo, there is a huge potential, and need, to translate technology research into life-changing improvements for those with incontinence. By providing appropriate contacts, funding and guidance, research networks like IMPRESS can help bring about this change and engage a wider community in the engineering sciences. Ultimately, we believe this can move toward continence technology designed for all and which goes beyond the ‘functional’ to empower those who use it.

Ethical Approval: Not relevant.
Funding Source: This research is supported by UK NIHR-EPSRC EP/M000109/1 and EP/N027345/1.
CO-ELECTROSPUN MESHES: A NOVEL APPROACH FOR PELVIC ORGAN PROLAPSE REPAIR AND REGENERATION

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1 School of Mechanical Engineering, University of Leeds, UK
2 School of Design, University of Leeds, Leeds, UK
3 Applied Biomedical Engineering Group, University College London, London, UK

Introduction: Pelvic organ prolapse is an increasingly prevalent health condition, which occurs in 50% of adult women, affecting their quality of life and requiring surgical intervention in 11% of cases. Current surgical treatment focuses on the use of meshes that improve structural support and enhance tissue repair. While mesh-based approaches have considerably improved POP treatment, there are still significant complications associated with their use (i.e. inadequate mechanical properties, fast degradation rate, possibility of shrinkage, infection risk and erosion). To help overcome these current challenges, the aim of this work was to develop a co-electrospun biodegradable mesh, which mimics the three-dimensional architecture of the pelvic floor, allowing better biomechanical integration into the host tissue, and exhibiting an antibacterial action.

Methods: Chitosan (CS) and poly(ε-caprolactone) (PCL) were dissolved using a solvent mixture consisting of formic and acetic acid, and subsequently processed through needleless Nanospider™ (Elmarco, Czech Republic) electrospinning technology. After an initial optimisation process of the electrospinning parameters (i.e. voltage and collector distance), selected CS and PCL concentrations were blended and processed until a bead-free three-dimensional (3D) electrospun scaffold was obtained. Physico-chemical, thermal and mechanical properties were then assessed. Furthermore, fibroblast viability and metabolic activity were evaluated using a Live-dead assay and an MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide) assay at different time points.

Results: For the first time a blend of CS/PCL 3D fibers was produced by using a needleless Nanospider™ (see Fig. 1). The morphology of the electrospun fibres, obtained from 0.5wt% CS and 6wt% PCL, is shown in Fig.1. The resultant meshes consisted of fine fibres (~250 nm) with no significant variations in diameter. Viscosity measurement of the blended polymers was undertaken to understand its effect on solution spinnability. Additionally, FTIR spectra confirmed the presence of the two polymers in the resulting meshes, and their homogenous distribution. Finally, cellular tests demonstrated efficient fibroblast attachment, evidence for cell proliferation, and combined with MTT data that they were also metabolically active.

Conclusion: This preliminary work demonstrates that the use of needleless electrospinning, with a blend of CS/PCL solutions, has the potential to generate novel surgical meshes as innovative treatments for POP.

Ethical Approval: Not relevant.

Funding Source: This research is supported by the UK NIHR-EPSRC IMPRESS Network: (EP/M000109/1 and EP/N027345/1).

Fig. 1: SEM image of electrospun fibers (blend of 6 wt% PCL with 0.5 wt% CS); scale bar 1 µm.
A PHYSICAL SIMULATION TO INVESTIGATE THE EFFECT OF ANORECTAL ANGLE ON CONTINENCE

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¹ School of Mechanical Engineering, University of Leeds, Leeds, UK
² NHS Leeds Teaching Hospitals, Leeds, UK

Introduction: This poster investigates the effect of the anorectal angle on continence using a physical model of the anatomical pelvic floor system.

Materials and Methods: 1.1.1.1 A method to fabricate, measure and control a physical model for the simulation of human faecal continence is presented. A model rectum and associated soft tissues, based on geometry from an anonymised CT dataset, was fabricated from silicone and showed behavioural realism to ex vivo tissue. Simulated stool matter with similar rheological properties to human faeces was developed. instrumentation and control hardware are used to regulate injection of simulated stool into the system, define the anorectal angle and monitor stool flow rate, intra-rectal pressure and puborectalis force. A study was then conducted in which simulated stool was introduced to the system for anorectal angles between 80° and 100°.

Results: At angles of 80° and 100° respectively, mean mass leakages of 0.0139 kg (STD 0.0082 kg) and 0.0301 kg (STD 0.0028 kg) were measured, see figure 1. Results obtained from the study give insight into the effect of the anorectal angle on continence. Stool leakage was reduced as the angle became more acute. Conversely, intra-rectal pressure increased.

Discussion: This research demonstrates that despite the complexities of the human faecal continence system, it is possible to develop, instrument and control physical models that provide valuable insight into physiological behavior. Our results demonstrate that the anorectal angle is fundamental in maintaining continence, acting to complement occlusion of the anal canal by the anal sphincter. Future work will consider the inclusion of an anal sphincter system to explore their combined effects on continence.

Conclusion: This work is valuable in helping improve our understanding of the physical behaviour of the faecal system through the use of repeatable physical models. It has particular relevance facilitating improved technologies to treat or manage severe faecal incontinence.

Ethical Approval: None.

Funding Sources: This research has received support from UK NIHR-EPSRC IMPRESS Network: (EP/M000109/1 and EP/N027345/1).

Figure 1 Faecal mass passed, PR force and IR pressure versus time for different ARA values. Each plot shows mean (N=5) in solid with 1 STD as shaded region.
STRETCHABLE ELECTRONICS BASED WIRELESS AND PASSIVE BLADDER SENSOR

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² Neuro-Urology, Spinal Cord Injury Center & Research, University of Zurich, Balgrist University Hospital, Zurich, Switzerland
³ Brain Research Institute, University of Zurich and Department of Health Sciences and Technology, ETH Zurich, Zurich, Switzerland
⁴ Zurich University of Applied Sciences, School of Engineering, Center for Communications Systems, Switzerland

Introduction: Spinal cord injury (SCI) has far-reaching consequences for the individual’s health and social life. Most of these patients will develop neurogenic lower urinary tract dysfunction (NLUTD), which has a highly negative impact on patients’ health-related quality of life and may progressively lead to end stage renal failure. Other neurological diseases can also cause bladder dysfunctions like incontinence and urinary retention. Modern proactive neuro-urological management aiming at the preservation of upper urinary tract function, the control of urinary tract infection, and the maintenance of a low-pressure bladder that is both continent and capable of complete emptying has revolutionized the treatment of SCI patients [1]. Nevertheless, lower urinary tract function remains one of the most important issues in health and general life of a SCI patient. However, all currently available treatments for NLUTD are only symptomatic, i.e. there is a complete lack of causal therapies, which are urgently needed.

In the last decade, significant progress has been made towards stretchable electronics. Conductive elastomers have interesting properties for use in diverse conformal devices for implantable and wearable applications for monitoring, diagnosing and therapeutic purposes in medicine. Electrically interfacing tissue with stretchable conductors is promising for chronic implants in vivo due to their minimized mechanical mismatch at the implant-tissue interface, which leads to improved adaption to tissue movement and potentially to less foreign body reaction. The electromechanical material properties of novel stretchable conductors combining high conductivity while being thin, soft and stretchable enables novel implantation sites (especially for chronic use) hence allowing innovative applications where hard or flexible electrodes are prone to fail.

Using recent advances in stretchable electronics, we are developing a novel bladder implant providing the patient with a continuous, long-term feedback of the fullness of the bladder.

Results and Discussion: We developed soft & stretchable conductors with improved electromechanical properties based on elastomers filled with metallic micro- and nanomaterials. Using novel micro-fabrication methods for simple and fast prototyping, we produced highly stretchable conductors with minimal fatigue even at high strains well above 50% [2,3]. We designed a passive and wireless implant using a highly stretchable electronic resonance circuit that could be implanted minimal invasively onto or into the bladder wall/muscle. The sensor element can stretch with the bladder and changes its resonance frequency linearly with strain. This can be readout wirelessly using electromagnetic coupling by a portable device connected to a mobile phone.

Next Steps: We are currently iterating sensor design, charactering the bladder sensor in vitro on a bladder phantom model and working towards animal trials.

References:

Funding Source: The research was financed by the Swiss Nanotera SpineRepair project, ETH Zurich, the Swedish Research Council, the Swiss Academy of Medical Sciences and the Swiss Continence Foundation.
EXTERNAL CATHETER SYSTEM PROVIDES EFFECTIVE INCONTINENCE MANAGEMENT FOR WOMEN

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² EC-Service, Inc., Centerville, UT, USA
³ Weber State University, Ogden, UT, USA

Aims of the Study: Studies on 16 bedbound women were performed to determine effectiveness, ease of use, comfort and acceptability of a new, innovative external catheter system for women.

Device Description: The PureWick® External Catheter for Women provides non-invasive, safe and effective urine capture (Figure 1). An alternative to indwelling and intermittent catheters, the soft and flexible external catheter wick connects to wall vacuum systems (Figure 2) or an optional DryDoc Vacuum Station™ (Figure 3). The wick is designed to capture up to 100% of urine, regardless of flow rate. The wick does not attach to or enter the body. It may be used lying down on back or side or while seated. The wick does not require a doctor’s order and may be placed by any trained healthcare worker. This external catheter system is an FDA 510(k) exempt Class I device.

Study Design: The 16 bedbound women varied in age from 61-99 and suffered functional incontinence due to physical and/or mental issues associated with their diagnoses and health status (Figure 4). The women used the catheter connected to the vacuum system for varying periods of time. Placement of the external catheter was between the labia and in contact with the labia minora and the superficial urethral opening. The external catheter does not penetrate the urethral opening. The study was a survey about using the device, and patients were monitored for function, infection, discomfort and irritation. Various device features were evaluated for impact on performance and user interaction.

Results: The external catheter effectively managed urinary output, with 95-99% of urine output collected. Users were not required to be awakened for incontinence management, allowing improved sleep quality. The external catheter was reported as easy to use in 14 out of 16 patients surveyed. Urine capture was hindered in 3 cases due to significant fecal incontinence, or dementia patients tampering with the external catheter.

The external catheter induced no skin irritation. In some instances, appropriate medical adhesive tape was used to secure the external catheter and as a barrier to prevent irritation from more aggressive adhesives. No symptomatic UTI’s or cases of Cystitis occurred in 1,843 external catheter use days. Only one preexisting case of Bactiuria was observed. Patients were successfully transitioned off indwelling catheters while using the external catheter and pre-existing pressure ulcers were shown to improve.
Effectiveness of external catheter was significantly better when it was fit snugly to the anatomy of the user, with an effectiveness of 95 to >99% urinary collection. Caregiver and user feedback indicated improved sleep, reduced incontinence management, reduced bedding changes, increased comfort, and high tolerance for the external catheter.

Summary of Results: The external catheter effectively collected 95-99% of urinary output. Caregiver and user feedback indicated improved sleep, reduced incontinence management, reduced bedding changes, increased comfort, ease of use, and high tolerance for the external catheter.

Conclusion: The external catheter is a safe, effective, efficient and comfortable solution for women with incontinence.

Ethical Approval: The study was determined to be exempt according to 45 CFR 46.101(b) by Integreview IRB.

Conflicts of Interest: Camille Newton, MD, is the founder and President of PureWick Corporation; Kelvin S.L. Chan and Evan Call have received compensation for consulting services provided to PureWick Corporation.

Funding Source: None

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Figure 4. Patient age and diagnosis/health status
DEVELOPMENT OF AN ADVANCED WATER BASED TOILETING SYSTEM FOR THE MANAGEMENT OF FECAL AND URINARY INCONTINENCE, THE SCHWABCARE WELLNESS SEAT

Brian Murray, MD
Director of Urology St Peter’s Health Partners, Albany NY, USA, Chief Medical Officer, Whole Bath LLC, Albany, NY

Introduction: Urinary and Fecal incontinence represent an increasing medical, social and economic issue worldwide. The inability to self-toilet remains a major driver of progression of care and has a significant impact on patients’ quality of life. These issues have led to the development of new treatment modalities to manage incontinence. Despite this advance in therapies for urinary and fecal incontinence the number of patients who remain symptomatic is still greater than complete responders.

Water based toileting was first initiated in the 1750’s with manual pump spray system. The current modern bidet toilet took roots in the early 1900’s with the progression to a modern-style bidet seat in the 1960’s. The fundamental design has not changed much since the 1980’s. During this time, seats have been used extensively outside the US with a high adoption rate in Japan. Several studies have been done looking at water based toileting alone for patient management; however, results fell short due to issues with cleansing, time to dry and continued need for skin care management.

Project Method and Materials: Our goal was to develop a comprehensive wellness system that would serve as an assistive device for patients with decreased mobility but also help manage incontinence-associated dermatitis. The long-accepted management algorithm for perineal care has been gentle cleansing, drying and application of barrier spray where needed. The compliance with therapy has been a problem at home, institutional and assistive settings due to multiple factors. We have sought to develop a wellness system that would allow for improved perineal cleansing via hands free application of cleanser followed by water lavage, efficient drying and the hands free application of barrier spray as needed.

The system utilizes; an automated cleanser application, on demand water heating system for gentle washing via programmable spray head, advanced dryer and optional programmable hands free bottom up barrier spray applicator. A series of single touch activation buttons located at the front of the seat allows the individual to choose from a wash and dry only, initial cleanser, or complete cycle with; cleans, wash, dry, and barrier spray application.

Next Steps: We are now in final phase of development and are beginning clinical studies of the system for patients suffering from incontinence associated dermatitis, patients with decreased mobility affecting their ability to self-toilet, and those at high risk for progression of care due to incontinence. In December 2016, four clinical study sites for home based therapy and one site for assisted living applications were established. The initial test group is being evaluated for general preference for settings of water and air temperature and duration of wash cycle. They are also having weekly skin assessments to evaluate dermatitis and response to the automated barrier spray application.

Ethical Approval: All patients enrolled have or will be screened and administered informed consent approved by applicable institutions review boards.

Funding Source: All funding for the studies and product development have been supported by Whole Bath, LLC.
A SYSTEMATIC REVIEW OF INTERVENTIONS THAT SEEK TO DIMINISH THE SELF-STIGMA ASSOCIATED WITH HEALTH CONDITIONS: SYNTHESIS OF STUDIES THAT EMPLOYED QUALITATIVE METHODOLOGIES

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Introduction: The onset of illness and disability can threaten self-identity and be accompanied by feelings of loss. Compromises in functional independence can have important negative impacts on psychological and social functioning, and ultimately may make individuals eligible for rehabilitative services. While many adults with health conditions acknowledge the potential benefits of rehabilitation services, others feel stigmatized about accessing such services because they may make disability and vulnerability conspicuous. While the stigma process is frequently cited in health care literature, health care educators lack necessary guidelines on how stigma should be accounted for in rehabilitation intervention design and implementation. Ultimately, the quality of patient care may be less than optimal, and the potential for social disconnectedness persists. Stigma delays the recognition of health symptoms and early identification of health conditions, and serves as a barrier to help-seeking. In order to design and implement effective rehabilitation intervention programs for this population, a better understanding of the stigmatization process and its manifestations is vital. Surprisingly, very few health care initiatives have attempted to design and evaluate interventions to diminish the self-stigma associated with health conditions, despite the substantial social, psychological and physical ramifications. In order to support a healthy level of social integration of individuals with health conditions, it is necessary to design and evaluate efficacious and reliable interventions to diminish self-stigma associated with health conditions.

The fundamental questions of this research study were: does there exist, scientifically based, well designed and scientifically valid and evidence based intervention programs that reduce the self-stigma among individuals know to display an identity threat because they possess a stigmatizing trait? If so: (1) what are the components of efficacious anti-stigma programs and (2) what is the structure of these programs?

The goal of this presentation is to summarize findings from research studies that used qualitative research methodologies to investigate the effects of treatment programs designed to reduce self-stigma in adults who have a stigmatizing health condition.

Methods: For this poster, we will present a synthesis of evidence based intervention programs that aimed to reduce the self-stigma associated with a health condition employing qualitative methodologies. These data are a subset of a more comprehensive systematic review conducted by our team.

Search and inclusion criteria: For the parent study, search strings were developed for three themes: self-stigma, intervention, and health conditions. Searches were conducted in six electronic databases: PsycINFO, MEDLINE, Cochrane Database of Systematic Reviews, CINAHL, EMBASE and Google Scholar. We limited our search to English-language studies published between 1990 and 2014. Studies were included for full review if 1) participants or their entourage presented a health condition, either physical or mental, 2) the study reported on the implementation of an intervention and 3) the study reported measures of the intervention’s impact on self-stigma related concepts. During this process, we set aside studies that employed qualitative research methodologies. Our search uncovered nine studies.

Analysis: To assess these data, we conducted a thematic analysis of intervention outcomes reported in the qualitative studies. We sought to answer the question, ‘what are the investigators doing (testing) to diminish
self-stigma? Specifically, we extracted the results section of each study, and conducted a thematic analysis of this text. A coding manual was created and applied to relevant excerpts. Recurring concepts across studies formed the basis of theme development. We also assessed the quality of the retained articles using a modified version of ‘Pro Forma Criteria for Scoring Qualitative Articles’ (Walter et al., 2004).

**Results:** At a general level, the interventions employed psychoeducation and cognitive behavioral therapy, and included strategies such as participation in support groups, web-based interventions, and activities that involved creative expression.

The participants reported that the treatment program they participated in had a positive effect in one or more of three personal levels: emotional, cognitive and behavioral. Effective self-stigma treatment interventions addressed self-stigma with three moderating factors: peer support, disclosure and participants’ active role in the intervention. These approaches aimed to reduce the self-stigma associated with their health condition, while increasing self-confidence and empowerment. These ideas will be explored further in the presentation.

**Conclusion:** Our analyses revealed evidence that supports the ongoing development of intervention programs aimed at reducing self-stigma. Specifically, in this subset of studies that employed qualitative methodologies, researchers sought to decrease stigma by increasing empowerment and by improving the participants’ self-esteem and self-image. This line of enquiry warrants further exploration.

**Conflicts of Interest:** None.

**Funding Source:** The Simon Foundation for Continence
HOW DOES A COMPLIANT AIR-FILLED INTRAVESICAL BALLOON INCREASE THE ABDOMINAL PRESSURE REQUIRED TO INDUCE STRESS URINARY INCONTINENCE RELATED LEAKAGE?

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Aims of the Study: Stress Urinary Incontinence (SUI) related urine leakage occurs when intravesical pressure momentarily exceeds the urethral pressure, which commonly occurs during a cough, sneeze, or physical exertion. A recent published study[i] clinically evaluated an air-filled intravesical balloon as a means to reduce transient intravesical pressure and urinary leakage. The study reported a statistical difference in the number of patients with the Vesair® intravesical balloon that did not leak during a VLPP test vs. control patients without a balloon. The authors have assessed an attenuator in-vitro to evaluate its ability to reduce leakage by attenuating short-duration transient intravesical pressure events. The authors have also assessed the increase in abdominal pressure required to generate a defined intravesical pressure when the balloon is placed in an in-vitro model.

Project Materials and Methods: A Vesair balloon was constructed of thin polyurethane material with a one-way valve to permit filling with air. In-vitro feasibility assessment was made using a custom-built bench-top acrylic chamber. Computer controlled valves, connected to a compressed air source, were used to pressurize a 250cc chamber to transient pressure of 70 and 140 cm H2O to simulate an intravesical pressure which may result in stress urinary incontinence leakage. Pressure in the chamber was recorded without the balloon, and then with a 30ml balloon. Pressure pulse duration was 20 msec, 40 msec, 80 msec and 120 msec to represent a typical duration of a leakage-inducing transient pressure event. In a separate test, the intravesical pressure in the chamber with a balloon was set to both 70 and 140cmH20 at the pulse widths mentioned above and the external pressure exerted on the chamber was then recorded (simulated abdominal pressure).

Results: The results of in-vitro measurements using 20 msec pulses in the acrylic chamber are shown in Figure 1. For a 20msec pulse, the amplitude of a transient pressure pulse was reduced by 80% from 140 cm H2O to 28 cm H2O when the balloon was placed in the chamber. For a 40msec pulse, the amplitude of a transient pressure pulse was reduced by 65% from 140 cm H2O to 49 cm H2O. The required simulated abdominal pressure increased 238% to 334cm H20 to generate a 140cmH20 intravesical pressure (at 80msec) when the Vesair balloon was placed in the chamber.

Figure 1 Reduction of Intravesical Pressure with Vesair Balloon, 20msec pulse.

Conclusion: The in-vitro test results are consistent with engineering and physics principles. For volumes and pressures that approximate physiological values, very significant pressure attenuation can be obtained using a balloon volume that is approximately 10-15% of a typical functional bladder capacity. The findings warrant further investigation to reduce leakage associated with SUI.

References:
1. Rovner et al, A Randomized, Controlled Clinical Trial of a Novel Intravesical Pressure Attenuation Device for the Treatment of Stress Urinary Incontinence. J Urol. 2013. 190 No. 6: 2243-50

Ethical Approval: None
Funding Source: Solace Therapeutics, Inc.
Conflicts of Interest: Scott Duncan and Kevin Connors are employees of Solace.
ANALYSIS OF SEDIMENT FORMATION ON LONG TERM INDWELLING FREE-FLOATING INTRAVESICAL BALLOONS FOR THE TREATMENT OF SUI FROM TWO MULTICENTER RANDOMIZED CONTROLLED CLINICAL STUDIES

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Aims of the Study: A novel free floating, non-occlusive, compliant intravesical balloon filled with compressible gas has been evaluated in US and European multi-center randomized controlled clinical trials for the treatment of SUI. The balloon aims to reduce transient spikes in intravesical pressure that are common to all forms of SUI, regardless of their etiology. Encrustation is a concern with any intravesical device, as the chemical constituents of the urine combine with the device to produce a matrix for the growth of stones. This formation may impact the efficacy of the device or result in stones dislodging from the device and becoming obstructive. The two previous prospective, randomized, single blind, multicenter studies assessed the safety and efficacy of this intravesical therapy on two different patient populations.1, 2 Balloons from these clinical studies were analyzed after removal from the patient to evaluate the formation of calcium oxalate and its impact to the efficacy of the device or the potential for stone formation.

Study Design: This study evaluated a total of 632 balloons removed from patients from two separate clinical studies. The balloons were removed under direct visualization using a custom optical grasper and placed in a specimen collection mailer and sent to a central location for analysis. All balloons were retained after analysis. The balloons were analyzed by visual inspection for sediment using a 10-point scale ranging from 0 (0 to 0.1mm), 1 (0.1mm – 1.49mm), 2 (1.5mm to 2.49mm) up to 10 (>9.5mm). For each device, the thickest deposit was measured at its thickest point. 539 balloons were from 159 patients in Study 1, which used a seamed pressure-attenuation balloon with a valve welded into the seam (Figure 1A) that was filled with 15cc of air. In Study 1, the protocol indicated that the balloons were intended for removal and replacement every 90 days. 93 balloons were from 79 patients in Study 2, which used a seamless Vesair® pressure-attenuation balloon with a valve welded to a small fill port (Figure 1C) that was filled with 30 cc of air. In Study 2, the protocol indicated that the balloons were intended to remain indwelling for up to one year.

Results / Expectations: 482 (89.4%) of the balloons in Study 1 had no measurable sediment formation (Score =0). 33 had a score of 1, 15 had a score of 2, four had a score of 3 and three had a score of 4. All sediment for balloons with a score greater than 1 was located at the valve/seam interface. The median indwell time was 89 days, with a range of 0 to 313 days. 89 (96%) of the balloons in Study 2 had no measurable sediment formation (Score = 0.) The remaining four balloons had a score of 1. The mean indwell time was 159 days, with a range of 4 to 413 days. A representative sample of removed balloons is shown in Figures 1B and 1D. Sediment formation that was measurable on the devices did not affect the device functionality and did not result in any obstructive issues.

Interpretation of Results: Sediment formation was much less than expected, and the design changes implemented in Study 2 further reduced sediment formation.
**Next Steps and Conclusion:** Compared to other intravesical devices, the balloon evaluated in this study was free floating, compressible, and buoyant so that it floats at the dome of the bladder, not at the base of the bladder where sediment resides. Further study is required to better understand which of these factors resulted in the reduction of sediment formation.

**References:**

**Ethical Approval:** Ethics Committee or IDE from US FDA and IRB approval with informed consent from every subject.

**Funding Source:** Solace Therapeutics.
SYNERGISTIC ELECTRICAL ACTIVITY OF ABDOMINAL MUSCLES DURING MICTURITION IN FEMALE MICE

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Introduction/Objectives: Urinary continence is maintained by a precise coordination between the detrusor and the external urethral sphincter. Simultaneous activation of neighboring striated muscles has been reported, but their role during micturition remains controversial in human and rodents [1]. The objective of the present study was aimed at determining the synergy of abdominal muscles during micturition using multi-channel intra-muscular electromyogram (EMG) recordings in intact mice.

Materials and Methods: Anesthesia was induced in female C57Bl6/J mice by subcutaneous injection of urethane (1.2 g/kg). An abdominal incision was made, and a suprapubic catheter was implanted into the bladder dome for saline infusion. Flexible spring electrodes were bilaterally placed at the external oblique (EO), internal oblique (IO), and both rostral and caudal parts of the rectus abdominis (RA) muscle [2]. Micturition was induced by saline infusion (20 μl/min). A high concentration of pancuronium-bromide (1 mg/ml) was applied on top of the full abdominal muscle after five complete voiding events were recorded. EMG and cystometrogram (CMG) were recorded using a RHD2000 amplifier (Intan Technologies) with a sampling rate of 5 kHz (EMG) and 1.25 kHz (CMG).

Results: Figure 1 shows 8-channel EMG signals simultaneously recorded with CMG. A continuous muscle firing was found in the EO during bladder filling phase but not the other muscles. During voiding, an increased firing frequency was observed from all recording channels except the two on the rostral RA muscle. This characteristic EMG activity also occurred during non-voiding contractions, but with lower amplitude. Paired recordings (signals recorded from left and right side of...
the same muscle) did not show parallel firing patterns. Inhibition of nicotinic receptors with pancuronium importantly suppressed the activation of EMG signals, and decreased the maximal voiding pressure during bladder contractions.

**Conclusion and Perspectives:** Our protocol provides a comprehensive way to simultaneously evaluate the activation of different motor units of abdominal muscles during micturition by multi-channel recordings. Inhibition of nicotinic receptors suggests that abdominal muscles can increase intra-abdominal pressure to facilitate voiding. This mouse model may be used as a pre-clinical approach for evaluating the role of abdominal muscles in patients with incontinence and/or urinary dysfunction.

**References:**

**Ethical Approval:** The experimental protocol was approved by the IACUC from Houston Methodist Research Institute and performed in accordance with the guidelines established in the Guide for the care and use of laboratory animals (National Research Council of the National Academies).

**Funding Sources:** This work was supported by the Brown Foundation, the Houston Methodist Foundation, NIH DK082644, and the University of Houston.
INVESTIGATING MECHANICAL INTERACTIONS BETWEEN SKIN AND FABRICS

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Introduction and Aims of the Study: When a compliant sheet of material is dragged over a convex surface, the frictional forces generated can be many times greater than they would be for a planar interface. This phenomenon is known to contribute to the abrasion damage to skin often suffered by wearers of incontinence pads and bed/chairbound people susceptible to pressure sores[1]. Experiments that attempt to quantify these forces often use a simple capstan-type equation to obtain a characteristic coefficient of friction [2]. In general, the capstan approach assumes the ratio of applied tensions depends only on the arc of contact and the coefficient of friction and ignores other geometric and physical considerations; this approach makes it straightforward to obtain explicitly a coefficient of friction from the tensions measured. In this paper, two mathematical models are presented that compute the material displacements and surface forces generated by, firstly, a membrane under tension in moving contact with a rigid obstacle and, secondly, a shell-membrane under tension in contact with a deformable convex substrate. The results from these models are then compared to the predictions from a capstan-type model to determine its accuracy.

Models and Results: The first model presented determines the coefficient of friction in the contact region between a thin membrane pulled dynamically at a constant speed and a rigid underlying body. Kikuchi and Oden's model for Coulomb's law of static friction [3] was extended to curvilinear coordinates, and a numerical model was used to investigate how the calculated coefficient of friction varies with different material and physical parameters. For parameters such as Poisson's ratio of the membrane, Young's modulus of the membrane and the speed of the membrane there was no significant variation in the determined coefficient of friction; this indicates that a capstan-type approach with no dependence on these parameters should still produce accurate results. However, changes to the mass density of the fabric and the lateral (and thus Gaussian) curvature of the underlying body appear to lead to a significant variation in the determined coefficient of friction which would not be captured by a capstan model.
In varying the Gaussian curvature of the underlying body, the numerical model suggests that for a saddle-type geometry (as often observed in real experiments) the capstan approach may lead to a significant underestimate of the coefficient of friction. On the other hand, for a barrel-geometry with positive Gaussian curvature the converse is true with the capstan equation potentially overestimating the coefficient of friction. The numerical model also indicates the intriguing possibility of an optimal barrel geometry where the coefficient of friction is minimised - a surprising result.

The second model is for a thin shell-membrane under tension in frictional contact with an elastic foundation where static friction is imposed in the region of contact. The fact that our frictional law (e.g. Coulomb's law of static friction) must now be imposed on a free boundary because we no longer know a priori the location of the contact region significantly increases the computational complexity. To combat this, a modified, more computationally tractable, displacement-based static friction condition is derived from Kikuchi & Oden's law of static friction [3] in curvilinear coordinates. We then show that a set of governing equations for a two-body contact problem that incorporates this displacement-based static friction condition yields a unique solution. A numerical scheme for the two-body static friction contact problem is then developed where, this time, the coefficient of friction needs to be specified. Using this model, we examine how the normal and tangential stresses and displacements computed by the model vary as we vary the stiffness and thickness of the underlying body.

The shell-membrane in contact with a deformable elastic foundation model appears to indicate that both elastic and geometrical properties of the elastic foundation can significantly affect the stress and
deformation of the underlying tissue. Indeed with the applied tension and coefficient of friction fixed in the numerical model, the amount of stress experienced by the underlying elastic body appears to depend rather significantly on its geometry (thickness and curvature) and elastic properties, which are features that are typically neglected in capstan-type model approaches.

**Conclusions and Next Steps:** The models presented in this paper indicate some very interesting results and lead to a number of questions which should be pursued in terms of experimental design and to further quantification of the friction forces generated by nonwoven fabrics. The results show that while the use of a capstan equation remains fairly robust in some cases, effects such as the curvature and the flaccidity of the underlying body, and the mass density of the fabric can lead to significant variations in stresses generated in the contact region and, thus, the coefficient of friction determined by a capstan model may not be an accurate reflection of the true frictional behaviour of the contact region. One important issue to examine next is how to measure the curvature of the contact region and designing experiments that can see how curvature affects the relationship between normal and tangential forces in the contact region. It would also be wise to test if the experimental results are indeed sensitive to variations in the mass density of the fabric. Experiments involving deformable underlying bodies with well-known material parameters would be useful to validate our second model and further our understanding about how experiments on quantifying frictional forces involving human subjects should deal with significant skin deformation.

**References:**

**Ethical Approval:** None

**Funding Sources:** This work was supported by The Dunhill Medical Trust [grant number R204/0511] and a UCL Impact Studentship.
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.

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