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CHOOSING THE RIGHT PRODUCT FOR BLADDER LEAKAGE: ALL PADS ARE NOT CREATED EQUAL

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Problem definition: Women are not aware of the range of options available for management of Light Bladder Leakage (LBL), and often do not consult their doctors because they are too embarrassed or don't want to admit they have a problem. Even if consulted, not all doctors are aware of the absorbent product options available. Many doctors and women with LBL do not realize the benefits of using an absorbent product designed for urine vs. a menstrual product.

Design description: Bladder leakage products are designed specifically for urine leaks. They:

- Protect against odors
- Lock wetness away to keep users dry, even under pressure
- Have many choices with different absorbencies and options for the right fit
- Offer up to 3x as much absorbency as similarly categorized menstrual pads/liners

Results and Design Validation: In laboratory testing comparing similarly defined products (Ultrathin to Ultrathin or liners to liners), products designed for the needs of light bladder leakage and incontinence deliver much higher performance in several key areas.

- The amount of urine LBL products can absorb ranges from twice to three times as much as similar menstrual products.
- The ability to hold urine locked into the absorbent core, under pressure, is much better for targeted products as compared to menstrual products; it can be up to ten times better.
- Product dimensions are more similar than you might expect. Ultrathin pads for LBL are nearly exactly the same size as menstrual Ultrathins.

Conclusions: On a measurable level:

- Bladder leakage pads are superior in lab tests vs. menstrual products. (total absorbency, rewet, rewet under pressure, odor neutralization, other...).

On a perceptual level:

- Women feel drier and more confident.
- The risk of accidents is lower.
- Products provide discreet and worry-free protection, whenever you need it.

Source of Funding: Kimberly-Clark's Poise® and Depend® branded businesses

Conflict of Interest: The authors work for Kimberly-Clark, the manufacturer of Poise® and Depend® products. These products are designed to meet the needs of men and women who experience light bladder leakage or incontinence.

URINARY INCONTINENCE: KNOWLEDGE, ATTITUDES, AND HEALTHCARE SEEKING BEHAVIORS AMONG OLDER HISPANIC FEMALES

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Introduction and Hypothesis: This study aimed to investigate the knowledge and attitudes of Argentine women 65 years of age and older regarding urinary incontinence (UI).

Methods: A cross-sectional study of 238 community-dwelling Argentine women 65 years of age and older was conducted in Argentina. Data were collected in Spanish by in-person interviews at an outpatient clinic.

Results: Regarding knowledge, 232 (97.5%) of the women surveyed were familiar with the term urinary incontinence. However, 152 (63.9%) incorrectly thought that UI is a normal part of aging, and 163 (68.5%) did not know about pelvic exercises or a surgical option to treat UI. Nearly half of the women with UI did not report their symptoms to a healthcare provider. The prevalence of UI increased almost two-fold (from 24.4% to 44.5%) when women were asked specifically about their symptoms rather than whether they suffered from UI.

Conclusions: Argentine women 65 years of age and older are poorly informed about UI. Misconceptions and a lack of knowledge lead to the under-treatment of UI symptoms. Providing accurate information to women is imperative to ensure the proper treatment of this disorder. Healthcare practitioners need to be more proactive in (i) educating older Argentine women about the causes and treatment options of UI and encouraging women to report their symptoms to physicians for treatment and (ii) disabusing older Argentine women of their notion that UI is an inevitable part of aging. When screening for UI, healthcare providers should ask directly about symptoms and avoid vague medical terminology. Healthcare providers and community workers can design targeted educational materials aimed to increase UI awareness based on what this study has established as the current level of knowledge in older Argentine women.

Source of Funding: The first author received funding for airfare from the International Committee at the Weill Cornell Medical College.

Conflict of Interest: None

Table 1 Knowledge of and attitudes about UI (N = 238)

Variables	Yes, # (%)	No, # (%)	I don't know # (%)	Association with Education
Familiarity with the topic of UI				
Do you know what UI is?	232 (97.5)	6 (2.5)	N/A	
Do you know a woman that has UI?	129 (54.2)	109 (45.8)	N/A	
Do you talk with your female friends about UI?	124 (52.1)	114 (47.9)	N/A	
CAUSES OF UI				
Do you think women develop UI more frequently than men?*	105 (44.1)	8 (3.4)	125 (52.5)	P<.01
Do you think over-the-counter medications can cause UI?*	50 (21.0)	5 (2.1)	183 (76.9)	
Relationship of aging and UI				
Do you think UI is a normal part of aging?***	152 (63.9)	35 (14.7)	51 (21.4)	P<.01
Doctor-patient communication about UI				
Has your doctor asked you about UI symptoms?	95 (39.9)	143 (60.1)	N/A	
Do you think older women with UI discuss their symptoms with a doctor?***	128 (52.5)	21 (8.8)	92 (38.7)	
Do you think it would be helpful for a woman with UI symptoms to tell her doctor?***	218 (91.6)	2 (0.8)	18 (7.6)	P<.01
Treatment options for UI				
Do you know about pads, diapers, or catheters to treat UI?	209 (87.8)	29 (12.2)	N/A	
Do you know about exercises that can help control UI?	75 (31.5)	163 (68.5)	N/A	P<.05
Do you know about an operation to treat UI?	75 (31.5)	163 (68.5)	N/A	

* "Yes" is the correct answer ** "No" is the correct answer *** "I don't have an opinion" replaced "I don't know" as an answer choice

TACKLING AGEING CONTINENCE THROUGH THEORY TOOLS AND TECHNOLOGY (TACT3)

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The TACT3 collaborative research programme is a three year multidisciplinary project funded by the UK's New Dynamics of Ageing (NDA) programme. The overall aim of TACT3 is to reduce the impact of continence difficulties for older people. We have three research work-packages focussed on different aspects of continence issues: 1) Challenging environmental barriers to continence; 2) Improving continence interventions and services; 3) Assistive technology (AT) development. The main focus of this abstract is the development of the two ATs that were originally inspired by a meeting with Cheryle Gartley at Innovating for Continence 2007.

The devices being developed are:

1. Smart underwear with integral sensors and detachable signalling system that can detect a leak from a continence pad into the underwear and alert the wearer (or carer). The alerting signal warns the wearer, allowing them to deal with the problem before the urine spreads to outer clothes or furniture. The device should save work and the cost of washing and cleaning. More importantly, it should increase the confidence of the wearer who will know immediately if the pad fails and not have to deal with the embarrassment of a wet patch on clothes or furniture.
2. A colour change odour detector that is able to detect sub-olfactory levels of ammonia. Worry about odour is a major concern for continence pad users and the level of concern is high, regardless of the severity of the continence problem. Therefore an objective measure of odour should be invaluable for increasing confidence and self esteem for pad wearers. The colour change odour detector we are working on reassures pad users by alerting them to the odour of stale urine before it can be detected by the human nose.

Conflict of Interest: None

21ST CENTURY CATHETER PROJECT ON THE WEB – www.21ccp.org

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“The indwelling urinary catheter is an anachronism, long past its sell-by date.”

The 21st Century Catheter Project (21ccp) was founded to revolutionise catheter design but this will only succeed if catheter users and carers rally their support.

With up to 25% of patients admitted to hospital, 25% in chronic care and 4% in community care requiring a catheter, catheters comprise a multimillion global market. But catheters account for one of the highest sources of healthcare-associated infections. Despite new biomedical materials and coatings, no convincing evidence has yet emerged of beneficial results. Surely the time has come to focus on the basic design of the indwelling catheter which has not been changed for over 70 years.

The catheter provides a conduit not only for urine to drain but for bacteria to enter and they colonise the bladder at a steady rate of 5% per day. Urinary infections follow causing virtually all the troublesome common complications with which catheter users are only too familiar, such as the blockages, leakages and episodes of fever.

Yet who knows about life with a catheter? How often is the subject ever mentioned?

Few people appreciate how many thousands of disabled and older people rely on an indwelling catheter to collect their urinary output or the recurrent problems they experience.

The healthy bladder resists infection by regularly washing out any bacteria that enter and those that remain are destroyed by specialised cells that line its interior. The Foley catheter impairs both mechanisms by obstructing bladder evacuation so a residual pool of infected urine remains and by damaging the cells protecting its walls from invasion.

A new system is needed, one that mimics and preserves normal bladder function. Your help is vital to create a strong active community of supporters and to raise the profile of catheter care. This new website opens an unprecedented opportunity for catheter users and carers to present their experiences, promote the need for research and seek the resources to transform this neglected field. Catheter-associated urinary infections present a worldwide threat and a review of catheter design is long overdue.

Your support and experiences are pivotal if our objective is to be achieved.

EVALUATION OF LONG-TERM PERFORMANCE UTILIZING A HIGH ABSORBENCY ADULT INCONTINENCE BRIEF IN A LONG-TERM CARE SETTING AND ITS IMPACT ON OVERALL SKIN HEALTH

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Objective: Determine whether the skin under a highly absorbent incontinent brief (HAB) remains as dry after 8 hours of urine incontinence as that of a participant's skin being changed every two hours with the Industry-Average Moderate/ Absorbency Brief (MAB)**.

Methods: 20 elderly participants residing in a long-term care facility participated in the trial. They underwent Trans Epidermal Water Loss (TEWL) readings with their usual Industry-Average Moderate/ Absorbency Brief (MAB). Measurements were taken using a Vapometer***. Subjects were acclimated to a High Absorbency Adult Incontinence Brief (HAB)****. Participants underwent repeated TEWL measurements for 11 days. Ten of the participants were monitored up to 8 consecutive hours in a single HAB. TEWL readings were measured and recorded approximately every 2 hours.

Results: A normal TEWL reading for an average healthy adult is 10 gm/m² +/- 5. Initial TEWL readings of all 20 participants revealed 13 residents with readings > 200 gm/m² (MAB), including one participant with a reading of 675 gm/m². These initial readings indicated an extremely high moisture level against the skin. Mean baseline TEWL readings prior to the MAB were 265.82 gm/m². HAB mean baseline TEWL readings decreased to < 100 gm/m² within 24 hours after changing to the HAB with mean readings of 42.74 gm/m² making this statistically significant using a student's T-test (P<0.05). Residents participating in the "8 hour" study achieved an average 622% reduction in the TEWL moisture level readings upon conversion to the HAB.

Conclusion: Longer wear times of the study's High Absorbency Adult Incontinence Brief resulted in dryer skin and lower TEWL readings than institutions standard product (MAB) being changed every 2 hours. This study suggests that the 5 layer proprietary design and construction of the High Absorbency Adult Incontinence Brief (HAB) does have an impact on TEWL readings.

*The Effect on Different Incontinence Briefs on Skin Barrier Function in Institutionalized Adults

**Industry-Average Moderate/Absorbency Brief (MAB), Kendall/Covidien (US Headquarters, Mansfield MA)

***Vapometer (Delfin Instruments, Finland)

**** High Absorbency Adult Incontinent Brief (HAB), Tranquility Disposable Absorbent Underwear and All Through The Night Disposable Brief (Principle Business Enterprises, Ohio)

Source of Funding: An unrestricted research grant was given to Karen Kennedy.

Conflict of Interest: Kelly Barba and Steve Salomon are both employees of Principle Business Enterprises, Inc.

THE EFFECT OF DIFFERENT INCONTINENCE “GEL-BASED” BRIEFS ON SKIN BARRIER FUNCTION IN INSTITUTIONALIZED ADULTS

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Introduction: Transepidermal Water Loss (TEWL) is defined as the measurement of the quantity of water that passes from inside the body through the epidermal layer of the skin to the surrounding atmosphere via diffusion and evaporation processes.

Objective: To determine the effects of diaper/brief construction on TEWL rates in elderly institutionalized adults.

Methods: 25 elderly institutionalized subjects underwent repeated TEWL readings using their usual incontinence management product (UIM)* using a Vapometer**. Subjects were then standardized to a superabsorbent gelling incontinence brief*** (SEP). After one week, subjects underwent repeated TEWL measurements. The patients returned to UIM again repeating TEWL readings after one week.

Results: Mean baseline TEWL readings prior to the SEP were 26.6 gm/m² increasing to 103.1 gm/m² at incontinent episodes. SEP mean baseline TEWL readings decreased to 14.9 gm/m² with mean readings of 36.2 gm/m² at incontinent episodes. Returning to the UIM, baseline TEWL measurement readings increased to a mean of 23.6 gm/m² with TEWL rates of 250.4 gm/m² with incontinent episodes. There is statistical significance at $p < 0.05$ using a Student's t test.

Conclusions: This study found statistical differences in TEWL rates in each resident between baseline and a standardized diaper product that uses a super absorbent gelling material.

*Cloth reusable, Tena, Rite-Aid or Depends disposable briefs

**Vapometer (Delfin Instruments, Finland).

***Tranquility SlimLine Disposable Brief (Principle Business Enterprises, Ohio)

Source of Funding: An unrestricted research grant was given to Cathy Milne.

Conflict of Interest: Kelly Barba and Steve Salomon are both employees of Principle Business Enterprises, Inc.

DEVELOPMENT OF AN 'EARLY WARNING' SENSOR FOR DETECTION OF PROTEUS INFECTION IN URINARY CATHETERS

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Objectives: Urinary catheter blockage is a common and potentially serious problem for long-term catheterised patients, which increases both patient morbidity and health care costs.

Urinary catheter blockage stems from infection with urease-producing bacteria, particularly *Proteus mirabilis*. Urease produces ammonia from urea, which then causes an increase in urine pH. Under the alkaline conditions, crystals of calcium and magnesium phosphate form and it is these that block the flow of urine from the bladder.

The aim of this project was to develop a sensor that allowed early prediction of catheter blockage following infection with *P. mirabilis*.

Methods: Silicone sensors were produced using mixtures of vinyl terminated polydimethylsiloxane polymers, hydrophilic fillers, cross-linkers, matrix stabilisers and an appropriate pH indicator. Developed sensors were integrated into an established *in vitro* catheter infection model and assessed following infection of artificial urine with bacterial species.

Results: A variety of different sensors were successfully developed that when incorporated into the infection model were able to predict catheter blockage approximately 16 h in advance of occurrence. Triggering of the sensor was not evident in cases where catheter blockage did not occur. Further studies will involve the production of injection moulded sensors and their evaluation in catheterised patients attending treatment at the Bristol Urological Institute.

Conclusions: Sensors were constructed that had the ability to predict impending urinary catheter blockage in *in vitro* infection models. Successful translation of these sensors to a clinical environment will allow the timely and appropriate management of catheter blockage in long-term catheterised patients.

Conflict of Interest: Mark Waters and Leo Basil are directors of Principality Medical Ltd. David Stickler has received research support from Principality Medical and Coloplast A/S. None of the other authors have any conflicts of interest.

KEEPING IT BRIEF, IMPROVING CONTINENCE CARE AND UTI REDUCTION IN LONG-TERM CARE

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Introduction: The Jewish Nursing Home is a 200-bed long-term care facility in Longmeadow, MA.

Background: Urinary Incontinence (UI) and Urinary Tract Infections (UTI) are a prevalent and costly healthcare problem in Long-Term Care. Residents with UI should have a basic assessment. UI and UTI's can often be managed and modified, even in frail elders in LTC.

Research indicates greater than 50% of Long-Term Care Residents are incontinent of urine. Risk factors include skin breakdown, falls and fractures and urinary tract infections.

Method: Per Federal Tag 315 incontinent residents are to be identified, assessed and provided individual treatment plans of care. Using Quality Indicator Reports residents were identified as candidates for the Continence Program. The Continence Specialist evaluates and assesses residents and provides individualized treatments.

Three day bladder diaries were obtained prior to the first exam. Post void residual via Bladderscan helped differentiate residents who had retention issues. Careful review of medical history and interviews with staff, residents and family members assisted in understanding residents' bladder issues. Cystometrogram was performed to establish baseline bladder capacity. Urogyn exam was essential to determine which residents had prolapse or atrophy and assisted in determining course of treatment. Ongoing educational in services provided to licensed and skilled staff on prevention and care helped the staff better understand their patients Urogyn system.

Treatment: Pt treatment was individualized. Over active bladder antimuscarinics were used to decrease urgency and frequency and increase baseline bladder capacity. Topical vaginal estrogen helped shift vaginal pH to a more acidic position which decreased UTI's. Vaginal tissue was rejuvenated which created more pt comfort by improving vaginal atrophy. Pessaries were placed to improve prolapse which assisted in more complete bladder emptying. Pelvic muscle exercises were taught via Biofeedback. This strengthened the pelvic floor which decreased UI. Toileting programs were individualized based on cognition and mobility.

Outcomes: Baseline bladder capacity increased by better than 30%, resulting in a more dignified quality of life. Less frequency and urgency as reported by staff reduced falls and fractures which decreased hospitalizations. UTI's were noticeably decreased and reduction in urosepsis allowed patients to remain in the facility. The reduction in UTI's decreased the overuse of antibiotics. This outcome decreases C-diff and antibiotic resistance (MRSA).

Source of Funding: None

Conflict of Interest: None

BLADDER QUIETING RESPONSES TO ELECTRICAL NEUROMODULATION OF PERIPHERAL NERVES

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Introduction: Stimulation of the sacral spinal nerve (SN) and the dorsal genital nerve (DGN) has been shown to promote continence in patients with overactive bladder. We have compared electrical stimulation of nerve targets equivalent to the human sacral SN and the DGN on the bladder micturition reflex using the bladder rhythmic contraction (BRC) model in the rat.

Methods: A wire electrode was placed under the L6 SN or the DGN bilaterally in anesthetized rats (urethane, i.p. 1.2g/kg). A pressure recording cannula was placed into the bladder via the urethra and the urethra was closed to ensure an isovolumetric bladder. Saline infusion induced bladder contractions. Electrical stimulation of the nerve targets evoked muscle contractions of the hind-toes and pelvic floor (SN) and external anal sphincter (DGN) respectively. Stimulation currents were adjusted for each animal as a function of motor threshold.

Results: Stimulation of the SN or the DGN significantly quieted the bladder by reducing the frequency of BRC in a current parameter-dependent manner. Ten Hz stimulation produced the greatest quieting and low and high frequency stimulation produced less or no attenuation of the BRC. At the threshold intensity, stimulation of the SN (0.18 ± 0.01 mA) produced a delayed and post-stimulation inhibition to $34 \pm 11\%$ (mean, SEM) of control ($n=10$, v.s. control, $n=13$, $p < 0.05$, two-way ANOVA) and stimulation of the DGN (1.04 ± 0.06 mA) generated immediate attenuation of the BRC during stimulation to $56 \pm 16\%$ of controls ($n=8$ v.s. control, $n=9$, $p < 0.05$). There was no significant difference in maximal bladder inhibition achieved from stimulating the DGN or the SN.

Conclusions: Compared with responses to SN stimulation, the absolute currents required to reduce the BRC using DGN stimulation appear to be higher. The results provide useful information of neuromodulation of peripheral nerves at different stimulation sites as potential therapy options for overactive bladder.

Source of Funding: The study was supported by Medtronic.

Conflict of Interest: Authors are employed by Medtronic and do not have a potential conflict of interest.

NOVEL METHOD AND MEASUREMENT OF THE VALSALVA LEAK POINT PRESSURE USING LUNG-GENERATED PRESSURES

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Introduction: Using the principles of Pascal's law, we identified and measured the relationship between lung and rectal pressures under Valsalva conditions. The premise is based on forces exerted to both cavities by the diaphragm and intercostal muscles, changing the pressures in both cavities in a proportional manner. It is also these pressures that act on the detrusor and urethra to cause leakage for the genuine stress incontinent patient.

Methods: Twelve subjects undergoing urodynamic studies were concurrently assessed with the 'Plung' device. Patients were instructed to lock their lips and mouth around the mouthpiece and performed a minimum of three Valsalva manoeuvres at various points during filling cystometry. Pabd was used as the reference channel for correlation calculations. Plung data points below 40cmH2O were excluded from analysis to remove the bias that differing baseline values introduces, as well observing a Valsalva leak point pressure (VLPP) below this point is not expected. (See Figure 1)

Results: The average coefficient of determination found between Pabd and Plung in this population was 0.75 (0.013 to 0.99) with a median of 0.88. During studies when poor correlation was observed, we believed these issues to be related to technique. These potentially included removing the mouthpiece before completing manoeuvre, not completely sealing with the mouth, inhaling in close proximity to the mouthpiece prior to placing in the mouth, among others. A considerable amount of patient coaching was necessary for proper technique. Other methodological issues influencing results included positioning of patient at the time of performing Plung, presence rectal contractions as well as catheter transmission quality.

Conclusion: This novel method of measuring the VLPP has revealed potentially significant diagnostic utility. Advantages include its non-invasive nature, eliminating the bias that catheters may present, as well as the rapid obtention of results to recommend further diagnostic testing or treatment options. The intricacies of this technique will be revealed as more experience is gained in future research.

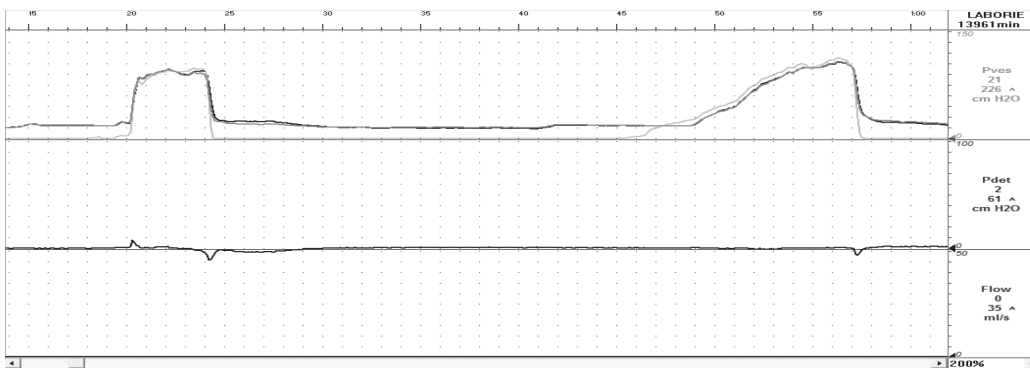


Figure 1. Male patient (66 years) performing Valsalva manoeuvres during urodynamic studies prior to beginning instillation. [Pabd (black), Pves (medium grey), Plung (light grey)]

References: Lewis P, Abrams P. Urodynamic protocol and central review of data for clinical trials in lower urinary tract dysfunction. BJU International 2000; 85 (Suppl. 1): 20-30.

Source of Funding: Laborie Medical Technologies, Inc.

Conflict of Interest: Ing Goping and Adele Campbell are employees of Laborie Medical Technologies, Inc.

CORRELATES WITH OVERALL CONTENTMENT IN SURVEY RESPONDERS

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Introduction: Urinary incontinence is a common problem that has a profound impact on quality of life (QOL). By understanding the QOL challenges of those seeking help for urinary incontinence service providers can determine the necessary direction required to assist in the development of services that improve QOL. This study assesses this overall contentment with life.

Methodology: A solicitation for participation in a comprehensive health and life assessment was posted on a website for those seeking assistance with urinary incontinence. It is recognized that those with urinary incontinence can be a difficult-to-reach population; therefore random sampling is not feasible. The assessment tool is a self-reported web based survey. It has been assessed for reliability (Cronbach's alpha = 0.89) and validity. A sample size of 397 was obtained (margin of error equals 5%).

Results and Discussion: Contentment, defined as comfort and a feeling of personal satisfaction, is central to the concept of quality of life. Sixty-three percent of respondents report being content with themselves. The data indicates that contentment strongly correlates with leading an active lifestyle and the ability to adapt to one's situation. Spouse/life partner communication and satisfaction with life issues of social, sexual, family life, leisure activities, and financial status are strongly correlated with overall contentment. Significant correlates with a lack of contentment include a higher body mass index, hygiene, fatigue or sleep issues, the need to change work habits, not being able to fully take care of one's self, and the need to manage fluid intake.

Conclusion: Interruptions of basic, daily activities due to incontinence issues are strongly related to how content these individuals feel. Whereas contentment shows correlations with a positive life view, discontentment follows from daily disturbances. Health professionals and service organizations addressing these aspects may be able to assist those with incontinence to increase the quality of their lives.

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Satisfaction Levels of Those Seeking Assistance with Incontinence Management

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Introduction: Urinary and fecal incontinence have profound impact on satisfaction with life and its relationship with quality of life (QOL). Health care professionals and organizations providing assistance to those experiencing incontinence need to understand their life issues. This study investigates satisfaction with sexual, social, family, and vocational life, as well as spouse/life partner relationships, leisure, and financial aspects.

Methodology: A solicitation for participation in a comprehensive health and life assessment was posted on a website for those seeking assistance with urinary and fecal incontinence. The assessment tool is a self-reported web based survey. It has been assessed for reliability (Cronbach's alpha = 0.89) and validity. A sample size of 397 was obtained (margin of error equals 5%).

A stepwise regression was chosen to identify life aspects contributing most to overall contentment.

Results/Discussion: The data indicates that satisfaction with leisure time has a major impact on the lives of those with incontinence in 38 percent of the sample. This is followed by satisfaction with spouse/partner (8%) and financial situation (6%). However, when stratified by gender differences are noted, with leisure time explaining 44% of the variance in males, followed by satisfaction with sexual life (6%), while in females, satisfaction with family life takes precedence (47%), followed by leisure time (10%) and financial situation (5%).

Conclusions: Satisfaction scores may provide insight into priorities of those with incontinence. Whereas leisure time and financial situation are important to men and women, family life is especially meaningful to this female population. The results also suggest that one's financial situation may be more important as one ages. In order to best service this population, it is important for health care professionals and organizations to ask about the significance of these aspects to one's quality of life.

Acknowledgements: The authors wish to express their gratitude to the Simon Foundation for Continence for their support of this project.

Source of Funding: The support of Hollister Incorporated for this presentation is gratefully acknowledged.

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CHANGING OUR METHODS OF ADULT INCONTINENCE MANAGEMENT TO DECREASE SKIN BREAKDOWN AND IMPROVE PATIENT SATISFACTION

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Purpose: Improve the management of adult urine and fecal incontinence to decrease skin breakdown and improve patient satisfaction.

Background: In our acute care community hospital, adult urine and fecal incontinence was managed with diapers and a thin chux pad under the patient. We were seeing a significant number of Stage 1 and 2 pressure ulcers, along with incontinence associated dermatitis. On doing a literature review, we found that our protocols and some products did not follow current evidence based practice.

Objectives:

1. Decrease our number of inpatient Stage 1 and 2 pressure ulcers
2. Update our management of adult incontinence to reflect current evidence based guidelines and practice

Methods: Based on a literature review, we identified products and methods to make our practice in line with current recommendations. We selected several products and performed trials and evaluations. Nurses perceptions and feedback were collected, both verbally and written. We also obtained verbal feedback from patients about their comfort and satisfaction with the plan of care. Based on the information collected, products were chosen, protocols updated, the staff was educated, and a revised plan of care was implemented.

Outcomes: In a data comparison for a selected period prior to implementation in 2008 and after implementation in 2009, the number of consults for incontinence was similar: 59 in 2008, 62 in 2009. However there was a significant decrease in Stage 1 pressure ulcers: 49 in 2008, 37 in 2009; and Stage 2 pressure ulcers: 205 in 2008, 130 in 2009.

Conclusion: The revised plan of care decreased the incidence of Stage 1 and 2 pressure ulcers and was positively received by staff and patients.

Source of Funding: Support from Attends Healthcare is acknowledged.

Conflict of Interest: None

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A COMPARATIVE EFFECTIVENESS STUDY OF OVERACTIVE BLADDER (OAB) TREATMENT USING A PELVIC FLOOR FITNESS PROGRAM FOR SENIOR WOMEN

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Introduction: This study compared the efficacy of a chair-based pelvic fitness/educational program to an educational program only for senior women with OAB in residential living facilities. The chair-based pelvic fitness/educational program was adapted from an evidence-based all-ages program previously demonstrated to improve OAB symptoms.

Methods: Following IRB approval, independent-living women (>65 years) with OAB were assigned (4 treatment: 1 control) to twice weekly chair-based program (9 -15 women each) for 6 weeks vs an education only. Standardized pre/post assessments included Visual Analog Scale (VAS) measuring symptom level, Urinary Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), and Timed Up & Go Test (TUG).

Results: Fifty-seven of 65 enrolled women completed the study: 43 fitness:14 control. The mean age was 83 years (67-95), most (96%) were Caucasian and 84% had a prior pregnancy (median vaginal parity 3). We did not detect significant demographic differences between groups. Baseline OAB symptoms were similar in the chair-based program vs. control: moderately/greatly bothered by leakage related to urgency (49% vs. 38%), frequency (67% vs. 46%) and urge incontinence (27% vs. 25%). Baseline IIQ and UDI-6 scores were similar (6.5 vs. 4.5; 1.0 vs. 1.0, respectively). Post-study, 91% were satisfied, 83% reported urinary symptom improvement and 2/3 achieved pre-study goals. More women in the chair-based program reported symptom improvement as measured by IIQ-7 ($p < .0001$) and UDI-6 scores ($p = .0036$). 82% planned to continue the program on their own. Statistically significant changes were also seen in TUG score in treatment compared to control ($p = .0129$). Several study participants also reported less night urgency, better bladder management, increased confidence, better posture and awareness of bladder-related health and nutrition. There were no adverse events.

Conclusions: The efficacy of this chair-based pelvic fitness program is a promising approach to reduce OAB symptoms and improve activity levels, function and overall quality of life for women over 65 with OAB.

Table 1: Pre versus Post Fitness Class Urinary Distress Inventory (UDI-6)*

Symptom (UDI-6)	Before Class	End of Class	P
TOTAL SCORE	6.50 (1.00, 12.00)	4.00 (1.00, 10.00)	<.0001
Frequent urination	2.00 (0.00, 3.00)	1.00 (0.00, 3.00)	<.0001
Urine leakage related to feeling of urgency	1.00 (0.00, 3.00)	1.00 (0.00, 2.00)	<.0001
Urine leakage related to physical activity, coughing, or sneezing	1.00 (0.00, 3.00)	1.00 (0.00, 3.00)	<.0001
Difficulty emptying bladder	0.00 (0.00, 3.00)	0.00 (0.00, 3.00)	0.3662
Pre versus Post Fitness Class Incontinence Impact Questionnaire (IIQ-7)			
Symptom	Before Class %	After Class %	P
TOTAL SCORE*	1.00 (0.00, 15.00)	0.00 (0.00, 12.00)	0.0036
Household chores	21.95	7.32	
Physical recreation	20.95	16.67	0.1088
Entertainment activities	27.50	12.50	0.1088
Ability to travel	29.27	12.20	0.0522
Participation in social activities outside of home	29.27	14.63	0.0578
Feeling frustrated	50.00	28.27	0.0027

* analysis of ordinal variables

Source of Funding: Investigator Initiated Research Grant from Pfizer, Inc.

Conflict of Interest: None

NVC-422 PREVENTS URINARY CATHETER BLOCKAGE AND ENCRUSTATION

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Introduction: Untreated *Proteus mirabilis* infections can lead to pyelonephritis and septicemia. *P. mirabilis* forms a crystalline biofilm composed of struvite and hydroxyapatite that affects many patients with long-term indwelling urinary Foley catheters. These crystalline biofilms, if not treated, can result in the blockage of urine flow leading to urine leakage or painful distention of the patient's bladder. NovaBay is developing NVC-422 (*N,N*-dichloro-2,2-dimethylaurine), a fast-acting, broad-spectrum antimicrobial instillation solution, with an excellent safety profile for the treatment of urinary catheter blockage and encrustation (UCBE).

Methods: Experiments were performed in our laboratory models of a catheterized bladder fed artificial urine at 0.5 mL per minute. The artificial bladder chamber was inoculated daily with *P. mirabilis*. NVC-422 or control solutions were instilled through the catheter every other day. These experiments were conducted for 14 days or until the catheters blocked. The pH of the effluent, CFU counts and the time to catheter blockage were recorded. Blocked catheters were examined using Stereo Zoom and/or scanning electron microscopy.

Results: In control samples the urinary pH increased from 6 to 9, high CFU counts were observed, resulting in blockage by 58 hours; a crystalline biofilm was clearly evident in the catheter eyeholes and lumen. Catheters treated with 0.2% NVC-422 formulated in acetate saline at pH 4 drained freely throughout the 14 day study, maintained a neutral pH, had lower CFU counts and showed only traces of crystalline material.

Conclusions: NVC-422 instillations were effective in preventing crystalline biofilm formation caused by *P. mirabilis* in catheters in our *in vitro* UCBE model. The design of our clinical protocol is based on these results.

Source of Funding: NovaBay Pharmaceuticals, Inc.

Conflict of Interest: All authors are employees of NovaBay Pharmaceuticals, Inc.

SURPRISING THINGS PATIENTS DON'T KNOW

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Introduction: Published medical research on patient knowledge about incontinence is limited, but does expose a poor understanding of biology. Research is even more limited on knowledge of American products. Diana Hankey Underwood, MS, Board Certified Women's Health Nurse Practitioner, is Executive Director of Grace Anatomy, Inc. and a member of the Alabama State Obesity Initiative Steering Committee. In 2006, Ms. Underwood attended two anorectal and urological birth defect conferences, observed excellent education of minors and combined that information with Simon Foundation for Continence materials, plus literature reviews, to organize adult incontinence classes approved for reimbursement by insurance. Classes covered emotional impacts, products and devices to improve quality of life, biology and infection control. Since 2006, Ms. Underwood has also conducted continuing education classes for home aids, nurses, nurse practitioners, physical therapists, social workers, and case managers. Audience members have come primarily from New York, Alabama and Tennessee and classes have ranged in size from 10 -140 men and women. In classes and at health fairs, Ms. Underwood has received hundreds of questions and comments. No attempt to systematically study the comments and insights of the class participants has yet been undertaken. However, comments about problems and potential solutions have surfaced repeatedly and exploring these will be the focus of this poster presentation.

Objectives: Areas of research paucity will be highlighted, (including needs of obese patients), along with areas of product ignorance. Requests for help and illustrative patients' stories will be shared.

Implications for Practice: Unprompted, confidential patient questions and comments following education meetings and during health fairs, provide informal and antidotal data, which can stimulate ideas for formal research, cue advertising directions and may begin to inform product manufacturers about improving product instructions, thereby offering relief to those who suffer from incontinence and the shame and embarrassment that accompanies it.

Conflict of Interest: None

CONTROL OF MICTURITION BY ELECTRICAL STIMULATION OF THE PUDENDAL NERVE

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Introduction: Based on the physiology of the urogenital system and a set of preliminary experiments conducted in canine and swine models, we propose that controlled bladder voiding, or micturition, can be achieved in a novel way by: 1) selective stimulation of pudendal nerve afferent fibers that mediate detrusor contraction, and 2) selective blocking of pudendal nerve efferent activity that mediates urethral sphincter contraction. This treatment would negate the need for catheterization, major reconstructive surgery, or other neuromodulation techniques that require a dorsal rhizotomy. Moreover, selective low frequency stimulation of urethral sphincter efferent nerve fibers in the pudendal nerve may provide a novel therapy for some forms of urinary incontinence.

Results: We have achieved such selective afferent stimulation and efferent blocking with extrinsic currents passed through individual electrodes of Utah Slanted Electrode Arrays (USEAs) that have been implanted intrafascicularly in the pudendal nerve of anesthetized canines. The USEA contains one hundred 0.5 to 1.5 mm long microelectrodes that project out from a 4mm x 4mm silicon substrate. The active tips of subsets of USEA electrodes abut efferent nerve fibers that innervate the external urethral sphincter or afferent fibers that cause reflexive contraction of the detrusor bladder muscle. We have passed low frequency (33 Hz), constant voltage square wave stimuli through individual USEA electrodes in order to characterize to what extent such stimulation can control detrusor contractions. We have also used high frequency (2 kHz), constant voltage sine wave stimuli injected via different USEA electrodes in order to characterize to what extent such stimulation can block efferent excitation of the external urethral sphincter, thereby relaxing it. Finally, we delivered simultaneous low and high frequency stimulation through selected pairs of USEA electrodes and achieved limited, but controlled micturition. We are transitioning work to a feline model as other studies have shown this animal model to be a more stable preparation for studying the control of micturition using electrical stimulation. If these preliminary results can be extended to chronically implanted animals and then human trials, this technology would improve health and quality of life for the large segment of our population with bladder dysfunction.

Source of Funding: University of Utah MD-PhD Training Program & University of Utah President Research Grant

DESIGN ISSUES AND OBSTACLES FOR EVERYDAY USE OF INTERMITTENT URINARY CATHETERS

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Introduction: Persons using intermittent catheterization (IC) as a permanent bladder management method must be able to manage the technique 4-5 times a day consistently. This study was to identify IC users' self-management issues and concerns.

Methods: This qualitative descriptive study involved in-depth tape-recorded telephone interviews with people using permanent IC, mostly those with spinal cord injury or multiple sclerosis. Recruitment was through several Internet sites where persons could link to the study website and then contact the researchers. The sample included 34 participants, 13 males and 21 females, aged 21-72 (mean 42). Content analysis for qualitative data involved iterative comparisons of summaries, transcripts, and memos.

Results: Intermittent catheterization was a part of living with a disability or disease. Perceptions varied from very positive related to freedom from being wet to rather negative due to problems. Some study participants did not have the equipment they needed to manage day to day activities with ease, and they devised homemade catheterization kits, extensions to reach the toilet, or equipment to stabilize when catheterizing by fastening to the toilet. Small bathrooms with doors that do not close behind a person in a wheelchair violated their privacy. Pre-lubricated catheters were liked by some, but others could not manage anything slippery. Many persons had not tried a variety of products and did not know how to trial new ones. Insurance coverage was a mystery to some who had used whatever their health care provider suggested years ago. Yet other persons who had tried different products seemed to be more satisfied with their choices. Some persons complained that these types of problems interfered greatly with travel, holding a job, and recreation with friends or family.

Conclusions: Quality of life could be enhanced by catheter companies partnering with people who use these products, particularly severely disabled persons.

Source of Funding: Project was funded by Hollister Incorporated, a totally unrestricted grant (potential conflict of interest) and by the Center for Evidence Based Practice and Research, University of Rochester, School of Nursing.

CONSUMER PERSPECTIVE ON UI SOLUTIONS & DESIRED QUALITY OF LIFE. ABSORBENT PRODUCTS AND MEDICAL SOLUTIONS

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Problem Definition: People with urinary incontinence (UI) have diverse set of requirements for desired outcome in the management of their UI needs. The segmentation varies from being in denial, using absorbent products, using therapies, to using surgery. Consumers have difficulty reaching out and/or accessing competent sources of information.

Design Description: This poster will include sources from external literature and selected highlights of consumer research related to the algorithm for evaluation and treatment of UI and solutions consumers are willing and not willing to try.

Results and Design Validation: Many people, particularly those with light urine loss, are reluctant to consult with doctors. Absorbent products specially designed for urine management play an important role for these individuals. Highlights of published technical reviews on treatment success rates will be shared for different types of UI, as well as quality of life (QOL)/satisfaction.

Urine management solutions:	% People Willing to Try	% People NOT willing to try	Quality of Life Assessment/Satisfaction
Lifestyle Changes			
Non-invasive products, e.g. pessaries			
Behavioral therapies			
Physical therapies			
Drugs			
Surgical			

Conclusions: The consumer is the one that makes the ultimate decision on what solution to use for her/his desired quality of life. Medical professionals are incorporating the patient's desired QOL outcome into the recommended treatment. Absorbent products, representing a diverse portfolio of UI options, play an important role in the mix of solutions since so many people are not talking to doctors.

Source of Funding: Kimberly-Clark's Poise® and Depend® branded businesses

Conflict of Interest: The authors work for Kimberly-Clark, the manufacturer of Poise® and Depend® products. These products are designed to meet the needs of men and women who experience light bladder leakage or incontinence

A MULTICENTER, DOUBLE-BLIND, RANDOMIZED TRIAL COMPARING PERCUTANEOUS TIBIAL NERVE STIMULATION TO A SHAM INTERVENTION FOR OVERACTIVE BLADDER SYNDROME

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Introduction: Overactive bladder syndrome (OAB) affects the lives of millions of people. Neuromodulation therapy uses electrical stimulation to target specific nerves in the sacral plexus controlling bladder function. Urgent® PC percutaneous tibial nerve stimulation (PTNS) targets the sacral plexus from an accessible, minimally invasive entry point into the nervous system via the posterior tibial nerve. This is the first IRB-approved, sham-controlled trial evaluating the efficacy of PTNS conducted at 23 U.S. urology and urogynecology centers.

Methods: 220 subjects (174 females, 46 males) were randomized 1:1 to PTNS or validated sham interventions over twelve 30-minute weekly sessions. See figure 1 for illustration of interventions. Subjects completed questionnaires and 3-day voiding diaries after 12 treatments. The primary endpoint was to assess the efficacy of PTNS compared to an inactive sham intervention in subjects with overall OAB symptoms in a Global Response Assessment (GRA) intent-to-treat (ITT) analysis.

Results: The subject mean duration of incontinence history was 10.2 and 9.8 years, PTNS and sham, respectively, with corresponding mean subject age of 62.5 and 60.2 years. In an ITT analysis after 12 treatments, the GRA found 54.5% were responders (moderately or markedly improved) in the PTNS group compared to 20.9% in the sham group ($p < 0.001$). All PTNS as-followed GRA and OAB-q quality of life questionnaire outcomes were significant after 12 treatments compared to sham. When stratified by age, < 65 years vs. ≥ 65 years, no significant difference in efficacy was found in either study arm. No significant changes in sexual function indices were reported by either study arm or gender, and no serious treatment-related adverse events were reported.

Conclusion: This pivotal multicenter, double-blind, randomized, sham-controlled trial provides evidence that PTNS is safe and effective in treating women and men of all ages and supports the use of peripheral neuromodulation therapy for OAB.

Figure 1.



Table 1. Comparison of PTNS to Sham at Follow-Up after 12 Interventions

Global Response Assessment Results				
GRA Outcome	Group	After 12 Interventions	p-value	
Overall Bladder Symptoms (Intent to Treat)	PTNS	60/110 (54.5%)	<0.001	
	Sham	23/110 (20.9%)		
Overall Bladder Symptoms	PTNS	60/103 (58.3%)	<0.001	
	Sham	23/105 (21.9%)		
Urgency	PTNS	44/103 (42.7%)	0.003	
	Sham	24/103 (22.9%)		
Frequency	PTNS	49/103 (47.6%)	<0.001	
	Sham	23/105 (21.9%)		
Urge Incontinence	PTNS	39/103 (37.9%)	0.02	
	Sham	23/104 (22.1%)		
Voiding Diary Results (Episodes Per Day)				
Voiding Diary Parameter	Group	Baseline	After 12 Interventions	p-value
Frequency (mean intentional voids)	PTNS	12.3 ± 3.2	9.8 ± 2.8	0.01
	Sham	12.4 ± 3.0	11.0 ± 3.1	
Nighttime Voids (mean waking episodes)	PTNS	2.9 ± 1.6	2.1 ± 1.4	0.04
	Sham	2.9 ± 1.7	2.6 ± 1.6	
Moderate to Severe Urgency (median)	PTNS	8.3	3.7	<0.001
	Sham	8.0	5.0	
Urge Incontinence (median)	PTNS	3.0	0.3	0.002
	Sham	1.8	1.0	

Source of Funding: Uroplasty, Inc.

Conflict of Interest: Authors are clinical or regulatory affairs employees of Uroplasty, Inc.

CLINICAL RESULTS OF POLYDIMETHYLSILOXANE INJECTION FOR FEMALE STRESS URINARY INCONTINENCE

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Introduction: Textured polydimethylsiloxane (PDMS) elastomer implants (Macroplastique®) suspended in water-soluble polyvinylpyrrolidone hydrogel are used to bulk the urethral tissue near the bladder neck to treat stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). This review describes an IRB-approved RCT conducted at 12 North American urology and urogynecology centers.

Methods: 122 adult females diagnosed with SUI primarily due to ISD were treated with approximately 5 ml of PDMS endoscopically placed at three circumferential locations around the urethra near the bladder neck. As a control, 125 additional patients were implanted with crosslinked bovine collagen (Contigen®) using the same procedure. Patients not cured at 3 months follow-up were allowed 1 retreatment in both arms. Patients were evaluated at 12 and 24 months (PDMS only) after their last treatment. The primary outcome measure was a decrease in Stamey grade, a physician-assigned score of SUI severity ranging from 0 (dry regardless of activity) to 3 (complete incontinence). Additional outcome measures included patient and physician assessments of improvement, pad weight, and safety assessment.

Results: Mean patient age was 61 years with a mean 11.2 year incontinence history. At 12 months, 75 of 122 PDMS patients (61.5%) had improvement of ≥ 1 Stamey Grade (patients lost to follow-up were considered failures) and 45 patients (36.9%) were cured. Of the 84 PDMS patients attending the 24 month visit, 63 (75%) maintained ≥ 1 Stamey Grade improvement, and 49 were cured. Typical adverse events included implantation site pain, dysuria, and hematuria. No serious treatment-related adverse events were reported.

Table 1 Study Outcomes

Outcome Measure From Baseline	12 Month Results PDMS Arm	12 Month Results Control Arm	24 Month Results PDMS Arm
Stamey Score Improvement	61.5% (75/122)	48.0% (60/125)	75.0% (63/84)
Stamey Score - Cure (0)	36.9% (45/122)	24.8% (31/125)	58.3% (49/84)
Decrease in pad weight from baseline	25.4 grams	22.8 grams	24.8 grams
Patient Assessment: Percentage Dry or Improved	77.4%	68.1%	75.9%
Physician Assessment: Percentage Dry or Improved	80.4%	74.4%	77.3%

Conclusions: PDMS achieved comparable results to the control at 12 months. The observed adverse events were typically anticipated and transient. Substantial improvement of incontinence symptoms was observed after treatment with PDMS at both 1 and 2 years post-treatment, indicating its safety and effectiveness as a urethral bulking agent.

Source of Funding: Uroplasty, Inc.

Conflict of Interest: The authors are regulatory and clinical affairs employees of Uroplasty, Inc.

IMAGING URINARY CATHETERS BLOCKED BY *PROTEUS MIRABILIS* BIOFILMS

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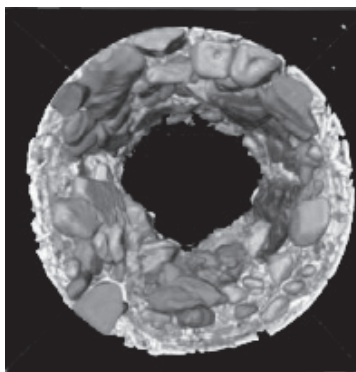
Introduction: Patients undergoing long-term bladder catheterization face significant risks from persistent urinary tract infections (UTIs). *Proteus mirabilis* is a common cause of UTI's, and is a particular concern in catheter-associated infections because it induces precipitation of mineral deposits that block catheters.

Methods: We imaged solid deposits formed by *P. mirabilis* by means of X-ray microtomography performed at the Advanced Photon Source, a synchrotron radiation source located at Argonne National Laboratory. In this method, extremely bright X-rays of a specific wavelength are used to obtain a 3D image of intact catheter sections containing biofilm deposits. We also performed X-ray diffraction (XRD) to evaluate the crystallinity and mineralogy of the solid deposits.

Results: Tomographic imaging reveals the spatial distribution of solid material within the biofilm. A typical image is shown in Figure 1. We persistently found a thin layer of fine deposits near the walls, with much larger, distinct crystals extending towards the center of the catheter. The precipitated material is highly persistent, and accumulates until it restricts fluid flow. XRD results indicate that the large crystals are struvite, as has been previously suggested, but the base layer is not hydroxyapatite, as previously surmised, and is probably amorphous. Different catheter materials, urine flow rate, and urine concentration change the rate of accumulation of solid material and thus the time required for blockage to occur, but do not appear to otherwise alter biofilm formation.

Implications and Conclusions: We demonstrated that synchrotron X-ray microtomography can assess the three-dimensional structure of catheter-blocking deposits in intact sections of urinary catheters. Additional X-ray based analysis can be used to characterize the composition and mineralogy of these deposits. These results improve our understanding of factors leading to catheter blockage during *P. mirabilis* infection, and can be used to improve the design of catheters to improve urine flow and delay or prevent blockage.

Figure 1:
Three-dimensional image of crystalline biofilm in a section of blocked urinary catheter. Colors indicate individual objects identified by image processing. (Scale: 6.4 microns x 6.4 microns – approx. 0.005 microns/pixel).



Source of Funding: This work was supported by grant number R21AI079640 from the National Institute of Allergy and Infectious Disease at the National Institutes of Health.

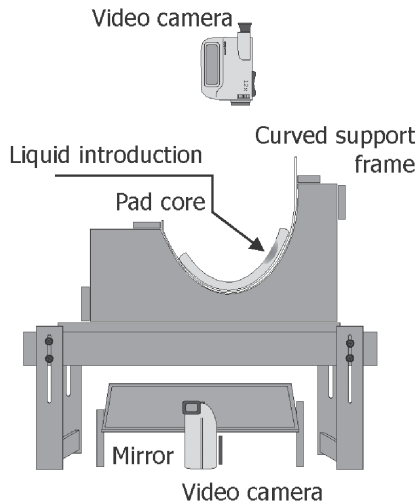
Conflict of Interest: None

THE DEVELOPMENT OF A NEW WASHABLE ABSORBENT PRODUCT FOR LIGHTLY INCONTINENT WOMEN

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Introduction: Existing washable pants with integral pad for lightly incontinent women are popular for their normal appearance (similar to regular underwear) and low per-use cost but their leakage performance is poor compared with disposable products. The aim of this project was to engineer an absorbent structure for the core of a new product which would provide improved leakage performance while retaining the cost advantage and good aesthetics of existing products.

Methods: Series of experimental fabrics were made in which the fibre blend and fabric structure were varied systematically and their fluid handling properties measured in the laboratory. The primary evaluation equipment was a vertical wicking rig (vertical distance and wicked mass logged as a function of time were measured) and a curved rig (below) designed to model the gross geometry of the perineum (the spread of fluid as a function of time and the volume of fluid held at leakage under standard conditions were determined).



Once fabrics with improved fluid handling properties were achieved, they were built into prototype products and evaluated by a cohort of up to 20 lightly incontinent women who were asked to compare the performance of prototype products with existing commercial products.

Results and conclusions: The poster shows preliminary results showing improvements in both vertical wicking properties (laboratory work) and product leakage performance (user evaluations) compared with existing commercial products. Subsequently, two patent applications were filed and two of the companies involved in the project are now working to bring a new product to market.

Source of Funding: UK Department of Health

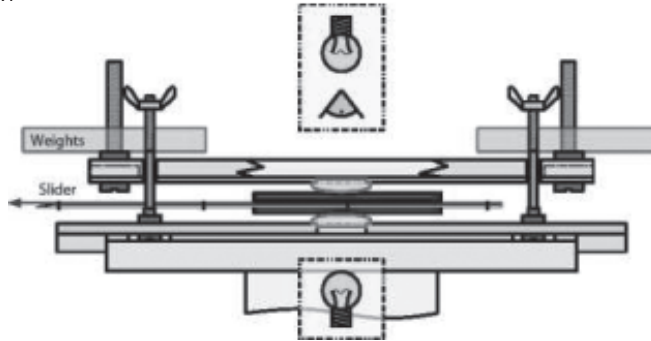
Conflict of Interest: The project involved collaboration with five companies: Lenzing, Wellman International, Cosmotec, Nonwovens Innovation and Research Institute and CUI International.

WHERE DOES FRICTION BETWEEN SKIN AND FABRIC COME FROM?

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Introduction: Disposable incontinence pads have a nonwoven “topsheet” which can cause damage to the skin by abrasive friction, especially if the skin or fabric is wet. However, such friction is not well understood. This project aims to develop understanding of skin / fabric friction, enabling design of improved products.

Methods: The key experiment in this study provides simultaneous friction force and microscopy data using the equipment below:



A tensometer is used to pull a slider – bearing skin (surrogate) – between two (to avoid confounding moments in the equipment) nonwoven-faced anvils (shaped to deliver uniform pressure to the interfaces) while the top skin / nonwoven interface is observed using the microscope. In microscopy a high magnification always leads to a shallow depth of field and this effect is very useful here: it can be used to establish what features constitute the skin / fabric interface. By comparing force / distance data from the tensometer with simultaneous qualitative and quantitative data obtained from microscopy, the principal mechanisms at play across the relevant velocity and pressure ranges are being identified.

Results and conclusions: The poster shows preliminary results. Work completed after the poster was created showed that data for three nonwoven / skin surrogate systems were consistent with an adhesion mechanism of friction. Work is now underway to see if this conclusion holds also for real skin and, if so, to identify strategies for developing nonwovens which are kinder to the skin.

Source of Funding: SCA Hygiene, Sweden and the Engineering and Physical Sciences Research Council

Conflict of Interest: The work was part funded by SCA Hygiene.

GENDER DIFFERENCES IN PREFERENCES FOR, AND PERFORMANCE OF, ABSORBENT PRODUCTS FOR COMMUNITY-DWELLING MEN AND WOMEN WITH MODERATE-HEAVY INCONTINENCE

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Background: Little is known about absorbent product management of community-dwelling people with moderate-heavy incontinence. There are two older (Pads, Diapers) and two newer disposable designs (Pull-ups: like toddler trainer-pants; T-shape diapers) but none are gender-specific. There are also Washable designs. The aim of this clinical trial was to compare these five designs.

Design/methods: Cross-over design. Three/two products represented each design and were tested for one week each (each design block 3/2 weeks, 14 weeks testing). Order was randomized. Product performance was characterized weekly, using a validated self-report questionnaire (five-point scale). Used pads were saved, weighed and severity of leakage rated (three-point scale). Numbers of laundry items, pads used and skin problems were recorded. Finally, participants were interviewed for preferences and overall acceptability ratings.

Results: 85 participants (49 men) completed the study (mean age 53). Results shown are statistically and clinically significant. Men had more severe urinary incontinence than women, mean daytime mass men:375g; women:215g, difference148g (CI:79.8,217.7) and more leakage (e.g. around 20% more with Pads). Pull-ups (most expensive) were better than all designs for women day and night. Although Diapers were better for leakage than Pads (the cheapest), women did not prefer them to Pads, but men did. The Washables were unacceptable to most (56/85) during the day and most women during the night 27/36, but most men (36/49) found them highly acceptable at night. The new T-shape diaper was not better or easier to apply than the Diaper.

Conclusions: Absorbent designs performed differently for men and women. For women Pull-ups were best (but expensive). For men Diapers (day) and Washables (night) were most cost-effective but are undesirable and there is a need for better, male-specific designs.

Source of Funding: National Institute of Health Research (UK) Health Technology Programme

Conflict of Interest: None

PERFORMANCE AND COST-EFFECTIVENESS OF ABSORBENT PRODUCTS FOR WOMEN WITH LIGHT INCONTINENCE – A RANDOMIZED CROSS-OVER TRIAL

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Background: Disposable pads (DPad) are the most common absorbent products used by women with light urinary incontinence, but other designs: menstrual pads (MPad), washable pants with integral pad (WPant), and washable pads (WPad) are cheaper. The aim of this clinical trial was to compare these four designs.

Design/methods: Cross-over design. Three products represented each design and were tested for one week each (each design block 3 weeks, total 12 weeks). Order was randomized. Product performance was characterised weekly, using a validated questionnaire (five-point scale). Used pads were saved, weighed and leakage severity rated (three-point scale). Numbers of laundry items, pads used and skin problems were recorded. Finally, participants were interviewed for preferences and overall acceptability ratings.

Results: 85 women (mean age 60) completed the study. 8691 pads were weighed. There were significant and substantial differences in leakage performance between the designs e.g. 85% of DPads did not leak compared to 46% of WPads OR:7.17 (CI:4.7,10.9) and 63% of WPants OR:3.5 (CI:2.3,5.6). The DPad was significantly better than the other designs on most variables (except for discreetness) and was acceptable in most situations, including going out. But some women preferred MPads (6/85) or WPants (13/85), both of which are >50% cheaper to use than DPads. Many more (60-90%) considered the MPad and WPant designs acceptable for home use. WPads were significantly worse than the other designs (72/85 unacceptable). There were more skin problems with the washable designs compared to the DP (P<0.05) and generally more practical problems with washables.

Conclusions: Disposable pads were the best, but most expensive design. Alternative cheaper designs may be acceptable, particularly in the home. Cost-effective management should involve offering choices and combinations of designs for different circumstances. Better washable designs are needed.

Source of Funding: National Institute of Health Research (UK) Health Technology Programme

Conflict of Interest: None

NOVEL TREATMENT OF FECAL INCONTINENCE USING MICRONEEDLES FOR LOCAL DELIVERY OF PHENYLEPHRINE THROUGH PERIANAL SKIN

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Introduction: Fecal incontinence induced by damage to the sphincter muscle is conventionally treated by surgical repair. There is no efficient drug therapy for treating fecal incontinence. We propose pretreatment using microneedles to increase perianal skin permeability for locally targeted delivery of phenylephrine (PE), a drug that increases resting anal sphincter pressure.

Methods: Microneedles arranged on a framed base were fabricated by micromolding poly-lactic-acid for the delivery of a PE gel into perianal skin. For the quantitative analysis of PE delivery, the amount of PE delivered into human cadaver skin was measured in vitro using high-performance liquid chromatography as a function of the number of holes generated by microneedles and concentration of PE gel.

Results: Five groups of rats (N of each group = 6) received various combinations of treatment with or without use of microneedles and with or without PE. One group was non-treated. Another group was treated with PLA microneedles but without PE gel. Another group D was treated with 30% PE gel only. Another group E was treated with PLA microneedles and 30% PE gel. A placebo (0% PE gel) was also applied to a fifth. The measurement of resting anal sphincter pressure was performed at specific durations after treatments using a water-perfused anorectal manometry system. When a 30% concentration of PE gel was applied on pretreated skin, the amount of PE delivered into the human cadaver skin was 6 times and 10 times larger at pretreatment using 50 microneedles and 100 microneedles, respectively, than when microneedles were not used. For rats pretreated with microneedles, topical application of 30% PE gel increased the mean resting anal sphincter pressure from 9 ± 2 cm H₂O to 44 ± 21 cm H₂O after 2 h.

Conclusions: There was a statistical difference in resting anal sphincter pressure resulting from local delivery of PE into the anus using microneedle pretreatment compared to groups that did not receive microneedle pretreatment.

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