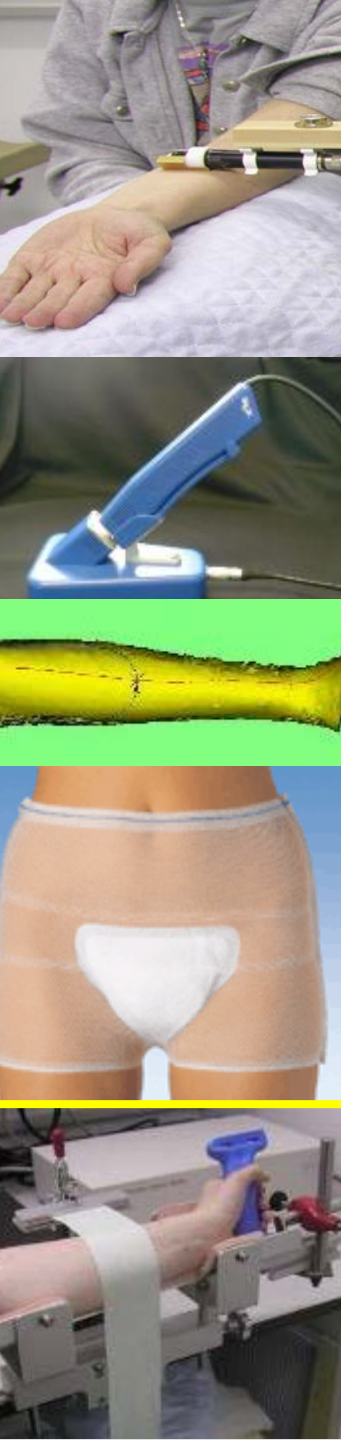


Skin damage associated with incontinence devices

Mandy Fader

Professor of Continence Technology
Faculty of Health Sciences
University of Southampton
UK

Medical Devices and Skin vulnerability sandpit





Background

Continence products are essential in enhancing the quality of life of those with bladder and/or bowel leakage who:

- Are unable to be (fully) cured.
- Are awaiting treatment.
- Are waiting for treatment to take effect.
- Elect not to pursue cure options.



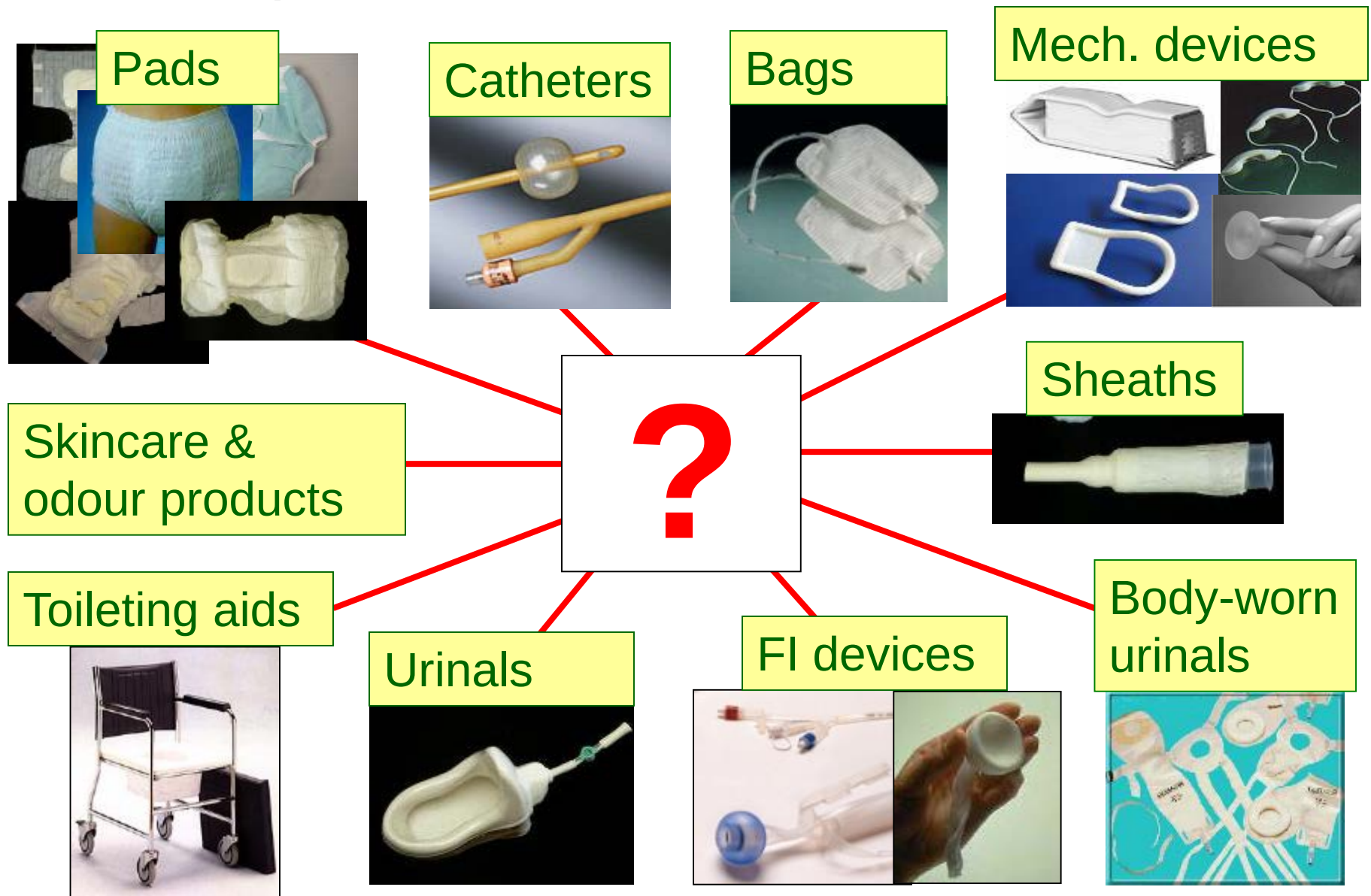
**5th International Consultation on
Incontinence
Paris: February 2012**

Prevalence and costs (UK)

- Around 400,000 NHS pad users
 - £96 million pa (CF 2000)
- Around 40-50,000 ICath users
 - £60 million pa (PCA 2009)
- Around 50,000 LTCath users
 - £20 million pa (PCA 2009)
- Around £20 million pa other products
 - DH Prescription cost analysis (PCA 2009)



Products for managing toileting, urinary retention, UI and FI



Absorbent pads

Disposable insert



Washable products



Disposable pull-ups



Disposable diaper/AIO



Disposable T-shaped diaper



Median urine mass per pad (g)



	Insert	Diaper / AIO	Pull-up	T-shape	Wash-able
Men	284	347	303	355	431
Women	147	203	176	186	311
N (pads)	1943	2196	2066	1426	819

Environment within wet pad:

- Skin over-hydration
- Increased skin permeability
- Higher skin friction coefficient
- Lower skin abrasion resistance
- Greater microbial load
- Increasing pH

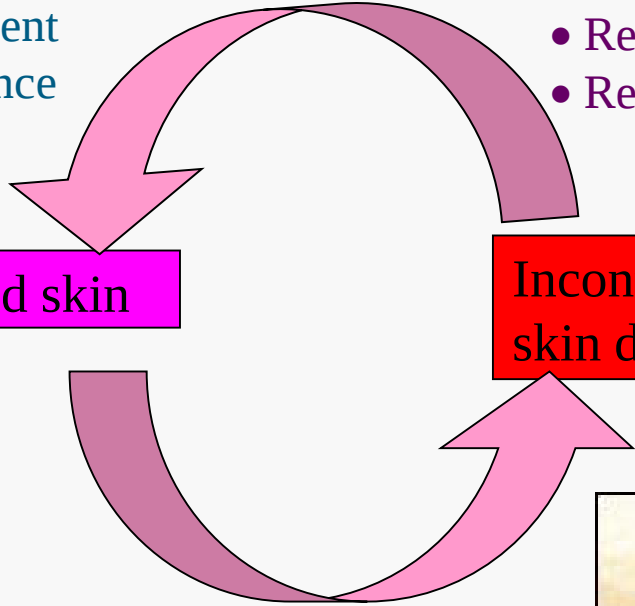
Clinical interventions to:

- Prevent water penetration (e.g. barrier products, pad changing improved pads)
- Minimise faecal contact
- Prevent irritation (low irritant cleansers)
- Reduce friction (shear/pressure)
- Reduce inflammation (topical creams/medication)

Healthy skin

Compromised skin

Incontinence-associated skin damage

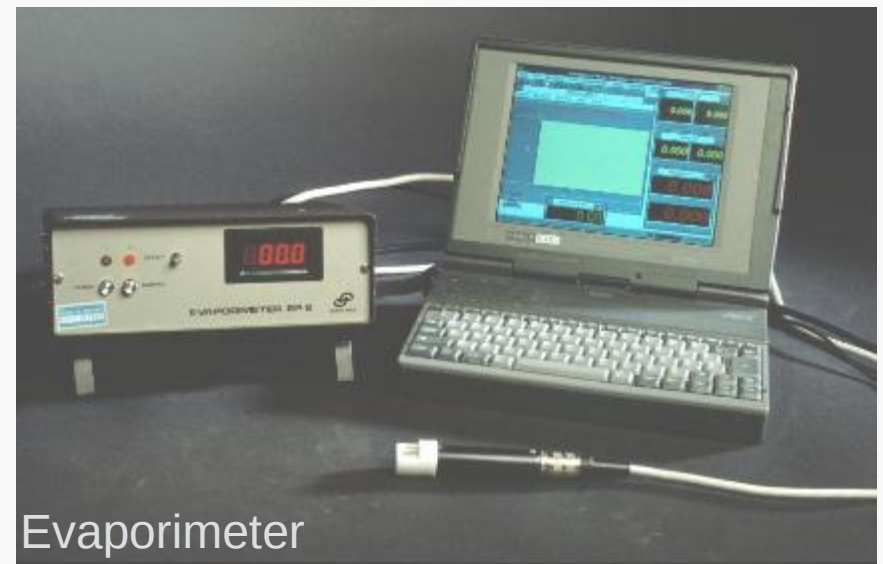


Model of incontinence-associated skin damage (based on Berg 1986)

Aetiological factors:

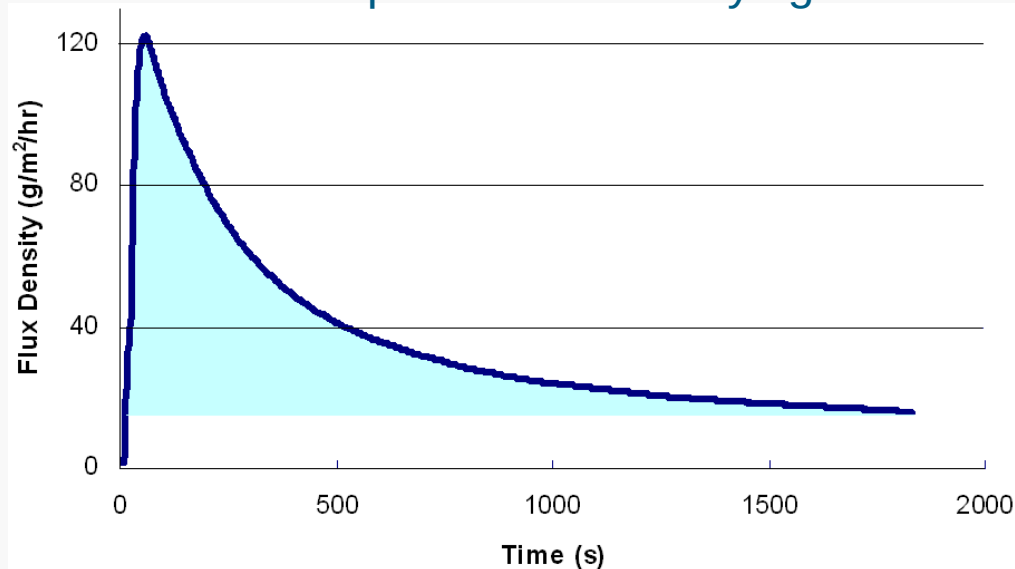
- Faecal enzymes
- Mechanical action (friction, shear, pressure)
- Chemical irritation (topical products)





Evaporimeter

Desorption curve for drying skin



M Fader, S R Clark-O'Neill, W K R Wong, B Runeman, A Farbrot and A M Cottenden. Review of methods used for quantifying excess water in over-hydrated skin using evaporimetry (Skin Research and Technology February 2010 16, (1) 1-8.

Development and preliminary testing of a standardized method for quantifying excess water in over-hydrated skin using evaporimetry. Physiological Measurement 2011, **32** 305-317.

Protecting skin from wet pads



Apply cream



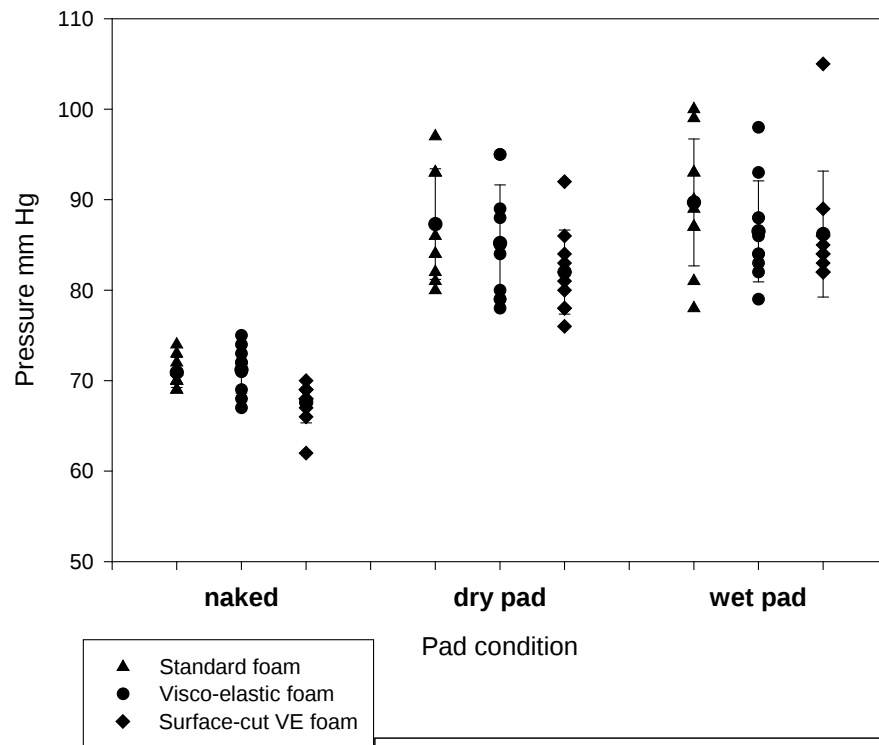
Wear saline-soaked patch for 20 min



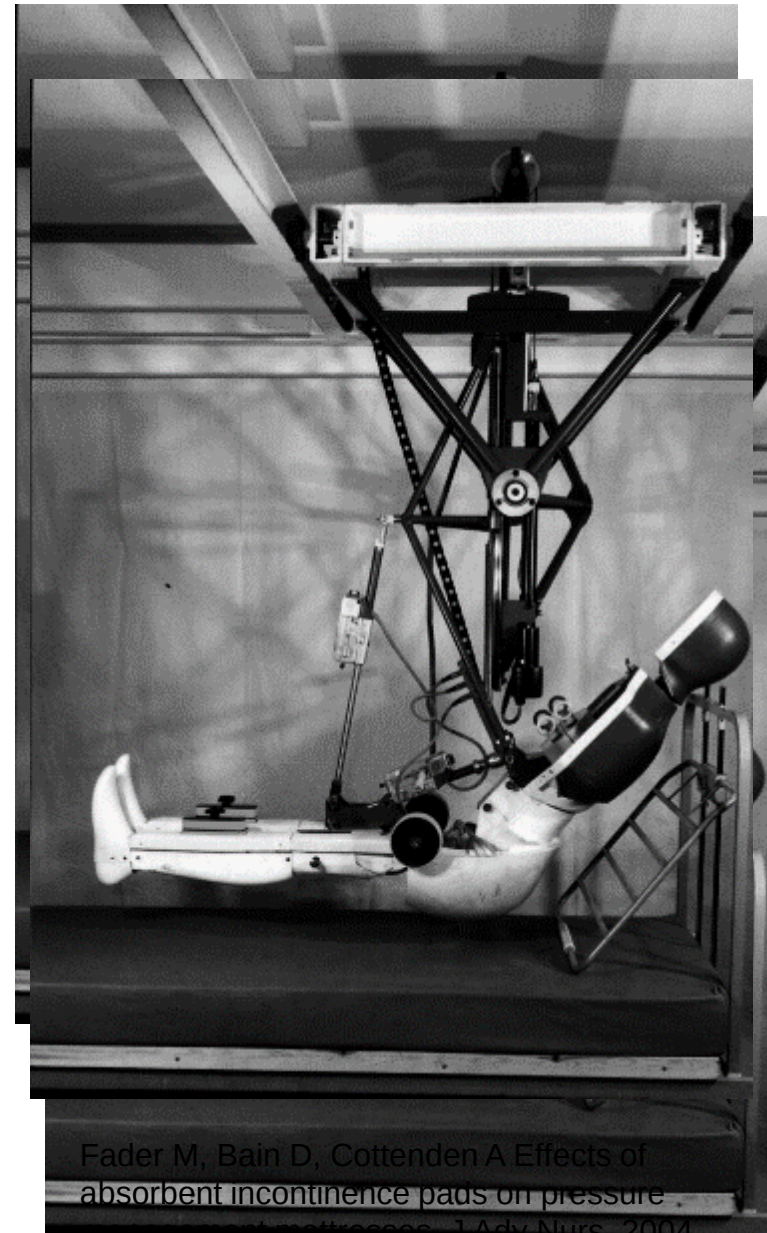
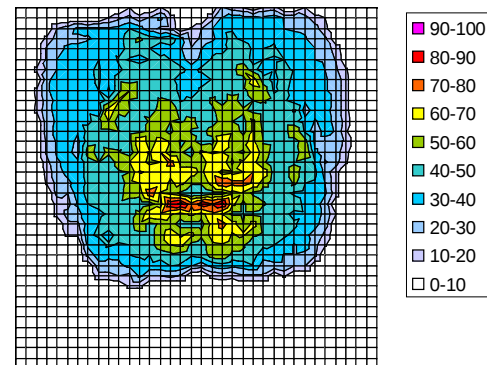
Monitor SSWL for 10 min

10 subjects, one measurement per treatment + control

- ◆ Peak pressures (SD) recorded from three mattresses (standard, visco-elastic, surface-cut foam) under three conditions (naked, dry pad, wet pad)

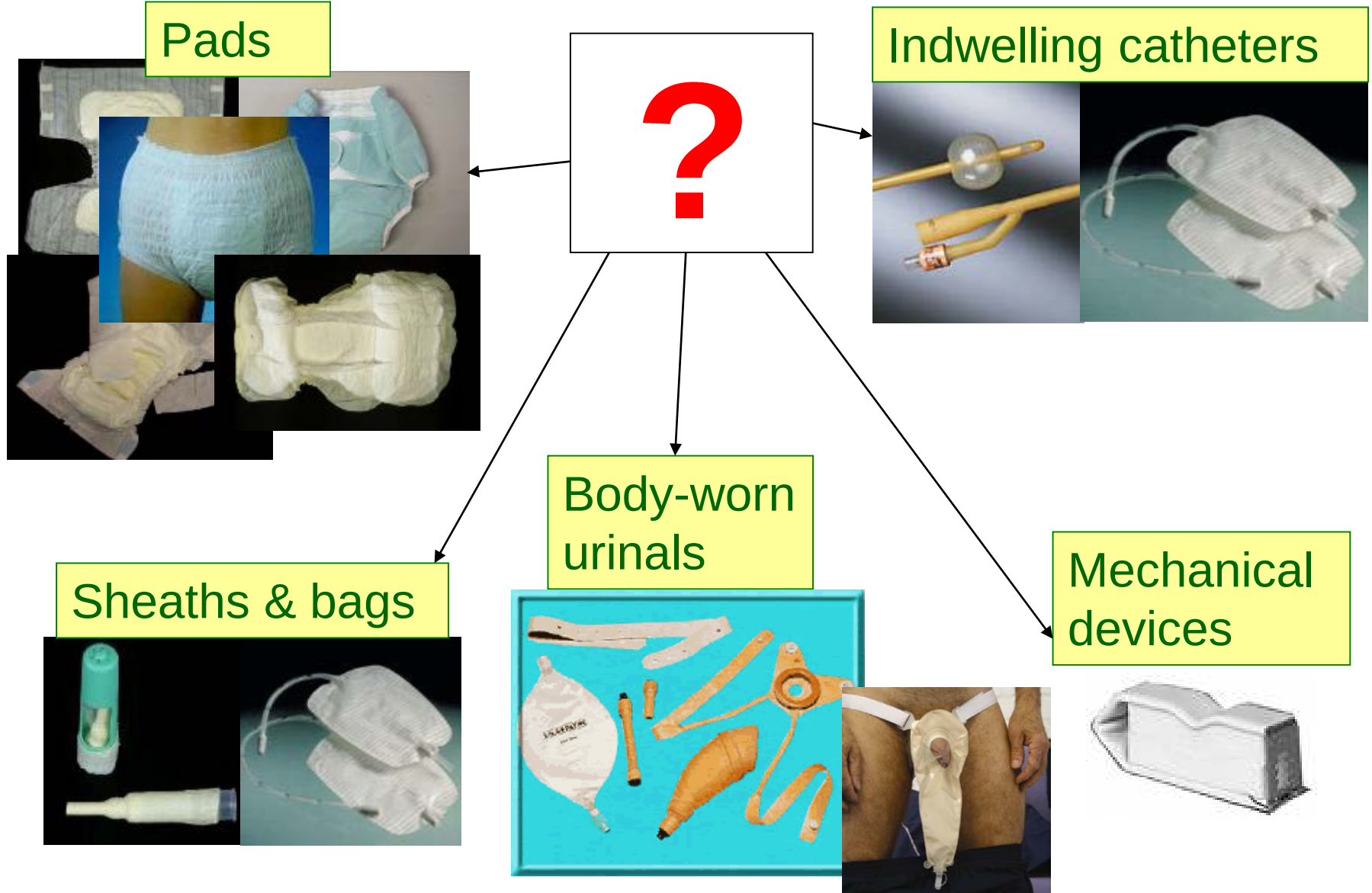


Unsmoothed pad on standard foam mattress



Fader M, Bain D, Cottenden A Effects of absorbent incontinence pads on pressure management mattresses. J Adv Nurs. 2004 Dec;48(6):569-74.

Products and devices for men



Sheath



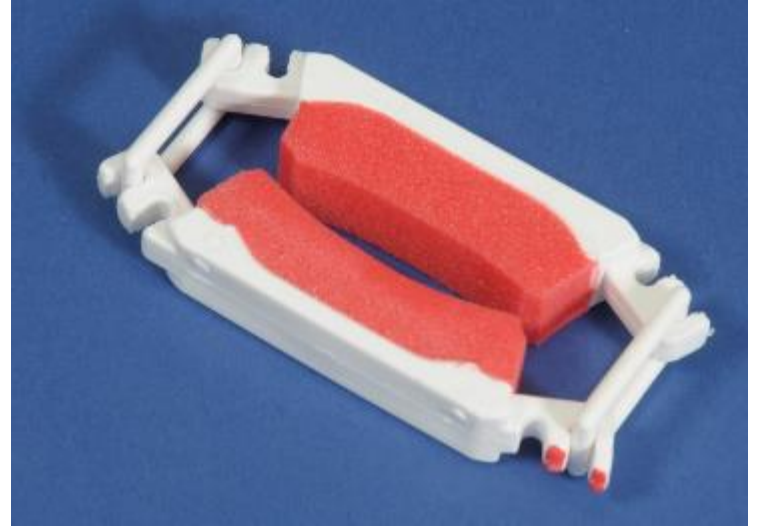
Body-worn urinals



Device briefs



Penile compression devices (clamp)



N=56 % = proportion of men rating as 'good' or 'acceptable' v 'poor' ✓ and ✗ = designs performed significantly better or worse than one, two or all other designs (p=0.05)	Pad %	Sheath %	BWU %	Clamp %
% reporting – No leak	21	49✓	36	75✓✓✓
% reporting - No smell	38	69✓✓	53	70✓
% reporting - Feels secure	46	38	32	68✓✓✓
% reporting – Can wear any clothes	38	42	38	68✓✓✓
% reporting - No pain	75	58	35**	11***
% reporting - Comfortable (dry)	77✓	64✓	38	n/a
% reporting - Easy to put on	84✓✓✓	43✓	25	51✓

Design differences
for key performance characteristics

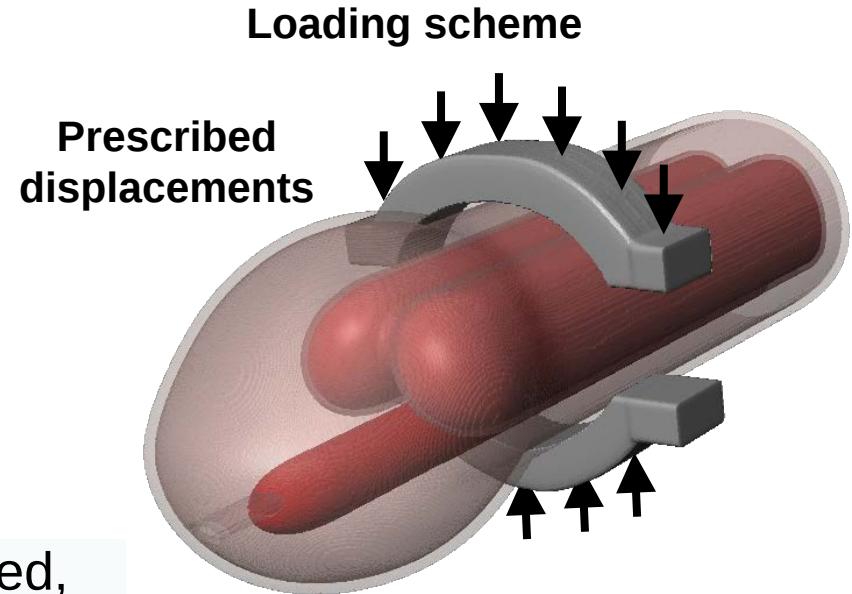
Measuring skin damage from clamps

- Laser doppler
- Sebutape - inflammatory markers
- Interface pressure sensors

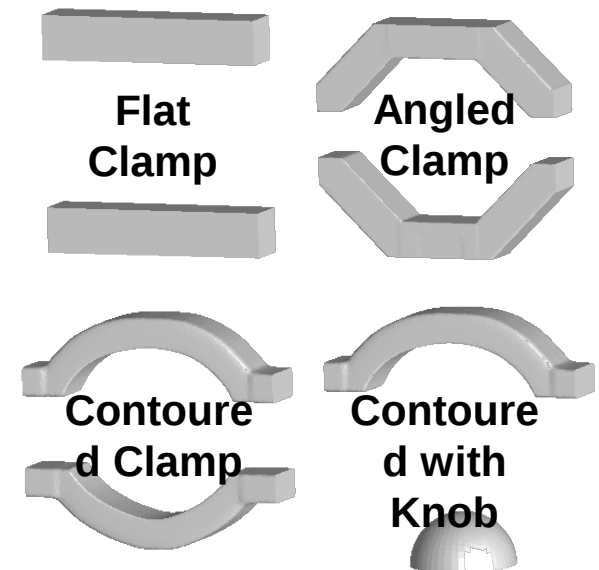


Methods

Clamp geometry	Stiffness [kPa]
Flat	25, 50, 100
Angled	25, 50, 100
Contoured	25, 50, 100
Cuff-type	None
Contoured with knob	50,100
Tilt 5°	50



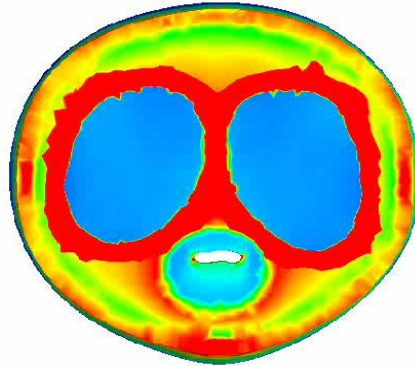
- 12 model variants were developed, representing five generic designs of incontinence clamps and three stiffnesses of interface materials
- Opposite vertical displacements were assigned to the top and bottom surfaces of every clamp to compress the mid-shaft
- Common target outcome of 50% occlusion of the urethra



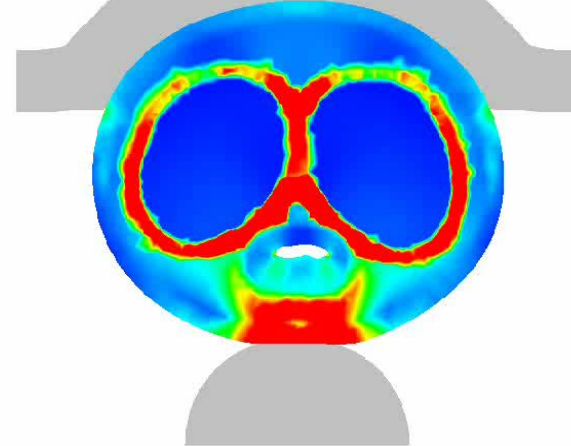
Results

Effective Stress Distributions

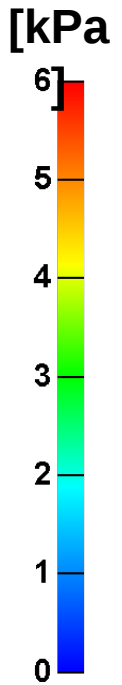
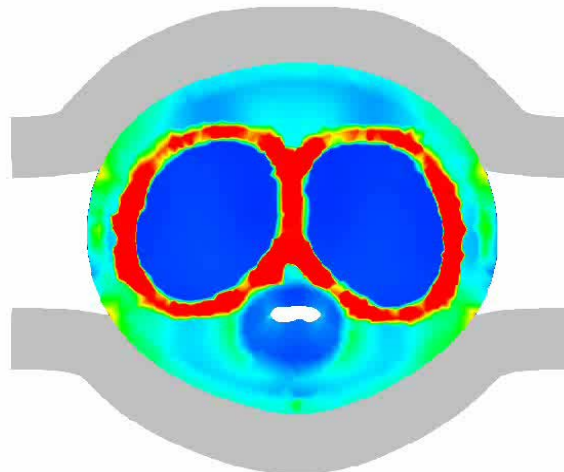
Cuff-Type Clamp



Contoured with Knob



Contoured Clamp





Female devices

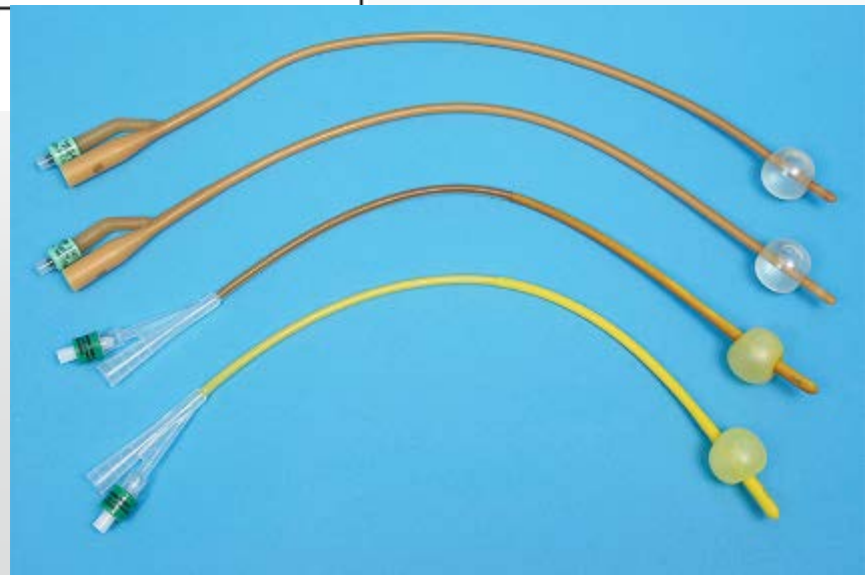
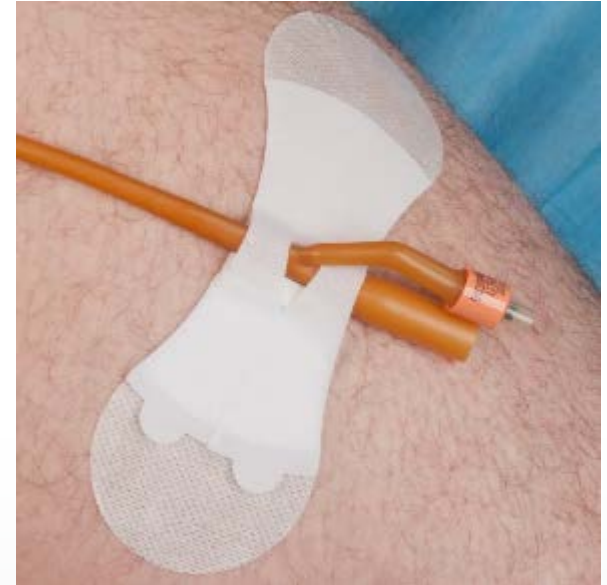
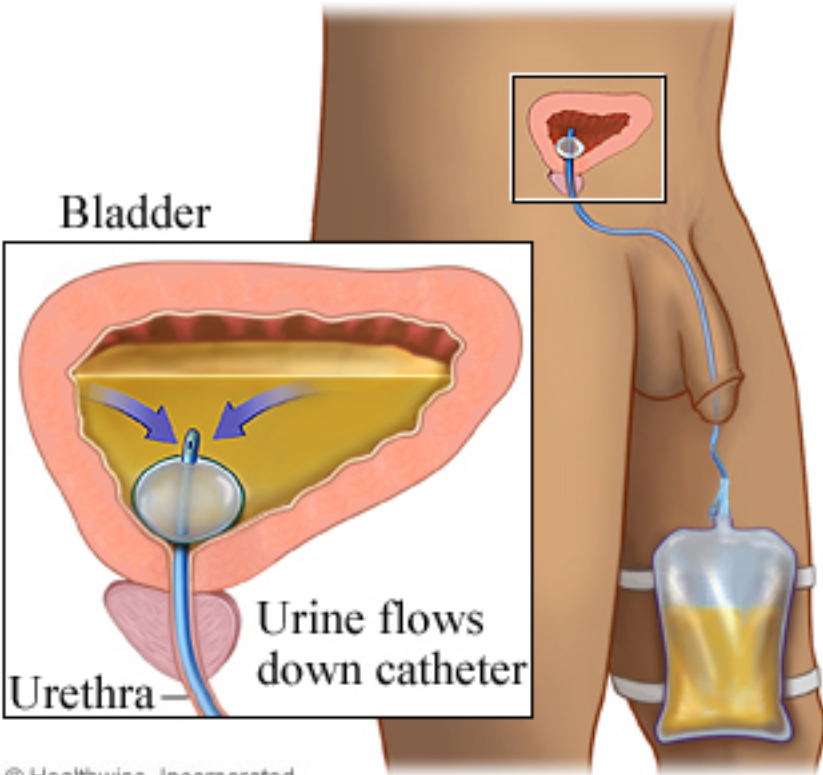
UNIVERSITY OF
Southampton



Female urinals



Urethral catheters



Faecal collectors



Skin damage associated with incontinence devices

Mandy Fader

Professor of Continence Technology
Faculty of Health Sciences
University of Southampton
UK

Medical Devices and Skin vulnerability sandpit

