Skin damage associated with incontinence devices

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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.
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

- Pads
- Catheters
- Bags
- Mech. devices
- Sheaths
- Skincare & odour products
- Toileting aids
- Urinals
- FI devices
- Body-worn urinals
Absorbent pads

- Disposable insert
- Disposable pull-ups
- Disposable diaper/AIO
- Disposable T-shaped diaper
- Washable products
# Median urine mass per pad (g)

<table>
<thead>
<tr>
<th></th>
<th>Insert</th>
<th>Diaper / AIO</th>
<th>Pull-up</th>
<th>T-shape</th>
<th>Wash-able</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td>284</td>
<td>347</td>
<td>303</td>
<td>355</td>
<td>431</td>
</tr>
<tr>
<td>Women</td>
<td>147</td>
<td>203</td>
<td>176</td>
<td>186</td>
<td>311</td>
</tr>
<tr>
<td>N (pads)</td>
<td>1943</td>
<td>2196</td>
<td>2066</td>
<td>1426</td>
<td>819</td>
</tr>
</tbody>
</table>
Environment within wet pad:
• Skin over-hydration
  → Increased skin permeability
  → Higher skin friction coefficient
  → Lower skin abrasion resistance
  → Greater microbial load
  → Increasing pH

Aetiological factors:
• Faecal enzymes
• Mechanical action (friction, shear, pressure)
• Chemical irritation (topical products)

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)

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

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)

<table>
<thead>
<tr>
<th>Pad condition</th>
<th>Pressure mm Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>naked</td>
<td>50</td>
</tr>
<tr>
<td>dry pad</td>
<td>60-70</td>
</tr>
<tr>
<td>wet pad</td>
<td>80-90</td>
</tr>
</tbody>
</table>

Products and devices for men

- Pads
- Indwelling catheters
- Body-worn urinals
- Sheaths & bags
- Mechanical devices
Sheath
Body-worn urinals
Device briefs

- Purpose designed compression boxer briefs
- The design of the underwear enables Acti brief Plus to be used with a mini pad for faecal incontinence
- The collection pouch has a non-return valve
- Applies the right amount of pressure to the pubic area to support the base of the penis
Penile compression devices (clamp)
<table>
<thead>
<tr>
<th>% reporting</th>
<th>Pad</th>
<th>Sheath</th>
<th>BWU</th>
<th>Clamp</th>
</tr>
</thead>
<tbody>
<tr>
<td>No leak</td>
<td>21</td>
<td>49✓</td>
<td>36</td>
<td>75✓✓</td>
</tr>
<tr>
<td>No smell</td>
<td>38</td>
<td>69✓</td>
<td>53</td>
<td>70✓</td>
</tr>
<tr>
<td>Feels secure</td>
<td>46</td>
<td>38</td>
<td>32</td>
<td>68✓✓</td>
</tr>
<tr>
<td>Can wear any clothes</td>
<td>38</td>
<td>42</td>
<td>38</td>
<td>68✓✓</td>
</tr>
<tr>
<td>No pain</td>
<td>75</td>
<td>58</td>
<td>35**</td>
<td>11***</td>
</tr>
<tr>
<td>Comfortable (dry)</td>
<td>77✓</td>
<td>64✓</td>
<td>38</td>
<td>n/a</td>
</tr>
<tr>
<td>Easy to put on</td>
<td>84✓✓✓</td>
<td>43✓</td>
<td>25</td>
<td>51✓</td>
</tr>
</tbody>
</table>

Design differences for key performance characteristics

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)
Measuring skin damage from clamps

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

<table>
<thead>
<tr>
<th>Clamp geometry</th>
<th>Stiffness [kPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flat</td>
<td>25, 50, 100</td>
</tr>
<tr>
<td>Angled</td>
<td>25, 50, 100</td>
</tr>
<tr>
<td>Contoured</td>
<td>25, 50, 100</td>
</tr>
<tr>
<td>Cuff-type</td>
<td>None</td>
</tr>
<tr>
<td>Contoured with knob</td>
<td>50, 100</td>
</tr>
<tr>
<td>Tilt 5°</td>
<td>50</td>
</tr>
</tbody>
</table>

- 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

[kPa]
Female devices
Female urinals
Urethral catheters
Faecal collectors
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