The Use of Multilayer Component Foam Dressings for Pressure Ulcer Prevention:

ORIGIN, DATA, and INTERNATIONAL CONSENSUS

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Objectives

- Describe the risks of OR acquired pressure ulcer development
- Discuss the results of prophylactic dressing use and OR association
- Describe how a dressing’s construction may or may not result in pressure ulcer prevention
- Discuss the development of guidelines for the use of dressings in pressure ulcer prevention by an expert consensus panel

Pressure Ulcers: High Volume & High Cost

- U.S. acute care facilities treat approximately 2.5 million patients with PU per year
- Approximately 60,000 patients die each year of PU complications
- Approximately $12 billion per year is spent treating PU
  - Federal estimate only, does not include state or private insurance figures (Lyder 2012)
  - $500-100,000 per ulcer
  - Depends on continuum of care
  - Infected ulcer may cost upwards of $250,000

Studies on ICU and PU Risk

- Surgical Intensive Care [Nijs, et al., 2008]
  - History of Vascular disease
  - Use of Dopamine (≥ 5 μg/kg/min)
  - Intermittent Hemodialysis (HDI)
  - CVVHD
  - Mechanical Ventilation

- Surgical ICU
  - Braden +following risk factors:
    - [Slowikowski & Funk, 2010]
    - Age >70
    - Diabetes Mellitus
    - Unable to turn, hemodynamically unstable

- Feuchtinger et al. (2007) Cardiac Surgery ICU
- Restraints in activity, mobility, nutrition, mechanical ventilation
- 90% were at risk via Braden within first 4 post surgical days
  - Use to identify patient specific risk factors

Publication Available from WCET Journal Regarding Early STICU Trial and Results:
Volume 30, 1, January-April 2010 Issue.

Operating Room PrU Incidence

- Incidence 12-66%[1], 4-45%[2], Average 25%[3]
- 1.3 million PrPU with 1 million stage II or worse
- Surgical Patients account for 42% of all HA Ulcers[1]
  - CABG 466,000/yr (29%)[4]
  - Total Hip Replacement 235,000/yr (42-55%)
  - Schoonhoven (2002) OR 52.9% heel ulcers
  - Scott-Williams (2005) OR 52% heel ulcers
  - Lindgren Study (Hips & Knees) 11% developed heel ulcers
OR Pressure Ulcers

1. Transfer (shear)
2. Time
3. Position
4. Patient (size/shape/risk factors)

Operating Room PU: Incidence

Reported Incidence in Literature Over Time

- 3-h surgery: 5.8%
- 4-5 h: 8.9%
- 5-6 h: 9.9%
- >7 h: 13.2%

Schoonhaven and colleagues report that for every 30 min surgery that prolongs over 4 h, risk of developing pressure ulcers is increased by 33%, (95% CI 13%-56%)

Is it an OR PRESSURE ULCER:

48-72 hours post op?
Associated with OR position?
Think Ahead:

NPUAP Recommendations

- Pre-operative positioning
- Consider pressure redistribution mattresses in the peri-surgical unit
  - POSITION
    - What position will the patient be in during surgery?
    - Instruct patient to lay in an alternate position until being taken back!
- Skin Assessment/Risk Assessment

What else can we do?


Cardiac Surgery ICU

- Cardiac Surgery Patients Incidence of PU: 29.5%

- RISK IS ELEVATED SECONDARY TO:
  - OPERATING ROOM
  - Cardiac surgery specific risk factors
  - Comorbidities
- Treatment Interventions

Source: Feuchtinger, 2006

Cardiac Surgery Specific Risk Factors

- Intraoperative Risk: (Shoemaker, 2007).
  - Patient Morbidity
  - Type of Surgical Procedure
  - Hypothermia
  - USE OF WARMING BLANKETS*
  - Anesthesia/Anesthetic agents
  - Hemodynamics
  - Time on OR table
  - Body Position
  - Shear
  - Intensity and duration of pressure
  - Moisture/pooled solutions
  - Impaired sensory perception

- Extracorporeal circulation:
  - Cooling, reheating, cooling time to normothermia.
  (Feuchtinger, 2006).
Study Design:
- Study Length: 3 Months
- Sample Size: 100
- 85 Met Criteria
- Standard Care: 35
  - 4/39 removed
- Intervention Group (MBS): 50
  - 6/56 removed
  - 5 lost forms of unknown group
- Standard PU prevention protocol applied to all patients including provision of specialised support surface.
- All patients received Mepilex Border during surgery – standard care group; dressing removed on admission to ICU. Intervention group retained Mepilex Border insitu.
- Intervention group underwent daily skin checks (lifting and replacing dressing); dressing replaced every 3 days unless required earlier.

LIMITATIONS of Study:
OR Prevention

“We acknowledge that subjects in intervention and comparison groups who underwent cardiothoracic procedures had the dressing applied during their surgical procedures. We observed that no PU developed until 6 days following surgical procedure in either group, suggesting that the dressing may have influenced the intraoperative risk of PU development.”

Primary Question Clinician May Have:
- “Did not reach statistical significance”…WHY?
  - Failed to achieve adequate POWER and SAMPLE SIZE
  - OR Limitations
- Multicenter study
- After VCU completion
  - 1 Facility had 6 mo. of QI data showing PU reduction using MBS, therefore their IRB wanted consent to NOT use the dressing
  - 2nd Facility had to drop out due to previous study approval for incontinence dermatitis study in same population.

Prophylactic Dressing Application to Reduce Pressure Ulcer Formation in Cardiac Surgery Patients. Brindle et al JWOCN 2012
Prophylactic Dressing Application to Reduce Pressure Ulcer Formation in Cardiac Surgery Patients

C. Ted Brindle • Jacob A. Wegelin

PURPOSE: The study was designed to determine if application of a self-adherent closure bandage dressing would reduce the incidence of pressure ulcer formation caused by standard procedure dressing among patients managed for cardiac surgery

The study included 1,017 consecutive patients undergoing cardiac surgery between January 2008 and December 2010 who were randomized to either the standard dressing group or the self-adherent closure bandage dressing group. The primary outcome measure was the incidence of pressure ulcers formed at the incision site during the hospital stay. The incidence of pressure ulcers was significantly lower in the self-adherent closure bandage dressing group (p = 0.004). The results of this study suggest that the use of self-adherent closure bandage dressings may be an effective method of prophylaxis for pressure ulcer formation in patients undergoing cardiac surgery.

Operating Room Pressure Ulcer Prevention Dressing Selection Guide

This guide provides information on the selection of pressure ulcer prevention dressings for use in the operating room. The dressings are designed to provide effective pressure ulcer prevention while minimally interfering with surgical procedures.

Use of a Silicone Bandage Foam Dressing as One Component of a Pressure Ulcer Prevention Program in the Intensive Care Unit

This article discusses the use of a silicone bandage foam dressing as a component of a pressure ulcer prevention program in the intensive care unit. The dressing is designed to provide effective pressure ulcer prevention while minimizing the risk of infection and other complications associated with traditional dressings.

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How is this possible?

- Why would this dressing be beneficial?
- Can you use just any dressing?
- Do all foams work?

Dressings for Prevention of Pressure Ulcers?

- Fact or Fiction?
- How would it work?
- Has this ever been done before?
- Can you show me some proof?

How would a runner reduce friction and shear...
What if the dressing reduced friction and shear...would that be enough?


- Film vs. hydrocolloid-ceramide-film
- Conclusion: dressings may reduce shear force, but do NOT affect pressure and CANNOT substitute heel elevation.

So would just ANY dressing work? Any dressing work?


What Does the Data Say About Pressure?-
Switch to foam

  - Reduction of impact pressures

DOES JUST ANY FOAM WORK?
NO....Construction Matters.

A DRESSING SHOULD:
- Depend on Body Location?
  - Larger than the bony prominence
  - Redistribute Pressure
  - Redistribute Shear
  - Reduce coefficient of Friction
  - Adequately manage microclimate (heat+moisture)

Can a Dressing Reduce the Impact of Moisture and Heat

Dressing applied to artificial skin that can sweat!
Measurement of moisture at skin interface and on top of dressing
Moisture that escapes reduces microclimate effect
Original Study:
- Septic Patient with anasarca
- Dressing saturated with fluid
- Patient losing 4+ liters of fluid daily

Explains why her skin remained dry and intact under dressing.

Can a Dressing Reduce the Impact of Pressure?

Direct pressure applied to “skin” with sensor

Pressure normally creates a “cone” of impact as tissue absorbs force

Deflection of pressure measured

Poster Presented @ SAWC 2012 by Evan Call et al
Motor Vehicle Crash with explosion and burn injury.

Poisson's ratio is a measure of load dispersion; higher numbers are greater pressure distribution.
Use of a Soft Silicone Bordered Sacrum Dressing to Reduce Pressure Ulcer Formation in High Risk Patients: A Randomized Clinical Trial

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Background of the Problem
• Pressure ulcers (PUs) cause harm to patients, causing pain, infections and extended lengths of stay; Increase health care cost and personal burdens; and involve legal and liability issues; ¹

• In 2007, the U.S. Center for Medicaid and Medicare Services (CMS) reported 257,412 cases of preventable pressure ulcers as secondary diagnoses. The average cost for these cases was $30,000 to $43,180 per hospital stay; ²

• Hospital acquired pressure ulcers (HAPUs) occur in 3% to 12.7% of acute care and intensive care patients; Around 70,000 people die each year from complications of PUs; ³

• Our hospital Baseline Pressure Ulcer Prevalence data (3.57 – 6.90) 2010-2011.
Primary Aim

• The aim of this randomized controlled trial (RCT) was to determine whether a prophylactic application of a self-adherent *Silicone Border Sacrum dressing (Intervention) would reduce the incidence of Pressure Ulcer (PU) formation in high-risk, intensive care unit (ICU) patients, when compared to a group (Control).

Secondary Aims

• To describe patient characteristics and examine the role of multiple variables (age, sex, condition related factors; treatment and patient related factors) as potential correlates to development of pressure ulcers.

Secondary Endpoints:

• Reduction in length of stay (LOS), resource utilization and incremental cost effectiveness.

• Evaluate the effectiveness of the Braden Scale 8 and our proposed skin care policy interventions for prevention.

Methodology

Design

An experimental, two-group study design was used to randomize (1:1 basis) a total of 367 patients into the study. (N=184) enrolled in the intervention group receiving the SKIN**Bundle and application of the Silicone Border Sacrum dressing, and (N=183) Control Group receiving usual care, including SKIN** Bundle.

Setting

Study was conducted over a 10-month period in 2011, at large, urban, academic teaching hospital, in the 31-bed Medical / Surgical/ Trauma intensive care unit; and a 23-bed cardiac care unit (CCU).
Methodology cont.

**Inclusion Criteria**
All patients admitted to the intensive care unit and cardiac care unit with a Braden Scale score ≤13, and intact skin, were study eligible.
- If eligible, patients/families were verbally consented (Approved Institutional Review Board (IRB) Script), then randomized to either the intervention or control group.

**Exclusion Criteria**
- Braden Scale Score ≥14
- Existing sacral pressure ulcers or moisture related skin damage
- Patients receiving end-of-life care or withdrawal of life-sustaining treatments

**Measurement**
1. **Demographic Recording Tool** – Investigator tool to record data on study variables from the electronic medical record (EMR), (age, date of birth (DOB); race; primary language; religion; gender; family status; length of stay (LOS); co-morbidities; length of ICU and hospital stay, diagnosis and risk factors).
2. **The Braden Scale** - Used as enrollment index. Braden Scale is used for Predicting Pressure Sore Risk, and is a validated tool that allows nurses and other health care providers to reliably score a patient’s level of risk for developing pressure ulcers.
3. **Daily Skin Assessment**; study team evaluated subject’s skin condition daily for signs of breakdown; and for use of SKIN** Bundle; and reviewed whether nurses applied the appropriate interventions per policy and procedure.
4. **Acute Physiology and Chronic Health Evaluation (APACHE) IV**; APACHE IV is a successful scoring system predicting severity of illness and prognosis of ICU patients, and is used for hospital mortality assessment for today’s critically ill patients. The first 24-Hour score is most predictive of survival. Range (.60-.90%) is high risk for death.

**SKIN** Bundle
Protect Your Patient’s SKIN Pressure Ulcer Prevention

- **Surface**: Specialty Mattress
- **Keep Turning**: Reposition at least every two hours; Offload heels; Remove pressure-generating devices every shift
- **Incontinence**: Perineal care every two hours Moisture barrier; Avoid diapers except for excessive stool, urine
- **Nutrition**: Dietary consult for nutritional deficits; Carry out orders

Tissue injury more than skin deep

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Study Procedures

**Intervention (Experimental) Group**
- Received Usual Care (daily Braden Risk Assessment; use of SKIN** Bundle protocol and the application of the Border Sacrum dressing.
- Study RN(s) were responsible for the initial application of Border Sacrum dressing; and changed it every 3 days and when it was dislodged or soiled.
  - Use of the SKIN** Bundle and skin assessment of sacral area beneath the dressing, and the condition of the Border Sacrum dressing.
  - Note: When the patient was discharged from the ICU, the bedside nurse removed the dressing, prior to transfer to regular ward.

**Control Group (usual care)**
- Received Usual Care to include (daily Braden risk assessment & preventive care per the SKIN* Bundle protocol)
- On-A-Daily Basis - all patients were assessed until discharge from the ICU or CCU. Registered Nurses (RNs) and study team used the National Pressure Ulcer Advisory Panel’s 2009 updated staging system.10

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**STUDY FLOW**
Diagram Showing Inclusion, Allocations, Follow-Up & Outcomes

- Screened for Eligibility (n=979)
- Excluded (n=512)
- End of Life Care (n=70)
- Refused (n=30)

- Enrolled (n=467)
  - Allocated to Intervention Group (IG) (n=184)
  - Allocated to Control Group (CG) (n=183)

- Randomized (n=367)
- Withdrawals (n=3)
  - IG Deaths (n=12)
- Follow-up

- Total Included in Final Analysis (IG) (n=169)
- Total Included in Final Analysis (CG) (n=166)
STUDY CHARACTERISTICS (N=367)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age; Mean ± (SD)</td>
<td>67.5 (15)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>60.3%</td>
</tr>
<tr>
<td>Female</td>
<td>39.7%</td>
</tr>
<tr>
<td>Braden Score; Mean ± (SD)</td>
<td>11.2 (1.12)</td>
</tr>
<tr>
<td>Co-Morbidities &gt;4 (%)</td>
<td>70%</td>
</tr>
<tr>
<td>Mechanical Ventilation (% of Patients who Developed PUs)</td>
<td>54%</td>
</tr>
<tr>
<td>Continuous Sedation/Paralyzing Medication &gt;48 hours</td>
<td>146 (40%)</td>
</tr>
<tr>
<td>Use of Vasopressor Medications &gt;48 hours</td>
<td>245 (67%)</td>
</tr>
<tr>
<td>Mortality</td>
<td></td>
</tr>
<tr>
<td>Intervention Group (184)</td>
<td></td>
</tr>
<tr>
<td>Control Group (183)</td>
<td></td>
</tr>
<tr>
<td>ICU Length of Stay (LOS) Range (0-120 days)</td>
<td>6.5 days</td>
</tr>
<tr>
<td>APACHE IV Mortality Risk (%)</td>
<td>(0.60-0.90)</td>
</tr>
</tbody>
</table>

Study Results

- 8 Pressure Ulcers developed during the 10-month study
- 7 in the Control Group and 1 in the Intervention Group

<table>
<thead>
<tr>
<th>CONTROL GROUP (N=7)</th>
<th>INTERVENTION GROUP (N=1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PU Location</td>
<td>PU Final Stage</td>
</tr>
<tr>
<td>Coccyx</td>
<td>Unstageable</td>
</tr>
<tr>
<td>Coccyx</td>
<td>Stage 2</td>
</tr>
<tr>
<td>Buttock</td>
<td>Stage 2</td>
</tr>
<tr>
<td>Buttock</td>
<td>Deep Tissue Injury</td>
</tr>
<tr>
<td>Coccyx/Sacrum</td>
<td>Unstageable</td>
</tr>
<tr>
<td>Coccyx</td>
<td>Stage 2</td>
</tr>
<tr>
<td>Coccyx</td>
<td>Stage 2</td>
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</tbody>
</table>

NPUAP Staging Guidelines Used™

Risk Factors as Predictors of Pressure Ulcers

Other risk factors found to be strong correlates ($r = 0.72$) among patients who developed PUs were:
- Altered Level of Consciousness
- Increased Length of Stay
- Vasopressors
- Mechanical ventilation
- 4+Comorbidities

Key Dressing Points
- Easily Applied and Painless to patient
- Remained in place, yet allowed daily inspection
- Atraumatic to skin
- Impermeable to stool and urine
- Absence of fungal infection or dermatitis beneath the dressing
Study Conclusions

• This RCT tested the efficacy of using Silicone Border Sacrum dressing as a preventive therapy among critically ill patients, to reduce the risk of hospital acquired, sacral PUs. Findings were statistically significant at (P=.001) among the treatment group.
• Our incidence rate among 367 study patients included the development a total of eight pressure ulcers (1- Intervention group and 7-Control Group), and a 2.2% prevalence rate among the study cohort.
• More than half the sample had >4.13, number of Comorbidities; and were on vasopressor medications.
• Approximately 54% of those who developed HAPUs were mechanically ventilated.
• Our overall findings validate recent studies 1,2,3,4, thus early adoption of this unique, low cost dressing for prevention is warranted.

Applying the Evidence to Clinical Practice:
Business Case to End Users

Nationally, over 900 hospitals in U.S. (>250 beds) have adopted the Silicone Sacrum Dressing for prevention

<table>
<thead>
<tr>
<th>Cost of Border Sacrum Dressing</th>
<th>$30,000/annually</th>
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<tr>
<td>Compared to:</td>
<td></td>
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</table>

Cost of Treating (1) Pressure Ucer

| Increased nursing time, LOS; Legal fees; cost of settlement; patient pain and suffering; even death | $30,000 to $43,180 per hospital stay |

• If Mepilex® was applied to all high risk patients; there would have been an estimated $210,000.00 cost savings by preventing the (7) pressure ulcers among the control group during the course of the study.

References

Should dressings be added to the prevention guidelines?

Joyce Black, PhD, RN, CWCN, FAAN
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Disclosure

- The ideas and work being presented in this talk are from a consensus panel sponsored by Mölnlycke.
- Panelists working on this project include:
  - Nick Santamaria, Australia
  - Michael Clark, UK
  - Carol Dealey, UK
  - Tod Brindle, US
  - Evan Call, US
  - Paulo Alves, Portugal

How are we doing with pressure ulcer prevention?

- Over the past 30 plus years, studies on prevention have not found a sustainable method of reducing ulcers.
- 10 guidelines on pressure ulcers in past decade.
- NPUAP monograph to be published later this year did not find significantly lower rates of pressure ulcers in any area.
- Brindle discovered that the use of a composite soft silicone dressing reduced ulcers in high risk patients in ICU and patients in OR.
**Adult ICU Risk Factors**

- 347 pts admitted to ICU over 7 months (10/2008-5/2009)
- Retrospective Correlational Design
- Risk Factors
  - Age
  - Length of Stay
  - Mobility
  - Friction/Shear
  - Nor-epinephrine Infusion
  - Cardiovascular Disease
  - 18.7% ulcer rate (65/347)
  - 58% of PrU were sacral

> (Can. J., 2011) Predictors of Pressure Ulcers in Adult Critical Care Patients

**Evolution in dressings for prevention**

- Use of dressings for friction long-standing
- Foam applied to the skin reduced shear
  - Normal subjects
  - Ohura, Takahashi from Japan
  - Mepilex prevented sacral ulcers in ICU patients
  - 93 patients in 2 groups
  - No ulcers in dressing group
  - 6 in control group
  - Brindle, 2009

**Consider the use of a multi layer silicone foam dressing to enhance, but not replace, pressure ulcer prevention strategies for the sacrum, buttocks and heel. (SOE = B)**

- Brindle: PrU rate lower in ICU (2010)
- Brindle: PrU rate lower in OR (2012)
- Chaiken: PrU rate fell from 13.8-1.8 in ICU (2012)
- Cherry: PrU in ICU rate fell to 0 (2012)
Before selecting a dressing consider the current status of the skin and the ease of dressing removal in order to prevent mechanical stripping (SOE= B).

- Skin injury can result from removal of strongly adhesive dressings (Dykes, 2001)

Vulnerable skin of the elderly

Apply the dressing to dry intact skin. Do not use emollients or other barriers. (SOE=C)

- Emollients and other skin preparations and barriers can reduce the adhesive properties of the dressing.

Zinc oxide and powder prevent dressing adherence

Choose a dressing[s] that exceeds the area of tissue at risk on the sacrum, buttocks or heel to be protected from pressure and shear. (SOE=C)

- Choose or make a dressing larger than body area at risk
  - Allows pressure and shear forces to be deflected into tissue outside the area of risk
- Multiple dressings may be needed

Choose or make a dressing larger than body area at risk
- Allows pressure and shear forces to be deflected into tissue outside the area of risk
- Multiple dressings may be needed
Inspect the skin beneath the dressing and change the dressing according to policy/manufacturer (SOE = C)

- Inspection of skin under dressing on each shift recommended
- Change dressing every 3-5 days unless soiled

Consider discontinuation of the dressing as the patient’s risk for pressure ulcer development decreases per clinical assessment (SOE=C).

- As clinical risk decreases, the dressing may not be needed

Consider placement of multi layer soft silicone foam dressings to the buttocks and sacrum prior to prolonged procedures or anticipated events when the patient cannot move or be moved from the supine position. (SOE=B)

- Dressing shown to reduce pressure in immobile patients in OR
- Time to develop OR ulcers is generally greater than 3 hours
Shear injury when HOB elevated can be reduced with layered dressing. (SOE = B)

- Sacral DTI with HOB up

Consider placement of multi layer soft silicone foam dressings to the heels prior to prolonged procedures or anticipated events when the patient cannot move or be moved from the supine position. (SOE=C)

- Heels at high risk for pressure
  - Immobile legs, neuropathy, arterial disease

Consider placement of multi layer soft silicone foam dressings to the heels for patients at risk of shear injury (SOE=C)

- Heel at risk for shear injury
  - Shear forces tear layers of skin/tissue
  - Leads to blisters
  - Shear forces best prevented by layered dressings
Inspect the skin beneath medical devices according to institutional policy or standards of care (SOE=C)

- Incidence of pressure ulcers in patients with medical devices
  - 35%-96% in adults, 50% in children

Consider the use of dressings that demonstrate pressure redistribution for body areas in contact with medical devices (SOE = B)

- Dressings shown to reduce ulcer incidence
  - Tracheostomy 8.1% to 3.4% (Boesch, 2012)
  - Oxygen tubing 37% to 0% (Turgania, 2011)
  - NIPPV (Weng, 2012)
    - Film dressing 13.3%
    - Hydrocolloid 40%
    - No dressing 96.7%

In addition to dressings applied beneath medical devices, continue to lift and/or move the medical device to examine the skin beneath it and reposition for pressure relief. (SOE = C)

- Skin inspection should be on each nursing shift (tour)
When simple repositioning does not relieve pressure, it is important not to create more pressure by placing dressings beneath tight devices. (SOE=C)

- Thin dressings shown to be effective (Weng, 2012, Bosch, 2012)
  - Film is not effective (Weng, 2012)

How can a dressing do all that?

Conclusions of Panel

- Pressure ulcer prevention should include dressings
  - Bench research on
    - Pressure redistribution
    - Shear reduction through layered design
    - Friction reduction with outer surface
    - Microclimate management with absorptive filler
  - Clinical research on
    - OR and ICU pressure ulcer reduction
      - Case series and historical controls
      - RCT in progress with Australia
    - Early analysis shows statistically less ulcers in dressing group
Conclusions of Panel

- Skin beneath medical devices should be padded with thin dressings
- Little direct evidence
  - Most studies address the issue of a specific product
    - Neck collars, stockings
  - Dressing cannot be too thick or it will add pressure
  - Device still needs to be moved for skin assessment or padded if skin assessment cannot be done
- Do you have evidence on this issue?

Dressings should be added to the pressure ulcer prevention guidelines

Bench science of their function is present
The structure of the dressing reduces shear and pressure
Clinical evidence to support their effect is building
Thanks to Mölnlycke for sponsoring this effort!

Questions?

Thanks to Mölnlycke for supporting this panel
References: