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Summary of Medical Devices and Vulnerable Skin Research Activities and Achievements

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Sandpit 4
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www.southampton.ac.uk/mdvsn/index.page

Medical device related pressure ulcers in hospitalized patients

Joyce M Black, Janet E Cuddigan, Maralyn A Walko, L Alan Didier, Maria J Lander, Maureen R Kelpe

Black JM, Cuddigan JE, Walko MA, Didier LA, Lander MJ, Kelpe MR. Medical device related pressure ulcers in hospitalised patients. Int Wound J 2010; 7:358–365

ABSTRACT

Most pressure ulcers occur over bony prominences such as heels and the sacrum. However, the National Pressure Ulcer Advisory Panel recognises that pressure ulcers can also occur on any tissue under pressure and thereby can develop beneath medical devices. This article reports on results from a secondary analysis of existing data collected by The Nebraska Medical Center on pressure ulcer quality improvement initiatives and outcomes. The purpose of this study was to quantify the extent of the problem and identify risk factors for medical device related (MDR) pressure ulcer development in hospitalised patients. A subset of data collected during eight quarterly pressure ulcer incidence and prevalence studies ($N = 2178$) was created and analysed. The overall rate of hospital-acquired pressure ulcers was 5·4% (113 of 2079). The proportion of patients with hospital-acquired ulcers related to medical devices was 34·5% (39 of 113). Findings indicate that if a patient had a medical device, they were 2-4 times more likely to develop a pressure ulcer of any kind. Numerous risk factors for pressure ulcer development were identified; however, none differentiated between those with MDR and traditional pressure ulcers.

Key words: Incidence • Medical device pressure ulcer • Pressure ulcer

Type of "offending" medical devices will include :-

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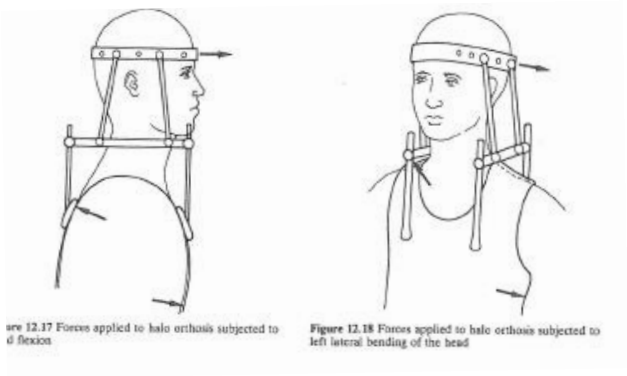

ure 12.17 Forces applied to halo orthosis subjected to d flexion

Figure 12.18 Forces applied to halo orthosis subjected to left lateral bending of the head

- Support surfaces – beds and chairs
- Orthotics

An externally applied device used to modify the structural and functional characteristics of the neuro-musculoskeletal system

- Prosthetics – particularly assocaited with the lower limb
- Devices in ICUs to support respiration and resuscitation
- Miscellaneous items e.g. tubing, nasal prong, electrodes

Locations and devices

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- General care items
  - Bedpans
  - Foley tubing
  - Naso-gastric tubes
  - Bed trash
  - Suture

Courtesy of Black

Medical-device related pressure ulcers (MDRPUs): location of the problem

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Location	Device	Non-Device
Head/face/neck	**70%**	**8%**
Heel/ankle/foot	20%	17%
Coccyx/buttocks	8%	68%
Sacrum	2%	17%
Other/multiple	22%	6%

Apold and Rydrych (2012) J Nursing Quality

MOTIVATION - Over 33% of pressure ulcers that occur in hospitals are related to medical devices *(Black et al, 2010)*

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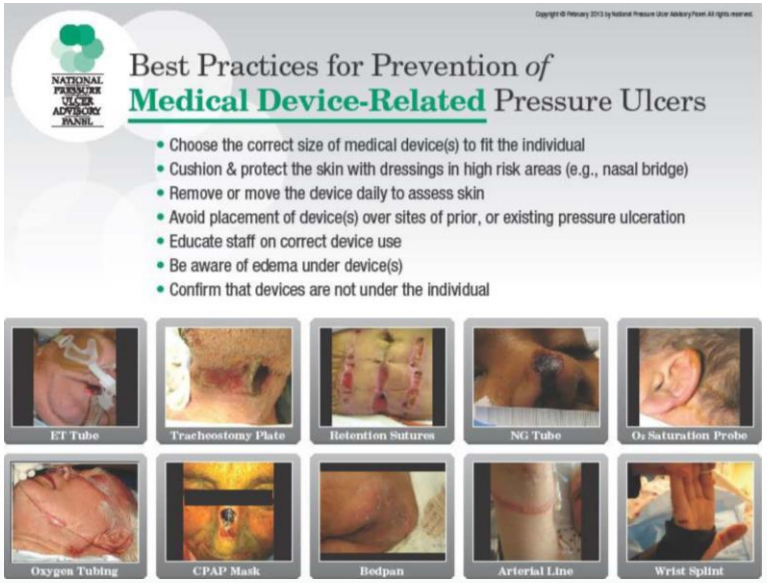
Patients with medical device were 2.4 times more likely to develop a Pressure Ulcer



NPUAP Consensus Meeting – June 2016

Agreed the term *Medical device related pressure injuries* to define that resulting from the use of devices designed and applied for diagnostic or therapeutic purposes. The resultant damage generally conforms to the pattern or shape of the device.

Editorial "What's in a name" Bader and Schoonhoven 2016 JTV 25; 191-2

Medical Devices and Vulnerable Skin Network and Network Plus (2014-19)

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Can fragile soft tissues be protected from medical device-induced damage causing chronic wounds by using novel designs incorporating matched interface materials and manufacturing capability ?

Major causes of this disparity:

- Devices based on generic designs which do not accommodate the vulnerability of the loaded skin tissues in specific sub-groups
- Materials used in medical devices use traditional polymers which are relatively stiff/rigid and do not match the compliance of the interfacial skin tissues

BUT functionality of these devices must be maintained

EPSRC-NIHR Medical Devices and Vulnerable Skin Network

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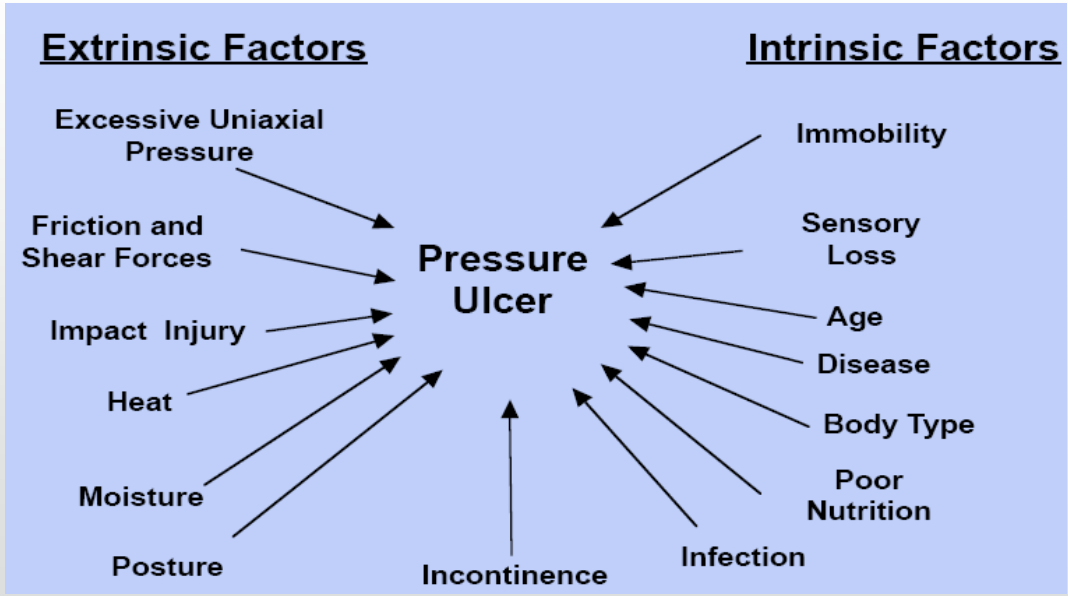
- Optimising Safety in Design (2014-2017)
- Intelligent Sensing to Promote Self-Management (2016-19)



Braden and Bergstrom (1987) Rehabilitation Nursing 12; 8-12

Current Activities within Medical Devices and Vulnerable Skin Network (MDVSN)

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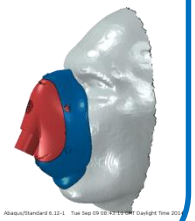
Respiratory Masks





Support Surfaces



Stump-socket interface

Prophylactic Devices


Incontinence Devices



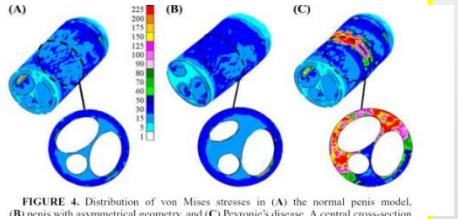


FIGURE 4. Distribution of von Mises stresses in (A) the normal penis model, (B) penis with asymmetrical geometry, and (C) Peyronie's disease. A central cross-section

Adult Respiration Devices

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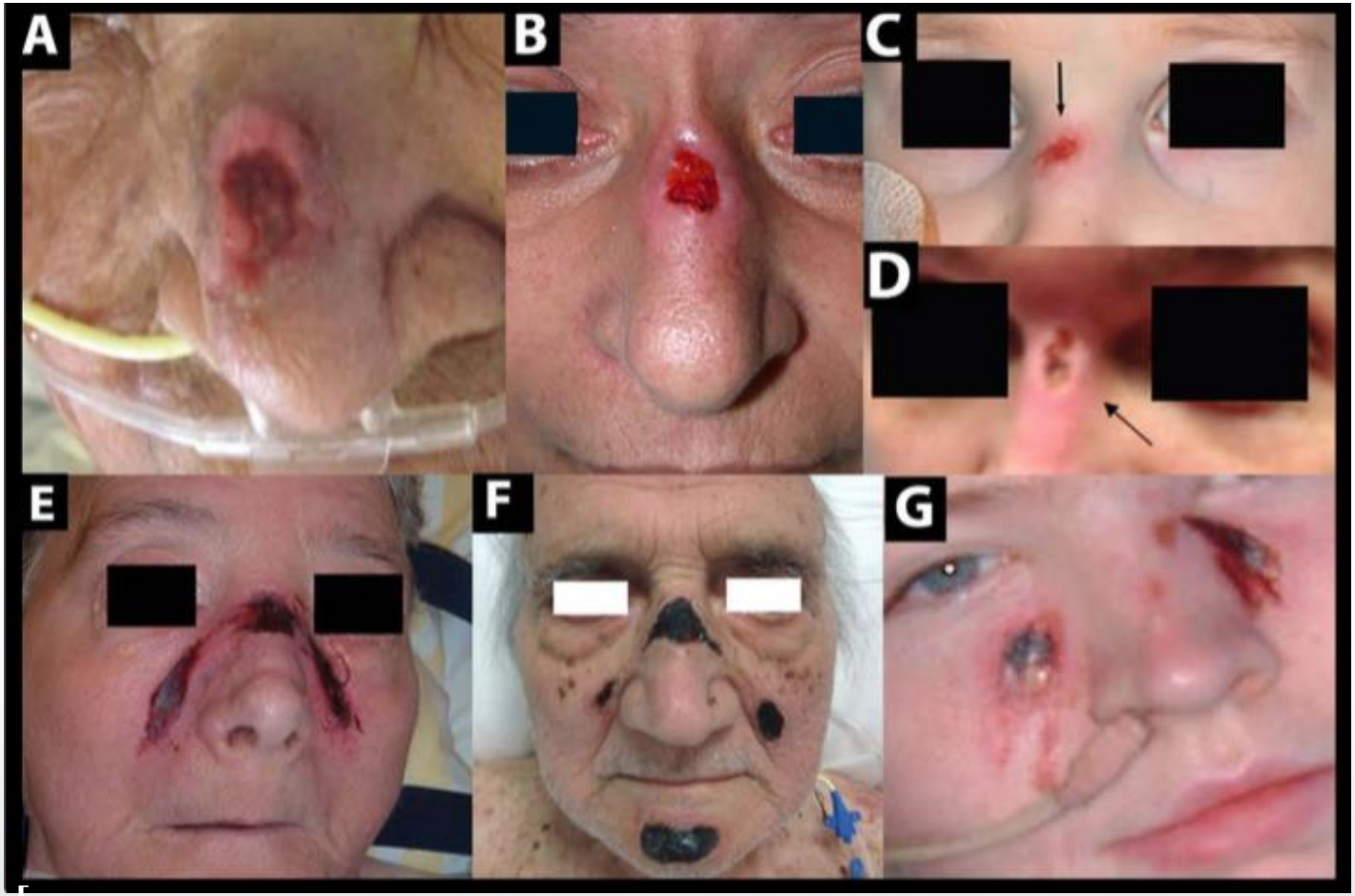

Sleilati et al. (2008). Br J Oral Max Surg. 46:411–2
Brill AK (2014) . Breathe 10, 231-242
Maruccia et al. (2015) Int Wound J 12: 451- 455
Visscher et al. (2015) Respir Care 60(11):1536- 1547

Computational Modelling Approach – Respiratory masks

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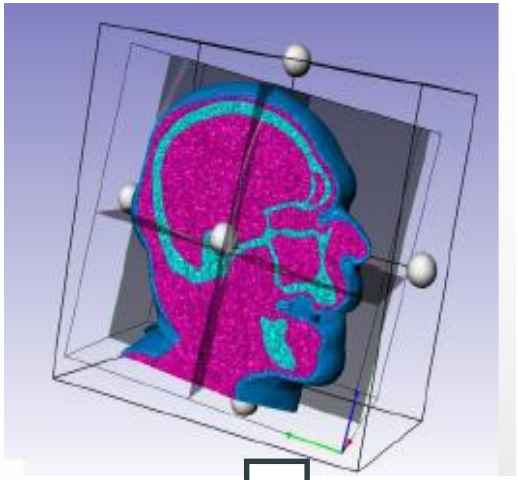
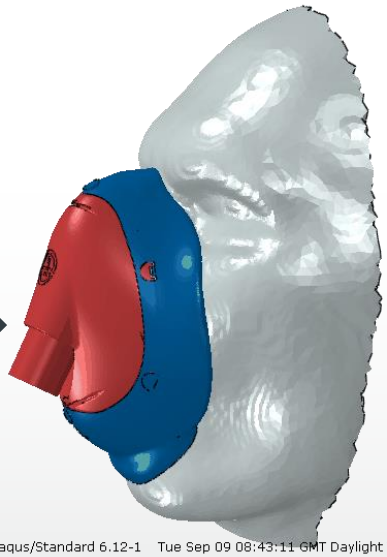
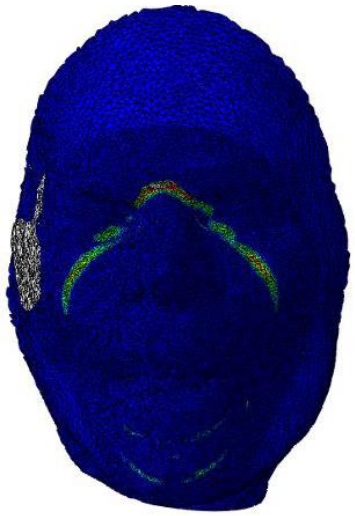




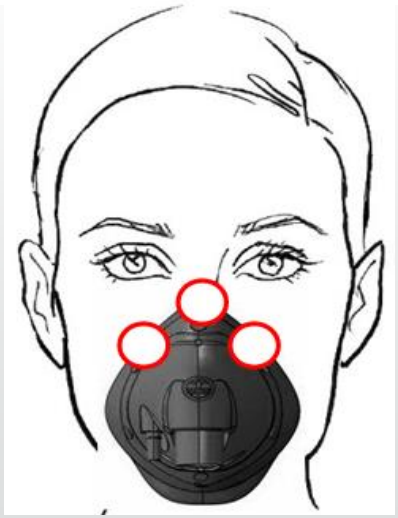


INTERSURGICAL COMPLETE RESPIRATORY SYSTEMS

FRAZER-NASH CONSULTANCY

Experimental Approach
Two Respiratory Masks

Tension strap



Biosensors

Placement of Sebutape for protein collection and cytokine analysis

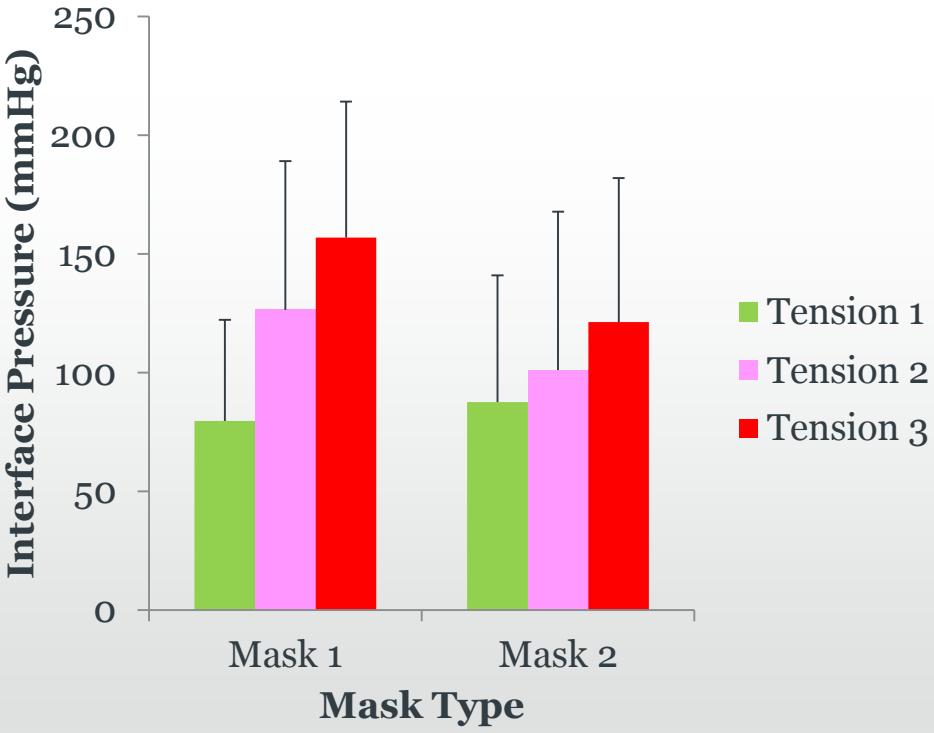
Physical Sensors

Placement of interface pressure sensors and temperature/humidity sensors prior to location of face mask

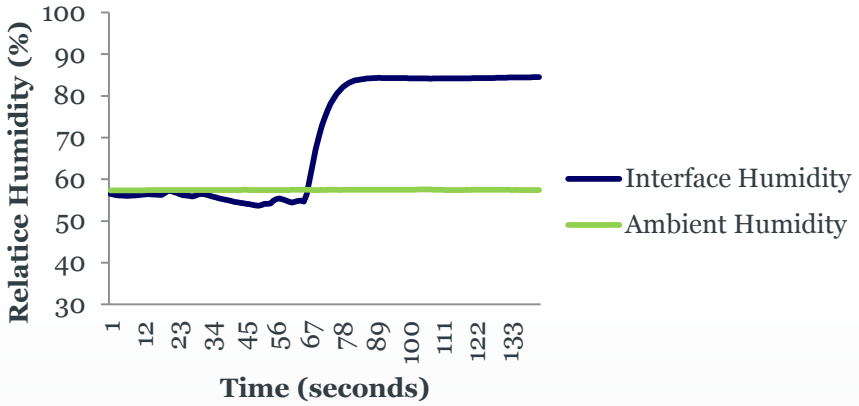
Results

Pressures and micro- climate at the skin-mask interface

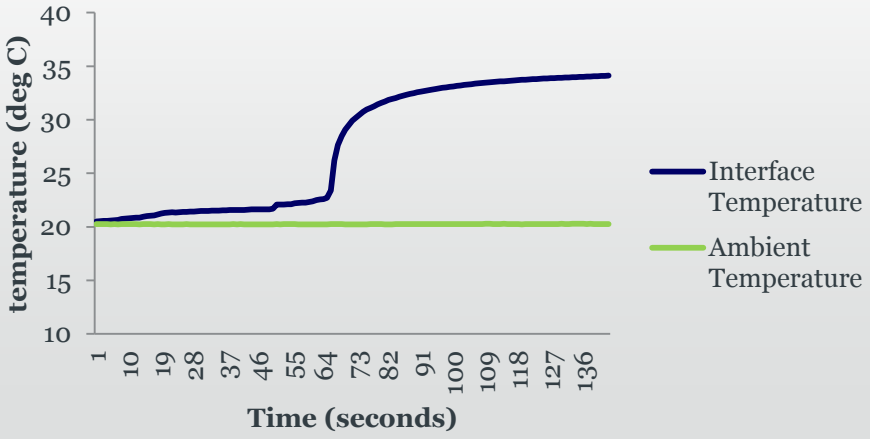
Interface Pressures (Mean +SD) at the Bridge of the Nose (n=13)



Humidity at the mask interface



Temperature at the mask interface



Results - Biomarkers

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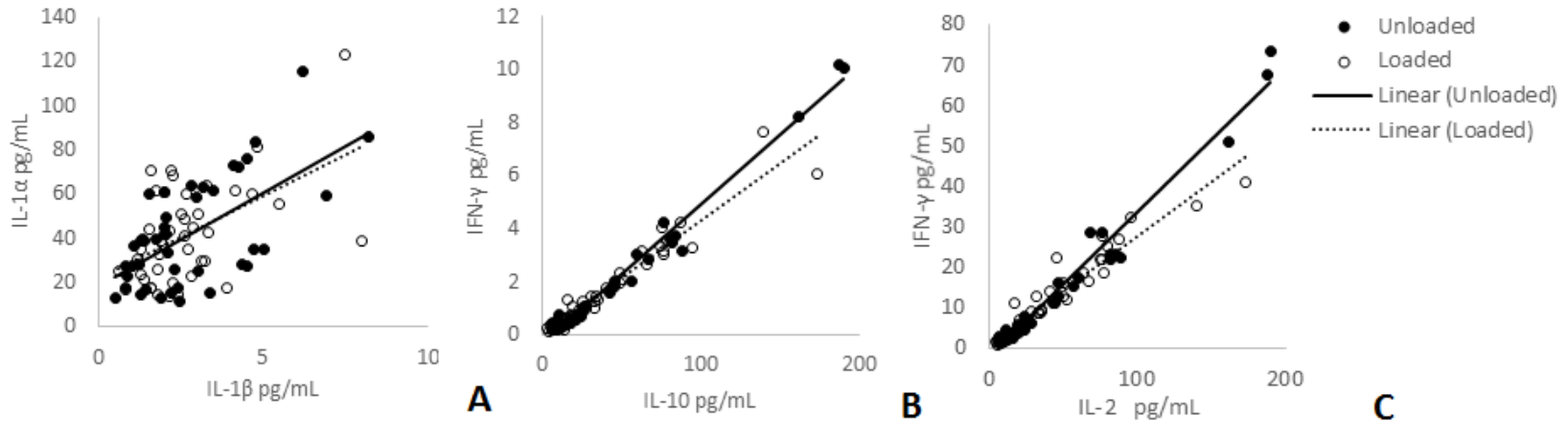
Interleukin IL-1 α

Ratios of selected Interleukins



Results – Biomarkers (n=13)

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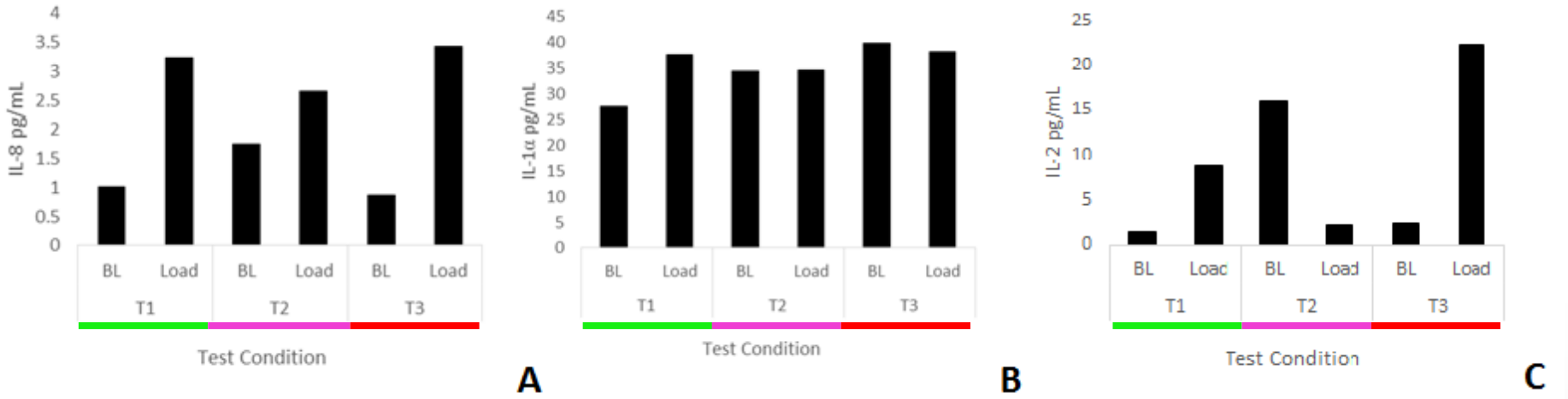
Worsley et al. 2016 Medical Devices:Evidence and Research



- Inter-subject variation is evident
- Temporal profiles of each cytokine need to be established
- Clinicians should consider the manner in which they apply the respiratory masks and the refractory period of off-loading in assessing accumulative effects on vulnerable skin
- Should use of a “mixed device” approach be considered ?

Vulnerable Skin Tissues

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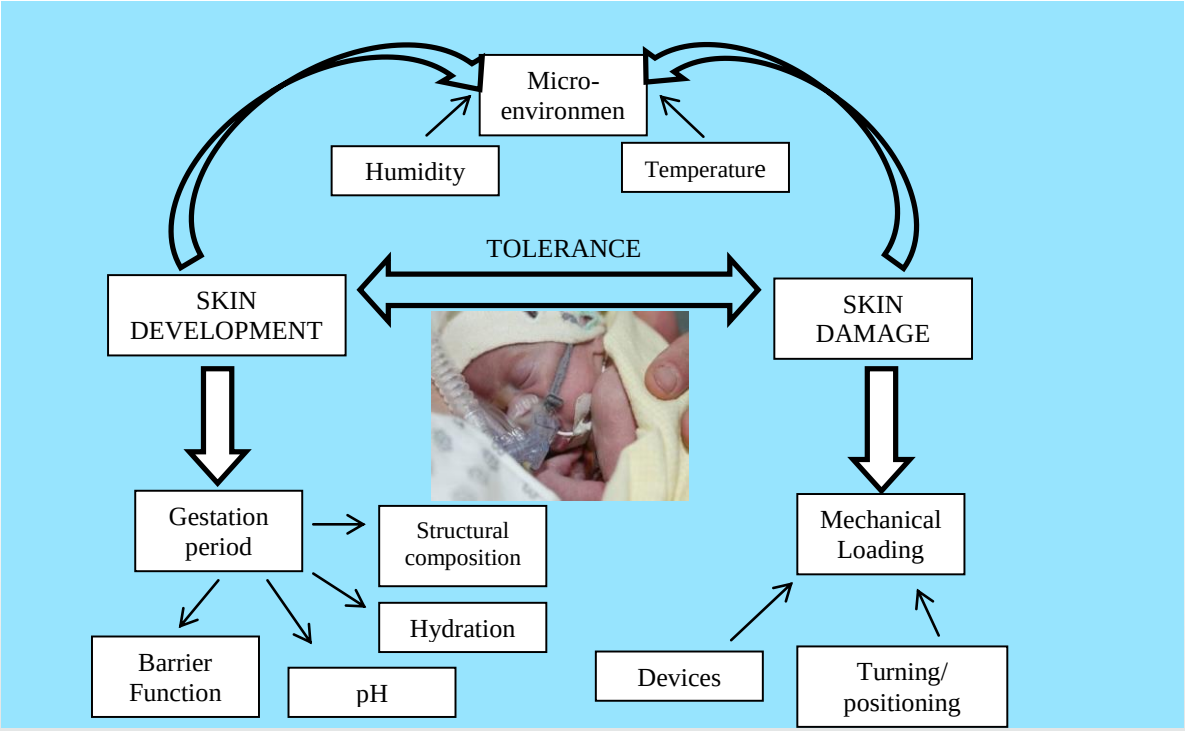
NIHR Healthcare Technology – Paediatric Theme

The design of respiratory medical devices to enable effective drug delivery and minimise traumatic damage to vulnerable paediatric tissues.

Prof. Howard Clark, Bader and Worsley



Completed prevalence and incidence survey of MDRPUs in Portsmouth and Southampton NICUs

Focus group activity

Ethics approval for monitoring study involving TEWWL, pH, US

Recruiting pre-term and term infants

Engagement with Clinicians

Following discussions at previous Sandpits ,we

- Organised Special sessions at the last 2 UK Tissue Viability Annual Meetings in Cardiff 2016, Birmingham 2017

- Agreed with TV Trustees to establish a Special Interest Group on “Medical Devices and Vulnerable Skin”

- Presented activity in the UK and overseas (TV Networks, EPUAP masterclass, NPUAP)

- Coordinated reporting of MDRPUs with international colleagues e.g. current survey of 5 adult ICUs in Linkoping

- Developing a communication Forum for TVNs on www.southampton.ac.uk/mdvsn

HTCs –Consultants to MDVSN^{Plus}

Drs Nicola Heron and Sarahjane Jones will

- Provide the interface to ensure new relevant and validated unmet needs are introduced to the MDVSN ^{Plus} contributing to a pipeline of high impact projects.
- Enable further clinical/academic interfaces as the network's projects expand and develop.
- Act as key liaisons with the Network Manager and provide expertise to develop PPI involvement.

Engagement with Industry and relevant organisations

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- Road trips to North East, Midlands/Yorkshire e.g. Peacocks, Fripp Design, Brightwake, Fraser Nash,
- Presented at BHTA –Support Surfaces group
- Co-organising meetings with Sumed, TITCH, Medstrom
- Links with other Networks e.g. CYCLOPS, IMPRESS, NewMind
- Hosted a number of international research visitors (2-3 months), including Prof. Bates-Jensen from UCLA and external international students

Clinical advice to deal with defective devices – Prof. Black

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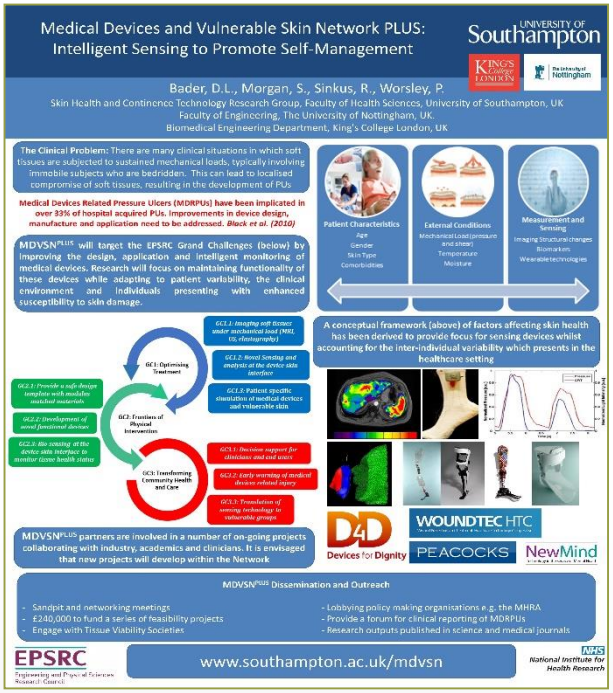
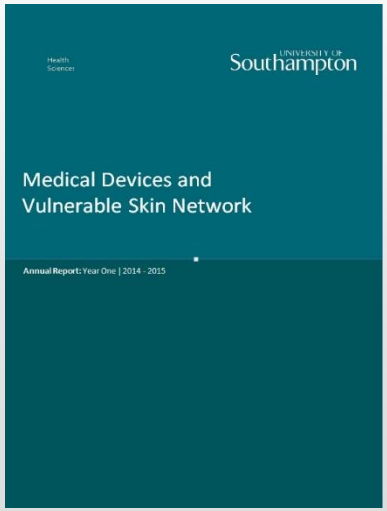
- Remove or move device on each shift
- Examine skin beneath device and do not replace device back on to injured tissues
- Defective devices must be returned!
- Industry and Regulatory bodies must be notified
- Consider the use of prophylactic devices, although for some allergic subjects, silicone-based dressings can lead to rash with erythema
- MDPUs need to be counted and prevented
- Beneath most devices, there may be a problem !

MDVS and MDVS Plus Network





http:/www.southampton.ac.uk/mdvsn/index.page

Dissemination – Selected Papers

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Woodhouse M, Worsley PR, Voegeli D, Schoonhoven L, Bader DL (2015). The physiological response of soft tissue to periodic repositioning as a strategy for pressure ulcer prevention. *Clinical Biomecha*nics, 30(2): 166-74.

Mirtaheri P, Gjøvaag T, Worsley PR, Bader DL. (2015) A review of the role of partial pressure of carbon dioxide in mechanically loaded tissues: The Canary in the Cage singing in tune with the pressure ulcer mantra. *Ann. Biomed. Eng*., 43(2): 336-347

Herniman J. Thornhill R, Worsley PR, Bader DL, Langley G (2015) The analysis of sweat biomarkers in mechanically-loaded tissues using SFC- MS. *ASMS*, St Louis, US

Dickinson AS, Steer, JW, Woods, CJ, Worsley, PR (2015) Registering a methodology for imaging and analysis of residual limb shape in below knee amputees. *J. Rehab. Res. & Dev*, 53: 207-218

Laszczak P, McGrath M, Tang J, Gao J, Jiang L, Bader DL, Moser D, Zahedi S. (2016) A pressure and shear sensor system for stress measurements at the lower limb residiuum/socket interface *Med. Eng. & Physics*, 38(7):695-700.

Worsley PR, Prudden G, Gower G, Bader DL. (2016) The effects of strap tension during non-invasive mask application: a combined biomechanical and biomarker approach. *Med Devices*, 9:409-17

Worsley PR, Parsons B, Bader DL. (2016) An evaluation of fluid immersion therapy for the prevention of pressure ulcers. *Clinical Biomechanics*, 40:27-32.

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- Prof Cees Oomens and colleagues at Eindhoven University
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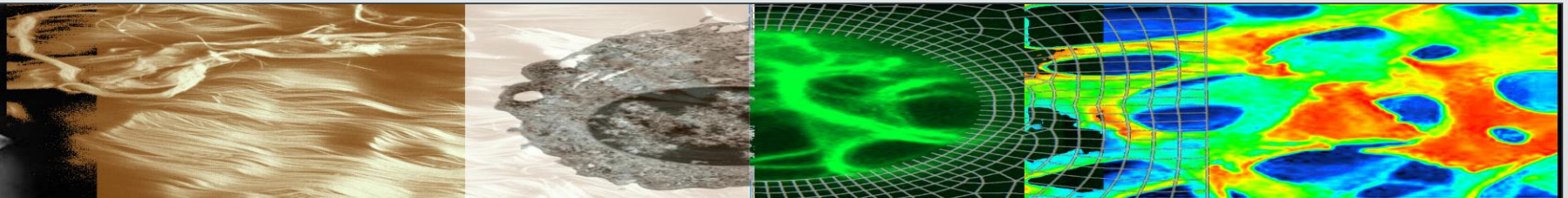
- Industrial colleagues in various companies
- Clinical colleagues including Prof. Howard Clark and team and UK TV Society



Funding Bodies and Partners

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