

# Summary of Medical Devices and Vulnerable Skin Research Activities and Achievements

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Sandpit 4

Chilworth Manor, 25<sup>th</sup> May 2017

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# 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 Kelpé

Black JM, Cuddigan JE, Walko MA, Didier LA, Lander MJ, Kelpé 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 :-

- Support surfaces – beds and chairs
- Orthotics

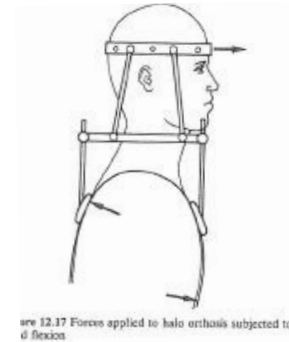


Figure 12.17 Forces applied to halo orthosis subjected to 6° flexion

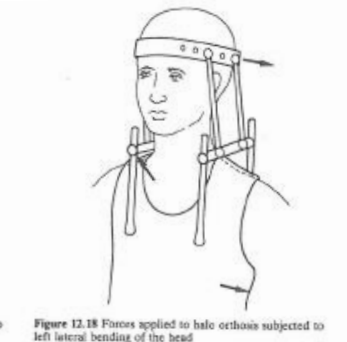


Figure 12.18 Forces applied to halo orthosis subjected to left lateral bending of the head



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

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



# Locations and devices

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



*Courtesy of Black*

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

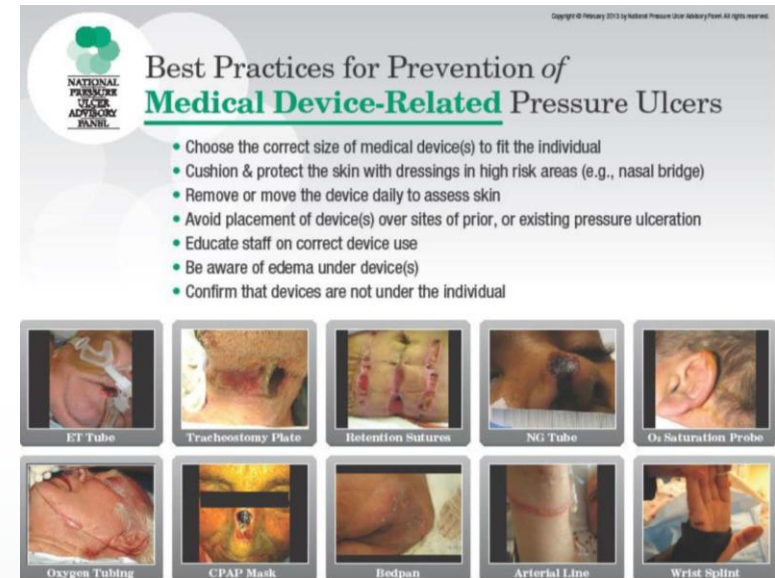
Location	Device	Non-Device
Head/face/neck	70%	8%
Heel/ankle/foot	20%	17%
Coccyx/buttocks	8%	68%
Sacrum	2%	17%
Other/multiple	22%	6%

*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*)

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 <sup>Plus</sup> (2014-19)

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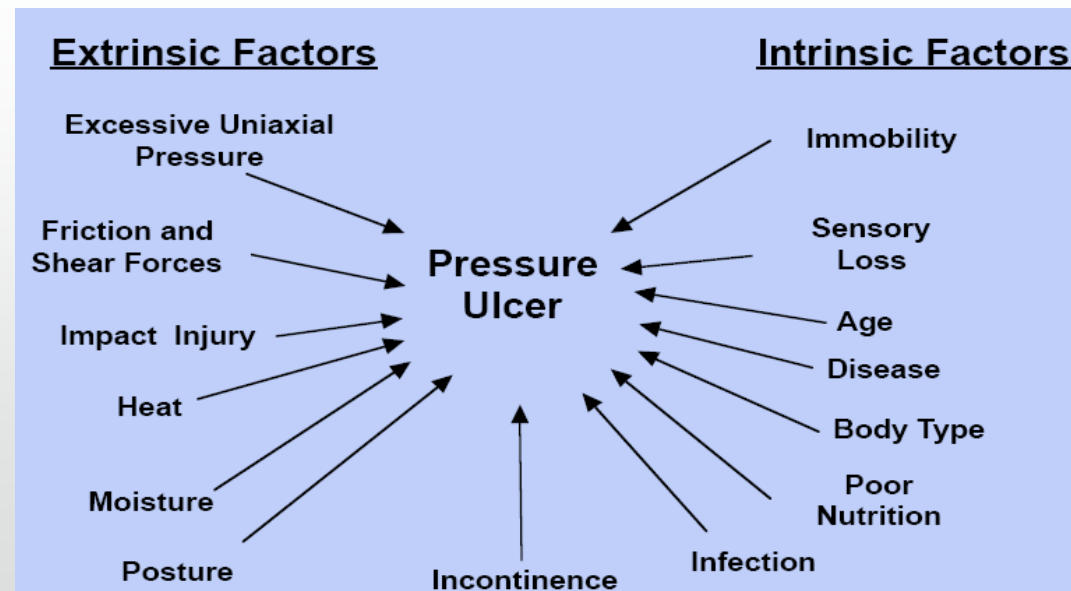
*Can fragile soft tissues be protected from medical device-induced damage causing chronic wounds by using novel designs incorporating matched interface materials and manufacturing capability ?*

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

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



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



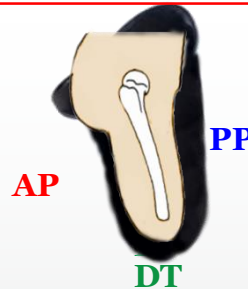
# Current Activities within Medical Devices and Vulnerable Skin Network (MDVSN)

## Respiratory Masks



AlibabaStandard 6.10-1 Tue Sep 08 02:29:59 GMT Daylight Time 2015

## Support Surfaces



## Stump-socket interface

## Prophylactic Devices



## Incontinence Devices

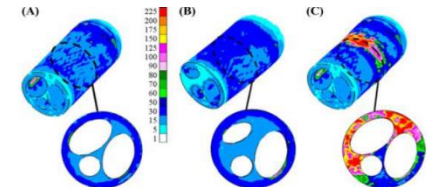
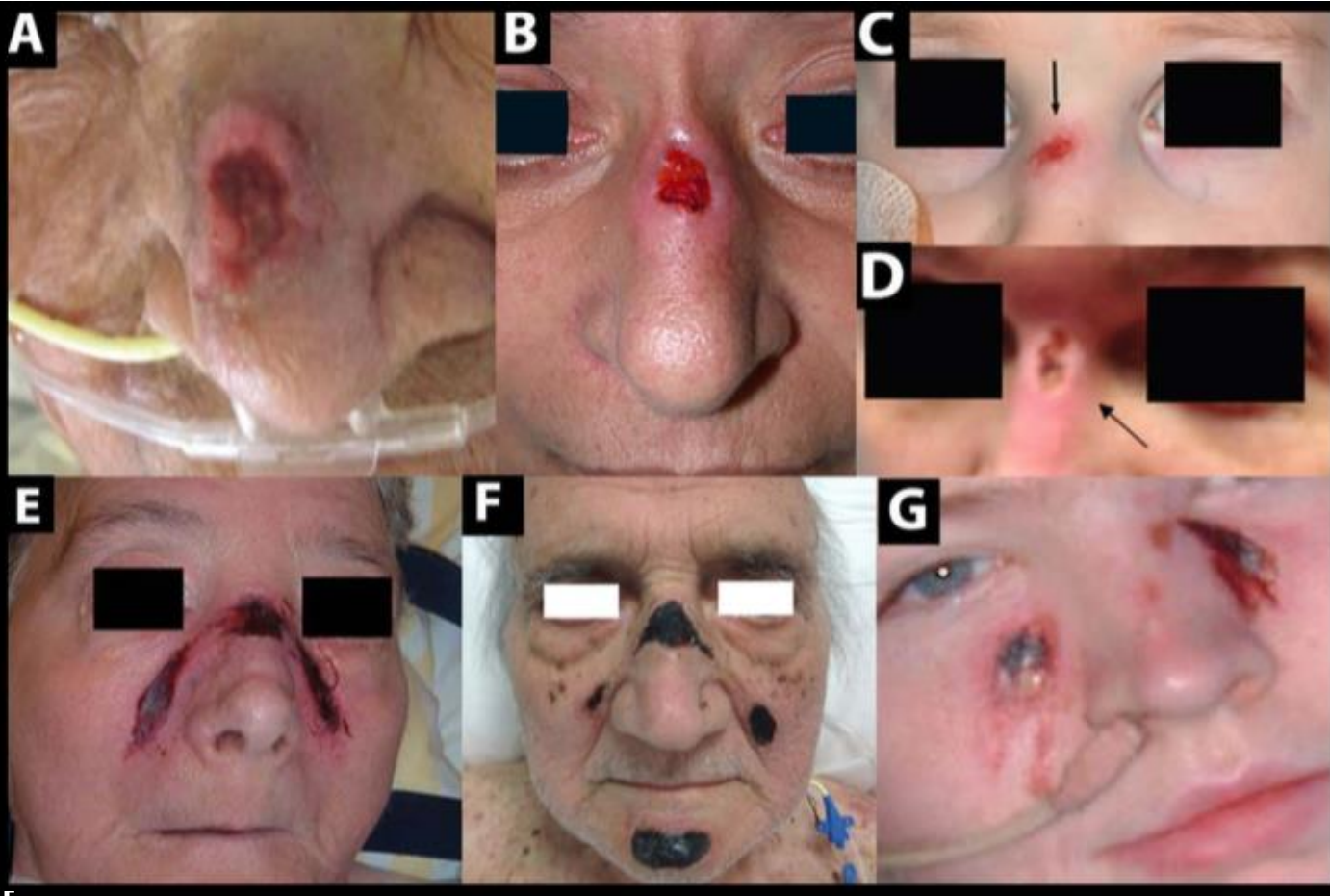


FIGURE 4. Distribution of von Mises stresses in (A) the normal penis model, (B) penis with asymmetrical asymmetry, and (C) Peyronie's disease. A central cross-section

# Adult Respiration Devices



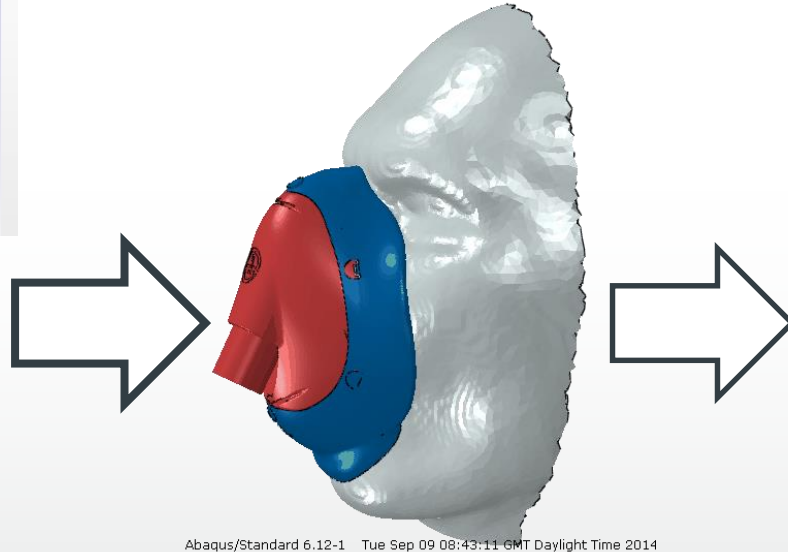
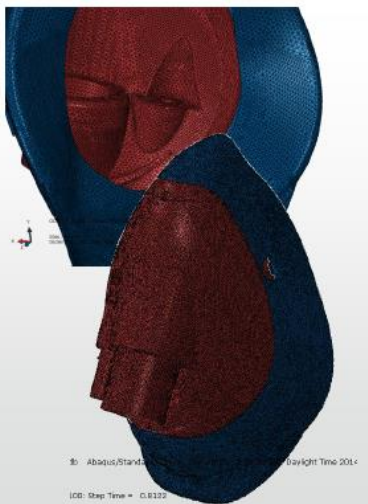
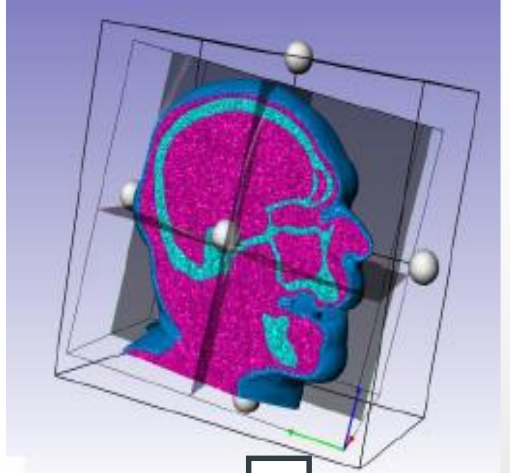
*Sleilati et al. (2008). Br J Oral Max Surg. 46:411–2*

*Brill AK (2014) . Breathe 10, 231-242*

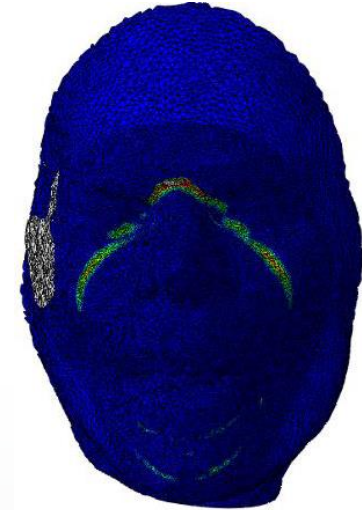
*Maruccia et al. (2015) Int Wound J 12: 451- 455*

*Visscher et al. (2015) Respir Care 60(11):1536- 1547*

# Computational Modelling Approach – Respiratory masks



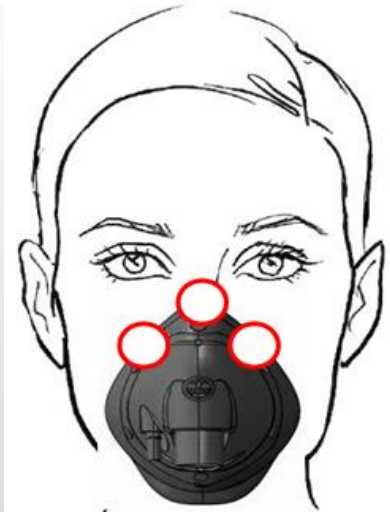
Abaqus/Standard 6.12-1 Tue Sep 09 08:43:11 GMT Daylight Time 2014





# Experimental Approach Two Respiratory Masks

Tension strap



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## Biosensors

Placement of Sebutape for protein collection and cytokine analysis



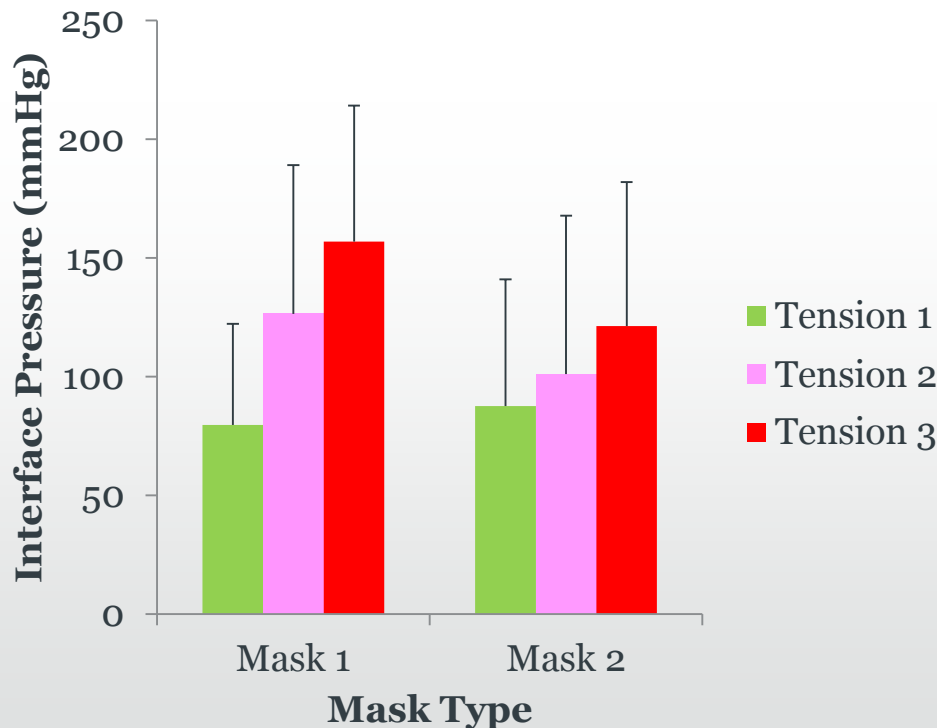
## Physical Sensors

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

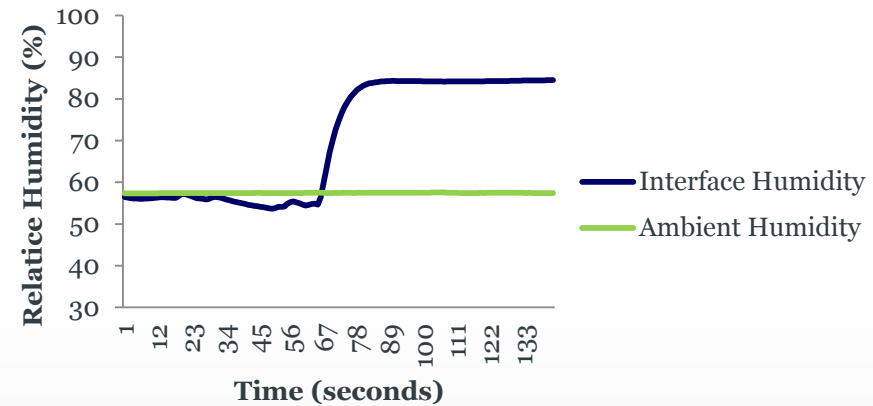
# Results

## Pressures and micro- climate at the skin-mask interface

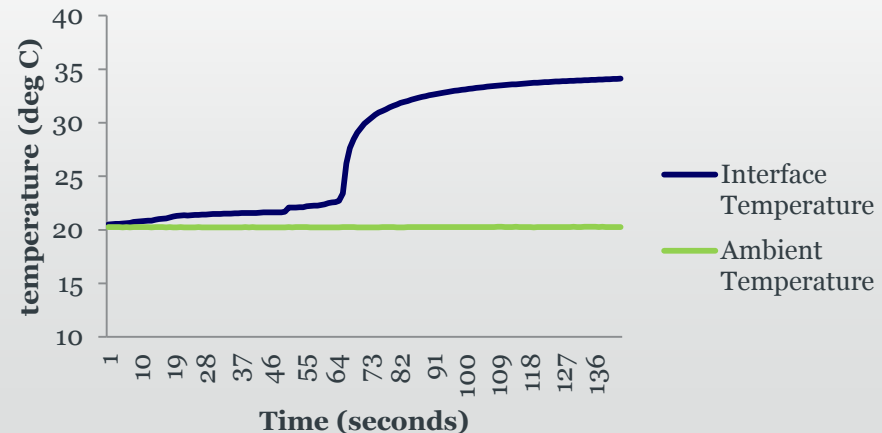
Interface Pressures (Mean +SD)  
at the Bridge of the Nose (n=13)



Humidity at the mask interface



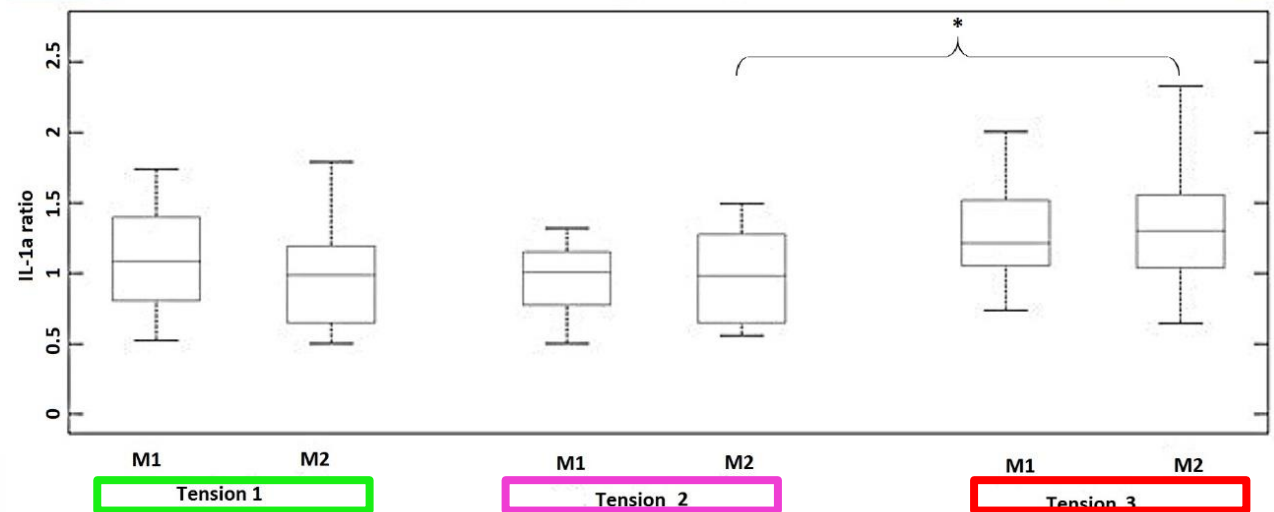
Temperature at the mask interface



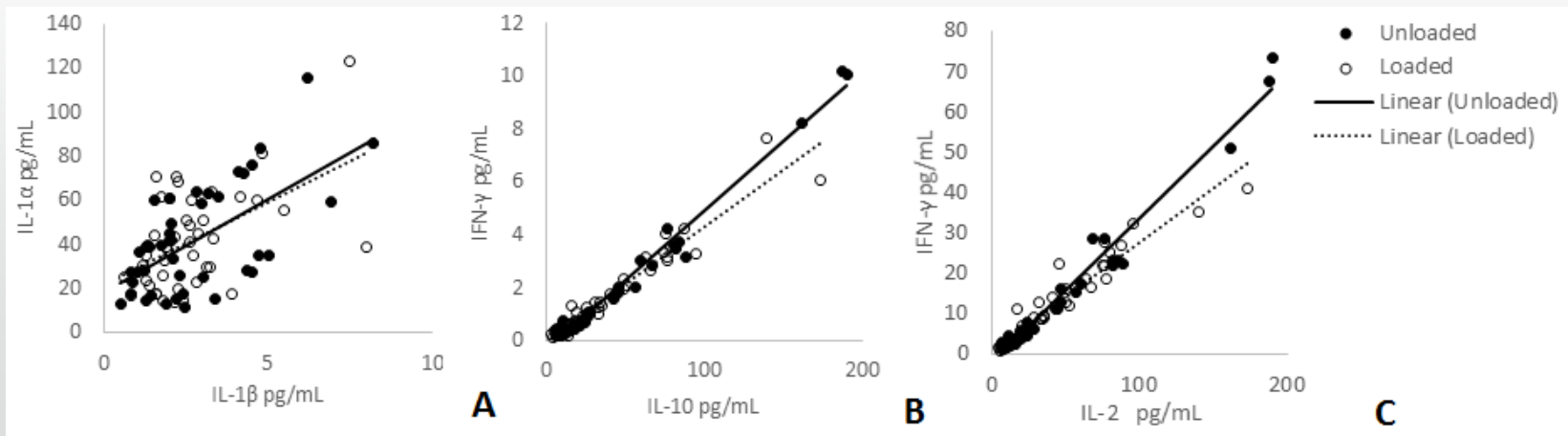


# Results - Biomarkers

Interleukin IL-1  $\alpha$

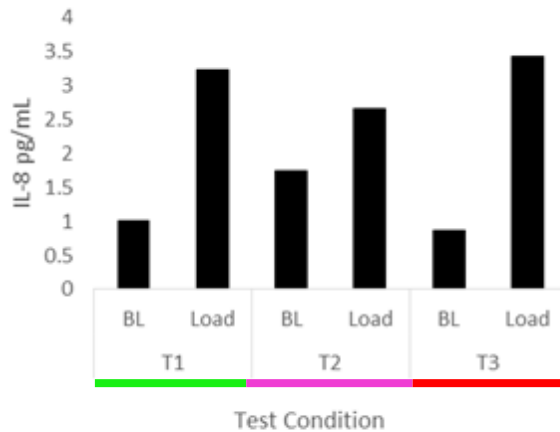


## Ratios of selected Interleukins



# Results – Biomarkers (n=13)

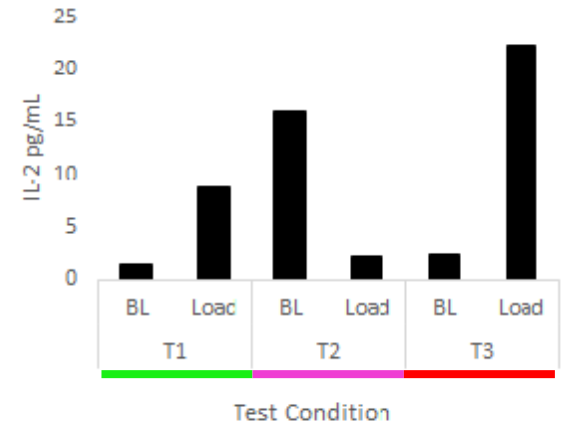
*Worsley et al. 2016 Medical Devices: Evidence and Research*



**A**



**B**



**C**

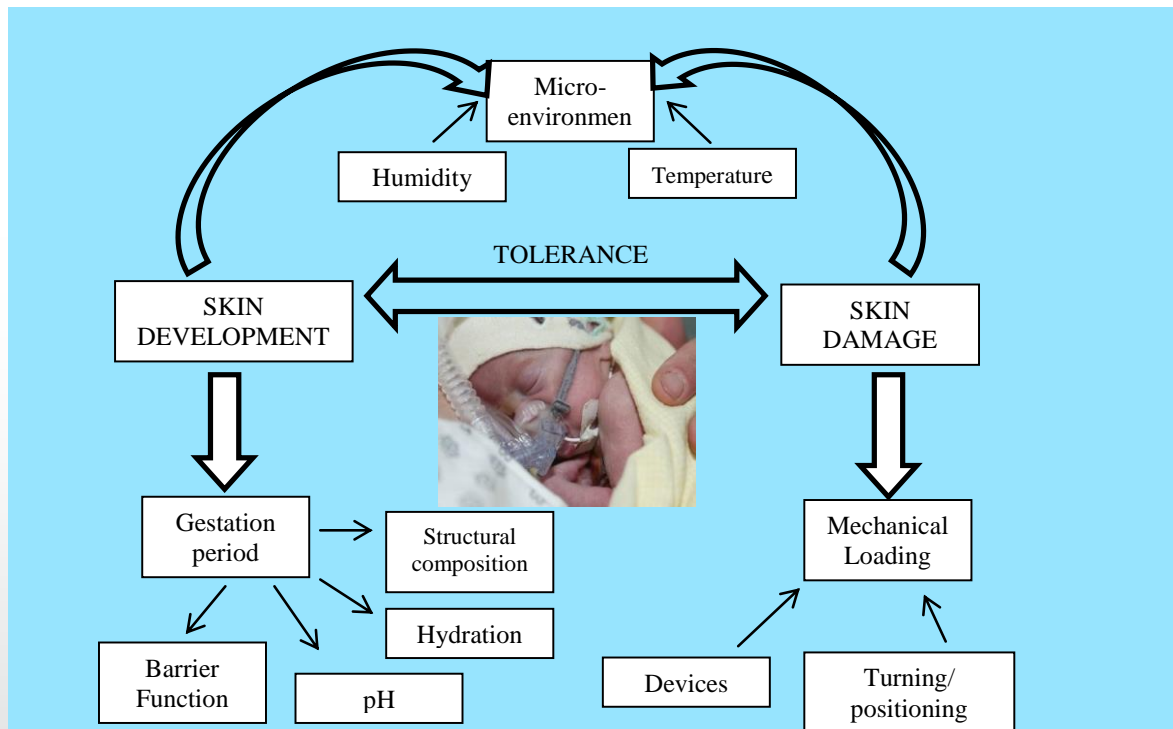
- Inter-subject variation is evident
- Temporal profiles of each cytokine need to be established
- Clinicians should consider the manner in which they apply the respiratory masks and the refractory period of off-loading in assessing accumulative effects on vulnerable skin
- Should use of a “mixed device”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

# Vulnerable Skin Tissues

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 Linköping
- Developing a communication Forum for TVNs on [www.southampton.ac.uk/mdvsn](http://www.southampton.ac.uk/mdvsn)

# HTCs –Consultants to MDVSN<sup>Plus</sup>



Drs Nicola Heron and Sarahjane Jones will

- Provide the interface to ensure new relevant and validated unmet needs are introduced to the MDVSN<sup>Plus</sup> 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

- 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

- 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 UNIVERSITY OF Southampton

**Medical Devices and Vulnerable Skin Network Southampton**  
- Optimising Safety in Design

Bader, D.L., Worsley, P.R., Groot, P.

Skin Health and Contingence Technology Research Group, Faculty of Health Sciences, University of Southampton, Southampton and Florence Nightingale School of Nursing and Midwifery, King's College London, UK

**The Clinical Problem:** There are many clinical situations in which soft tissues are subjected to sustained mechanical loads, typically involving immobile subjects who are bedridden. This can lead to localised compromise of soft tissues, resulting in the development of PUs.

**The Medical Devices and Vulnerable Skin Network (MDVSN)**  
The MDVSN has been created to integrate expertise required to introduce cutting edge technologies to reduce the incidence of chronic wounds arising from interventional medical devices.

Medical Devices have been implicated in over 30% of hospital acquired PUs. Improvements in device design, manufacture and application need to be addressed. *Black et al. (2010)*

Non-healing wounds represent a major Quality of Care issue, with an estimated financial burden of £4 billion pa, representing 3% of NHS expenditure

The MDVSN has developed from established Health Technology Cooperatives: Devices for Dignity (D4D) and Wound Prevention and Treatment.

MDVSN partners are involved in a number of on-going projects collaborating with industry, academics and clinicians. It is envisaged that new projects will develop within the Network and beyond

**Support surface devices**

**Incontinence devices**

**Prophylactic devices for vulnerable individuals e.g. Epidermolysis Bullosa (EB)**

**Medical Devices**

**Timing/positioning**

**Micro-environment**  
Humidity  
Temperature  
TOLERANCE

**SKIN FUNCTION**

**SKIN DAMAGE**

**Age**  
Skin Function  
Skin Hydration  
Skin Composition  
Structure

**MDVSN Dissemination and Outreach**

- Annual sandpit and networking meetings
- Exploratory partner project meetings
- MDVSN website for dissemination of project activities
- Lobbying policy making organisations e.g. the MHRA
- Provide a forum for multidisciplinary research
- Research outputs published in science and medical journals

**EPSRC**  
Engineering and Physical Sciences Research Council

**NHS**  
National Institute for Health Research

[www.southampton.ac.uk/mdvsn](http://www.southampton.ac.uk/mdvsn)

**Medical Devices and Vulnerable Skin Network PLUS:**  
Intelligent Sensing to Promote Self-Management

Bader, D.L., Morgan, S., Sinkus, R., Worsley, P.

Skin Health and Contingence Technology Research Group, Faculty of Health Sciences, University of Southampton, UK  
Faculty of Engineering, The University of Nottingham, UK  
Biomedical Engineering Department, King's College London, UK

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**Medical Devices Related Pressure Ulcers (MDVRPU)** have been implicated in over 33% of hospital acquired PUs. Improvements in device design, manufacture and application need to be addressed. *Black et al. (2010)*

**MDVSN<sup>PLUS</sup>** will target the EPSRC Grand Challenges (below) by improving the design, application and intelligent monitoring of medical devices. Research will focus on maintaining functionality of these devices while adapting to patient variability, the clinical environment and individuals presenting with enhanced susceptibility to skin damage.

**MDVSN<sup>PLUS</sup> partners** are involved in a number of on-going projects collaborating with industry, academics and clinicians. It is envisaged that new projects will develop within the Network

**MDVSN<sup>PLUS</sup> Dissemination and Outreach**

- Sandpit and networking meetings
- £240,000 to fund a series of feasibility projects
- Engage with Tissue Viability Societies
- Lobbying policy making organisations e.g. the MHRA
- Provide a forum for clinical reporting of MDVRPU
- Research outputs published in science and medical journals

**Grand Challenges:**

- G1.1: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.2: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.3: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.4: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.5: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.6: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.7: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.8: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.9: Develop a soft sensor which monitors local PUEC (inflammation)
- G1.10: Develop a soft sensor which monitors local PUEC (inflammation)

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**Medical Devices and Vulnerable Skin Network**

Annual Report: Year One | 2014 - 2015

**Medical device-related pressure ulcers account for over 30% of hospital-acquired pressure ulcers #TVS2016**

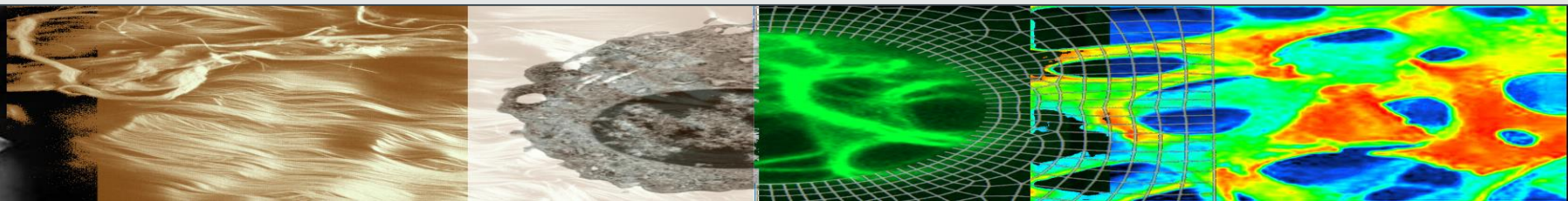
<http://www.southampton.ac.uk/mdvsn/index.page>

# Dissemination – Selected Papers UNIVERSITY OF Southampton

- 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 Biomechanics*, 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 residuum/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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- Colleagues overseas – Prof Amit Gefen, Dr Kath Bogie, Dr Sara Bergstrand, Jillian Swaine
- 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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