

Medical Devices and Vulnerable Skin

UNIVERSITY OF
Southampton

Progress of Activities 2014-15 and

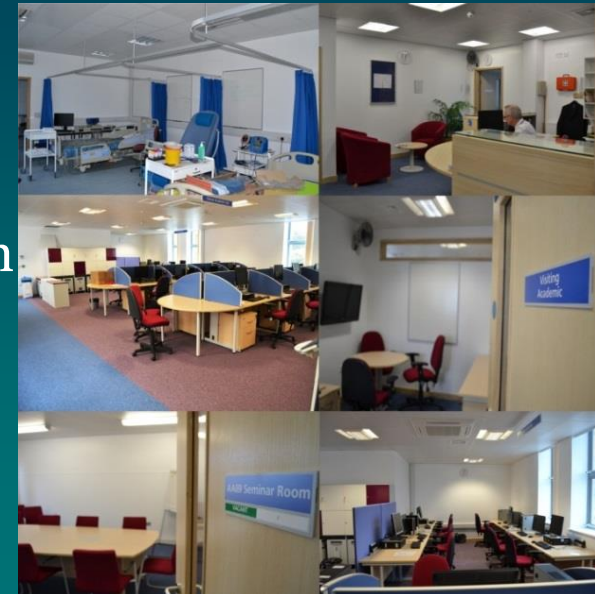
Future opportunities



Dan Bader ¹

Peter Worsley ¹

Patricia Grocott ²



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² Division of Health Policy and Management, King's College London

Sandpit 2 MDVSN, Southampton 8th October 2015

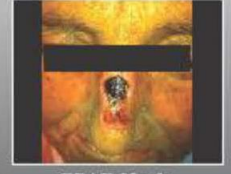
Over 33% of pressure ulcers that occur in hospitals are related to medical devices (MDRPUs) - *(Black et al, 2010)*

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

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 **Best Practices for Prevention of Medical Device-Related Pressure Ulcers**

- Choose the correct size of medical device(s) to fit the individual
- Cushion & protect the skin with dressings in high risk areas (e.g., nasal bridge)
- Remove or move the device daily to assess skin
- Avoid placement of device(s) over sites of prior, or existing pressure ulceration
- Educate staff on correct device use
- Be aware of edema under device(s)
- Confirm that devices are not under the individual

 ET Tube	 Tracheostomy Plate	 Retention Sutures	 NG Tube	 O ₂ Saturation Probe
 Oxygen Tubing	 CPAP Mask	 Bedpan	 Arterial Line	 Wrist Splint

Research Question underpinning MDVS Network

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

Major causes of this disparity:

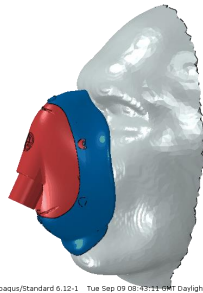
- Devices based on generic designs which do not accommodate the vulnerability of the loaded skin tissues in specific sub-groups
- Materials used in medical devices use traditional polymers which are relatively stiff/rigid and do not match the compliance of the interfacial skin tissues

This must be achieved

- While maintaining the functionality of these devices

Current Activities within MDVSN

Respiratory Masks and Vulnerable Skin



Abaqus/Standard 6.12-1 Tue Sep 08 00:42:11 GMT Daylight Time 2014

Support Surfaces



Prophylactic Devices



Incontinence Devices

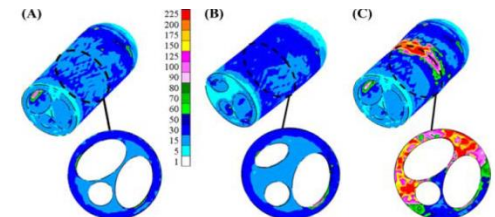


FIGURE 4. Distribution of von Mises stresses in (A) the normal penis model, (B) penis with asymmetrical geometry, and (C) Peyronie's disease. A central cross-section

In-vivo studies – Support Surfaces

Clinical Biomechanics 30 (2015) 166–174



Contents lists available at ScienceDirect

Clinical Biomechanics

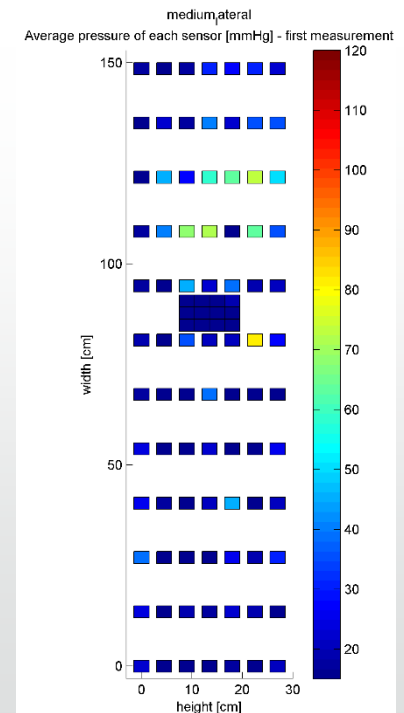
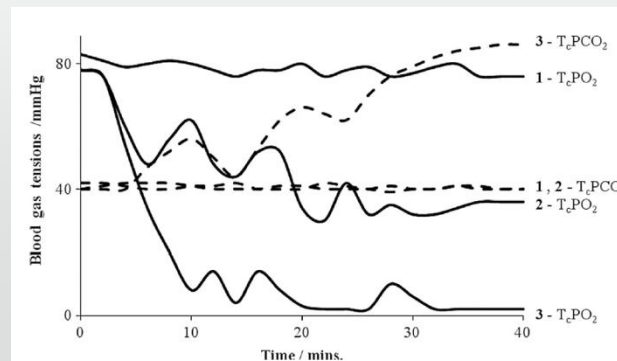
journal homepage: www.elsevier.com/locate/clinbiomech



The physiological response of soft tissue to periodic repositioning as a strategy for pressure ulcer prevention

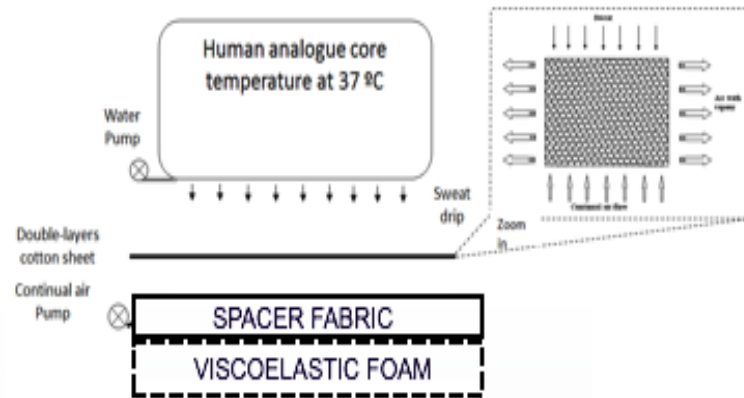


Marjolein Woodhouse ^{a,b}, Peter R. Worsley ^{a,*}, David Voegeli ^a, Lisette Schoonhoven ^{a,c}, Dan L. Bader ^a



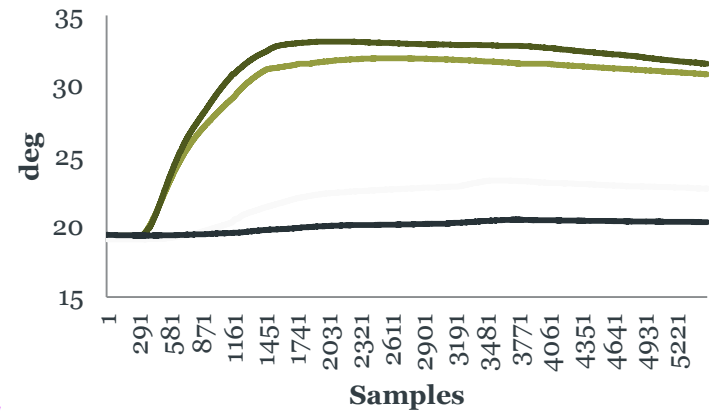
In-vitro studies – Microclimate Management of Support Surfaces

Figloila (2003)

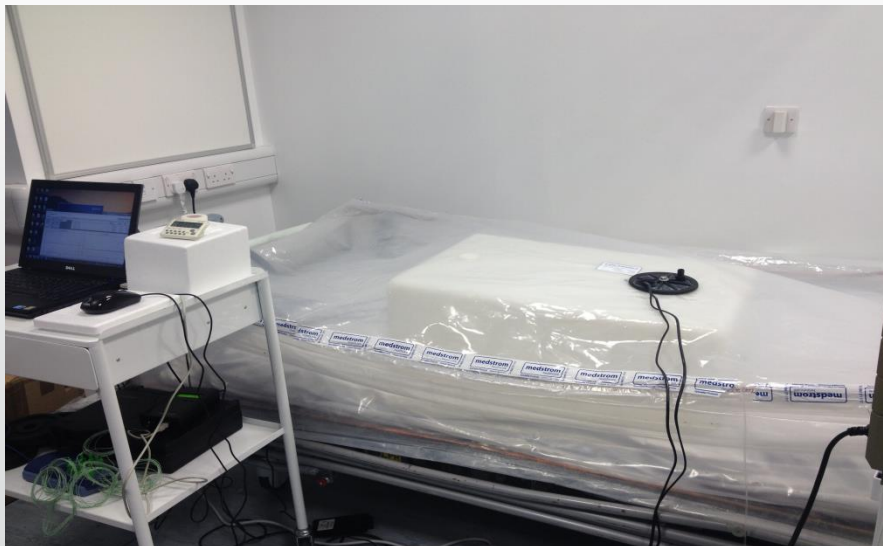
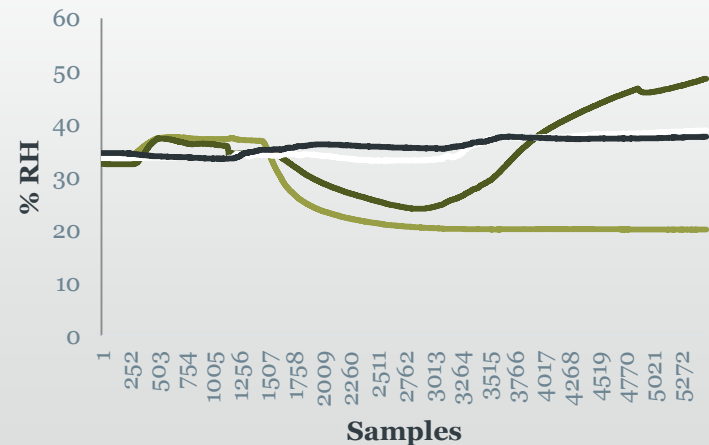


Chai PhD 2011

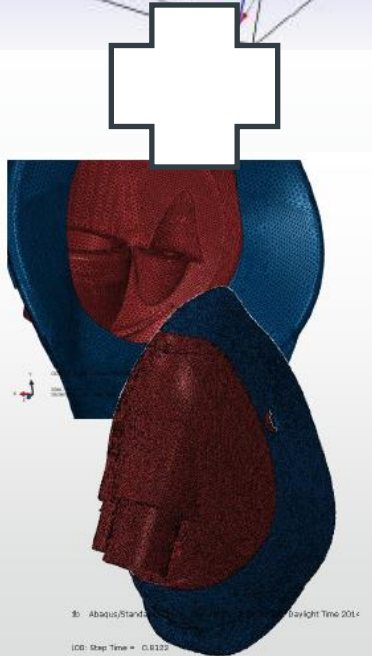
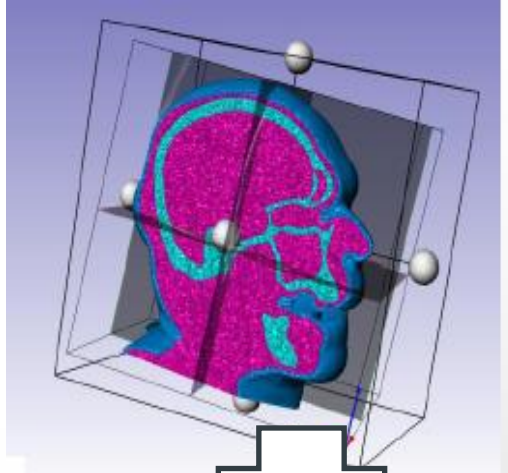
Temperature



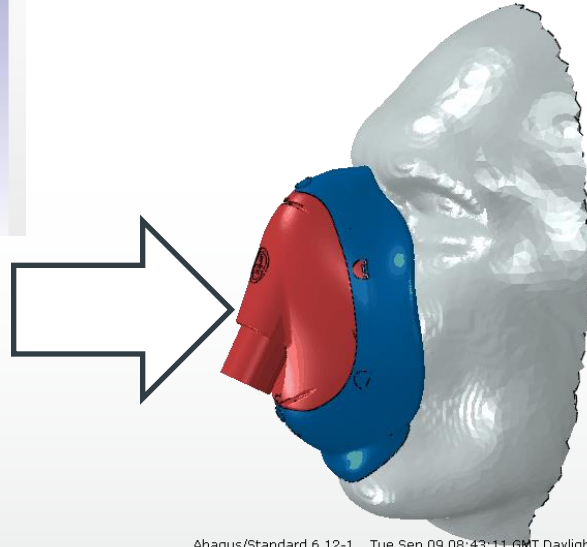
Humidity



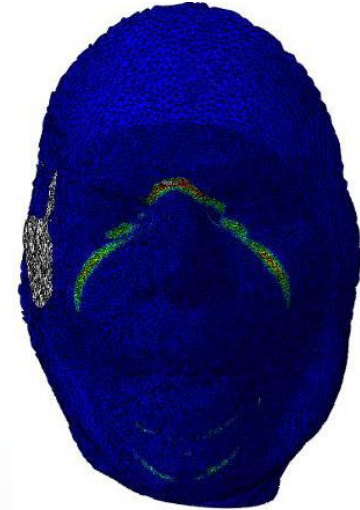
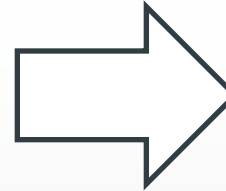
Computational Approach – Respiratory masks



Abaqus/Standard 6.12-1 Tue Sep 09 08:43:11 GMT Daylight Time 2014
JOB: Step Time = 0.8122



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

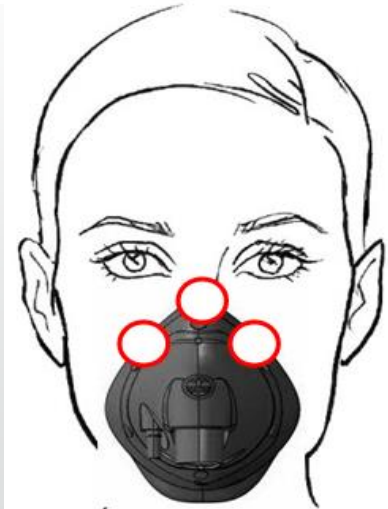


Tentative Discussion

- Initial Analysis for the FaceFit mask
- The model is realistic with respect to the clinical scenario
- Changing the modulus of the mask and skin has a significant effect on the stresses/strains at the patient-support interface
- Experimental data input is needed
- Further research will develop the model for expansive analysis of device design incorporating optimum material properties to accommodate mask position and alignment

Experimental Approach

Tension strap



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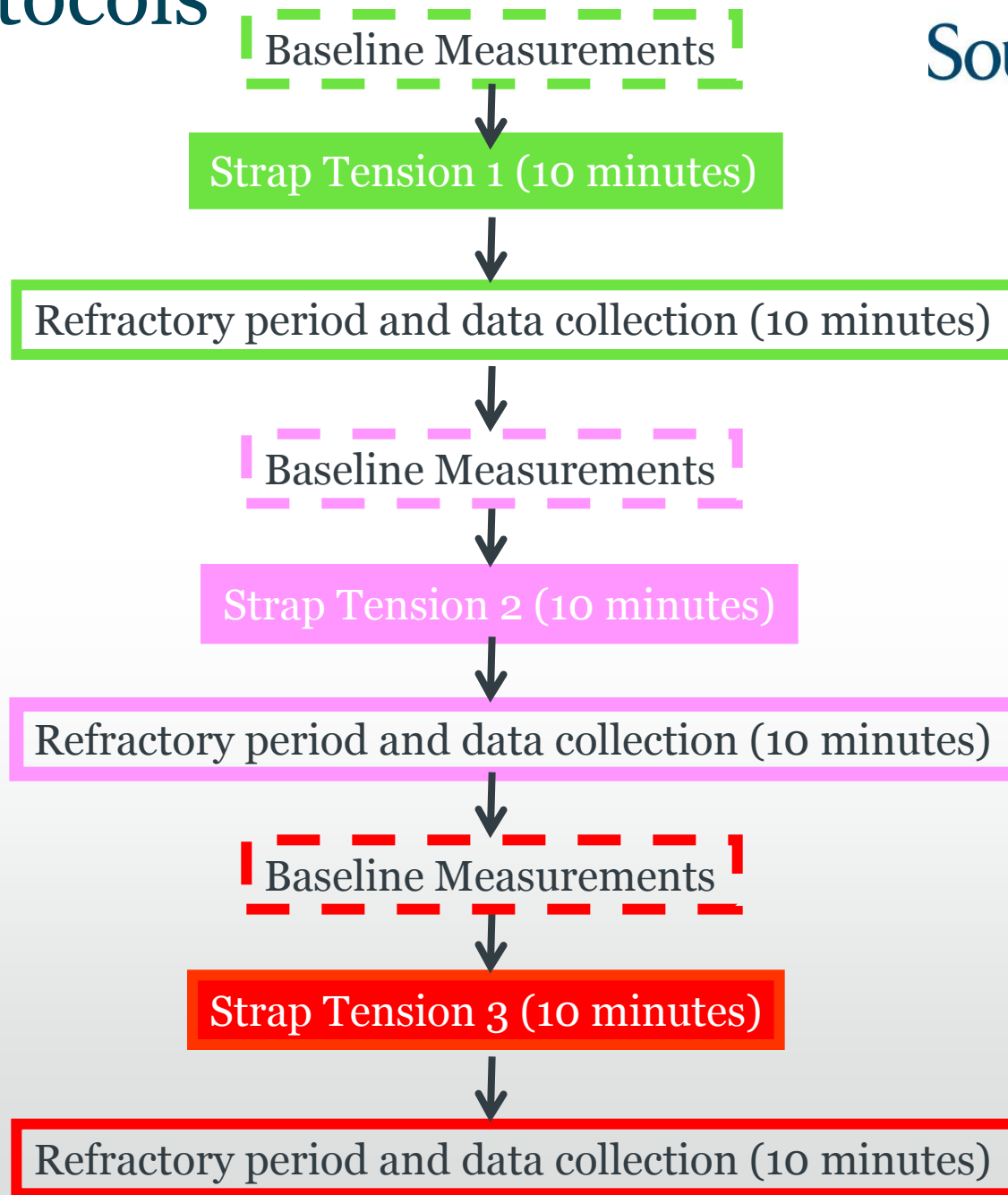


Placement of Sebutape for protein collection and cytokine analysis



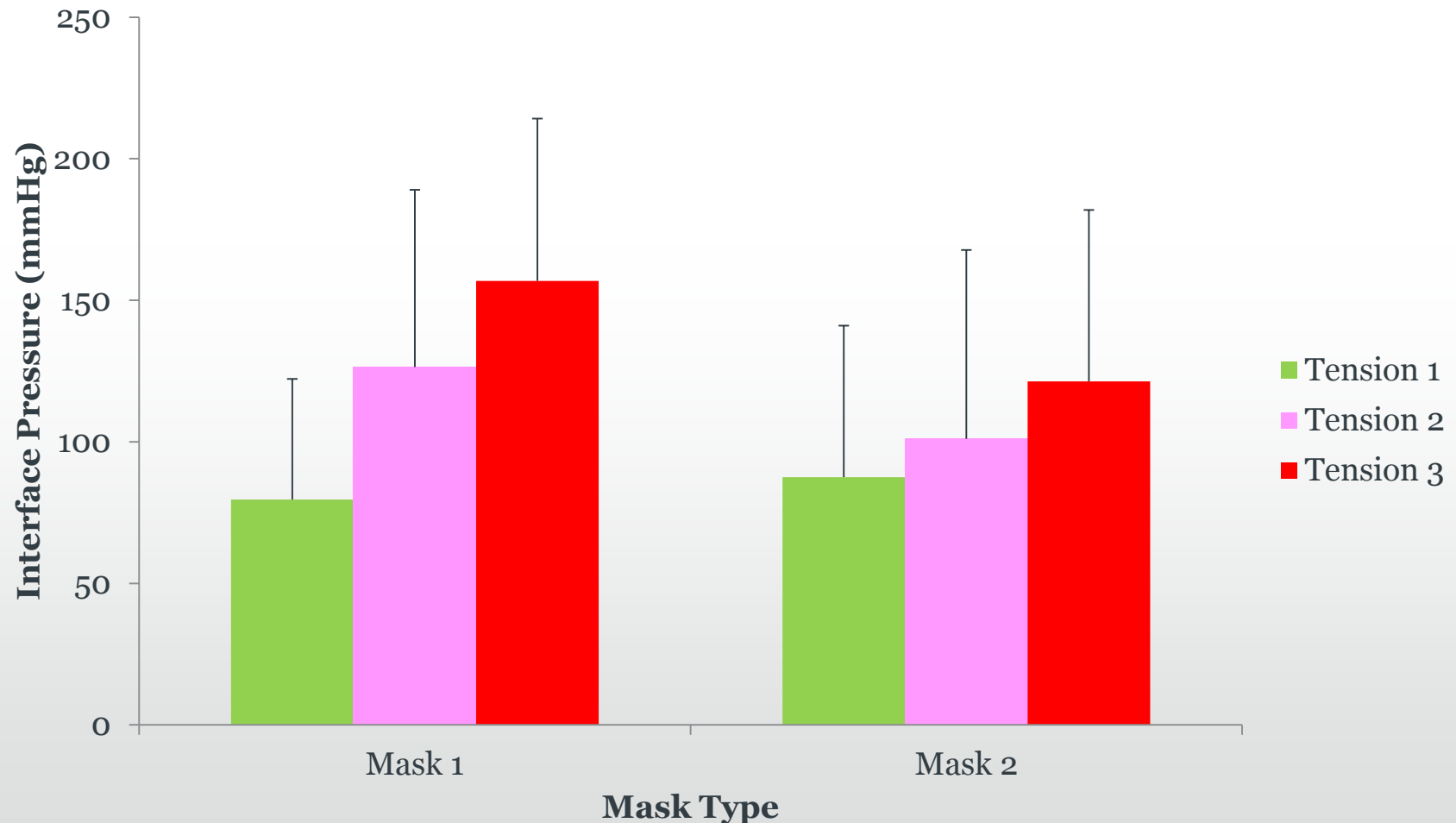
Placement of interface pressure sensors and temperature/humidity sensors prior to location of face mask

Test Protocols

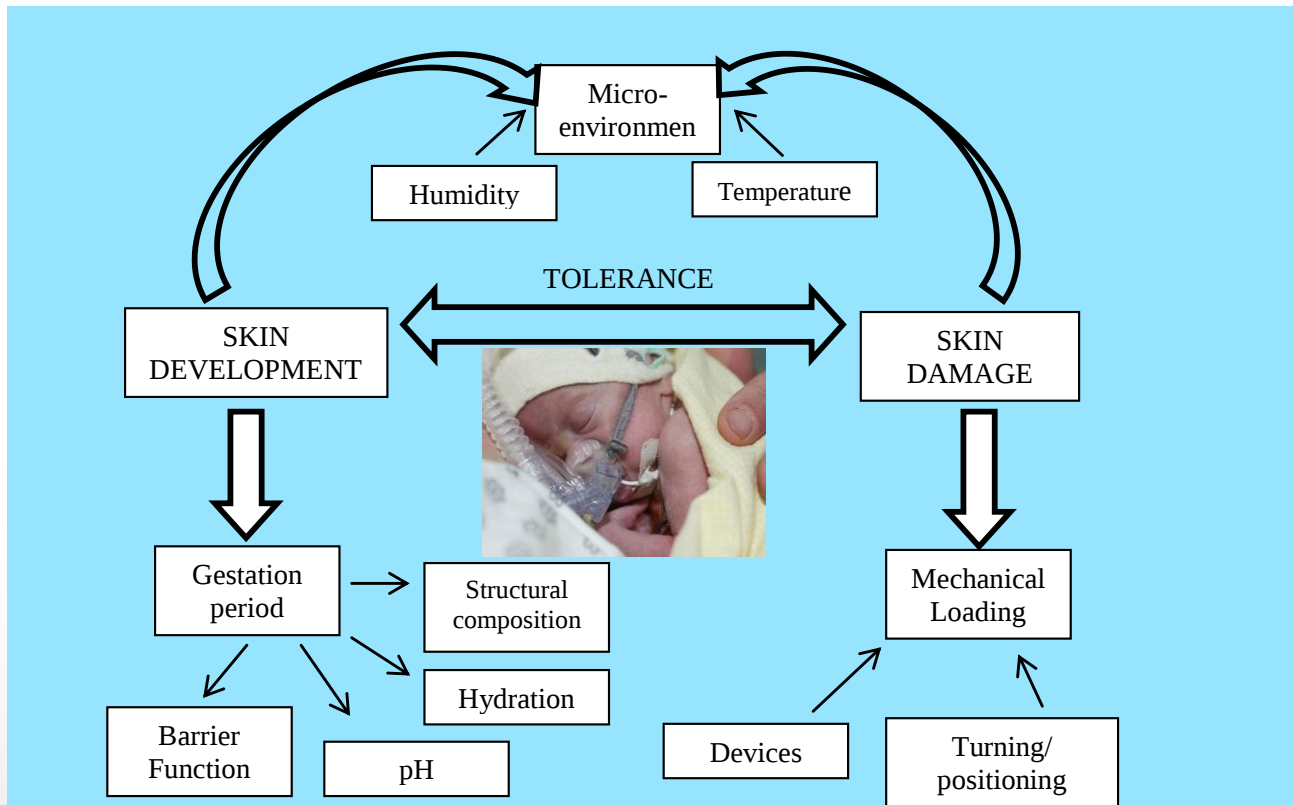


Results – Interface pressures under two masks at three tensions

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



Vulnerable Skin Tissues



NIHR Healthcare Technology – Paediatric Call

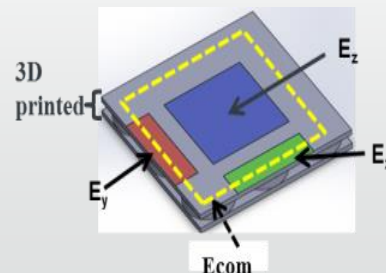
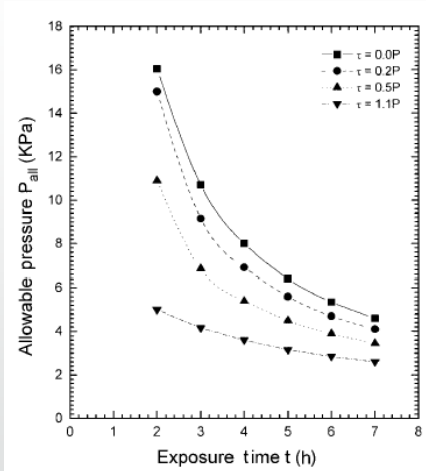
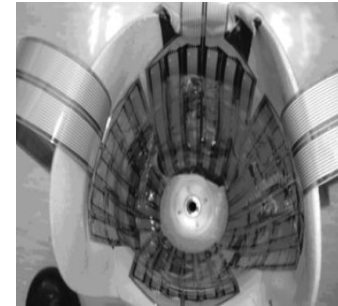
The design of respiratory medical devices to enable effective drug delivery and minimise traumatic damage to vulnerable paediatric tissues.

Prof. Howard Clark (Prof. of Child Health, Southampton), Bader and Worsley

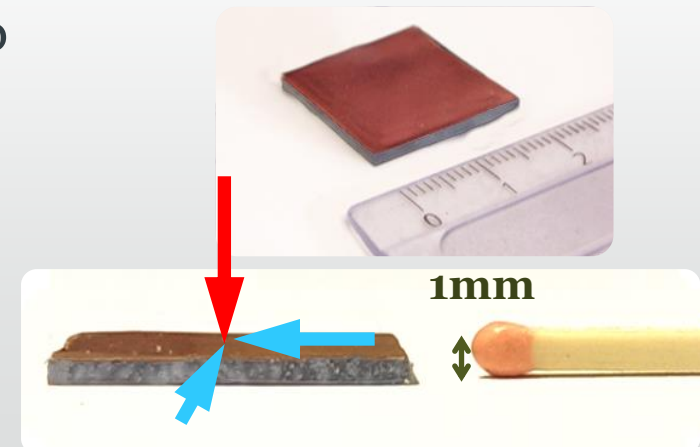
Monitoring Pressure and Shear at the Stump-Socket Interface



- >30% of amputees dissatisfied with their socket fit comfort – average socket lifetime of 1 year
- Pressure and shear can cause stump breakdown
- Tissue tolerance levels are reduced in the presence of shear forces
- Research based sensors have been added to the socket and/or stump



Laszczak et al. 2015



Dissemination Strategy

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

Bader, D.L., Worsley, P.R., Groot, P.
Skin Health and Continence 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.

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.

WOUNDTEC HTC
Wound Prevention and Treatment Health Technology Cooperative

D4D
Devices for Dignity

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

Respiratory devices for Adults and Neonates in Intensive Care

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

SKIN FUNCTION ↔ **SKIN DAMAGE**

Micro-environment (Humidity, Temperature) ↔ **TOLERANCE**

Age (Barrier function, pH, Hydration, Structural composition) ↔ **Mechanical Loading** (Medical Devices, Turning/positioning)

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

Health Sciences: **Southampton**

Medical Devices and Vulnerable Skin Network

Annual Report: Year One | 2014 - 2015

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Medical Devices and Vulnerable Skin - Optimising Safety in Design

Medical Devices and Vulnerable Skin Network

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

Projects
The Medical Devices and Vulnerable Skin Network is involved in a number of projects looking at where medical devices impact on vulnerable skin, collaborating with industry, academics and clinicians.

Latest News

Date	Event
2015/04/15	Health Sciences news roundup
2015/04/09	Health Sciences news roundup
2015/04/02	Health Sciences news roundup

Partners
The Network engages with other partners, in particular our two supporting HTCs to ensure the Research & Treatment and Devices for Dignity.

Biographies
The Network has brought together a multidisciplinary skill sets and expertise, led by the University of Southampton and King's College London.

NHRI Devices for Dignity Healthcare

NHRI Woundtec Healthcare

Website <http://www.southampton.ac.uk/mdvsn/index.page>
Twitter @MDVSNNetwork

Future Opportunities

- More pilot studies are encouraged with existing and new clinical, academic and industrial collaborators
- Improved reporting in the UK. We need to match that of the US Food and Drug Administration (FDA) MAUDE website, where clinicians report incidences of device-related harm
- Increased collaborations with other EPSRC Networks e.g. IMPRESS and NewMind
- Submitted MDVSN *Plus* proposal to EPSRC on 6th October 2015

Acknowledgements

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Industrial Partners
Academics
Clinicians
Funding Bodies

