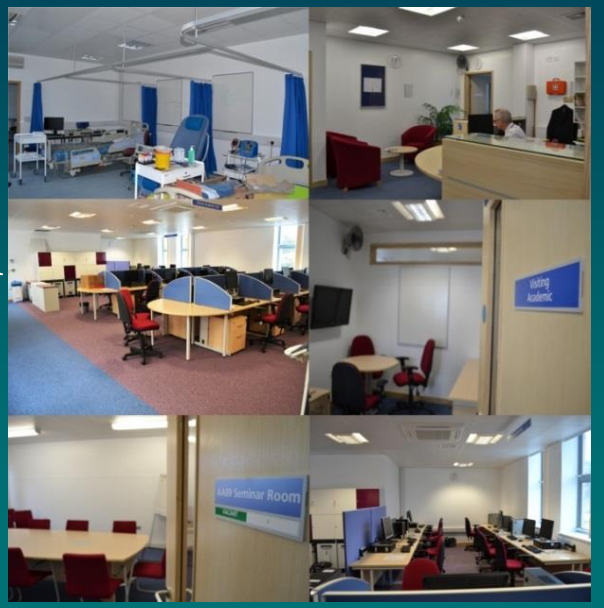
Medical Devices and Vulnerable Skin
Progress of Activities 2014-15 and Future opportunities

Dan Bader [1]

Peter Worsley [1]

Patricia Grocott [2]



[1] Faculty of Health Science, University of Southampton

[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)*

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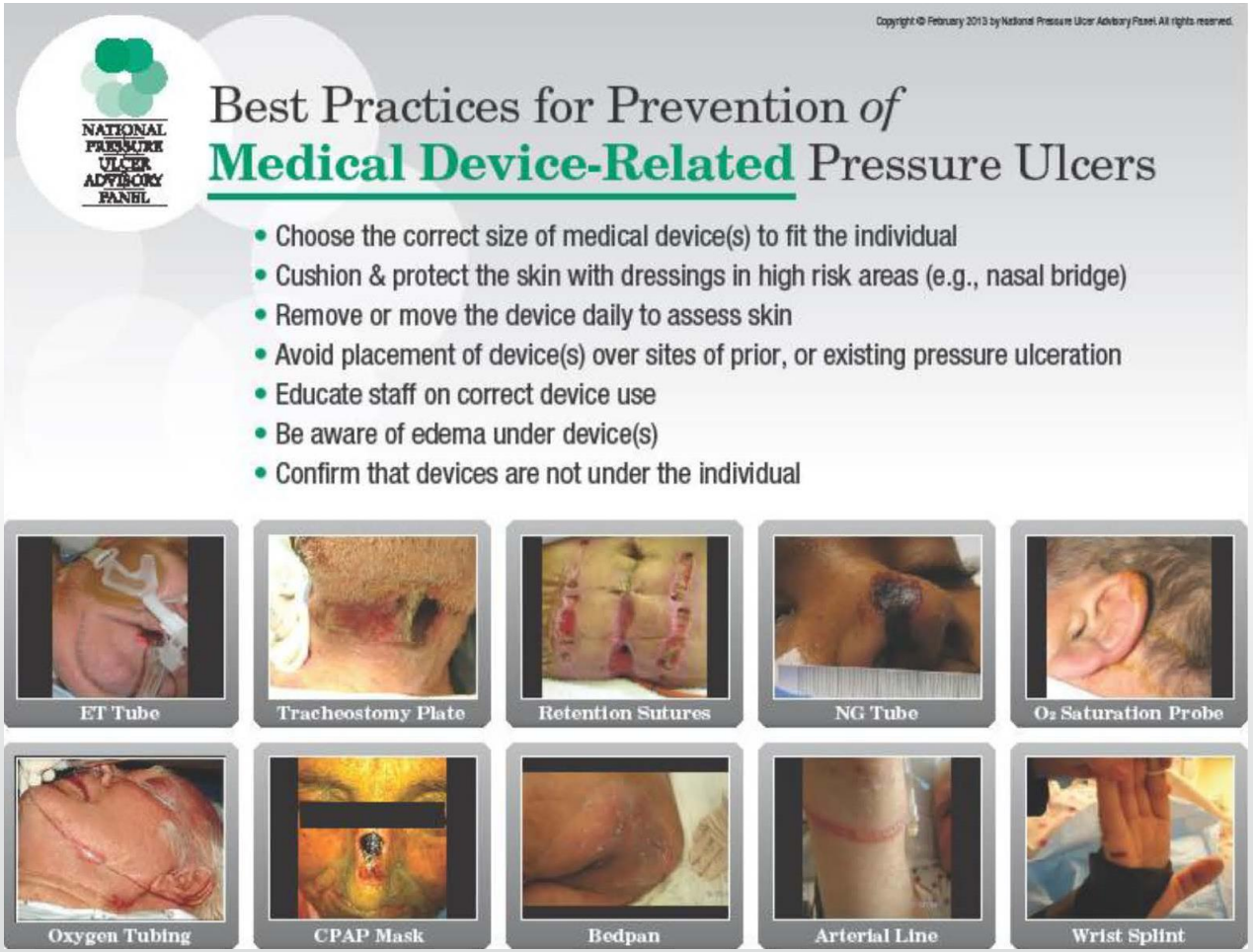
Patients with medical device were 2.4 times more likely to develop a Pressure Ulcer



Research Question underpinning MDVS Network

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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

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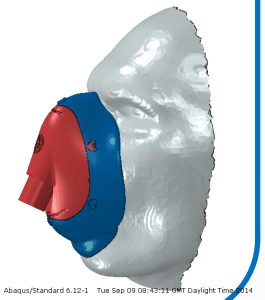
Current Activities within MDVSN

Respiratory Masks and Vulnerable Skin



Support Surfaces

Prophylactic Devices

Incontinence Devices

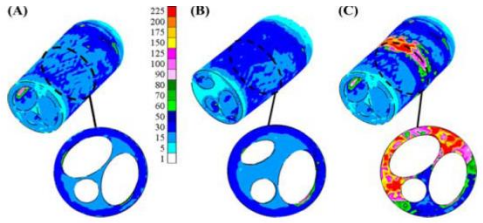


FIGURE 4. Distribution of von Mises stresses in **(A)** the normal penis model, **(B)** penis with asymmetrical geometry, and **(C)** Peyronie's disease. A central cross-section

In-vivo studies – Support Surfaces

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Clinical Biomechanics 30 (2015) 166–174

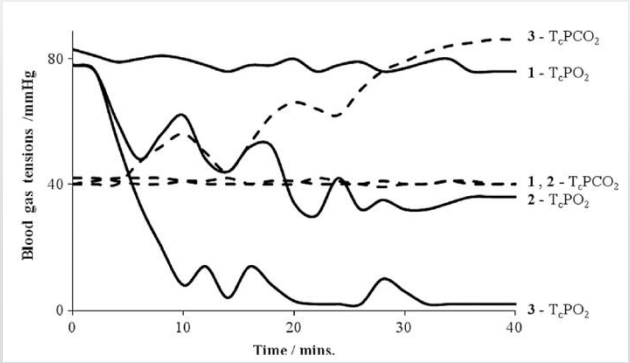
Contents lists available at ScienceDirect

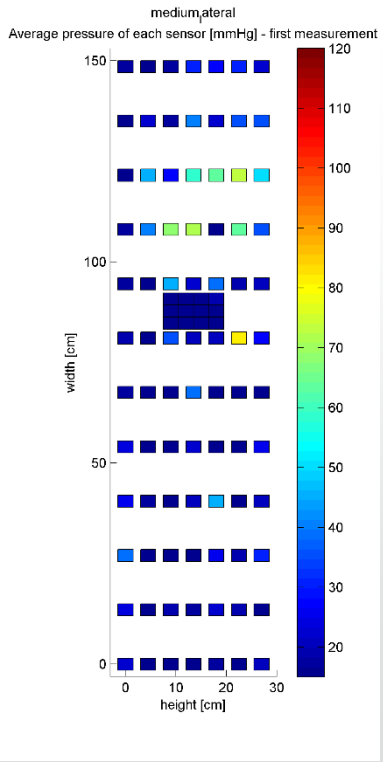
Clinical Biomechanics

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

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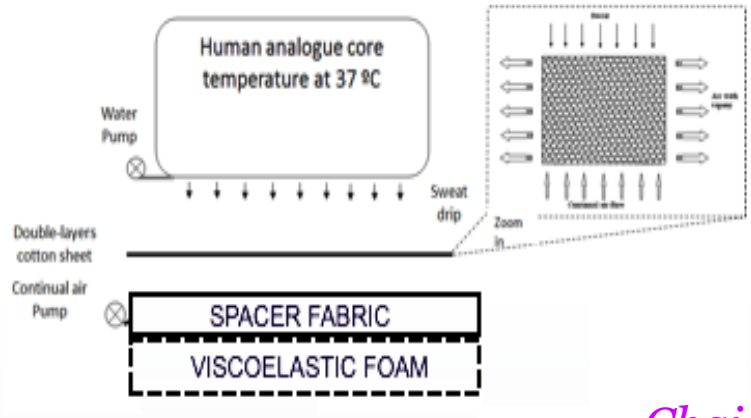
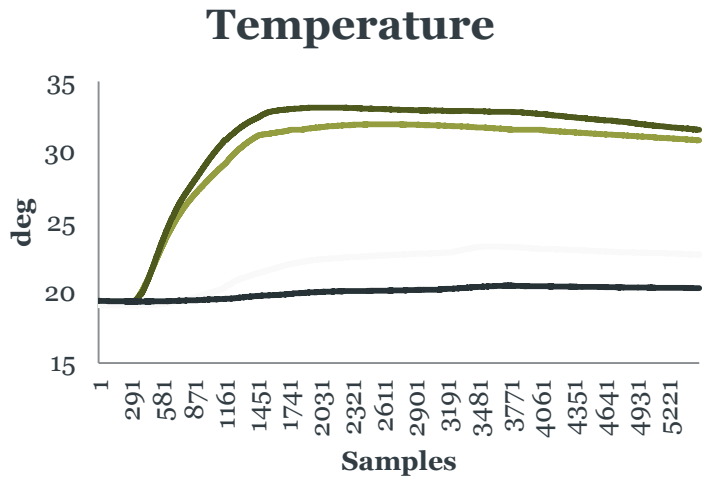
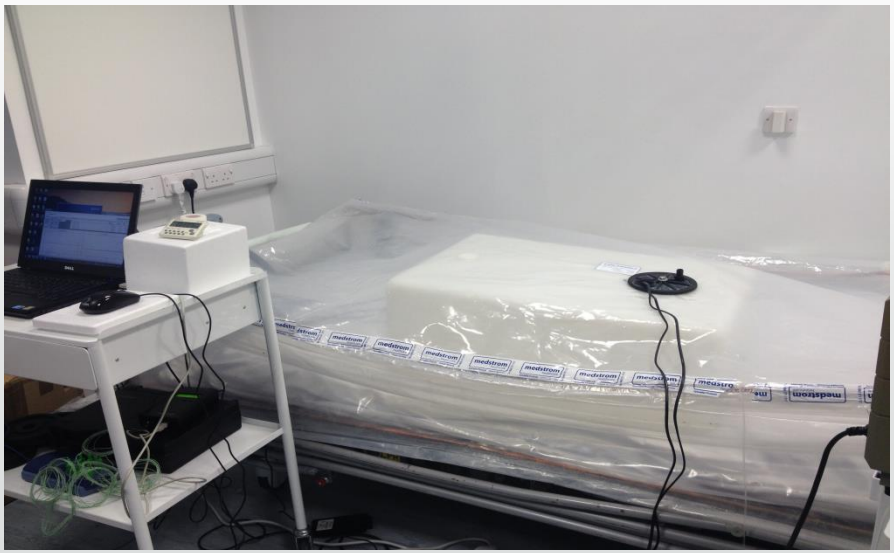
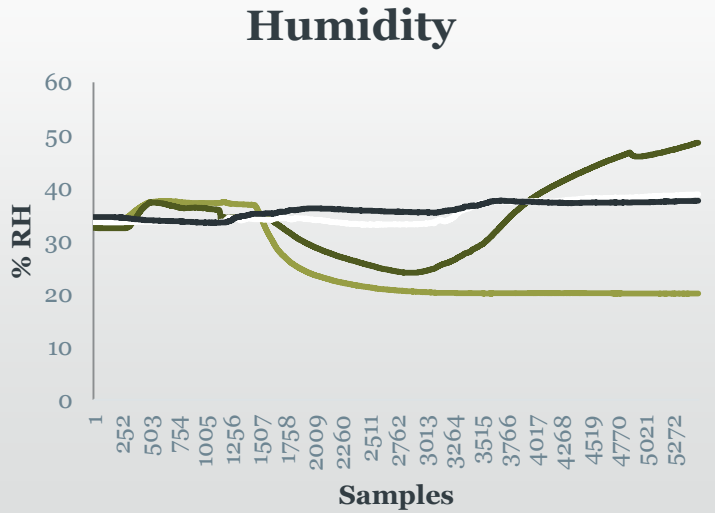
Figloila (2003)





Chai PhD 2011





Computational Approach – Respiratory masks

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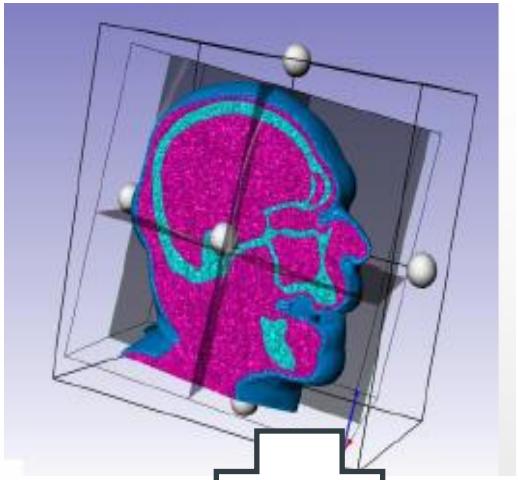

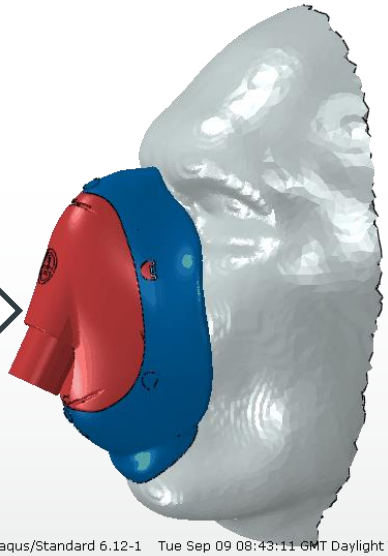

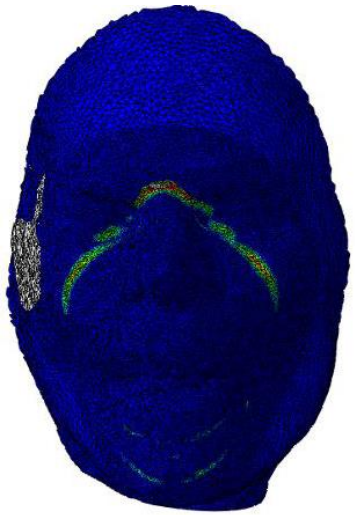

INTERSURGICAL COMPLETE RESPIRATORY SYSTEMS

FRAZER-NASH CONSULTANCY

Tentative Discussion

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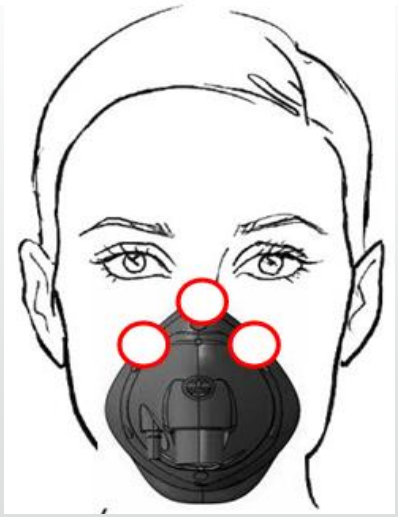
- Initial Analysis for the FaceFit mask
- The model is realistic with respect to the clinical scenario
- Changing the modulus of the mask and skin has a significant effect on the stresses/strains at the patient-support interface
- Experimental data input is needed
- Further research will develop the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

Experimental Approach

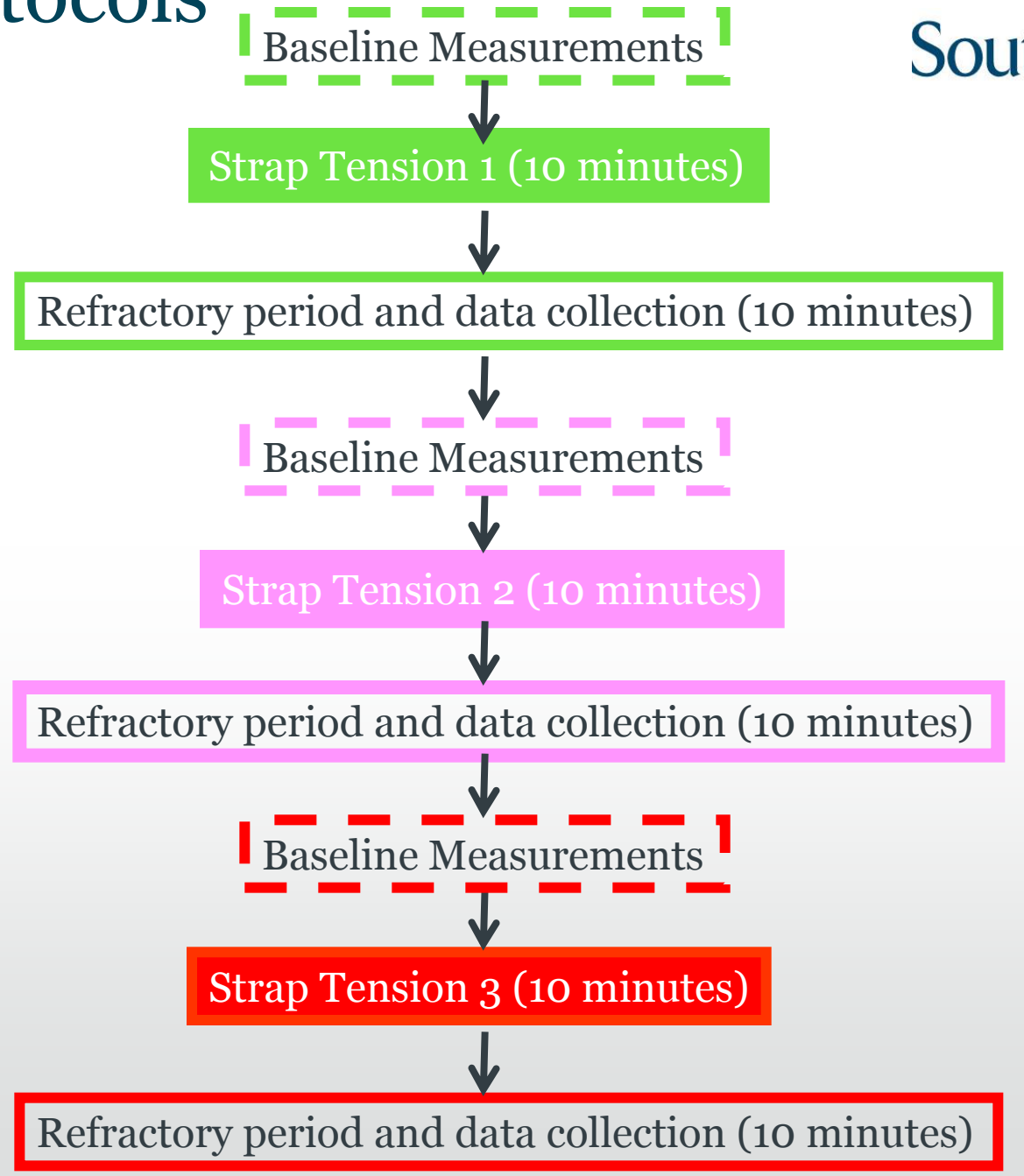
Tension strap



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

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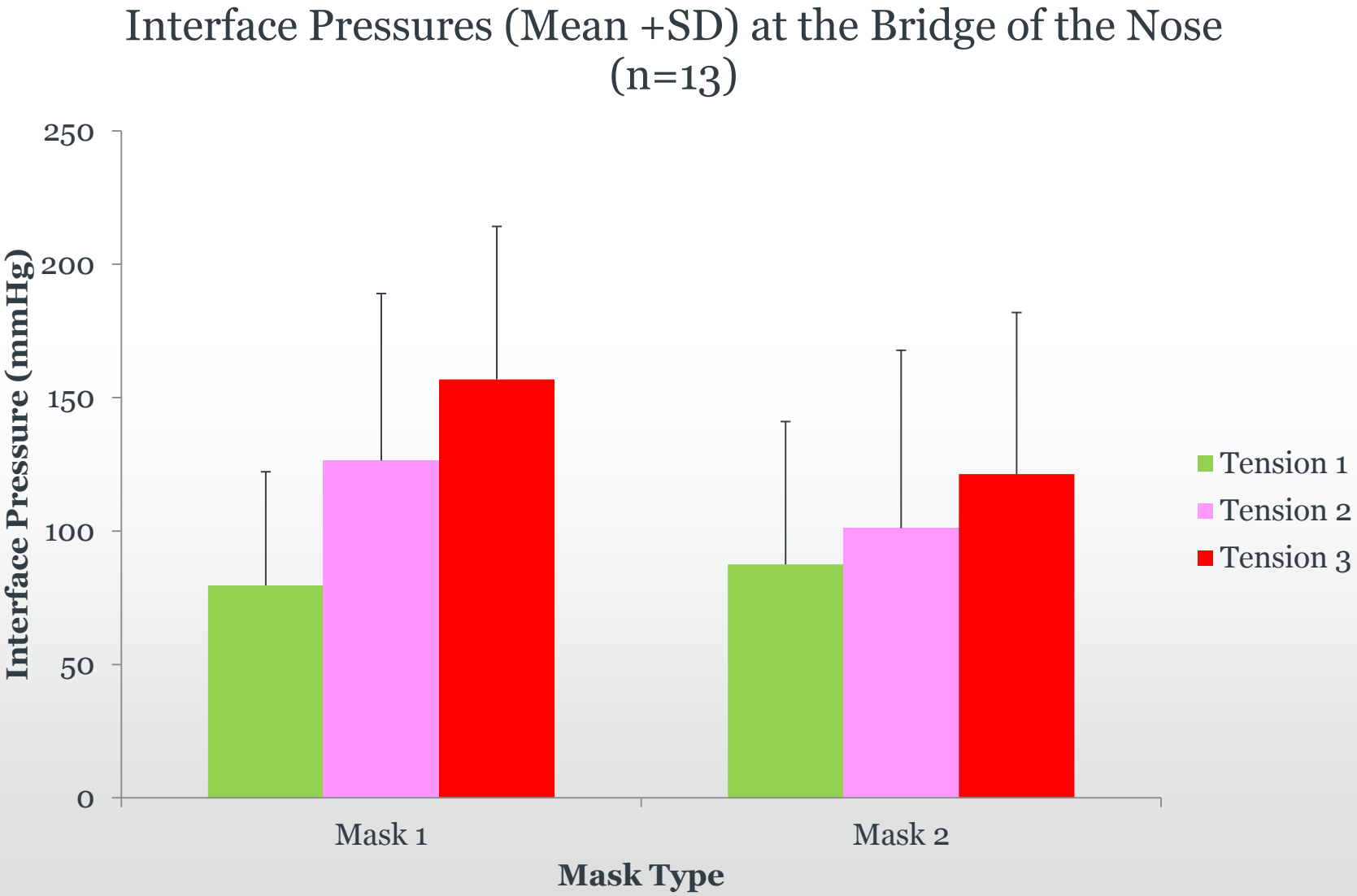
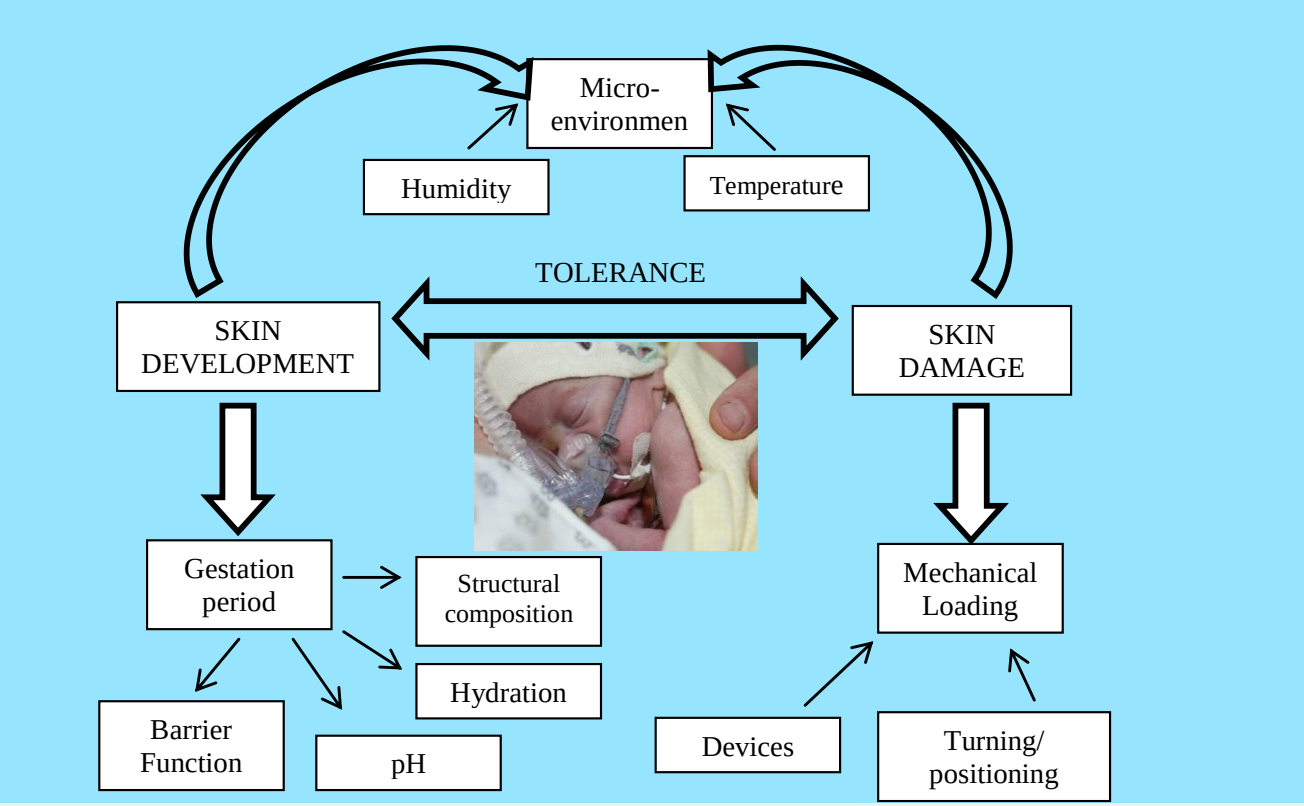


Vulnerable Skin Tissues



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

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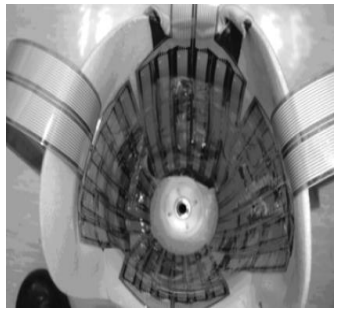
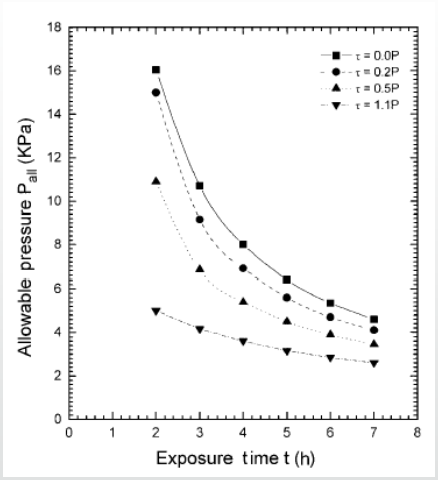
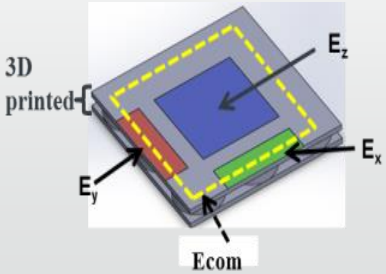
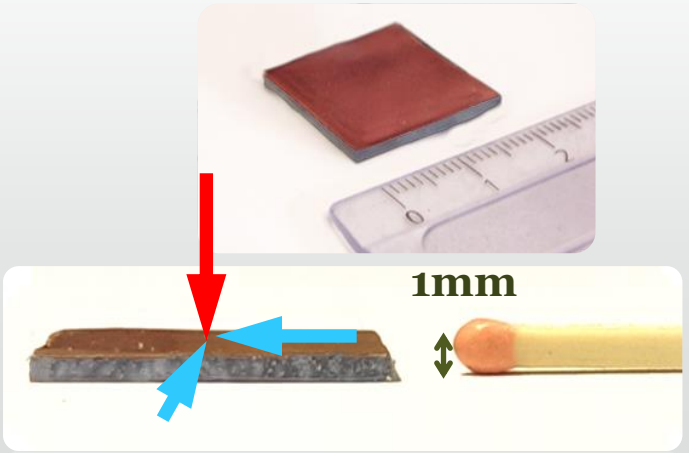
- >30% of amputees dissatisfied with their socket fit comfort – average socket liftetime of 1 year
- Pressure and shear can cause stump breakdown
- Tissue tolerance levels are reduced in the presence of shear forces
-
- Research based sensors have been added to the socket and/or stump







Laszczak et al. 2015



Dissemination Strategy

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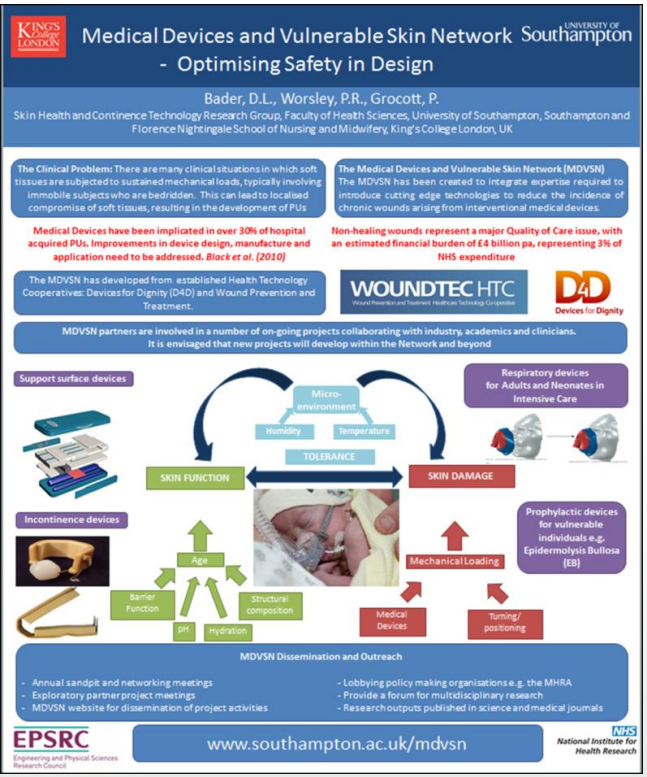

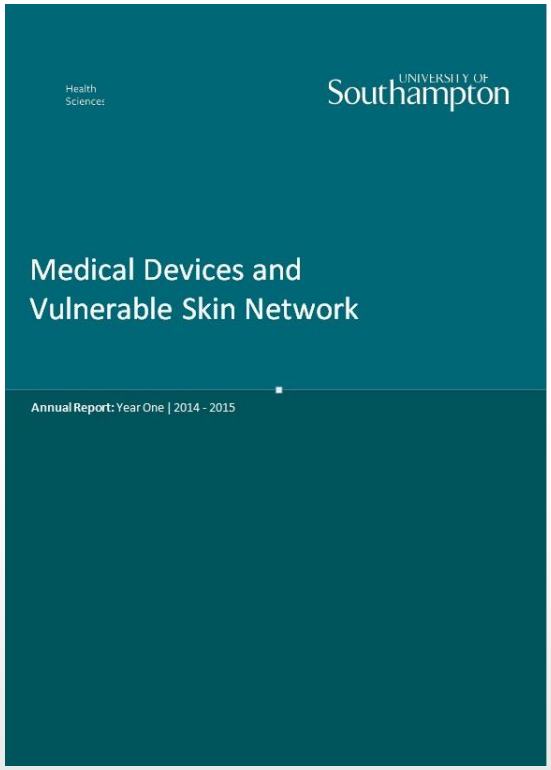

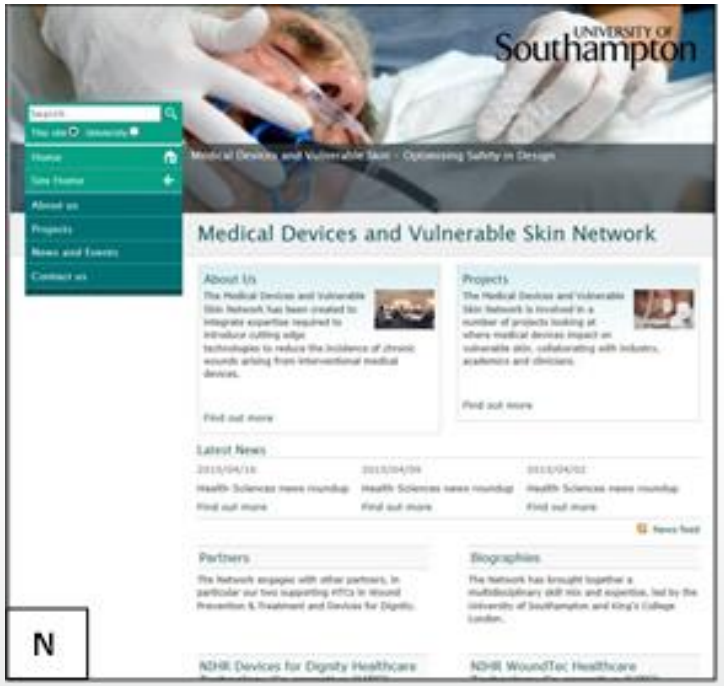

Website http:/www.southampton.ac.uk/mdvsn/index.page
Twitter @MDVSNetwork

Future Opportunities

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- 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

- Industrial Partners
- Academics
- Clinicians
- Funding Bodies