Medical Devices and Vulnerable Skin

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Celebrating our Collaborations
MDVSN^{PLUS}, Southampton 29thMay 2019

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

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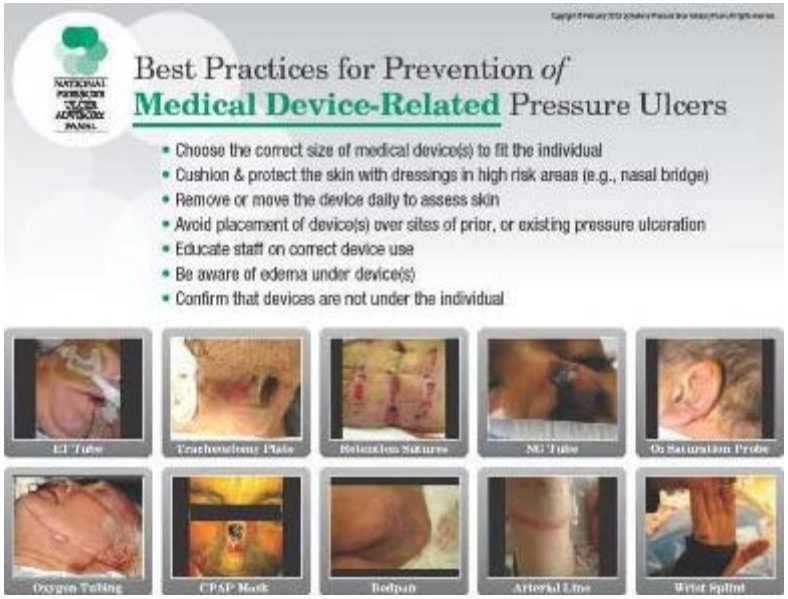
Patients with medical device were 2.4 times more likely to develop a Pressure Ulcer



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

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

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

Twitter @MDVSNetwork

Specific Features of MDRPUs

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- Usual pressure redistribution/relief strategies involving support strategies are not appropriate
- Medical devices are designed to fit in a fixed position
- Limited advice on device application can lead to asymmetric loading
- Patients often require prolonged/continuous useage e.g. respiratory masks in ICUs
- Generic designs do not accommodate individual morphologies and tissue characteristics
- Limited considerations to materials employed at the interface i.e. compliance

Intrinsic Risk Factors
Concept of Tissue Tolerance

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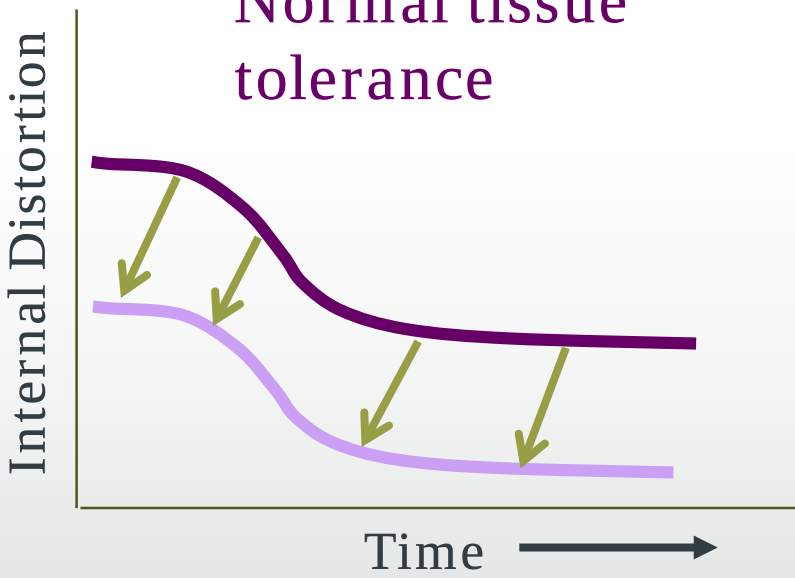
Subjects have limited mobility

Subjects have impaired sensitivity

Tissues are more vulnerable than normal to pressure-induced damage

Unconditioned tissues

- Location – head/neck/face (70%)
- Ageing/immaturity, co-morbidities
- Atrophy, dehydration, lack of muscle tone



Gefen 2006

Combined experimental and computational approach

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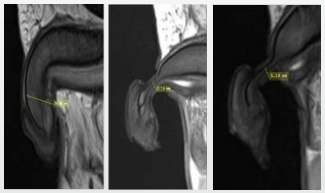
Human Experiments



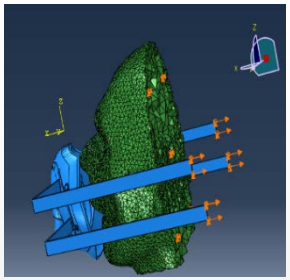
Pain
Skin irritation
MDRPUs

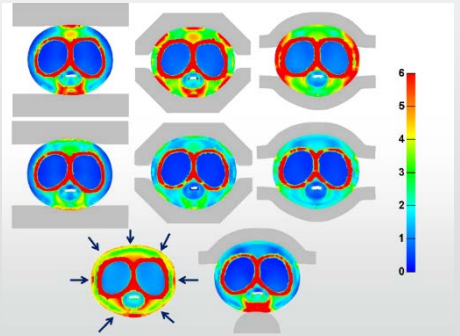
External mechanical loading for prolonged periods

Internal local tissue deformations

Local soft tissue damage

Finite element modelling





Medical Devices and Vulnerable Skin Network and Network^{PLUS} (MDVSN^{PLUS})

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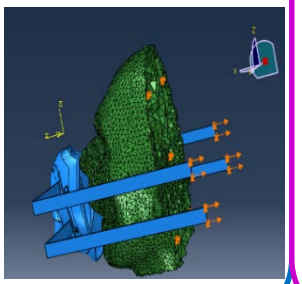
Respiratory Masks

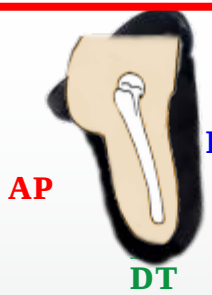




Support Surfaces



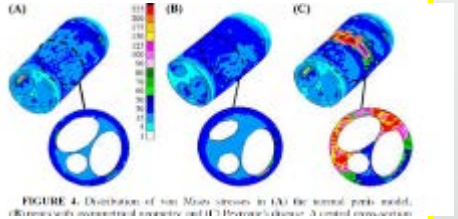
Orthotics and Prosthetics



Prophylactic Devices

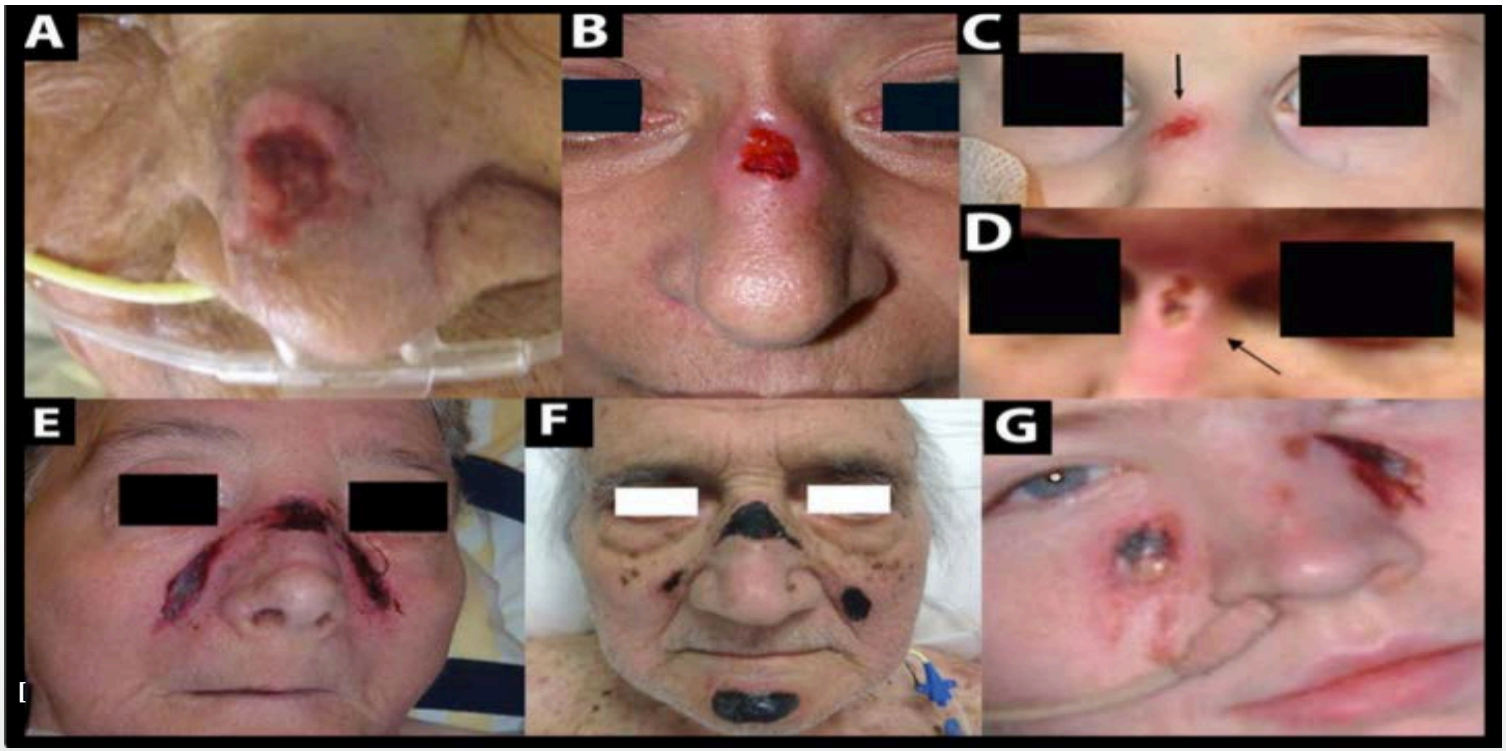

Incontinence Devices





How can research help prevent MDRPUs?

Example 1 : 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

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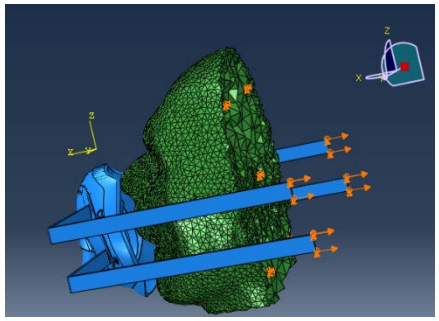
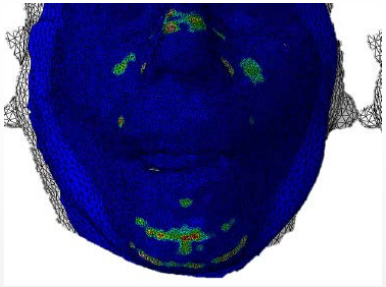
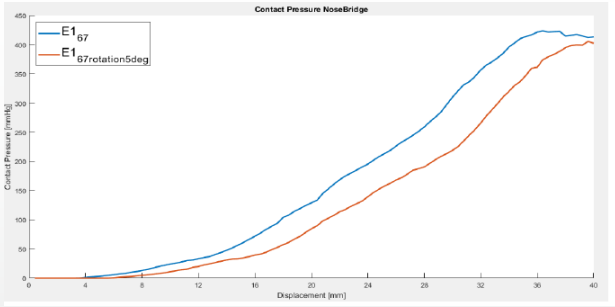


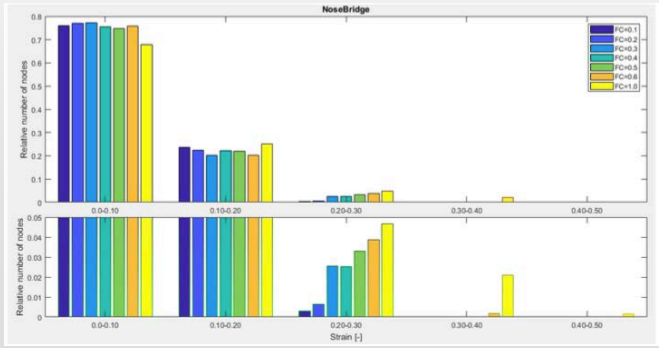
- A platform to examine device design, material and application – identify critical design features
- Boundary conditions provided through experiments
- Run sensitivity analyses to assess variables



- Mask orientation and rotation has a significant effect on contact pressures

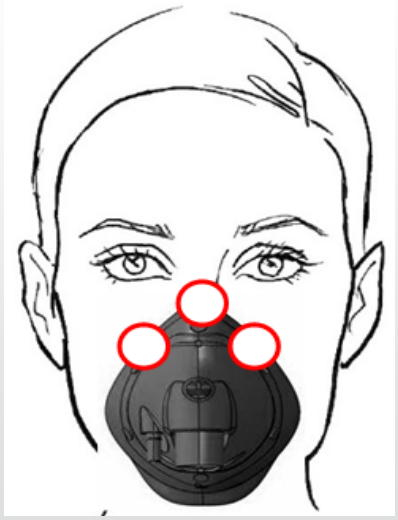


- Increased stiffness of the silicone resulted in larger strains over bridge of nose



Experimental Approach

Tension strap



Placement of Sebutape for protein collection and cytokine analysis e.g. IL-1α and IL-RA

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

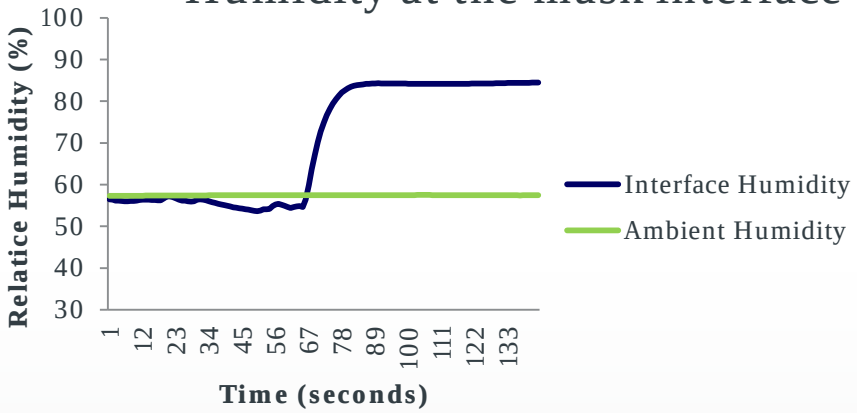
Comfort scores (VAS) and device functionality was also assessed

Results

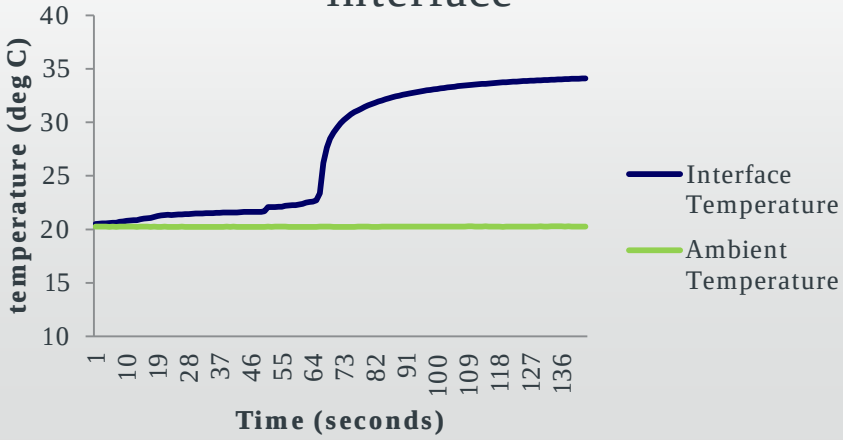
Pressures and micro- climate at the skin-mask interface

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

Humidity at the mask interface



Temperature at the mask interface



Results : Biomarkers (n=13)

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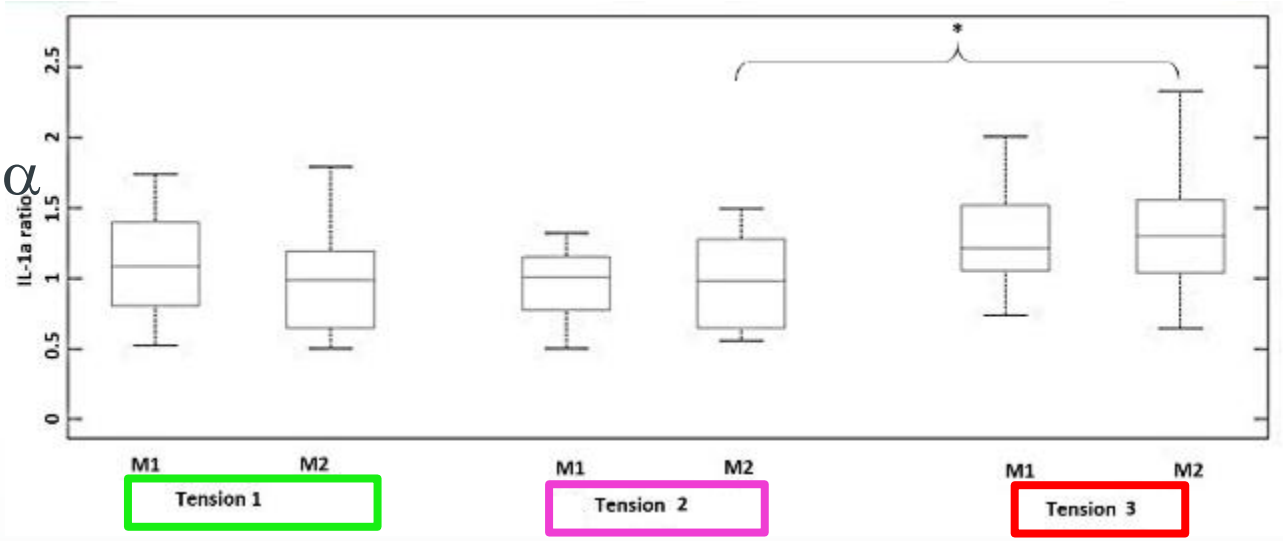
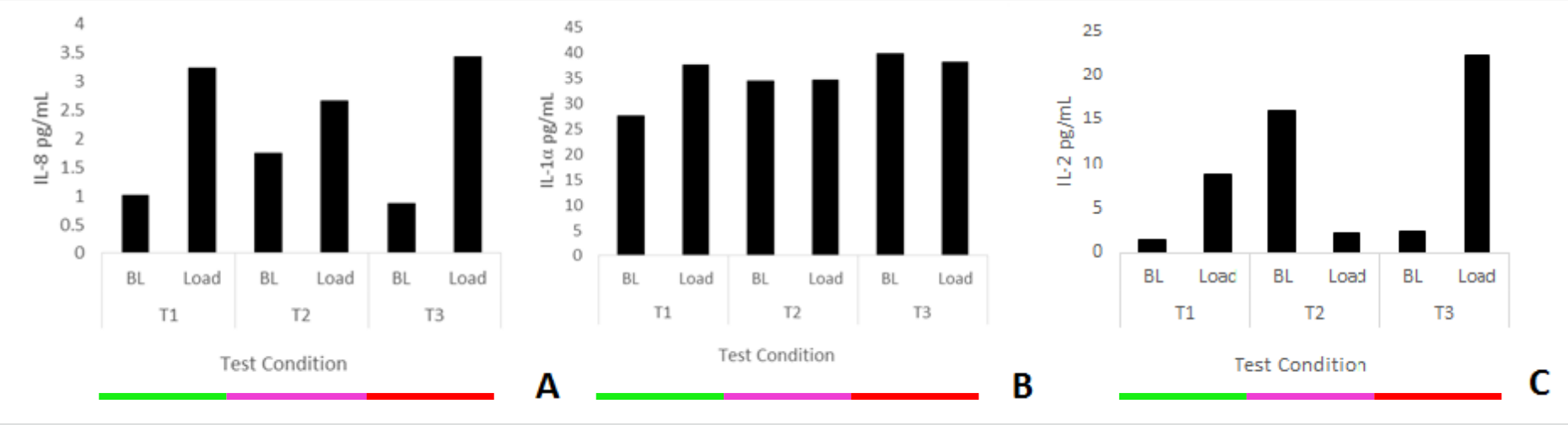
Worsley et al. 2016 Medical Devices:Evidence and Research

Interleukin IL-1 α



Individual Variability



Discussion

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- Inter-subject variation is evident – concept of cluster analysis
- Temporal profiles of a range of cytokines need to be established
- Clinicians should consider
  - the manner in which they apply the medical device
  - the refractory period for off-loading when assessing the accumulative effects on vulnerable skin
- Should a “mixed device” approach be considered ?

How can research help prevent MDRPUs?

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Example 2 : Penile Clamp Designs

- Current designs look like they belong in the Dark Ages
- 10-15% of men will have intractable urinary incontinence following prostatectomy
  - Anecdotal evidence suggests >40% at 12 months
- Penile Clamps offer a discreet and very secure, effective solution to containing urine
- BUT the clamps can cause discomfort, pain and MDRPUs

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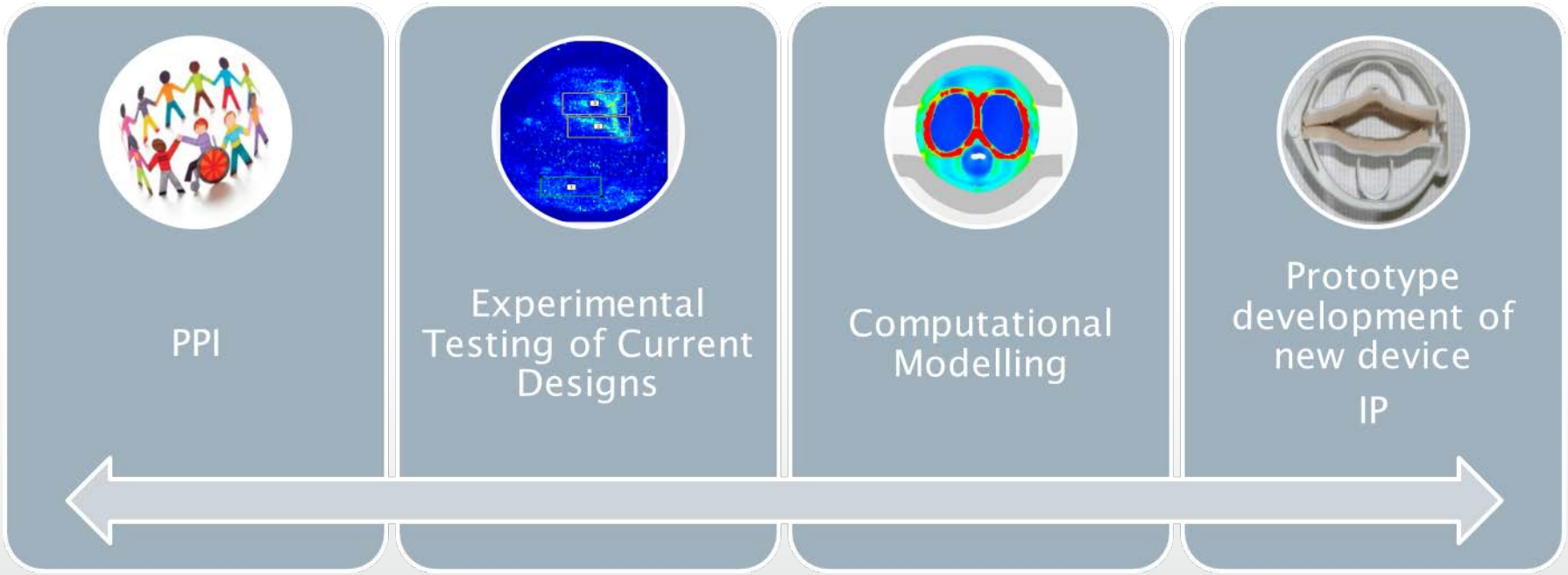
Research Methods



Evaluation of current designs

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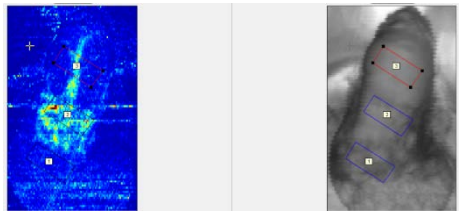
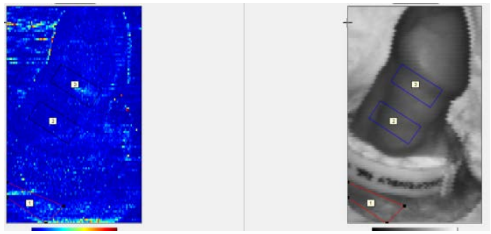
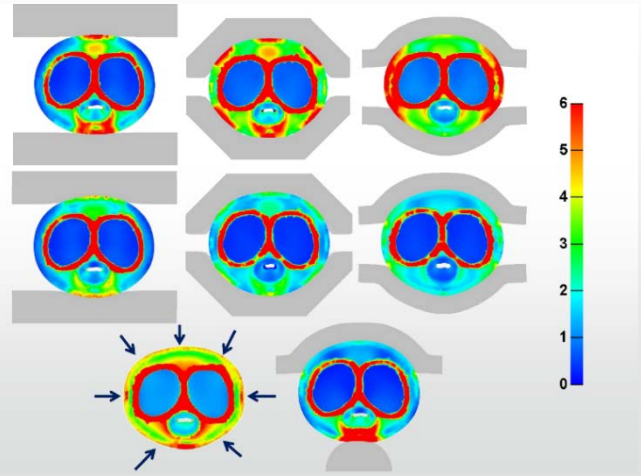
- Patient reported pain and discomfort with some device designs, others were ineffective
- Experimental data using current designs revealed:
  - high interface pressures,
  - ischemia in the penis
  - inflammatory response
- Computational modelling revealed the effects of design on tissue strains

Before clamp application



During clamp application



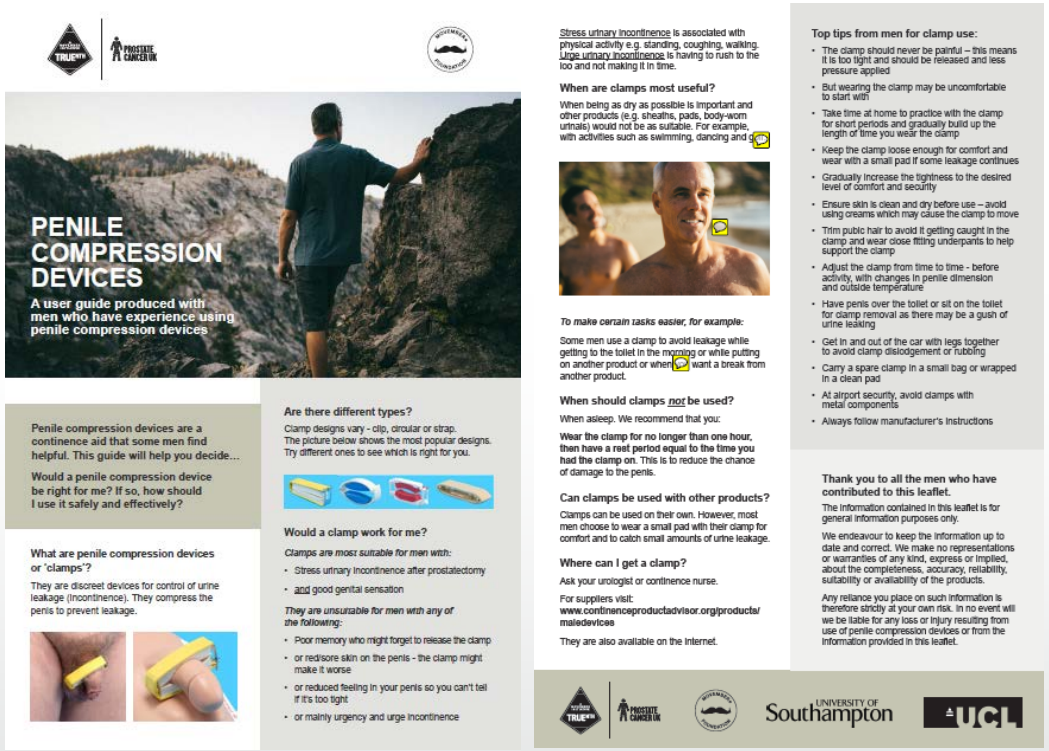


Lemmens et al. (2019) Medical Devices (in press)
Levy et al. (2018). Neurourol Urodyn. 36(6):1645-1650

Evidence based device design and clinical guidelines

New prototype has been developed and tested

- Lower peak pressures
- Higher perfusion rate
- Equivalent clinical effectiveness



- Patent - WO 2019/063994 AI
- Created a new clinical guideline for application

Interactions with Networks

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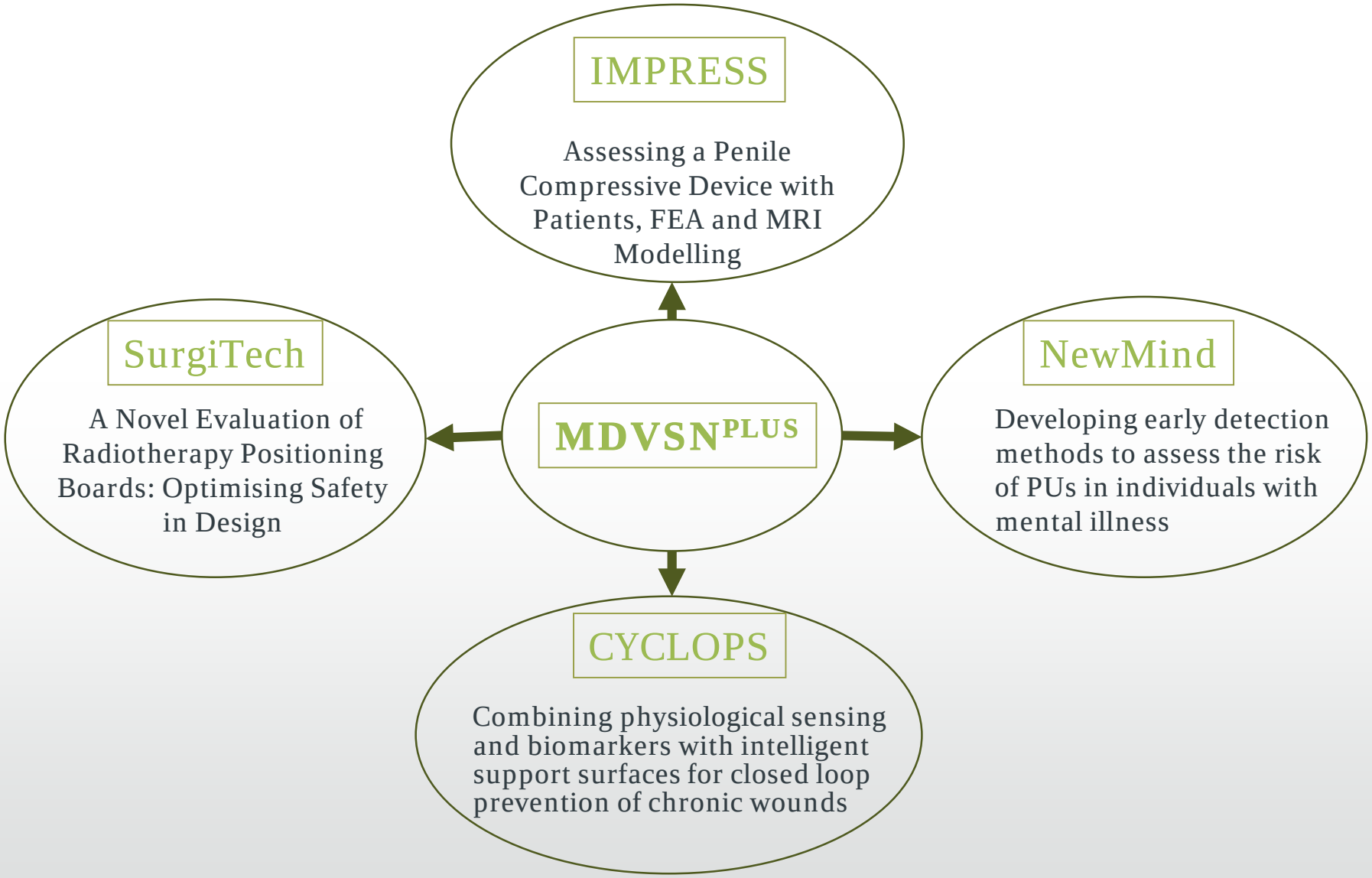

Other Funded Projects

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- EPSRC CASE PhD Studentship with SUMED "Identifying Robust Algorithms to Monitor Patient Mobility in the Community: an indicator of developing pressure ulcers" – 10/2016 (36 months)
- NIHR Healthcare Technology – Paediatric Call "*The design of respiratory medical devices to enable effective drug delivery and minimise traumatic damage to vulnerable paediatric tissues*" – 11/2015 (24 months)
- EPSRC/NIHR Global Challenges Research Fund (GCRF) "*A Step Change in LMIC Prosthetics Provision through CAD, actimetry and database technologies*" – 02/2018 (36 Months)
- Health Foundation Scaling Up Fund "*PROMISE - Pressure reduction through continuous monitoring in community settings: reducing and preventing avoidable and unavoidable PUs* "–11/2017 (36 Months)
- UK Knowledge Transfer Partnership (KTP 11095) with Blatchford "*Sensor Smart Liner*"–10/2018 (18 months)
- EU Innovative Training Networks (ITN) Call: H2020-MSCA-ITN-2018 with five European academic partners and 3 industrial partners "*STINTS - Skin Tissue Integrity under Shear*" - 01/2019 (48 months)

Exemplars of industrial impact

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- Our research has led to changes in default settings and clinical guidance for use in commercial systems (Dolphin Fluid Immersion, Joerns, US)– *Worsley et al. 2017*

- Microclimate control - Our experimental/computational approach has been used to evaluate the effectiveness of various commercial systems involving spacer fabrics – *Worsley & Bader, 2019*

- Sensing technologies – Research has provided evidence to support the CE marking of new sensing device (Sumitomo Riko, Japan) – *Internal report*

- Long-term pressure mapping (Sumed Ltd, UK and Xsensor, Canada) – we are developing predictive algorithms based on machine learning to identify features of posture and mobility, identified with risk - *Caggiari et al. 2019*

- Continence technologies – Our research has provided evidence of the performance of moisture-absorbing materials in devices (ESSITY, Sweden)– *Internal report*

Summary

Scientific approaches

- Lab-based and patient based testing - early detection strategies
- Computational modelling to identify critical design features

Engagement with appropriate community

- Adopt a multidisciplinary team approach
- Simple reporting strategies of MDRPUs with specific devices implicated e.g. Yellow Card
- Inform national bodies e.g. UK Medicines and Healthcare Products Regulatory Agency
- Collaboration with manufacturers of medical devices and healthcare products e.g. prophylactic dressings

Funding Bodies and Partners

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

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