

Medical Devices and Vulnerable Skin

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



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



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

- 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

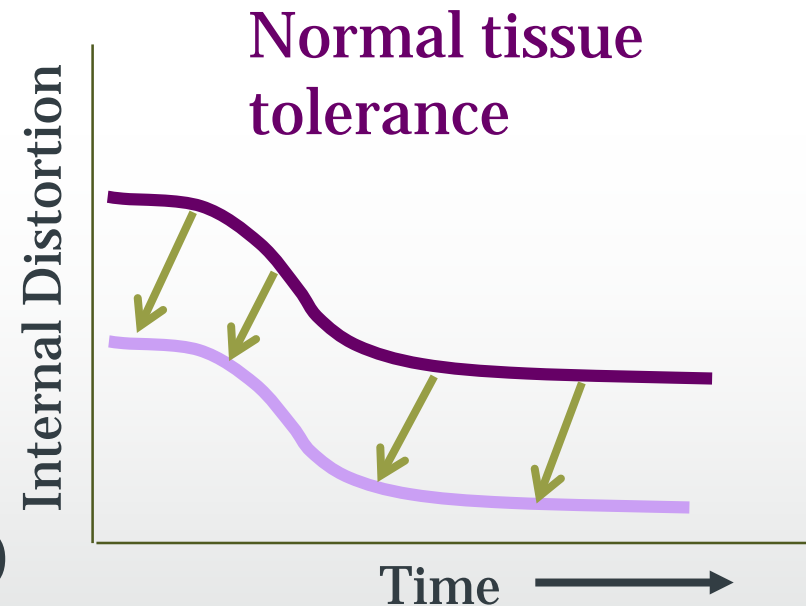
Subjects have limited mobility

Subjects have impaired sensitivity

Tissues are more vulnerable than normal to pressure-induced damage

Unconditioned tissues

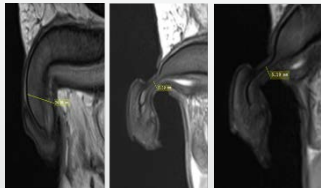
- Location – head/neck/face (70%)
- Ageing/immaturity, co-morbidities
- Atrophy, dehydration, lack of muscle tone



Gefen 2006

Combined experimental and computational approach

Human
Experiments



Pain
Skin irritation
MDRPU_s

External mechanical loading
for prolonged periods

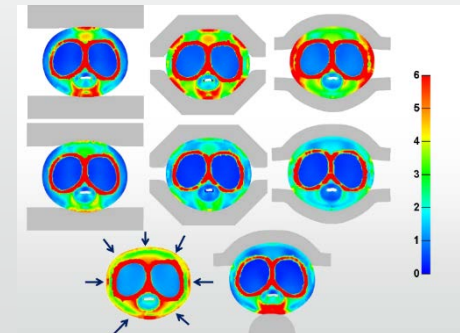
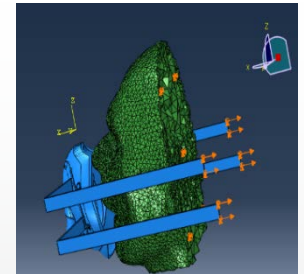


Internal local tissue deformations



Local soft tissue damage

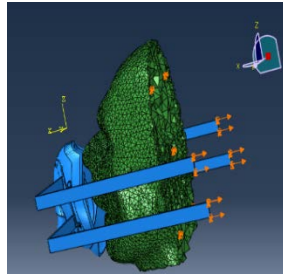
Finite element
modelling



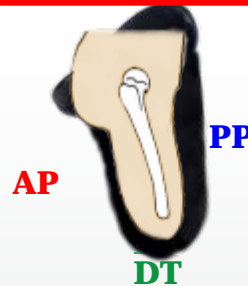
Medical Devices and Vulnerable Skin Network and Network^{PLUS} (MDVSN^{PLUS})

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Respiratory Masks



Support Surfaces



Orthotics and Prosthetics

Prophylactic Devices



Incontinence Devices

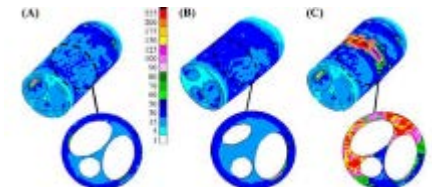
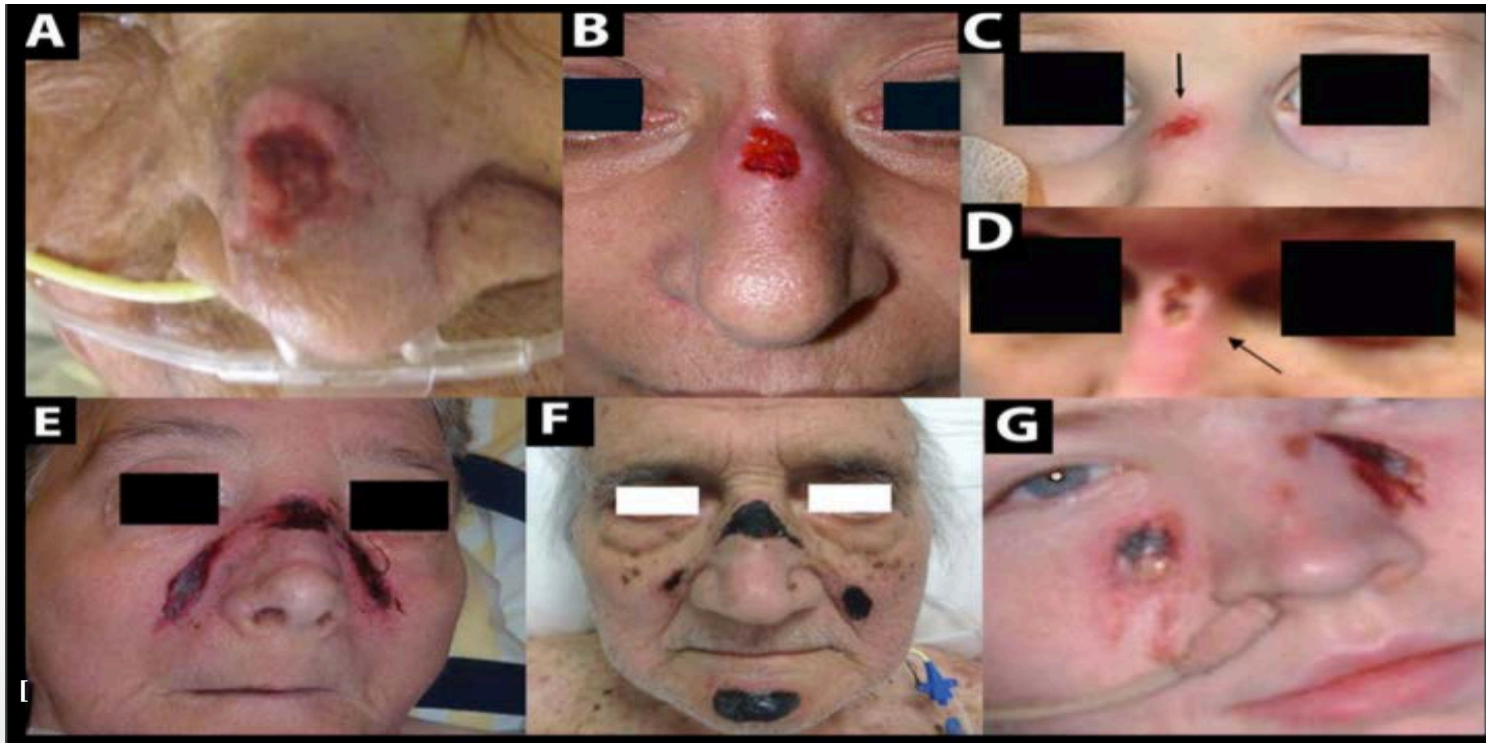


FIGURE 4. Distribution of von Mises stresses in (A) the normal penis model, (B) the penis with increased sensitivity, and (C) the penis with a control mechanism.

How can research help prevent MDRPUs?

Example 1 : Adult Respiration Devices



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

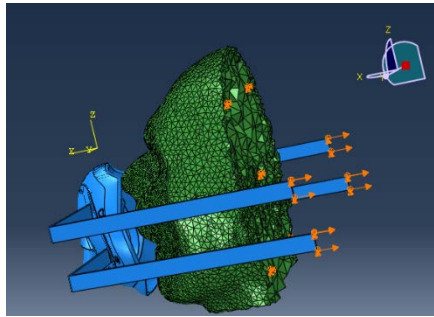
Brill AK (2014) . Breathe 10, 231-242

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

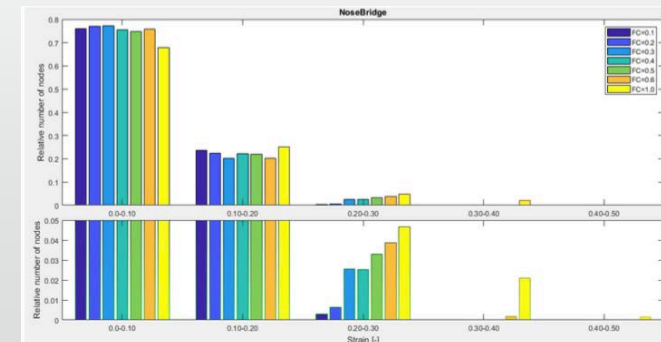
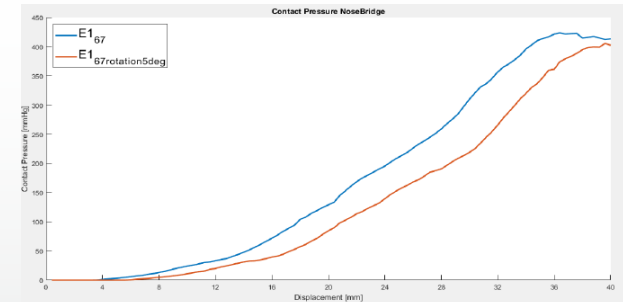
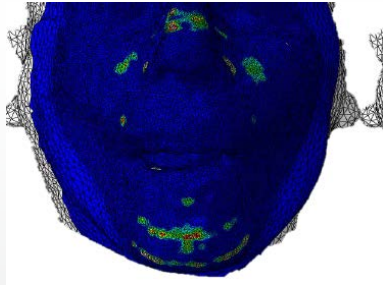
Visscher et al. (2015) Respir Care 60(11):1536- 1547

Computational Modelling

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

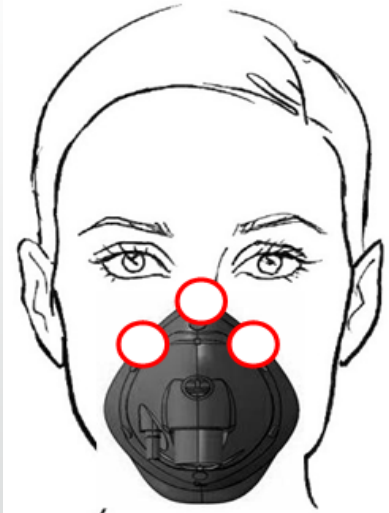


- Mask orientation and rotation has a significant effect on contact pressures
- Increased stiffness of the silicone resulted in larger strains over bridge of nose



Experimental Approach

Tension strap



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



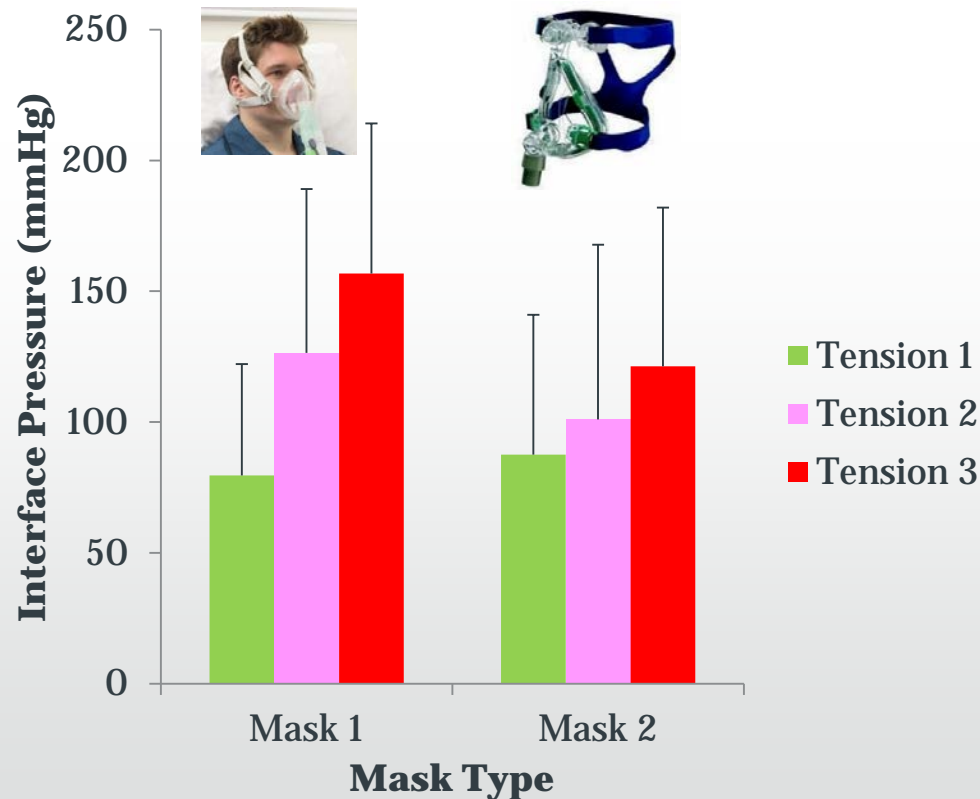
Placement of interface pressure sensors and temperature/humidity sensors prior to location of face mask

Comfort scores (VAS) and device functionality was also assessed

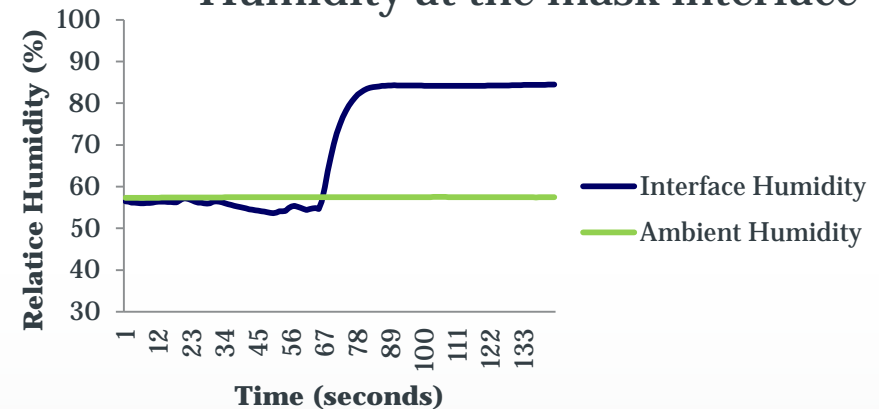
Results

Pressures and micro- climate at the skin-mask interface

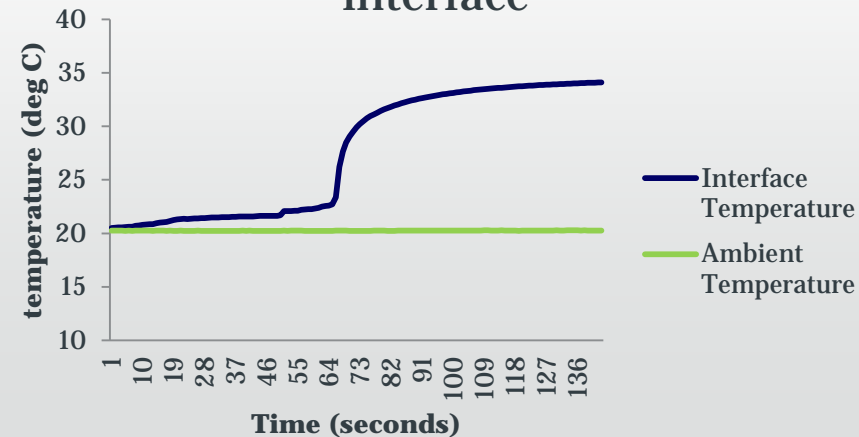
Interface Pressures at the Bridge of the Nose (n=13)



Humidity at the mask interface



Temperature at the mask interface

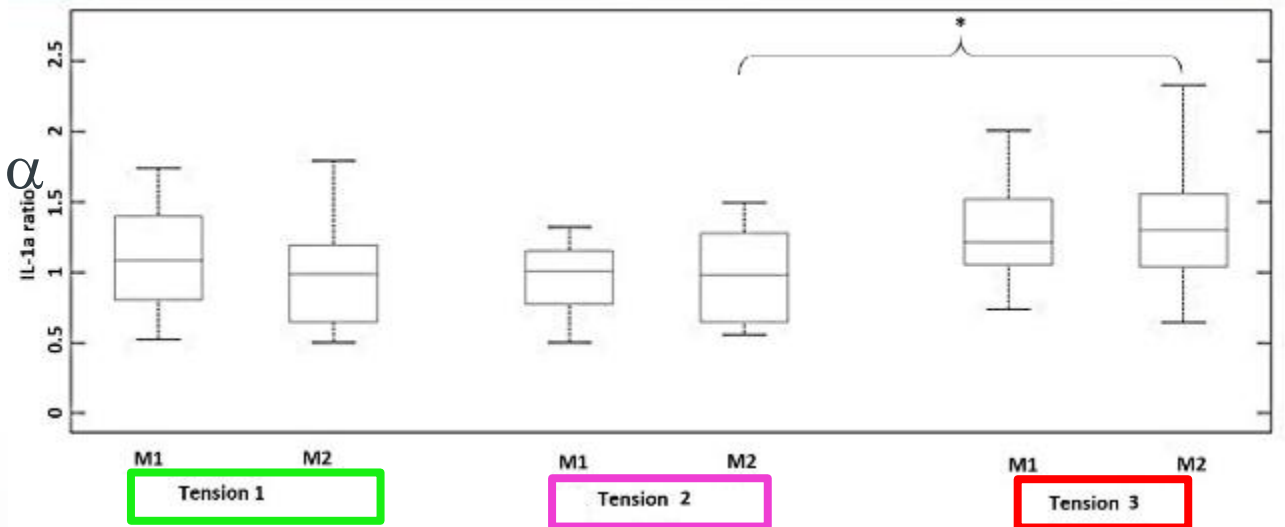


Results : Biomarkers (n=13)

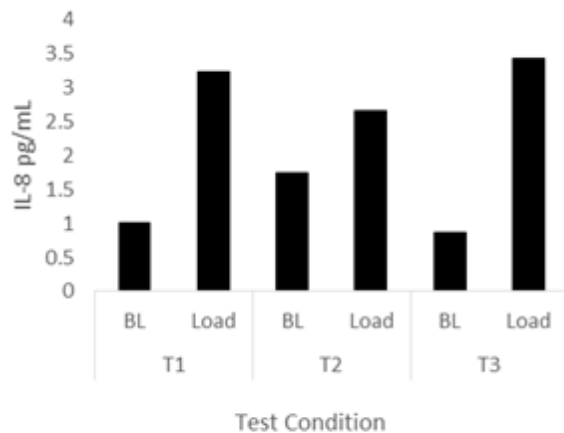
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Worsley et al. 2016 Medical Devices: Evidence and Research

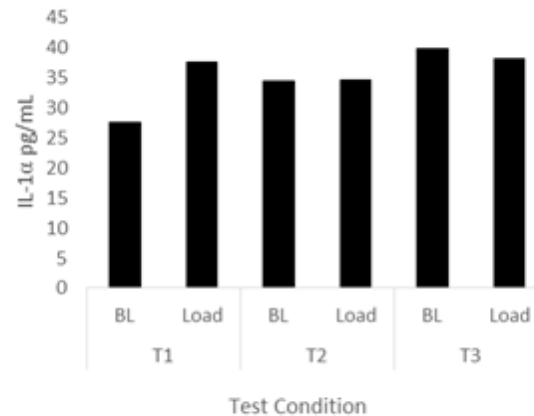
Interleukin IL-1 α



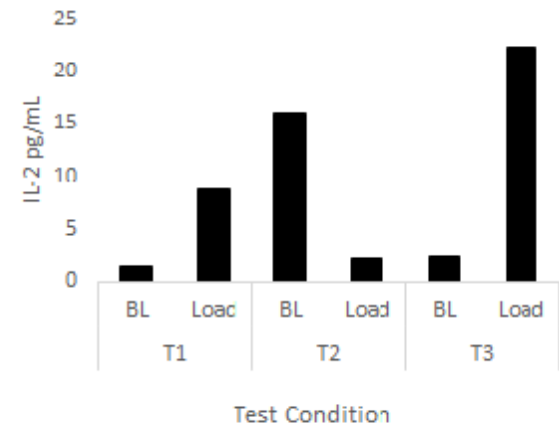
Individual Variability



A



B



C

- 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 ?

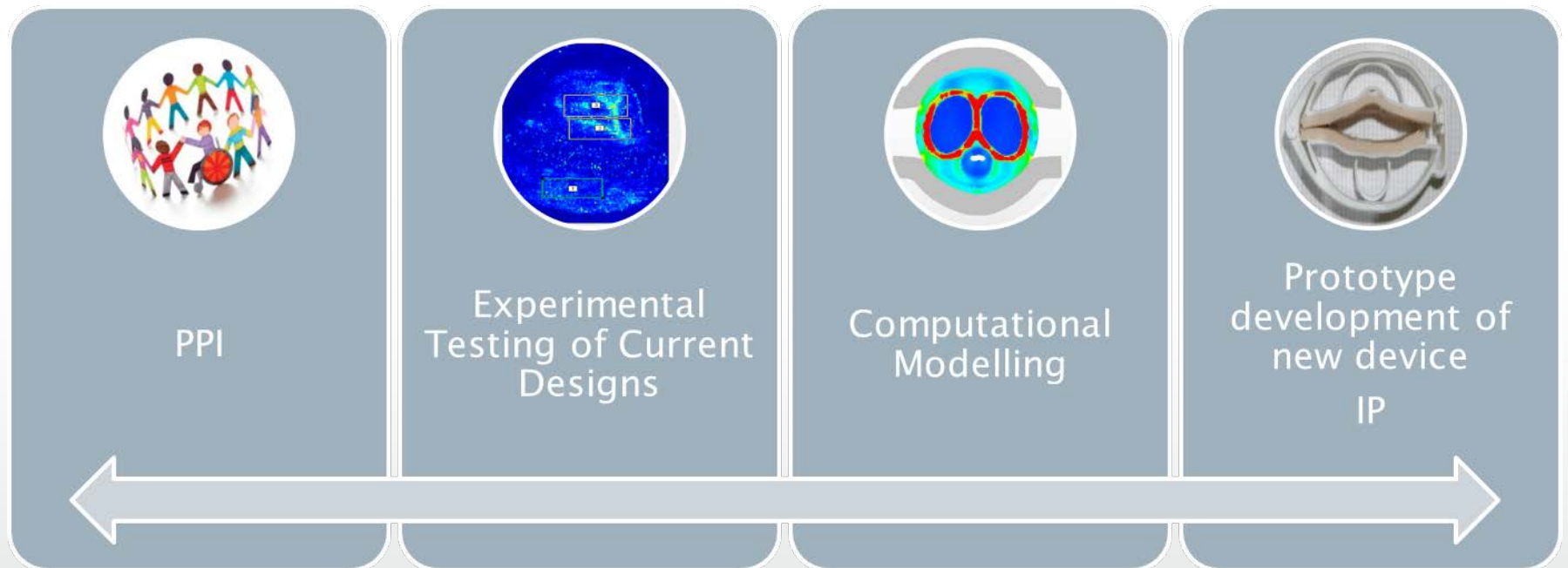
How can research help prevent MDRPUs?

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



Research Methods

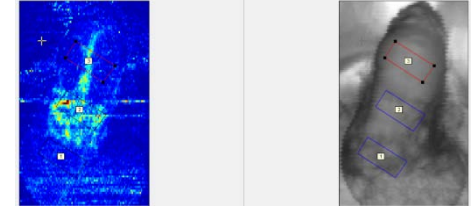


Evaluation of current designs

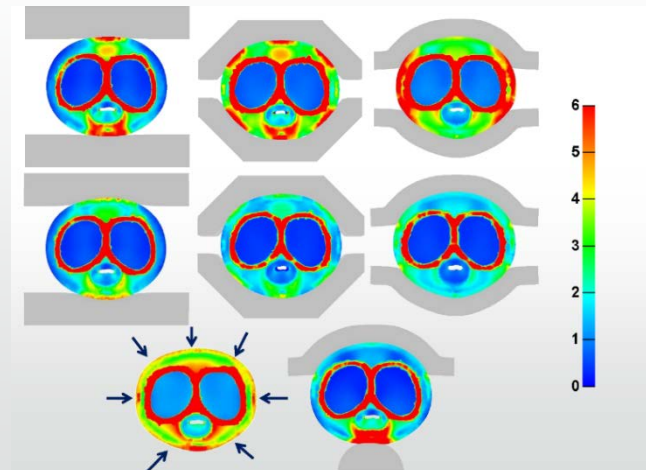
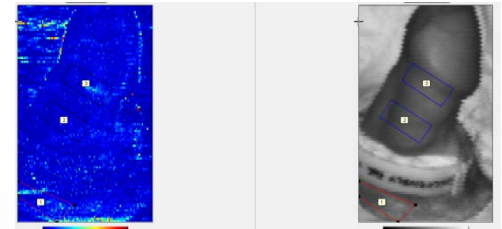
- Patient reported pain and discomfort with some device designs, others were ineffective
- Experimental data using current designs revealed:
 - high interface pressures,
 - ischemia in the penis
 - inflammatory response
- Computational modelling revealed the effects of design on tissue strains

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Before clamp application



During clamp application



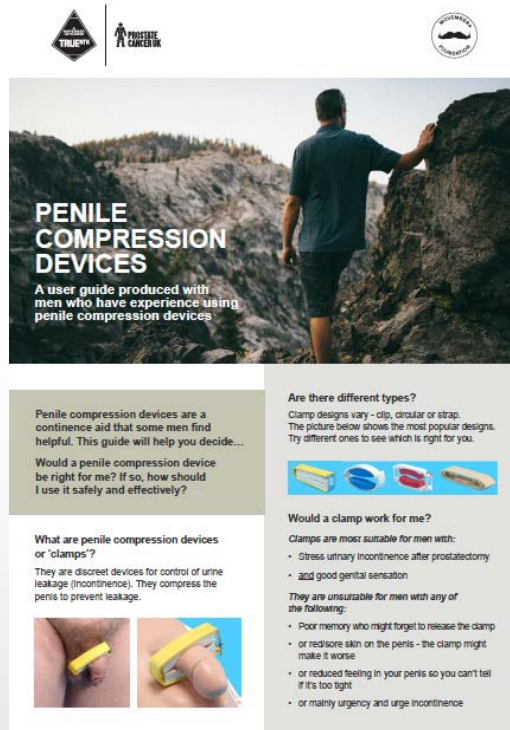
Lemmens et al. (2019) Medical Devices (in press)

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



PENILE COMPRESSION DEVICES
A user guide produced with men who have experience using penile compression devices

Penile compression devices are a continence aid that some men find helpful. This guide will help you decide...
Would a penile compression device be right for me? If so, how should I use it safely and effectively?

What are penile compression devices or 'clamps'?

They are discreet devices for control of urine leakage (incontinence). They compress the penis to prevent leakage.

Are there different types?

Clamp designs vary - clip, circular or strap. The picture below shows the most popular designs. Try different ones to see which is right for you.

Would a clamp work for me?

Clamps are most suitable for men with:

- Stress urinary incontinence after prostatectomy
- and good genital sensation

They are unsuitable for men with any of the following:

- Poor memory who might forget to release the clamp
- or red/sores skin on the penis - the clamp might make it worse
- or reduced feeling in your penis so you can't tell if it's too tight
- or mainly urgency and urge incontinence

Stress urinary incontinence is associated with physical activity e.g. standing, coughing, walking. Urge urinary incontinence is having to rush to the loo and not making it in time.

When are clamps most useful?

When being as dry as possible is important and other products (e.g. sheaths, pads, body-worn urinals) would not be as suitable. For example, with activities such as swimming, dancing and...



To make certain tasks easier, for example:

Some men use a clamp to avoid leakage while getting to the toilet in the morning or while putting on another product or when they want a break from another product.

When should clamps **not** be used?

When asleep. We recommend that you:

Wear the clamp for no longer than one hour, then have a rest period equal to the time you had the clamp on. This is to reduce the chance of damage to the penis.

Can clamps be used with other products?

Clamps can be used on their own. However, most men choose to wear a small pad with their clamp for comfort and to catch small amounts of urine leakage.

Where can I get a clamp?

Ask your urologist or continence nurse.

For suppliers visit:

www.continenceproductadviser.org/products/maledevices

They are also available on the Internet.

Top tips from men for clamp use:

- The clamp should never be painful – this means it is too tight and should be released and less pressure applied
- But wearing the clamp may be uncomfortable to start with
- Take time at home to practice with the clamp for short periods and gradually build up the length of time you wear the clamp
- Keep the clamp loose enough for comfort and wear with a small pad if some leakage continues
- Gradually increase the tightness to the desired level of comfort and security
- Ensure skin is clean and dry before use – avoid using creams which may cause the clamp to move
- Trim pubic hair to avoid it getting caught in the clamp and wear close fitting underpants to help support the clamp
- Adjust the clamp from time to time - before activity, with changes in penile dimension and outside temperature
- Have penis over the toilet or sit on the toilet for clamp removal as there may be a gush of urine leaving
- Get in and out of the car with legs together to avoid clamp dislodgement or rubbing
- Carry a spare clamp in a small bag or wrapped in a clean pad
- At airport security, avoid clamps with metal components
- Always follow manufacturer's instructions

Thank you to all the men who have contributed to this leaflet.

The information contained in this leaflet is for general information purposes only.

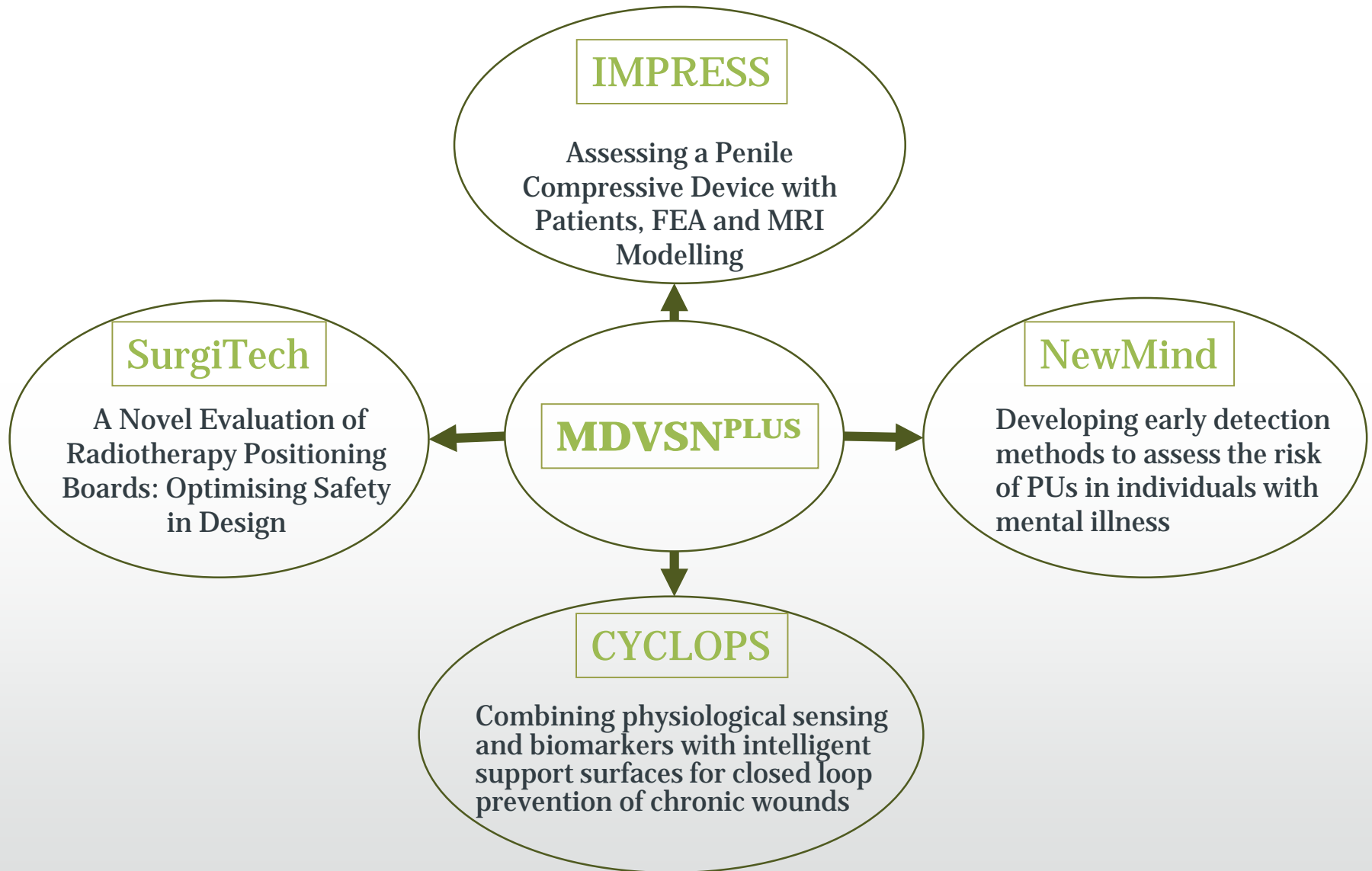
We endeavour to keep the information up to date and correct. We make no representations or warranties of any kind, express or implied, about the completeness, accuracy, reliability, suitability or availability of the products.

Any reliance you place on such information is therefore strictly at your own risk. In no event will we be liable for any loss or injury resulting from use of penile compression devices or from the information provided in this leaflet.

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



Interactions with Networks



Other Funded Projects

- **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

- 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

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