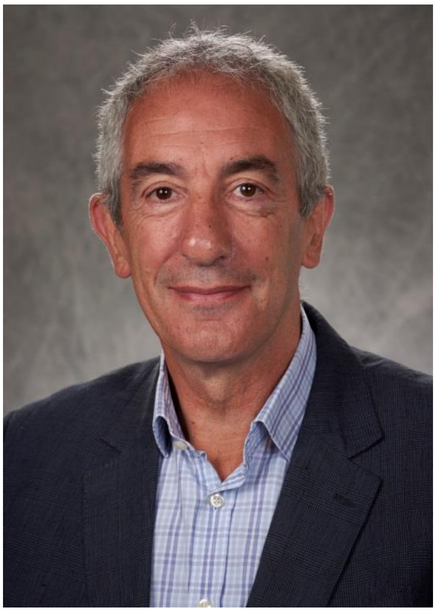
Health
Sciences

UNIVERSITY OF
Southampton

Medical Devices and Vulnerable Skin Network

Annual Report: Year Three | 2016 - 2017



Welcome to the third Annual Report for 2016-2017 for the Medical Device and Vulnerable Skin Network (MDVSN) and Medical Device and Vulnerable Skin Network^{PLUS} (MDVSN^{PLUS}).

Following the success of the current EPSRC-NIHR HTC Partnership Award: Medical Devices and Vulnerable Skin: Optimising safety in design, 'PLUS' funding was secured on the 1st of July 2016 to provide the basis to expand both the scope of our activities and our outreach to academic, industrial and clinical partners.

The global aim of the MDVSN^{PLUS}: Intelligent sensing to promote self-management is to bring disruptive technologies to the medical device market to promote sustainable evolution and long-term healthcare improvements. MDVSN^{PLUS} has started work with our new partners to produce cost-effective functional medical-device and sensing technologies and novel materials and designs that can minimise the risk of damage to vulnerable tissues to improve patient safety.

Over the past 12 months, we have funded three Research Stimulus Projects from the University of Nottingham, Queen Mary University of London and the University of Leeds from MDVSN pump priming funds. In addition, we have funded a further three new projects aligned to the MDVSN^{PLUS} Intelligent sensing to promote self-management aims, announced in October 2016:

1. **Imaging the mechanical properties of vulnerable skin** - King's College London
2. **Optical fibre sensing at the interface between tissue and orthosis or prosthesis** – University of Nottingham with Peacocks Medical Group, Podfo and Footfalls and Heartbeats
3. **Early Detection of Pressure Injury Using Novel Wireless Epidermal Textile Sensors in Wheelchair users Living with Spinal Cord Injury** - Yang Hao – Queen Mary University of London with Middlesex and Royal National Orthopaedic Hospital, London

We have also attended a significant number of International events and conferences, bringing the MDVSN and MDVSN^{PLUS} to new audiences and forging new relationships with partners to collaborate on projects that will deliver the maximum impact for the Network. In addition, we have a hosted a number of undergraduate internships from the Netherlands and Professor Barbara Bates-Jensen from the US, each of whom have conducted specific research projects generated within the Network.

In January 2017, Dr Luciana Bostan joined the Network as Research Fellow and Network Manager, responsible for the management of MDVSN^{PLUS}, liaising with the senior academic partners, associated industrial and clinical collaborators. Sustainability of the Network will be ensured by its integration into an International Skin Health research group and further associations with other EPSRC/NIHR funded Networks e.g. IMPRESS, CYCLOPS, NewMind etc. During the funded period we aim to generate intellectual property and establish spin off activities associated with the manufacturing of novel medical devices and sensing technologies.

Thank you for your continued support.

Professor Dan Bader, Professor of Bioengineering and Tissue Health, University of Southampton
Principal Investigator, Medical Devices and Vulnerable Skin Network

THE MDVSN^PLUS: INTELLIGENT SENSING TO PROMOTE SELF-MANAGEMENT

With the new grant from EPSRC-NIHR HTC Partnership Award 'Plus' - MDVSN^PLUS Intelligent sensing to promote self-management, the Network benefits from expertise from two Co-Investigators:

Professor Ralph Sinkus from King's College London, who has extensive experience in developing imaging technologies associated with MR and US elastography. His expertise will offer the potential to establish material properties e.g. compressive modulus of soft tissues. This is critical if we are to design mechanical devices with interface materials for medical devices, which can match the properties of vulnerable skin.

Professor Steve Morgan, from the University of Nottingham, who provides expertise in optical fibre sensors, which can be used to detect a range of biomarkers at the device-skin interface. Sensing elements can either be embedded within the device or incorporated into a separate platform, such as a textile or smart bandage. This offers the potential to detect early signs of damage resulting from prolonged use of medical devices.

To complement the local UK expertise (Worsley, Dickinson), the Network is engaging with world leading researchers with capabilities in multi-scale computational modelling (Oomens, the Netherlands; Gefen, Israel), both of whom have long-standing association with the PI. They have adopted the approach of converting MR images of patient specific models into finite element (FE) models. In particular they have demonstrated the effects of mechanical loading on the internal stresses/strains of soft tissues in several settings, including seated spinal cord injured individuals (*Linder-Ganz et al, 2007*), volunteers lying on spine boards (*Oomens et al, 2013*) and the stump-socket interface of amputees (Portnoy et al, 2009).

This approach has identified strain thresholds above which soft tissues will be mechanically damaged (*Oomens et al, 2010*). MDVSN^PLUS proposes to add complementary physical and biochemical measurements coupled with enhanced imaging capabilities to provide accurate estimations of the mechanical properties of skin and soft tissues, thereby providing realistic materials properties for input into sophisticated FE models. These simulations will be verified with respect to their predictive capability for determining threshold values of tissue tolerance and will provide a platform for sensitivity analyses of varying patient populations, medical device design features and material properties.

In order to influence the standards to which devices are manufactured MDVSN^PLUS will continue to lobby key agencies (MDRA, BHTA) and be involved in ISOs. Research output will provide methodologies incorporated into a repository of valid Standard Testing Protocols (STPs) and Operating Procedures (SOPs) for testing of medical devices. This provides the potential for establishing an independent test bed facility, self-sustained with funding from various sources including industry.

THE CLINICAL CHALLENGE

We have continued to seek answers to our research question: **Can the safety of medical devices be improved with novel designs incorporating matched interface materials and enhanced clinical guidance?**

At the start of the Network, we highlighted three diverse clinical exemplars, where medical devices can cause damage to vulnerable skin, namely respiratory devices, prophylactic devices for patients with vulnerable skin and incontinence device e.g. penile clamps

It has been evident in discussions with both existing and new partners, particularly at our regular sandpit events, that we needed to expand the scope of MDVSN. For example, clinicians report that medical devices are designed to match patient needs at the time of fitting, ensuring the device is both functional and comfortable to wear. However, there are temporal changes in circumstances and demands between the individual and the device, which lead to loss of functionality and, in some cases, the use of the devices prove unsafe and harmful. Thus many devices are rejected, placing individuals at risk and costing the healthcare provider valuable resources. New technologies are required to monitor both the functionality and safety of medical devices at the device-user interface.

OUR CURRENT PROJECTS

WP1 Respiratory devices - *Respiratory devices for adults and children in Intensive Care*

MDVSN has continued to work with industrial, clinical and academic partners to improve both the design and application of NIV respiratory masks. This includes masks used in both adult and paediatric/neonate critical care. Our approach has included in-vivo studies in the laboratory, (Figure 1a), in-silico models of respiratory masks (Figure 1b) and observational studies in healthcare settings. This research approach has provided the scope to achieve the following aims:

- To document prevalence and incidence of injury associated with respiratory mask devices
- To measure the interactions between devices and the skin by employing experimental research on healthy volunteers
- To create a series of simulations to improve design/application for use with vulnerable individuals (in-silico sensitivity analyses).

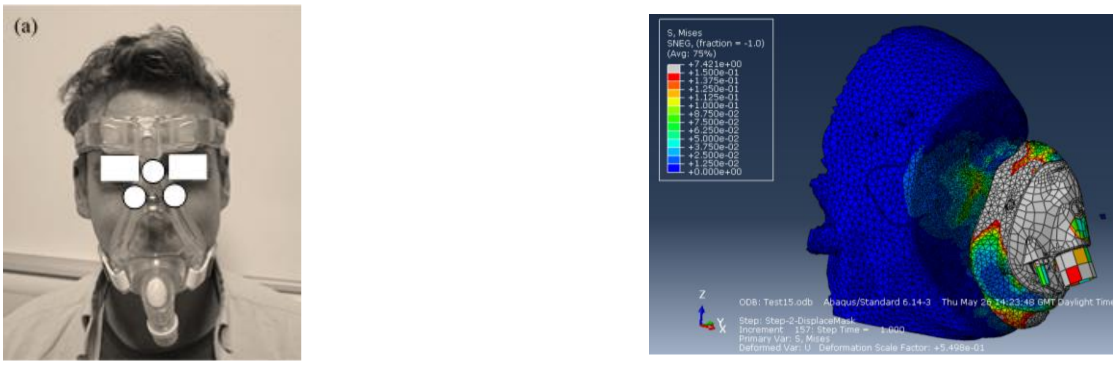


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Figure 1*: a) experimental testing of respiratory masks on healthy volunteers, measuring interface pressure, microclimate and inflammatory response at the skin; b) Finite element model of respiratory mask being displaced onto a reconstructed face, superimposed with resulting von Mises stresses.*

To date, our research has revealed that both mask design and strap tensions of application have a significant effect on the device-skin interface pressures, with an associated inflammatory response at key locations on the face after mask application (Worsley et al. 2016b). This experimental data has been used as boundary conditions for a series of computational FE models. In one such model, the mask was displaced onto the face and soft tissue/skin stresses and strains were estimated following mask loading (Figure 1b).

A secondary approach was to examine the effects of both rotation of the NIV mask on the adult face, as well as incorporation of tension straps to predict internal stresses/strains at critical locations under the mask with the experimental data used as boundary conditions. This is proving very complex to achieve even with the computing power at Southampton. The computational modelling has been supported by interns from both the UK (Frazer-Nash) and overseas (Eindhoven). This has provided an opportunity for skills/knowledge sharing across institutions/industry, with more interns planned over the coming 12 months.

Future work will include close collaboration with industry and healthcare practitioners to evaluate mask designs and provide evidence-based guidance for the application of devices using safe levels of strap tension and adequate fitting and the possible use of tapes and dressings.

WP2 Support surface devices - *Maintaining skin and soft tissue health in patients is a key element of care and represents challenges in everyday clinical management.*

There has been considerable effort in the healthcare industry to produce support surfaces which minimise tissue breakdown in susceptible individuals who spend much time in the lying position. Over the past 12 months, the Network has continued to work with a number of support surface manufacturers to provide scientific understanding of how their devices interact with vulnerable skin. Their performance has been evaluated using a range of biomechanical and physiological parameters, in conjunction with subjective values of pain and safety. Recent work has examined the effects of periodic repositioning on the tissue viability of a group of able-bodied volunteers encompassing a wide age range.

As an example, a new system has been designed to minimize tissue deformation and ischaemic damage by turning patients mechanically on an air mattress with localized alternating pressure. The mechanical tilt behaviour of the bed, termed Lateral Pressure Redistribution (LPR) therapy, was compared to manual repositioning with cushion support, the latter representing the conventional approach adopted in the hospital. Results indicated that an automated tilting mattress has comparable performance to a manual tilt in terms of both interface pressures and physiological responses, as measured using transcutaneous gas tensions (*Woodhouse et al., 2015*). However, differences did exist between the two techniques involving the degree of tilt angle achieved and perceived safety. Automated tilting mattresses offer the potential to reduce the burden of manually turning patients and could provide personalised care for individuals who are immobile who present a high risk of developing pressure ulcers. Using a similar assessment strategy we have recently assessed the performance of fluid immersion therapy in maintaining healthy physiological tissue status during prolonged loading (*Worsley et al., 2016*).

In addition, there is considerable industrial interest in developing novel materials within support surfaces, which control the microclimate at the loaded skin interface. This matches research expertise within the Network in monitoring temperature and humidity in both physical models and clinical situations. An example of this activity utilises a lab-based system, involving a sweating phantom (*Chai, 2011*), to examine the performance of support surfaces incorporating spacer fabrics, to allow for transportation of heat and moisture. The results from this in-vitro physical model testing have been subsequently simulated using both FE and compartmental modelling approaches (Fung, Eindhoven intern). Providing sound scientific basis for the design and clinical application of support surfaces remains a key target, building on the successful relationships with industry and healthcare clinicians.

The MDVSN is also targeting policy for support surface testing. This includes representation at the British Healthcare Trades Association (BHTA) meeting for support surface manufacturers (Bader and Worsley) and participation (Worsley) on ISO committees for the standardised testing of support surfaces (ISO/TC 173/WG 11).

WP3 Prophylactic devices- *Prophylactic hand devices to delay disease progression hand deformities for infants, children, adults suffering from Epidermolysis Bullosa GLOVE Project - Generation and evaLuation Of hand therapy deVices for Epidermolysis – (Grant Ref: II-LB-0813-20002)*

Epidermolysis Bullosa (EB) is an inherited life-limiting condition, which affects a small population (5,000 individuals in the UK). Dystrophic EB is a severe form in which the skin and internal body linings blister easily, from birth, causing painful wounds and a number of other problems, including hand contractures and finger webbing. Those affected require disproportionately large healthcare resources to manage the severity and progressive nature of their disease. Clinical goals include delaying the onset and progression of disease-related disability with hand devices: finger wrapping and/or gloves to delay webbing; dressings to heal blisters and post-operative wounds; and splints to delay contractures. Current devices are not tolerated and the resulting webbing and contractures require repeat surgery to maintain hand function.

With support from the Network, this long standing project is advancing on three hand therapy devices namely, a dressing glove; web-spacer glove and a dynamic splint glove. In addition a Hand Therapy Online system using TELER/Longhand Data system is well advanced.

Project Findings
WP1 User needs
Qualitative data derived from Workshops and face to face interviews yielded:

1) Design cues for a dressing glove, splint glove and revised Skinnies WEB™ web-spacer gloves
2) TELER indicators for measuring disease progression deformities and hand function
3) Hand Therapy Online (HTO) system, method of data recording
4) Cost effectiveness analysis of the dressing glove and Skinnies WEB™ web-spacer glove, and implementation of the HTO system.

WP2 Technical specification of hand therapy devices progressed to **WP3** Prototyping.

A prototype Viscose Dressing Glove V3 has been subjected to laboratory tests at SFM Limited and the Surgical Materials Testing Laboratory, together with surrogate tests at King's College, Skinwear Limited has CE marked the dressing glove as a Class 1 Medical Device. Colleagues from Cardiff University (Meyden) have advanced a number of actuator and sensing technologies into the prototypes. We have had joint meetings with the hand therapists, dermatologists, plastic surgeons, parents, children and adults with EB to prioritise the designs and appropriate technologies. To progress the splint glove technologies to commercialisation, we intend to resubmit a grant proposal to the MRC.

WP4 Clinical testing of prototypes has commenced, following Health Research Authority approval and R&D approvals at the co-sponsor site Guy's and St Thomas' NHS Foundation Trust (GSTFT). We currently await R&D approval at a second site, Great Ormond Street Hospital NHS Foundation Trust. The first patient at GSTFT has been recruited.

WP5 Integrated Hand Therapy Online (HTO) system and protocol for interface with NHS Electronic Patient Record systems for routine charting of hand deformities, therapy outcomes, bespoke glove manufacturing. With ethics and R&D permissions and approvals a pilot test has been conducted with patients/families (completed January 2017). The King's Team are leading on the Business Plan in collaboration with Longhand Data Limited and Deloitte, the latter providing their Business Plan template and guidance.

WP6 EB Hand Therapy Cost Effectiveness Ratio
The ongoing work of **WP2** is contributing to the development of the clinical and cost effectiveness measures (**WP6.1**) and the overall design and function of the Hand Therapy Online (HTO) system (**WP5**). This is being extended to (**WP6.2**) to identify and monetise the benefits to the NHS of providing the three hand therapy devices. Health economists at the University of Surrey are developing the value for money argument for the devices, including the splint glove. The costs of hand surgery for EB are high (>£60,000 per hand). The value for money argument is predicated on reducing episodes of hand surgery through effective orthotics and the Hand Therapy online system, to ensure effective hand therapy and remote patient monitoring.

WP4 Incontinence devices - *Clamps for males with persistent urinary incontinence*

Penile clamps represent the preferred option for some men to minimize urine leakage after prostate cancer surgery. However, such devices can cause soft tissue damage. To minimize this damage while maintaining device functionality, we have adopted a combined computational and experimental approach to assess existing commercial devices. This has involved a collaboration with colleagues in University of Southampton (Prof. Fader) and the University of Tel Aviv (Gefen).

The methodology involved segmentation (Simpleware® Ltd.) and meshing of a geometrical anatomical penile model including a number of tissue components. 3D orthotropic material properties were assigned to skin and tunic albuginea (TA), while other tissues were modelled as linearly elastic. Initially a uniform circumferential pressure was applied to simulate a soft cuff-type clamp. 12 model variants were developed, representing five generic clamp designs and interface materials with different material stiffness. Opposing vertical displacements were assigned to top and bottom surfaces of each clamp to compress mid-shaft. Both the effective and maximal shear strain and stress distributions were estimated during 50% urethral occlusion.

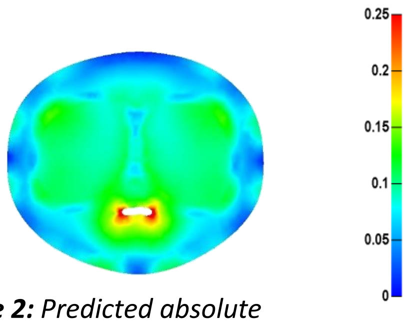

Figure 2: *Predicted absolute strains in a cuff-type penile clamp*

The model yielded effective strain & stress distributions in an axial cut through the model penis. Stresses in skin, fat and TA were found to regularly exceeded 10 kPa with corresponding maximum effective strains of between 14-22% (Figure 2). Maximal deformations were generally found in the corpus spongiosum (CS) around the urethra. The current findings indicate many clamp designs occlude soft tissue blood flow (*Levy et al. 2017*).

In addition, experimental parameters were measured on a small cohort of incontinent male volunteers. These included the measurement of interface pressures, blood flow using Laser Doppler imaging, and pro-inflammatory cytokine release.

One of the primary long-term goals of this project, as funded by Prostrate Cancer UK, is to identify a series of design characteristics, which will provide the safest mechanical conditions in penile soft tissues and thus minimize risk of tissue damage while effectively managing incontinence.
This has led to the design of a novel clamp, which has been manufactured and will be tested against a number of existing commercial designs.

WP 5: Prosthetics and Orthotics – *Sensing and imaging to improve the residual limb-socket interface.*

Research focusing on the design and application of prosthetics and orthotics represents an emerging theme (Figure 3). This has been driven by the established clinical need of individuals using these devices who have experienced pain, discomfort and skin breakdown. These symptoms are a result of pressures and shear forces applied through the device-skin interface, with the residual stump tissues of amputees not ideally capable of sustaining such loads. Indeed, these individuals often experience skin rubbing and excessive sweating through heat generation with added complications such as soft tissue atrophy or swelling causing an ill-fitting interface between the device and the soft tissues, which may lead to device rejection. MDVSN has partnered with several industrial (Chas. A. Blatchford & Sons Ltd, OpCare and Peacocks Medical Group), clinical (Disablement Services Centre, Portsmouth Hospital Trust) and academic partners (Prof. Jiang, Dr Dickinson University of Southampton) to investigate technological innovations to improve prosthetic and orthotic fitting. These projects include Biomedical Catalyst MRC funding to develop a novel sensor system for use at the stump-socket interface (*Laszczak et al, 2015, 2016*), validation studies for the use of white light and laser scanning technologies in the assessment of residual limb shape (*Dickinson et al, 2015*) and ongoing research studies investigating the application of orthotic devices such as cervical collars. MDVSN^{PLUS} has recently partnered with Peacocks Medical Group, where we will continue to develop innovate strategies to safeguard vulnerable skin from prosthetics and orthotic devices over the next three years. There has also been activity to translate the research activity into lower and middle income counties (LMICs). Worsley and Dickinson recently visited the Cambodian School of Prosthetics and Orthotics (CSPO) to disseminate their activity with CAD scanning and provide proof of concept for a Global Challenge Research Fund application.

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Figure 3: *a) Pressure and shear sensor developed to monitor the stump-socket interface of amputees; b) white light scanner being used to image the shape of residual limbs; c) cervical collar design to enhance comfort and safety.*

WP6: Paediatric Medical Devices - *Prophylactic device retention systems for paediatric patients and neonates in intensive care*

Functional medical devices are prescribed for children in many situations, ranging from respiratory devices (nasal cannula, continuous positive airway pressure masks and medical tape) in neonatal and paediatric intensive care units to orthotics to manage movement disorders. Given the immaturity in structure and function of skin, particularly in pre-term and term infants, it is unsurprising that these medical devices can cause mechanical- induced damage.

Working with WoundTec HTC and a clinical partner, Professor Howard Clark, Professor of Child Health at the University of Southampton, we are involved in a NIHR Paediatric Healthcare project entitled "The design of respiratory medical devices to enable effective drug delivery and minimise traumatic damage to vulnerable paediatric tissues" The project addresses two distinct research questions incorporates motivated by expert clinical opinion, namely,

- Can new delivery devices be developed to provide non-invasive delivery of pharmacological agents to the paediatric population to minimise iatrogenic lung injury?
- Can fragile soft tissues be protected from medical device-induced injury causing chronic wounds with novel designs incorporating matched interface materials and manufacturing capability?

This programme of research has included a survey of neonatal nursing practices in the Thames Valley & Wessex Neonatal Operational Delivery. 56 responses were returned, the majority of which (64%) were from staff with over 10 years' clinical experience. Its findings indicated that although staff were aware of methods to minimise damage, many of the available devices were inappropriate for this population. The incidence of skin damage was perceived to be high, with 26% of participants stating that they encountered damage daily. The survey also revealed barriers to protecting skin health due to constraints in training and availability of appropriate prophylactic resources. A multicenter survey was conducted involving prevalence and incidence across three large acute trusts within the Network (Southampton, Portsmouth and Oxford). Preliminary analyses of the data revealed a skin damage point prevalence of 48.5% and a cumulative incidence of 60.8% (32/53) in two intensive care neonatal units in the South of England.

As part of the research programme, research will examine the maturation of skin in premature neonates. Ethics was approved in April 2017 to take direct measurements of the structure and function of the vulnerable skin. This study involves measurements of trans-epidermal water loss, pH, inflammatory cytokines swabbed from devices and high frequency ultrasound imaging of the skin structure. Measurements are being conducted at the Princess Anne Hospital in Southampton. We have appointed a senior registrar to undertake the project (Dr Anushma Sharma) and have recruited our first patients. By establishing the properties of this highly vulnerable skin we can inform manufacturers of the tolerance to device related loading and support the design of safe medical devices with matched modulus materials.

MDVSN Funded Projects

MDVSN was granted a Research Stimulus Fund for 2014-2017. This was designed to pump-prime research activity from this multidisciplinary team that will ultimately lead to future collaborations and the development of full research grant or contracts proposals with partners.

Three external projects have been funded:

University of Leeds - Skin Sensing Assessment - *novel electrical measurement technique for real-time assessment of skin barrier function for at risk patient demographics principally incontinence and diabetes.*

This research evaluated the efficacy of using a novel electrical measurement technique for real-time assessment of skin barrier function for at risk individuals principally those with incontinence and diabetes. The research was based on previous work developing a galvanostatic measurement technique for tissue health assessment in colorectal cancer [1-4], which demonstrated the potential of the technique for fast (<1s), robust and sensitive measures of tissue health using human explant tissues. The system comprises a measurement probe with 4 electrodes which contacts with the target tissue, linked to a compact data acquisition device and laptop for analysis. The technique measures electrochemical properties which are fundamentally linked to the cellular composition of the target tissue and thus directly affected by the onset of disease. The aim was to translate this technology to identify at-risk patient demographics facilitating the stratification of care both in-institution and community informed by a rapid, but sensitive measurement method. The project comprised two phases, namely, a technical development to adapt the existing contacting probe into an appropriate form for testing on curved skin surfaces. Subsequently, the adapted system has been used in a small pilot study with diabetes patients at Leeds Community Healthcare NHS Trust.

Queen Mary University of London - **CO_2 and Glucose Monitoring -** *Design and In vitro testing of soft Biodegradable Electrochemical Sensors for CO_2 and Glucose Monitoring at Wound Sites*

Oxygen and glucose measurement at a chronic wound surfaces offers a route to tracking the progression of healing. As metabolic surrogates they can reflect a balance of regenerative, inflammatory and local vascularisation processes, particularly given the high metabolic activity of inflammatory cells. Techniques for direct, local measurement are limited to O_2 and not appropriate for bedside use. However, there is evidence that hypoxia compromises skin repair. This project investigated degradable protein-based electrochemical sensors formulated from multiple specialist protein layers for tracking wound pO_2 and glucose. Such devices would be conformal, non-intrusive and avoid the need for device retrieval. Measurement involved direct electrochemical detection of oxygen using at a cathodic polarised electrode surface and of glucose at an anodic surface *via* an immobilised glucose oxidase layer generating H_2O_2.

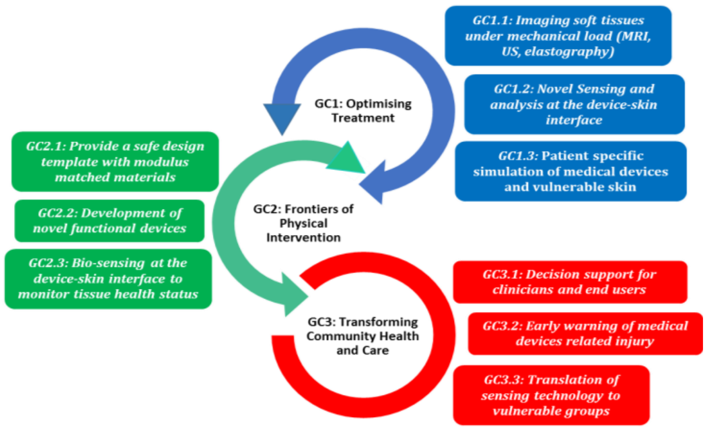
University of Nottingham – **PCO_2 Measurement** - *Development of a prototype optical fibre CO_2 skin gas sensor*

A recent review highlighted the importance of carbon dioxide in predicting early tissue damage and concluded that future research is needed to find technological solutions to measure PCO_2 in affected tissue continuously and non-invasively (*Mirtaheri at al. 2015*). The Optics and Photonics Group has developed optical fibre sensors for a number of applications, particularly in monitoring skin and in critical care, and for a range of parameters including gases. To achieve a sensitive and specific sensor response, the optical fibre was coated with a film whose refractive index or colour changes in the presence of selected analytes. As optical fibres are lightweight, flexible and compact they offer the potential to address the challenge of continuously and non-invasive monitoring of skin CO_2.

The project was designed to demonstrate proof of concept measurements of CO_2 emitted by the skin using an optical fibre sensor. This involves a number of tasks.

1) Coat an optical fibre with a dye compound sensitive to CO_2 (e.g. tetrasodium pyrophosphate)
2) Optimise the configuration of the optical fibre sensor by changing the dye concentration and with the use of long period grating
3) Characterise the sensor response by comparison with a commercial CO_2 sensor at different CO2 levels in a sealed chamber linked to gas cylinders
4) Demonstrate preliminary measurements on skin on healthy volunteers, by placing hand inside a bag containing the optical fibre sensor and commercial CO_2 sensor.

MDVSN^PLUS Funded Projects



At the sandpit in October 2016, delegates were invited to submit to the first MDVSN^PLUS funding call providing up to approximately £50k per project. Applications were required to represent a significant research advance in the performance of medical devices. Each application was considered by a panel of Network partners with an independent chairperson and consideration paid to how closely the research proposal matched the EPSRC Grand Challenges, as outlined in Figure 4.

Figure 4 *EPSRC Grand Challenges*

Three projects were funded.

Professor Ralph Sinkus, King's College London: Imaging - *Imaging the mechanical properties of the vulnerable skin*

Skin damage often resulting from the prolonged used of medical devices, as well as radiation-induced fibrosis represents a significant clinical burden to a range of individuals. Patient experience is traumatic and its impact on the healthcare system is substantial. Alterations in biomechanical characteristics, typically stiffness and viscosity, are central to these pathologies and can provide important makers for disease characterization. However, to date, their non-invasive measurement in the clinical setting has not been possible.

Accordingly, we propose to study the vulnerability of skin in the context of normal ageing, pressure ulcers, as well as radiation-induced damage using cutting edge MRI technology developed at KCL. In particular, we propose to use MR-Elastography for the non-invasive characterization of the biomechanical properties of the skin at imaging resolutions of 50micrometers. Such imaging, performed using clinical MRI systems, will enable the detailed characterization of skin stiffness as well as skin viscosity. The non-invasive methods have been recently demonstrated to detect fibrosis and inflammation in patients with liver conditions. The technique will be adapted to detect skin changes, using the latest transient 1D technology.

As fibrosis and inflammation represent key components for the vulnerable skin, we envisage providing a temporal atlas of biomechanical properties as a function of age and damage progression. This will enable us to provide distinct thresholds to both quantify the degree of skin damage and predict its risk progression.

Professor Steve Morgan, University of Nottingham: Optical Fibre Sensing - *Optical fibre sensing at the interface between tissue and orthosis or prosthesis*

Wearable sensors offer the potential to continuously monitor the device-skin interface in both the clinical and community settings. Optical fibre sensors are particularly useful as they are light weight, flexible, low cost, thin and can be used to measure the properties of the skin that are linked to tissue breakdown. The University of Nottingham has led research into the integration of optical fibre sensors into textiles. These are particularly relevant for this application as at the interface between tissue and orthosis/prosthesis is often a textile (sock). To date our group has demonstrated monitoring of pressure, temperature, humidity and a number of other useful indicators of tissue breakdown in the laboratory setting.

Within this project we aim to conduct a study to investigate the feasibility of using OFS to monitor parameters of interest at the tissue-device interface. We anticipate that the data obtained will support next stage funding applications for a wearable device that can be used to better understand tissue breakdown; to detect early signs of breakdown before injury occurs and support better design of orthoses and prostheses, particularly for individuals with vulnerable skin.

Professor Yang Hao, QMUL in collaboration with Royal National Orthopaedic Hospital, Stanmore Early Detection of Pressure Injury - *Early Detection of Pressure Injury Using Novel Wireless Epidermal Textile Sensors in Wheelchair users living with Spinal Cord Injury*

People living with spinal cord injury (SCI) are very prone to developing pressure ulcers. Indeed, up to 85% of adults with SCI present with a pressure ulcer during their lifetime. The disabling condition is very painful and can take a long time to heal. It represents a major burden of sickness and reduced quality of life for these patients and their carers. Accordingly, prevention and early detection of pressure ulcers is vitally important for people with SCI.

The overall aim of this project is to develop a low-cost microwave sensing device, which is flexible and can be integrated with mattresses and cushions to detect real-time and unobstructive detection of early sign of pressure injury in people living with SCI. The overall aim to incorporate the device into low cost garments with flexible electronics for telecare data management and evaluate the feasibility and reliability.

KEY ACTIVITIES

The third event of our Medical Devices and Vulnerable Skin Network took place on Thursday 20th October 2016. The event attracted 70 multidisciplinary delegates including academics, healthcare practitioners and industrialists to discuss a range of research themes encompassing functional medical devices and sensing technologies to improve patient safety. The event also incorporated an engagement workshop, which proved extremely popular with delegates. This resulted in an excellent response to our first call, which include 9 diverse applications.

Our final MDVSN event was held in conjunction with a MDVSN^{PLUS} Network Meeting on Thursday 25th May 2017. This event offered stakeholders, with an interest in functional medical devices and sensing technologies, the opportunity to develop collaborative proposals to submit for further funding calls from MDVSN^{PLUS} announced at the event.

Successful applicants from the MDVSN pump priming call (2014-2017) provided an overview of activities to date including Professor Pankaj Vadgama, Professor and Director of IRC in Biomedical Materials, QMUL presenting on "The design and In vitro testing of soft Biodegradable Electrochemical Sensors for biosensing at Wound Sites" and Dr Mike Bryant, IMPRESS Network, University of Leeds presenting a talk on "Breaking Barriers in Skin Sensing Assessment".

Dr Peter Worsley, MDVSN^{PLUS} Co-I concluded the morning session by introducing the second MDVSN^{PLUS} Funding Call for 2017 and provided an overview of the funded projects outlined above.

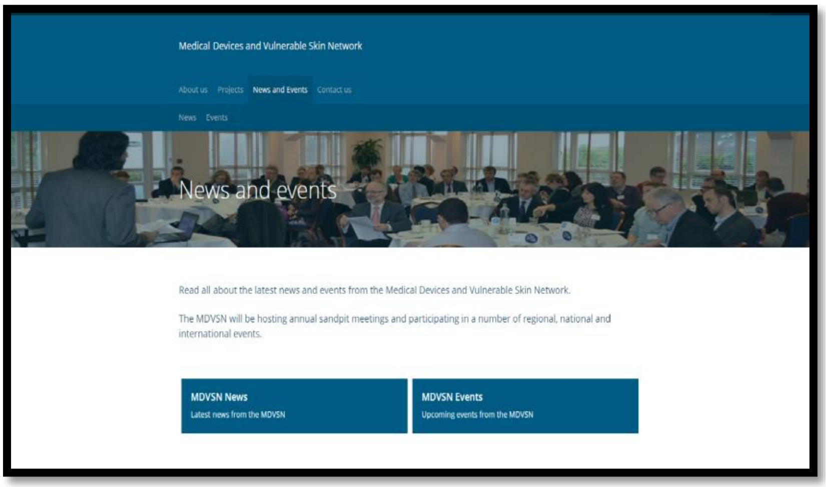
The second MDVSN^{PLUS} Funding Call (submission deadline end July 2017) is focused on intelligent sensing to promote self-management in core themes. Applications to clinical settings will typically include diabetic foot ulcers, sensing and remote monitoring in the community, improved devices in critical care and skin assessment and sensing. Partners were invited to apply for funding for projects up to a maximum budget of £25k to work in partnership with academics, industrial partners and clinicians to develop and test improved medical devices that will minimise damage to vulnerable skin and promote self-management. Each application will be considered by a panel of Network partners with an independent chairperson.

INDUSTRIAL SUPPORT

We have continued to work with key industrial partners such as support surface manufacturers, including Hill-Rom and Medstrom, to evaluate performance of a range of products including support surfaces designed to control microclimate and periodically redistribute pressures, which have provided performance indicators on existing and future products. Our Network has also been successful in attractive new collaborative industrial partners including Apex, SCA and Scarletred, as well as being awarded an EPSRC Case PhD Studentship with Sumed as partners. The latter project is designed to utilise prolonged pressure monitoring (24 – 48hr) as a surrogate for the analysis of movements. The developed algorithm will be tested on specified groups in both hospital and community settings.

MDVSN DISSEMINATION AND LOBBYING

In addition to the Sandpit events, we have continued to build upon the launch of the Network and been active in raising awareness of medical device-related injury. Our dedicated website continues to attract new members to the Network, who can provide expertise to our innovation platform and help disseminate the impact of our projects (Figure 5 and www.southampton.ac.uk/mdvsn). The website will also offer a forum for feedback of medical devices from clinicians and provide key links to the new NHS England-MHRA National Reporting and Learning System, which will act as an integrated reporting route for medical device incidents.



We were delighted to be invited by the Tissue Viability Society (TVS) to set up a Special Interest Group focused on Medical Devices and their impact on vulnerable skin. The TVS is the world's oldest society dedicated to all tissue viability issues and attracts members from all health care professions involved with tissue viability.

Figure 5: *MDVSN website* **www.southampton.ac./mdvsn**

We have introduced the aims and objectives of MDVSN at various events and meetings, including Networks of Tissue Viability nurses, NHS policy makers and local health care providers, forging new partnerships to collaborate on projects that will deliver the maximum impact.

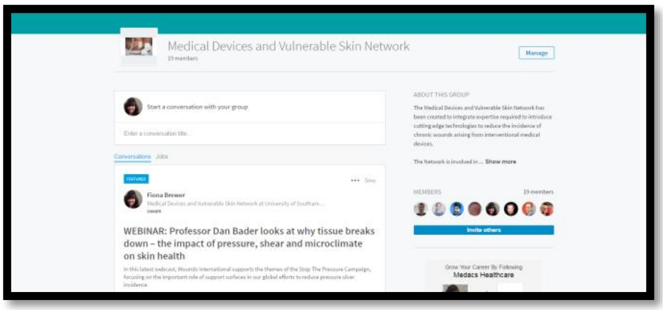
We have also been proactive in funding selected exploratory project meetings across the UK, often with involvement of our partner HTCs, to investigate mutual areas of expertise with new industrial partners. As an example, meetings with colleagues from National Physical Laboratory (NPL) and led by Professor Machin has highlighted the importance of accuracy in the measurement of parameters reflecting the microclimate at the loaded skin support surfaces.

We have been invited to present MDVSN-related activities at various 2016/2017 meetings including:

- British Health Trade Association – 7th Feb
- International Seating Symposium, Nashville – 1-4th March
- European Pressure Ulcer Advisory Panel (EPUAP) Masterclass, Ghent - 14-16 March
- Network Plus: Closed loop control systems for the optimisation of treatment (Cyclops), Nottingham - 20-21 March 2017
- Wounds UK, Manchester – 23rd March
- Annual Tissue Viability Society Meeting 2017, Birmingham – 5-6 April
- Sumed TV Southern Meeting, Southampton – 12th April
- International Society of Prosthetics and Orthotics, Cape Town – 8-11th May 2017
- East of England Tissue Viability Network, Cambridge – 23rd May
- International Lymphoedema Society, Sicily - 21 - 24 June 2017

The team continue to engage closely with the Thames Valley & Wessex Neonatal Operational Delivery Network, the respiratory Biomedical Research Unit in Southampton and Welsh Wound Innovation Centre with Profs Harding and Clark. We have recently engaged with Technology Innovation Transforming Child Health (TITCH), as part of the HTC Devices for Dignity, and plan to co-host events focusing on medical devices for neonates in the South of England.

As Editor in Chief of Journal of Tissue Viability journal, Prof Bader has encouraged submissions to the journal covering areas associated with the Medical Device and Vulnerable Skin Network.



a **b**

Figure 6: *a) MDVSN social media platforms have been established via Twitter and b) dedicated group - Medical Devices and Vulnerable Skin Network - on professional networking site LinkedIn to reach new audiences with an interest in medical devices and their impact on vulnerable skin.*

ACTIVE NETWORK PARTNERS

Successful collaborations within the MDVSN and beyond will facilitate multidisciplinary research and provide a platform for novel, translational ideas. We are grateful for the enthusiastic support of our current partners:

Industrial Partners include:

Podfo	Dr Jari Pallari
Peacocks Medical Group	Steve Cook
Fripp Design	Steve Roberts
Activa Healthcare	Jeanette Muldoon
Intersurgical	Mike Hinton
Medstrom	Michael Clancy, Rachel Apsey
Hill-Rom	Thierry Flocard, Philippe Kaikenger
Frazer Nash Consultancy	Dr Andrew Moore
Sumed International UK	Graham Collyer, Diane Hargrove
Crawford Healthcare	Ian Shurville
Fuel 3D	Andrew Smith
Longhand Data Limited	Roger Young
Skinwear Limited	Ian Davenport
SFM Limited	Matt Stratton
C.L.C. Design Consultants Limited	Alex Currie

Academic Partners include:

University of Newcastle	Professor Kenneth Dalgarno, Dr Javier Munguia
University of Nottingham	Professor Stephen Morgan, Dr Serhiy Korposh
University of Leeds (IMPRESS Network)	Dr Peter Culmer
University of Manchester (NewMind Network)	Professor Chris Taylor
National Physical Laboratory (NPL)	Professor Graham Machin, Drs Rob Simpson and Stephanie Bell

University of Southampton Institute of Life Sciences (IfLS)	Professors Mandy Fader, Lisette Schoonhoven, Howard Clark and Liudi Jiang, Drs Georges Limbert and Alex Dickinson Professor Peter Smith
King's College London	Professor Ralph Sinkus, Professor Patricia Grocott, Dr Yan-Shing Chang, Dr Anne Jones, Sheryl Gettings
Cardiff University	Dr Turgut Meydan, Dr Paul Williams, Dr Tomasz Kutrowski
Queen Mary University of London	Professors Pankaj Vadgama and Yang Hao
University of Surrey	Professor Graham Cookson
University College London	Professor Alan Cottenden, Margaret Macaulay
Tel Aviv University, Israel	Professor Amit Gefen, Ayelet Levy
Eindhoven University of Technology, The Netherlands	Professor Cees Oomens, Twan Rooijakkers, Dries van Roovert, Jacques Ernes, Man Teng Fung
University College Los Angeles, US	Professor Barbara Bates-Jensen

Clinical partners include:

Wound Tech HTC	Professors Peter Vowden and Steven Jeffrey, Hussein Dharma
D4D HTC	Dr Nicola Heron, Professor Wendy Tinsdale
TITCH	Nathaniel Mills
Southern Healthcare	Gina Winter-Bates, Paul Clarkson
Solent Healthcare	Dr Marjolein Woodhouse, Pam Woods
University Hospital Trust Southampton	Mr Rowland Rees, Dr David Land, Professor Howard Clark
Thames Valley and Wessex Neonatal Network	Kim Edwards, Hannah Liversedge
Portsmouth Hospital Trust	Chantel Ostler
King's Health Partners	Dr Catina Bernardis, Rachel Box, Dr Jemma Mellerio,
Sheffield Teaching Hospitals NHS Foundation Trust	Professor Chris Chapple
Salisbury Trust	Sarah Prior, Denise Major, Stephanie Scott
Great Ormond Street Hospital NHS Foundation Trust (GOSH)	Dr Anna Martinez, Dr Jemma Mellerio, Nicky Jessop, Jackie Denyer
Cornwall Partnership NHS Foundation Trust	Nicci Aylward-Wotton

INTERNATIONAL ACTIVITIES

Recent examples of international collaboration is our close partnership with Eindhoven University of Technology in the Netherlands, which has enabled us to recently host three Biomedical Engineering Masters students, each of whom worked on projects associated with the Medical Devices and Vulnerable Skin Network (MDVSN). In addition, Jibbe Soutens, a PhD student from Eindhoven, is working on biomarker collection and analysis with Bader and Worsley.

The distinguished expert in wound care from the University College of Los Angeles (UCLA), Professor Barbara Bates-Jensen, spent a two month-period with us as part of her sabbatical to evaluate an objective tool to measure sub-epidermal moisture in both volunteer and clinical cohorts, the latter in conjunction with Professor Lisette Schoonhoven.

SELECTED RESEARCH OUTPUT FROM THE MDVSN

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Dickinson AS, Steer, JW, Woods, CJ, Worsley, PR (2015) Registering a methodology for imaging and analysis of residual limb shape in below knee amputees. *Journal of Rehabilitation Research & Development*, 53, (2): 207-218

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Worsley PR, Smith G, Schoonhoven L and Bader DL (2016a) Characteristics of patients who are admitted with or acquire pressure ulcers in a district general hospital; a three year retrospective analysis. *Nursing Open*, 16;3(3):152-158

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ADDITIONAL REFERENCES

NPUAP/EPUAP Guidelines (2014) Prevention and Treatment of Pressure Ulcers

Black JM et al. (2010) Medical device related pressure ulcers in hospitalized patients. *Int Wound J.,* 7(5):358-65.

Carron M, Freo U, Bahammam AS, Dellweg D, Guarracino F, Cosentini R, Feltracco P, Vianello A, Ori C and Esquinas A (2013). *British Journal ofAanaesthesia,* 110(6): 896-914

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Linder-Ganz E, Gefen A, Elad D and Chen J (2007) A 3D model of the penis for an)alysis of tissue stresses during normal and abnormal erection *Annals of NY Acad. Of Sciences,* 1101: 464-76

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Medical Devices and Vulnerable Skin Network - Optimising Safety in Design

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

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

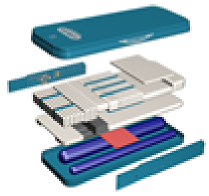
The MDVSN has developed from established Health Technology Cooperatives: Devices for Dignity (D4D) and Wound Prevention and Treatment.

WOUNDTEC HTC
Wound Prevention and Treatment Healthcare Technology Co-operative

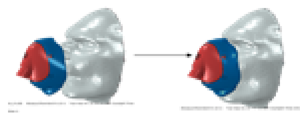
D4D Devices for Dignity

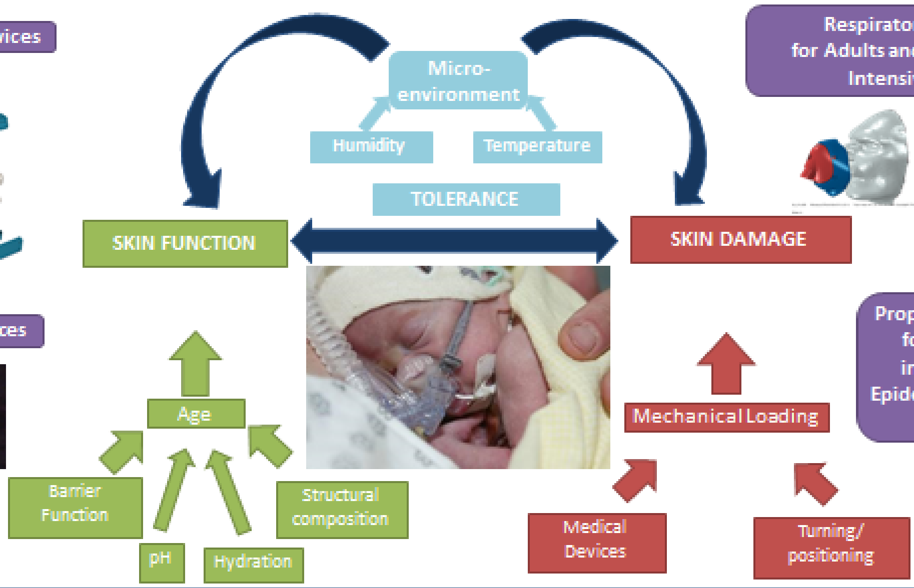
MDVSN partners are involved in a number of on-going projects collaborating with industry, academics and clinicians. It is envisaged that new projects will develop within the Network and beyond

Support surface devices



Respiratory devices for Adults and Neonates in Intensive Care





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

Incontinence devices

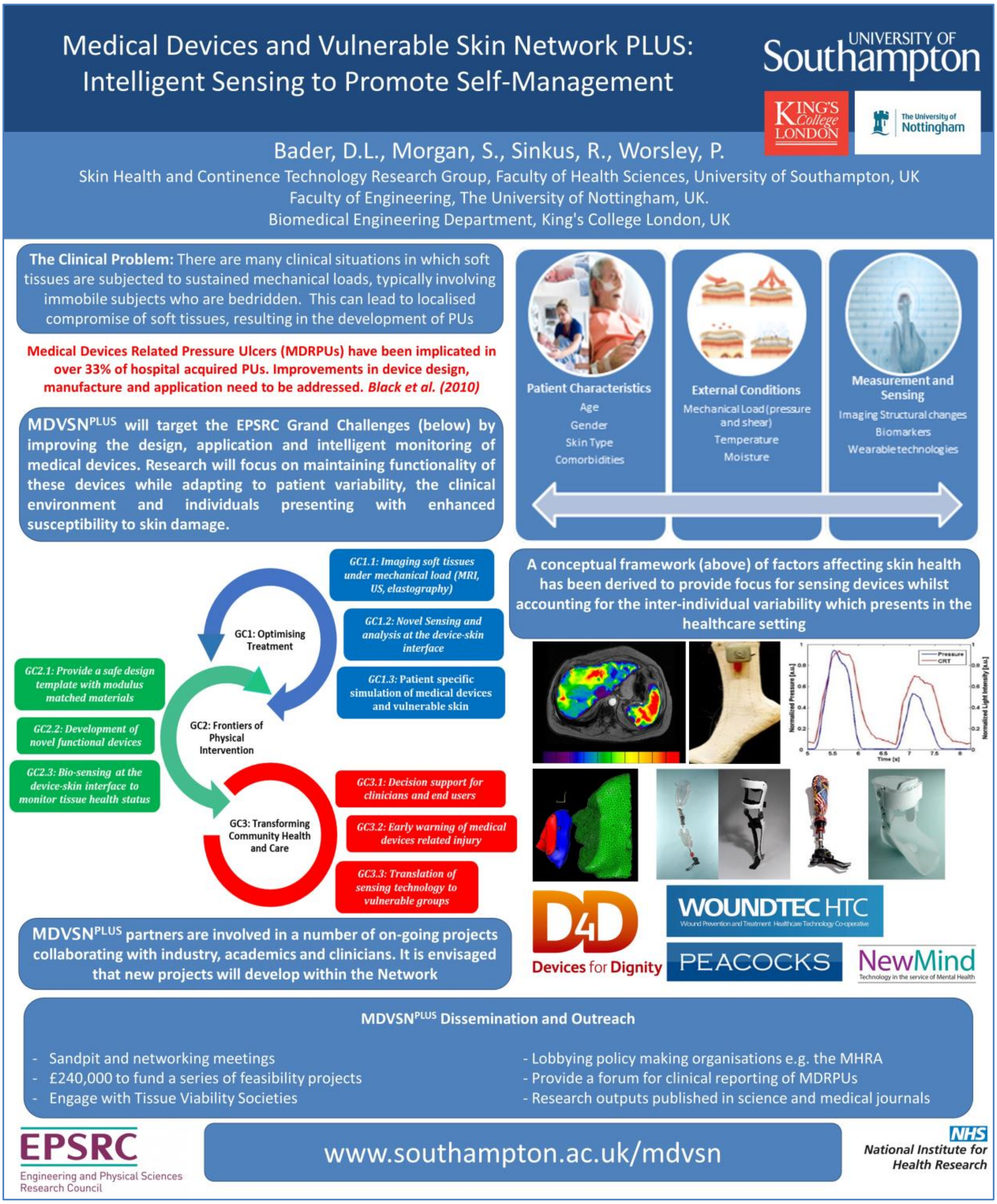
MDVSN Dissemination and Outreach

- 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

www.southampton.ac.uk/mdvsn

NHS National Institute for Health Research


Medical Devices and Vulnerable Skin Network PLUS:
Intelligent Sensing to Promote Self-Management
UNIVERSITY OF Southampton
KING'S College LONDON
The University of Nottingham
Bader, D.L., Morgan, S., Sinkus, R., Worsley, P.
Skin Health and Continence 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
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 Related Pressure Ulcers (MDRPUs) 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 PLUS 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.
Patient Characteristics
Age
Gender
Skin Type
Comorbidities
External Conditions
Mechanical Load (pressure and shear)
Temperature
Moisture
Measurement and Sensing
Imaging Structural changes
Biomarkers
Wearable technologies
A conceptual framework (above) of factors affecting skin health has been derived to provide focus for sensing devices whilst accounting for the inter-individual variability which presents in the healthcare setting
GC1: Optimising Treatment
GC1.1: Imaging soft tissues under mechanical load (MRI, US, elastography)
GC1.2: Novel Sensing and analysis at the device-skin interface
GC1.3: Patient specific simulation of medical devices and vulnerable skin
GC2: Frontiers of Physical Intervention
GC2.1: Provide a safe design template with modulus matched materials
GC2.2: Development of novel functional devices
GC2.3: Bio-sensing at the device-skin interface to monitor tissue health status
GC3: Transforming Community Health and Care
GC3.1: Decision support for clinicians and end users
GC3.2: Early warning of medical devices related injury
GC3.3: Translation of sensing technology to vulnerable groups
Pressure
CRT
Time [s]
MDVSN PLUS 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
D4D Devices for Dignity
WOUNDTEC HTC
PEACOCKS
NewMind
MDVSN PLUS 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 MDRPUs
- Research outputs published in science and medical journals
EPSRC Engineering and Physical Sciences Research Council
www.southampton.ac.uk/mdvsn
NHS National Institute for Health Research


UNIVERSITY OF Southampton
MEDICAL DEVICES AND INTELLIGENT SENSING
MEDICAL DEVICES AND VULNERABLE SKIN NETWORK[PLUS] (MDVSN[PLUS])
The global aim of the MDVSN[PLUS] is to integrate intelligent sensing to promote self-management for medical device users. In partnership with academics, industrialists and clinicians we aim to support the creation of cost-effective functional medical devices and sensing technologies to minimise the risk of damage to vulnerable tissues and improve patient safety. The implementation of these technologies will promote long-term healthcare improvement.
Find more online:
www.southampton.ac.uk/mdvsn
EPSRC
Pioneering research and skills
NHS
National Institute for Health Research
WOUNDTEC HTC
The University of Nottingham