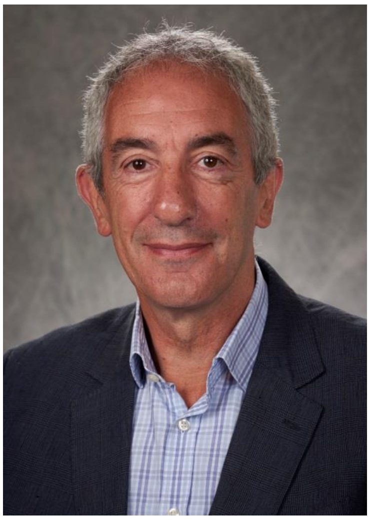
Health
Sciences

UNIVERSITY OF
Southampton

Medical Devices and Vulnerable Skin Network^{PLUS}

Final Report: Year Five | 2014 - 2019



It is with both sadness and pride that we present this the fifth and final Annual Report for 2018-2019 for the Medical Device and Vulnerable Skin Network^PLUS (MDVSN^PLUS). The global aim of the MDVSN^PLUS - Intelligent sensing to promote self-management - was designed to bring disruptive technologies to the medical device market to promote sustainable evolution and long-term healthcare improvements.

Over the Network^PLUS period, we have funded 14 external projects (~£280k), partnering with colleagues from over 30 academic, industrial and clinical disciplines to improve device design. This has involved a range of applications involving respiratory masks, support surfaces, prosthetic sockets for amputees and penile clamps for incontinent men.

Working in close collaboration with the industrial partners has ensured that our research is, and will continue to be, translated into safe and effective devices. We have also engaged with clinicians, including organising a regular session at the Annual UK Tissue Viability conference to highlight issues including reporting of medical device-related tissue damage.

Our research findings have been used by industrial partners to evaluate develop new medical devices which safely interface with patent's skin and our work has influenced the guidelines produced by the European, US and Pan-Pacific Panels (EPUAP/NPUAP/PPPIA). The document includes explicit recommendations and guidelines for pressure ulcer prevention and treatment that are used all over the world.

The MDVSN^PLUS has also targeted 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).

Although awareness has greatly improved over the last five years, many devices are still not fit for purpose both when used in the acute and community healthcare settings. In addition, reporting in the UK remains a significant issue. This is despite the fact that medical devices are known to cause up to 30% of hospital acquired pressure ulcers.

In May 2019, we hosted a MDVSN^PLUS conference: Celebrating our Collaborations where academics, clinicians, funders and industrial partners who have supported our aims to improve medical device design, gathered to discuss progress to date and future plans to improve device design and match this critical healthcare challenge.

We are delighted to confirm that some of our innovative research will be continued in the recent award from a 2020 EU Innovative Training Networks (ITN) Call. This will involve working with international academic and industrial partners who have already been established within MDVSN^PLUS

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**

OUR PROJECTS

There are a number of features which are characteristic of Medical Related Pressure Ulcers (MDRPU) including:

- 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 usage e.g. respiratory masks in intensive care units
- Generic designs do not accommodate individual morphologies and tissue characteristics
- Limited considerations to materials employed at the interface i.e. compliance
- Attach to tissue sites not routinely adjusted to load bearing
- Usual pressure redistribution/relief strategies involving support strategies are not appropriate

During the Network, we have worked with key industrial partners to address these MDRPU features and been successful in attracting over 20 new collaborative industrial partners from the UK and Japan, Sweden, Austria and France to improve medical device design. The development of new international collaborators has been facilitated by organisations such as the NIHR Office for Clinical Research Infrastructure (NOCRI).

The original network aim was to facilitate research into improving medical device safety using novel designs and matched manufacturing capability. In order to achieve this, we funded a total of 14 external projects with partners.

Medical Devices and Vulnerable Skin: Optimising safety in design

Project Title	Academic Collaborators	Industrial Collaborators	Clinical Collaborators
Optimising the design of respiratory masks	University of Southampton, Eindhoven University of Technology	Intersurgical Ltd. (UK)	*University Hospital Southampton Foundation Trust (UHS)*
Prophylactic devices for paediatric patients	King College London.	*NA*	*Great Ormond Street Hospital (GOSH)*
Improving the design of mattress support surfaces	University of Southampton	Hill-Rom (USA), Medstrom Ltd (UK), Care of Sweden (Sweden), HIVIX (Japan).	*NA*
Skin sensing assessment	University of Leeds.	*NA*	*Leeds Wounds Research Unit*
Monitoring at Wound Sites	Queen Mary University of London	*NA*	*NA*
Improving the Design of Prosthetics and Orthotics.	University of Southampton	Blatchfords Ltd (UK), Opcare Ltd (UK)	*Portsmouth Disablement Services Centre (DSC)*
CO2 Skin Gas Sensor	University of Nottingham, University of Southampton	*NA*	*NA*

Medical Devices and Vulnerable Skin 'Plus': Intelligent sensing to promote self-management:

Project Title	Academic Collaborators	Industrial Collaborators	Clinical Collaborators
Vulnerable Skin Imaging	King's College London	*NA*	University Hospital Southampton Foundation Trust (UHS)
Optical Fibre Sensing	University of Nottingham	*Peacocks Medical Group (UK), Footfalls and Heartbeats (UK)*	*NA*
Wireless Textile Sensors	Queen Mary University of London	*NA*	*Royal national Orthopaedic Hospital (UK)*
Conformable Pressure Sensors	University of Edinburgh	*Endura Ltd (UK)*	*MRC Centre for Reproductive Health, Queen's Medical Research Institute, Edinburgh*
Bespoke flexible sensors	University College London	*NA*	*Global Disability Hub*
Vulnerable skin-textile interactions	University of Sheffield	Essity (Sweden)	*NA*
Battery free smart bandage	University of Southampton	*Urgo Limited (UK)*	*NA*

The Network has also provided a platform to apply for additional funds in specific medical device research areas. Funding included successful applications to complimentary networks, UKRIs, NIHR, EU and charity organisations.

Funded Projects with other Networks:

- Surgical MIC (NIHR network), Leeds: *"A Novel Evaluation of Radiotherapy Positioning Boards: Optimising Safety in Design"* – to commence June 2019. £14k

- CYCLOPS Healthcare Network (EPSRC Network), Nottingham: MDVSN^PLUS in association with University of Nottingham and Birmingham City University *"Combining physiological sensing and biomarkers with intelligent support surfaces for closed loop chronic wound prevention"*- commenced Feb 2018: £42k

- IMPRESS Plus Network (EPSRC Network), Leeds: *"Assessing a Penile Compressive Device with Patients, FEA and MRI Modelling"* - commenced Dec 2017: £32k

- NewMind Plus Network (EPSRC Network), Manchester: MDVSN^PLUS in association with University of Manchester. *"Developing early detection methods to assess the risk of pressure ulcers in individuals with mental illness"* - commenced Feb 2018: £15k

Other Funded Projects:

- EPSRC/NIHR Global Challenges Research Fund (GCRF). (EP/R014213/1) *"A Step Change in LMIC Prosthetics Provision through Computer Aided Design, Actimetry and Database Technologies"* – commenced February 2018 (36 months): £900k

- EPSRC CASE PhD Studentship with SUMED "*Identifying Robust Algorithms to Monitor Patient Mobility in the Community: an indicator of developing pressure ulcers"*– October 2016 (36 months): £88k

- NIHR Healthcare Technology –Paediatric Call *"The design of respiratory medical devices to enable effective drug delivery and minimise traumatic damage to vulnerable paediatric tissues*"– November 2015 (24 months). Principal Investigator: Prof H Clark (Southampton): £142k

- UK Knowledge Transfer Partnership (KTP 11095) with Blatchford "*Sensor Smart Liner*"– October 2018 (18 months). Principal Investigator: Prof L Jiang (Southampton): £114k

- H2020-MSCA-ITN-2018 EU Innovative Training Networks (ITN) Call: with five European academic partners and 3 industrial partners. "STINTS -Skin Tissue Integrity under Shear" – January 2019 (48 months). Principal Investigator: Prof M Adams (Birmingham): Total Euros 3.6m

- Health Foundation Scaling Up Fund "*Pressure reduction through continuous monitoring in community settings (PROMISE): reducing and preventing avoidable and unavoidable pressure ulcers"* – commenced Nov 2017: £500k

As well as joint success within the Network and beyond, key members of the MDVSN team have been internationally recognised for their contributions:

- Institute of Physics and Engineering in Medicine (IPEM) - Fellowship, Prof Dan Bader (2018)
- EPUAP - Novice Investigator award, Dr Peter Worsley (2018)
- EPUAP - Trustee, Dr Peter Worsley (2018 -)
- EPUAP – Trustee, Professor Dan Bader (2011-17)
- Editorial board of Journal of Tissue Viability - Dr Peter Worsley (2015 -)
- Associate Editor of Journal of Clinical Biomechanics - Professor Dan Bader (2016 -)
- Editor in Chief of Journal of Tissue Viability - Professor Dan Bader (2011 -)
- BioMedEng Legacy Prize - Professor Dan Bader (2018)
- Tissue Viability Society – Fellowship, Professor Dan Bader (2019)
- ISO Committee for Standardised Testing of surfaces (ISO/TC 173/WG11) Dr Peter Worsley (2017 -)

OUR ACHIEVEMENTS:

- **Early detection of changes in loaded human skin:** MDVSN^PLUS has supported the development of techniques to assess the skin response to prolonged loading of medical devices. Using biomarker activity in sebum and sweat, our research has developed a methodology to estimate robust biomarkers, which reflect the status of loaded skin and the refractory period needed for skin recovery e.g. Worsley et al. 2016, Soutens at al. 2019

- **Lymphatic function in human skin:** We have supported the development, for the first time, of minimally invasive techniques to assess lymphatic function in loaded human skin. In addition, the techniques have been adopted to examine the effectiveness of compression garments to manage lymphoedema. Using ICG fluorescence imaging techniques, our research has developed an analytical methodology to estimate robust parameters which reflect the dynamic behaviour of transient lymphatic packets. This identified the role of lymphatic occlusion on the aetiology of skin breakdown (Gray et al. 2016). In addition, this approach has proved successful in monitoring the short-term effects of external compression garments on lymphatic function (Lopera et al. 2017).

- **Finite Element Modelling, Computer model/algorithm:** We have supported the development of computer simulation in the form of Finite Element (FE) models to predict soft tissue stresses and strains as a result of the application of medical devices (Levy et al 2017). The novel research has focused on two key medical devices; penile clamps and respiratory masks. Computer simulation provides the basis to conduct sensitivity analysis on both the design and material properties of devices to optimise the safety at the patient-device interface. It provides scientific evaluation of medical devices, *in silico*, thus providing a design template for improved device features for use with patients with vulnerable skin.

EXAMPLES OF OUR IMPACT:

- **Clinical Guidance:** Our research has led to changes in default settings and clinical guidance for use in commercial mattress systems (Dolphin Fluid Immersion, Joerns, US) – Worsley et al. 2016

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

- **Support Surface design** – We have interacted with several industrial partners to evaluate the efficacy of support surfaces for pressure ulcer prevention. Studies have identified features within mattress systems incorporating novel designs and interface materials, co-developed into clinical products (Aerospacer, Medstrom; MCM and LPR, HillRom). These systems include technologies to manage the microclimate at the patient interface, automated tilting to offload vulnerable tissues, and internal pressure signatures to maintain skin health (Chai et al. 2017).

- **Sensing Technologies** – Our research has provided evidence to support the CE marking of a sensing device (Sumitomo Riko, Japan). In addition, in concert with Industrial partners (Sumed Ltd, UK and Xsensor, Canada), we are developing predictive algorithms derived from continuous pressure monitoring to establish features of posture and mobility, identified with individuals at risk of pressure ulcers (Caggiari et al. 2019). These technologies have been translated to four UK community trusts, where nurses have implemented monitoring of patients to improve adherence to PU prevention and optimise support surface selection (PROMISE, Health Foundation).

- **Continence Technologies** – Our research with Essity (Sweden) has provided evidence of the performance of moisture-absorbing materials in devices (Bostan et al. 2019).

- **Penile clamp design** – Our bioengineering research approach has revealed that existing designs of penile clamps for males with incontinence created harmful deformations in the penile tissues restricting blood supply and their associated guidelines were deemed not fit for purpose (Lemmens et al, 2019). Subsequently, with the guidance of end-users, we have developed a novel penile clamp device incorporating an ergonomic design and matched interface materials. It is currently being evaluated on a small cohort of male incontinent participants. The design has recently been filed as international patent (WO 2019/063994). The project also created the first evidence-based guideline resulting in safer practice for end users and a reduction in potential damage due to these clamps. Collaboration with Prostate Cancer UK Movember represents a first in kind evaluation of these products and a step change in device design for these vulnerable individuals.

- **Public engagement** - MDVSN plus has successfully communicated and engaged with clinical, industrial, academic and organisational communities to raise the awareness of medical device-related injury though annual sandpit events. Knowledge gained was made available to existing local and UK events attended by clinicians, such as BHTA and Tissue Viability Society.

- **Research project design –** Where insufficient device testing standards exist, MDVSN Plus has specified methodologies to develop a repository of highly valid Standard Testing Protocols (STPs) and Standard Operating Procedures (SOPs). This involved test methods adopting a combinations of in-silco, in-vitro and in-vivo approaches.

- **Knowledge Impact –** MDVSN plus has supported fundamental scientific and technological advances in the field of medical device design and monitoring. Impact has been achieved through discipline leaders in physical monitoring, biomarker detection, medical imaging, computer simulation and innovative sensing. MDVSN plus has disseminated the research outputs through scientific journals (see publication list), conferences and lobbying activities. Knowledge transfer has been enhanced through studentships, mobilisation schemes and collaborative funding with academia.

- **Responsible innovation** - Targeting health research priorities that have been determined on a clinical needs basis, using information gathered by the existing Network and those still to be identified with discussions between clinicians, industrialists and academics.

- **User engagement** – Patient representatives and clinicians have been involved in the planning, undertaking and disseminating research originating from the Network.

- E**conomical and societal impact** – MDVSN plus has aimed to provide impact through improvements in medical device design. For example, the development of a first-in-kind penile clamp for males post- prostatectomy and associated clinical guidelines. In addition, the network has collaborated with a number of support surface manufacturers to co-develop novel features with mattress systems for pressure ulcer prevention (e.g. Hill-Rom ClinActiv+ MCM™ and Medstrom's Aerospacer products).

HOSTED INTERNATIONAL COLLEAGUES:

Colleague	Academic Institution	Dates
T. Rooijakkers	Biomedical Engineering, Eindhoven University of Technology, The Netherlands	04-07/2016
M.T.Fung	Biomedical Engineering, Eindhoven University of Technology, The Netherlands	09-12/2016
D.V.Roovert	Biomedical Engineering, Eindhoven University of Technology, The Netherlands	09-12/2016
J. Ernes	Biomedical Engineering, Eindhoven University of Technology, The Netherlands	09-12/2016
Professor B. Bates-Jensen	School of Medicine and Nursing, UCLA, US	10-12/2016
J. van Asten	Biomedical Engineering, Eindhoven University of Technology, The Netherlands	02-05/2018
W. van Zwam	Biomedical Engineering, Eindhoven University of Technology, The Netherlands	02-05/2018
L Peko-Cohen	Biomedical Engineering, Tel Aviv University, Israel	04-07/2018
Dr. F. Henshaw	School of Medicine and Health, Univ. of Western Sydney, Australia	05-08/2018
L. Crielaard	Biomedical Engineering, Eindhoven University of Technology, The Netherlands	02-05/2019

LOOKING FORWARD:

It is vital that the momentum gained from achievements with MDVSN is continued. This will be facilitated through projects which have secured funding beyond the Network. These include multi-disciplinary activities within the H2020-MSCA-ITN-2018 EU Innovation Training Network (ITN) research project "STINTS: Skin Tissue Integrity under Shear". The focus at Southampton with two Early Stage Researchers (ESRs) will be to continue the search for robust non-invasive biomarkers which are sensitive to spatial and temporal changes in skin, that can be translated into simple screening methods. Monitoring of these will be designed to indicate early damage in skin exposed to mechanical loading in the form of pressure, shear and friction. They will be validated in a range of clinical scenarios where chronic wounds can develop from prolonged loading e.g. pressure ulcers, diabetic foot ulcers and medical device-related skin damage. The EU project will incorporate a total of 13 ESRs located around Europe and based in both academic and large industrial companies. This will ensure continued collaboration with existing partners e.g. Professors Oomens, Gefen and Essity, as well as new partners e.g. Phillips Consumer Lifestyle.

The translation of scanning technologies project will also continue within the EPSRC Global Challenge Research Fund (GCRF) for adoption in Lower/Middle Income Countries e.g. Cambodia. In addition, the project involved in developing a predicting algorithm for movement analysis will be evaluated against data from patients in the community (PROMISE) and those specifically with spinal cord injury.

We will also continue to work with the MHRA and appropriate manufacturers to improve device safety, to be able to advise healthcare professionals on the safe use of devices in both acute and community settings. In addition, we will continue to engage with clinicians, such as Tissue Viability Nurses, and international organisations e.g. EPUAP.

OUR PUBLICATIONS

EP/M000303/1: Medical Devices and Vulnerable Skin: Optimising safety in design:

Correia R, Sinha R, Norris A, Morgan S et al. (2017). Optical fibre sensing at the interface between tissue and medical device. *SPIE.* doi: 10.1117/12.2269811

Dickinson AS, Steer JW, Woods CJ, Worsley PR. (2016). Registering methodology for imaging and analysis of residual-limb shape after transtibial amputation. *Journal of rehabilitation research and development, 53*(2), pp. 207-18. doi: 10.1682/JRRD.2014.10.0272

Gray RJ, Worsley PR, Voegeli D, Bader DL. (2016). Monitoring contractile dermal lymphatic activity following uniaxial mechanical loading. *Medical engineering & physics, 38*(9), pp. 895-903. doi: 10.1016/j.medengphy.2016.04.020

Macaulay M, Moore KN, Fader MJ et al (2015). A trial of devices for urinary incontinence after treatment for prostate cancer. *BJU international, 116*(3), pp. 432-42. doi: 10.1111/bju.13016

Mirtaheri P, Gjøvaag T, Worsley PR, Bader DL. (2015). A review of the role of the partial pressure of carbon dioxide in mechanically loaded tissues: the canary in the cage singing in tune with the pressure ulcer mantra. *Annals of biomedical engineering, 43*(2), pp. 336-47. doi: 10.1007/s10439-014-1233-z

Woodhouse M, Worsley PR, Voegeli D, Schoonhoven L, Bader DL. (2015). The physiological response of soft tissue to periodic repositioning as a strategy for pressure ulcer prevention. *Clinical biomechanics, 30*(2), pp. 166-74. doi: 10.1016/j.clinbiomech.2014.12.004

Worsley PR, Prudden G, Gower G, Bader DL. (2016). Investigating the effects of strap tension during non-invasive ventilation mask application: a combined biomechanical and biomarker approach. *Medical devices: Evidence and Research, 9*, pp. 409-417. doi: 10.2147/MDER.S121712

Worsley PR, Smith G, Schoonhoven L, Bader DL. (2016). Characteristics of patients who are admitted with or acquire Pressure Ulcers in a District General Hospital; a 3 year retrospective analysis. *Nursing open, 3*(3), pp. 152-158. doi: 10.1002/nop2.50

Worsley PR, Parsons B, Bader DL. (2016). An evaluation of fluid immersion therapy for the prevention of pressure ulcers. *Clinical biomechanics, 40*, pp. 27-32. doi: 10.1016/j.clinbiomech.2016.10.010

Vadgama P, Raja M, Shelton JC et al. (2019). An electrochemical study of acrylate bone adhesive permeability and selectivity change during in vitro ageing: A model approach to the study of biomaterials and membrane barriers. *Science Direct, Volume 2, July 2019, 100009* doi: 10.1016/j.acax.2019.100009

EP/N02723X/1: Medical Devices and Vulnerable Skin 'Plus': Intelligent sensing to promote self-management:

Alqahtani JS, Worsley PR, Voegeli D. (2018). Effect of Humidified Non-invasive Ventilation on the Development of Facial Skin Breakdown. *Respiratory care, 63*(9), pp. 1102-1110. doi: 10.4187/respcare.06087

Bader DL, Worsley PR. (2018). Technologies to monitor the health of loaded skin tissues. *Biomedical engineering online, 17*(1), pp. 40. doi: 10.1186/s12938-018-0470-z

Bostan L, Worsley, PR, Abbas S, Bader DL. (2019) The influence of incontinence pads moisture at the loaded skin interface. *Journal of Tissue Viability*. 28(3):125-132. doi: 10.1016/j.jtv.2019.05.002

Caggiari, S, Worsley, PR, Bader DL. (2019). A sensitivity analysis to evaluate the performance of temporal pressure - related parameters in detecting changes in supine postures *Medical Engineering Physics* 69:33-42. https://doi.org/10.1016/j.medengphy.2019.06.003

Chai CY, Sadou O, Worsley PR, Bader DL. (2017). Pressure signatures can influence tissue response for individuals supported on an alternating pressure mattress. *Journal of tissue viability, 26*(3), pp. 180-188. doi: 10.1016/j.jtv.2017.05.001

Dickinson AS, Steer JW, Worsley PR. (2017). Finite element analysis of the amputated lower limb: A systematic review and recommendations. *Medical engineering & physics, 43*, pp. 1-18. doi: 10.1016/j.medengphy.2017.02.008

Levy A, Fader M, Bader D, Gefen A. (2017). Penile compression clamps: A model of the internal mechanical state of penile soft tissues. *Neurourology and urodynamics, 36*(6), pp. 1645-1650. doi: 10.1002/nau.23172

Lemmens J, Bader D, Fader M et al (2019), Tissue response to applied loading using different designs of penile compression clamps. *Medical Devices: Evidence and Research*. Doi: 10.2147/MDER.S188888

Liu L, Hao F, Morgan S, Correia R, Norris A, Korposh S. (2019). A reflection-mode fibre-optic sensor for breath carbon dioxide measurement in healthcare. *Sensing and Bio-Sensing Research,* doi: 10.1016/j.sbsr.2018.100254

Lopera C, Worsley PR, Bader DL, Fenlon D. (2017). Investigating the Short-Term Effects of Manual Lymphatic Drainage and Compression Garment Therapies on Lymphatic Function Using Near-Infrared Imaging. *Lymphatic research and biology, 15*(3), pp. 235-240. doi: 10.1089/lrb.2017.0001

Soetens JFJ, Worsley PR, Bader DL, Oomens CWJ. (2019). Investigating the influence of intermittent and continuous mechanical loading on skin through non-invasive sampling of IL-1α. *Journal of tissue viability, 28*(1), pp. 1-6. doi: 10.1016/j.jtv.2018.12.003

Steer JW., Worsley PR, Browne M, Dickinson A (2019). Predictive prosthetic socket design: part 1—population-based evaluation of transtibial prosthetic sockets by FEA-driven surrogate modelling. *Biomechanics and Modeling in Mechanobiology*. https://doi.org/10.1007/s10237-019-01195-5

Wei Y, Yang K, Worsley PR, Browne, M, Bostan L (2019) Wearable Electrical Stimulation to Improve Lymphatic Function *IEEE sensors letters*. 3(2):1-4 doi: 10.1109/LSENS.2019.2893478

Woodhouse, M, Worsley PR, Bader DL et al. (2019). How consistent and effective are current repositioning strategies for pressure ulcer prevention. *Applied Nursing Research*. 48:58-62. doi: 10.1016/j.apnr.2019.05.013

Worsley PR, Bader DL. (2018). A modified evaluation of spacer fabric and airflow technologies for controlling the microclimate at the loaded support interface. *Textile Research Journal,* doi: 10.1177/0040517518786279

Worsley PR, Clarkson P, Bader DL, Schoonhoven L. (2017). Identifying barriers and facilitators to participation in pressure ulcer prevention in allied healthcare professionals: a mixed methods evaluation. *Physiotherapy, 103*(3), pp. 304-310. doi: 10.1016/j.physio.2016.02.005

Worsley PR, Stanger ND, Horrell AK, Bader DL. (2018). Investigating the effects of cervical collar design and fit on the biomechanical and biomarker reaction at the skin. *Medical devices (Auckland, N.Z.), 11*, pp. 87-94. doi: 10.2147/MDER.S149419

Worsley PR, Rebolledo D, Webb S, Caggiari S, Bader DL. (2018). Monitoring the biomechanical and physiological effects of postural changes during leisure chair sitting. *Journal of tissue viability, 27*(1), pp. 16-22. doi: 10.1016/j.jtv.2017.10.001

Worsley PR, Bader DL. (2018). Response to Letter from Abraham and colleagues, regarding "Monitoring the biomechanical and physiological effects of postural changes during leisure chair sitting". *Journal of tissue viability, 27*(3), pp. 189. doi: 10.1016/j.jtv.2018.05.006

Worsley PR, Conington C, Stuart H, Patterson A, Bader DL. (2018). A randomised cross over study to evaluate the performance of a novel ankle dorsiflexion measurement device for novice users. *Journal of foot and ankle research, 11*, pp. 45. doi: 10.1186/s13047-018-0286-x

Worsley PR, Bader DL, Gefen A. (2019). Bioengineering considerations in the prevention of medical device-related pressure ulcers *Clinical Biomechanics.* 28;67:70-77. doi: https://doi.org/10.1016/j.clinbiomech.2019.04.018

Medical Devices and Vulnerable Skin Network PLUS: Intelligent Sensing to Promote Self-Management

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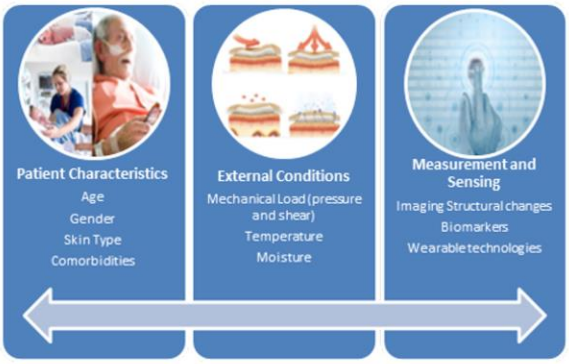
Faculty of Engineering, The University of Nottingham, UK.
Biomedical Engineering Department, King's College London, UK

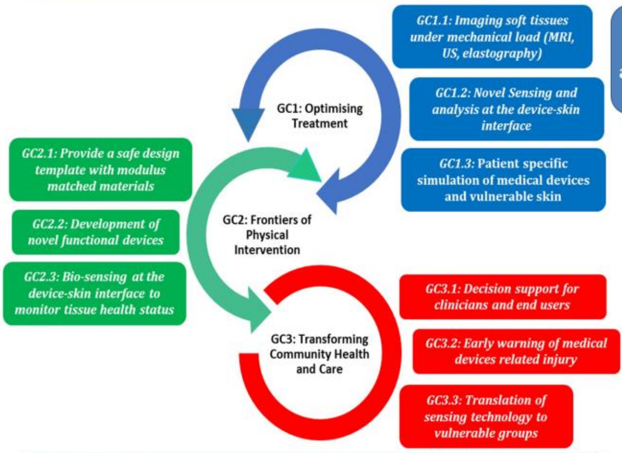
The Clinical Problem: There are many clinical situations in which soft tissues are subjected to sustained mechanical loads, typically involving immobile subjects who are bedridden. This can lead to localised compromise of soft tissues, resulting in the development of PUs

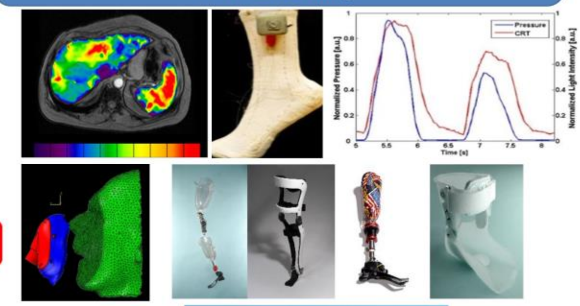
Medical Devices Related Pressure Ulcers (MDRPUs) have been implicated in over 33% of hospital acquired PUs. Improvements in device design, manufacture and application need to be addressed. ***Black et al. (2010)***

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.



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





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
Wound Prevention and Treatment Healthcare Technology Co-operative
PEACOCKS
NewMind
Technology in the service of Mental Health

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