

Medical Devices and Vulnerable Skin Network

Annual Report: Year Two | 2015 - 2016



INTRODUCTION

Welcome to the second Annual Report for 2015-2016 for the Medical Device and Vulnerable Skin Network (MDVSN).

We are pleased to report significant progress this year, which matches the aims of the Network, namely to introduce cutting-edge technologies and scientific understanding in order to reduce the incidence of mechanical-induced damage of vulnerable skin caused by interventional medical devices in various clinical settings.

Highlights include our annual sandpit meeting and clinical workshop, a special session at the Tissue Viability Society in April 2016, as well as a number of presentations as keynote speakers at international conferences and industrial events.

This year, we have continued to engage with clinicians, academics and industrialists to provide a platform for improving the design of medical devices. Several new projects, in the form of work packages, have resulted.

The focus of our activities have also been provided a major boost by the recent announcement from the National Pressure Ulcer Advisory Panel (NPUAP) consensus meeting in Chicago. They have, for the first time, provided an additional pressure injury definition: *Medical Device Related Pressure Injury*, defined as an injury, which results from the use of devices designed and applied for diagnostic or therapeutic purposes.

We have also attended a significant number of International events and conferences, bringing the MDVSN to new audiences and forging new relationships with partners to collaborate on projects that will deliver the maximum impact for the Network.

We have benefited from continuing support from our two NIHR HTCs, Design for Dignity (D4D) and WoundTec. As an example, they have introduced us to various healthcare companies and groups, such as Technology & Innovation Transforming Child Health (TITCH), which have made a positive impact on expansion and diversification of Network activities. In addition, both HTCs have provided invaluable support to our successful awards to the EPSRC and NIHR.

Thank you for your continued support. By working together, we can continue to raise the profile of chronic wounds arising from interventional medical devices to all stakeholder groups, record device related events and, where appropriate, promote changes in device design.

Professor Dan Bader, Professor of Bioengineering and Tissue Health, University of Southampton

Principal Investigator
Medical Devices and Vulnerable Skin Network

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 clinical exemplars, diverse in nature, 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

In 2015-2016, we increased the breadth of this activity by including a number of new projects including lower limb prosthetics and paediatric medical devices. This has resulted in significant progress supported by our academic partners (Grocott, KCL; Fader and Clark University of Southampton; Gefen Tel Aviv University), industry (Fraser Nash, Intersurgical, Blatchford, Medstrom, Hill-Rom), and existing/new funding streams (e.g. MRC, NIHR and Prostrate Cancer UK.)

It was evident in discussions with both existing and new clinical and industrial partners that the scope of MDVSN could be further expanded. 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, 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.

These events have been observed in functional orthotics for the spine, neck and ankle foot complex, the stump-prosthetic socket interface of lower limb amputees, and in other cases highlighted by the MDVSN (face masks, penile clamps etc.). This will inevitably affect a range of patient groups, with increasing involvement in community settings. Indeed in a recent community-based study up to 64% of amputees rejected their prosthesis within a year due to discomfort and skin health issues (*Roffman et al., 2014*). Such a situation can only be addressed with the development of intelligent sensing, preferable in conjunction with prosthetic liners, to provide a feedback mechanism to the clinician in prosthetic fitting and ultimately a self-management detection system alerting the amputee of impending damage at the stump/socket interface. Ill-fitting or inappropriate medical devices, which attach to vulnerable skin share common causal injury mechanisms, which include sustained pressures, shearing forces and microclimate changes (temperature and humidity) at the device-skin interface.

This year, we started to address this clinical challenge with the introduction of scientific assessment of device-related injuries and the development of translational sensing technologies to provide monitoring of device performance and promotion of self-management strategies. This new research agenda will target a range of medical devices that extends the scope of the original MDVSN. For example, potential industrial collaborators, including Peacocks, Beagle Orthopaedic and Blatchford, each with manufacturing capabilities e.g. Additive Manufacturing, sensing and actuating systems, have expressed interest in engaging with research activities associated with prosthetics and orthotics.

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 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 institutions. 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 away from vulnerable individuals (in-silico sensitivity analyses).

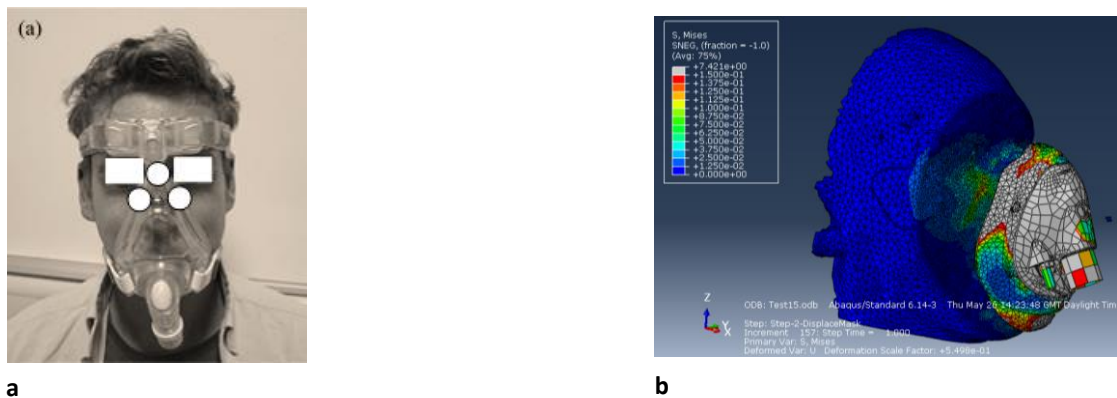


Figure 1: a) experimental testing of respiratory masks on health volunteers, measuring interface pressure, microclimate and inflammatory response at the skin; b) Finite element model of respiratory mask being displaced onto a reconstructed face, superimposed with resulting von Mises stresses.

To date our research has revealed that both mask design and tension of application has a significant effect on the device-skin interface pressures, with an associated inflammatory response being observed on key locations on the face after mask application. This experimental data has been used as boundary conditions for the computational finite element models. Here the mask is displaced onto the face and soft tissue/skin stresses and strains are estimated following mask loading (Figure 1b). 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 appropriate 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 MDVSN has continued to work with new and established 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 of 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 by 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 at 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.

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 MDVSN 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 heat and moisture transfer. The results from these studies were presented by Worsley at the 2015 EPUAP Annual Scientific Meeting in Belgium. Providing sound scientific basis for the design and clinical application of support surfaces remains a key target of MDVSN, 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 on ISO committees for the standardised testing of support surfaces (ISO/TC 173/WG 11, Worsley).

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. It affects a small population with 5,000 cases in the UK representing approximately 1 in 17,000 live births. 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. Due to the severity and progressive nature of the condition, individuals with EB require disproportionately high level of healthcare resources. Hand deformities arise from repeated blistering of the hands and healing by scar formation, which results in webbing of the digits and hand and wrist contractures. The resulting deformities worsen with age, and surgical correction, starting around the age of seven, becomes increasingly difficult to manage.

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; the resulting webbing and contractures require repeat surgery to maintain hand function.

This project is in its second year. Partners within the MDVSN, including King’s College London, Cardiff University, University of Surrey, Longhand Data Limited, Fuel 3D Limited, SFM Limited; Skinwear Limited; C.L.C. Design Consultants together with clinical colleagues within Dermatology at King’s Health Partners and Great Ormond Street Hospital NHS Foundation Trust are co-designing and developing hand therapy devices with the end users.

These include: a disposable dressing glove to aid healing of blisters and post-operative wounds; a novel design for web-spacer glove; a dynamic splint glove to delay contractures, which incorporates sensors to monitor glove performance; and a digital Hand therapy-online system to enable routine charting of hand deformities, clinical outcomes and costs from birth. The new devices are at the concept prototype stage. The dressing glove and web-spacer glove are undergoing surrogate test prior to patient proof-of-concept tests. A range of splint glove prototype technologies are being developed and one or two designs will be prioritised for further development. The Hand Therapy Online system is at an advanced stage of development and will be piloted with patients and parents following Ethics and R&D permissions and approvals.

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 (Prof. Amit Gefen).

The methodology involved segmentation (Simpleware® Ltd.) and meshing of a geometrical anatomical penile model including skin, fat, tunica albuginea (TA), corpus cavernosum (CC) and corpus spongiosum (CS) (Linder-Ganz *et al.*, 2007). 3D orthotropic material properties were assigned to skin and TA, while all 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 and determined device skin-interface conditions and physiological responses of soft tissues. Experimental parameters included interface pressures, blood flow using Laser Doppler imaging, and pro-inflammatory cytokine release.

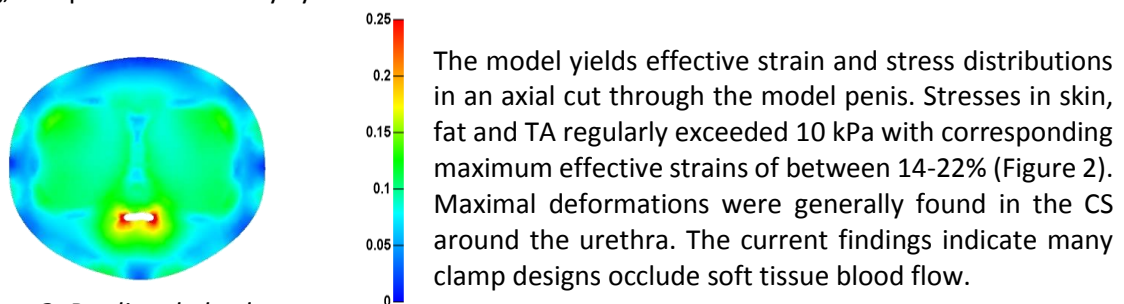


Figure 2: Predicted absolute strains in a cuff-type penile clamp

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.

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 for MDVSN (Figure 3). This has been driven by the known 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 limb tissues not ideally capable of sustaining such loads e.g. residual limb of an amputee. Indeed, such 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 novel sensor at the stump-socket interface of amputees (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 orthotic devices such as cervical collars (partnered with Aspen Medical) and thumb splints. Indeed, following this growing research activity we have partnered with Peacocks Medical Group for the MDVSN^{PLUS}, where we will continue to develop innovate strategies to safeguard vulnerable skin from prosthetics and orthotic devices over the next three years.

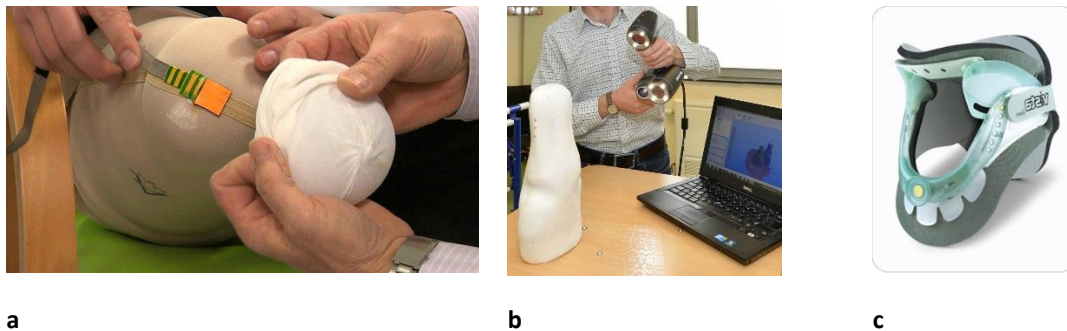


Figure 3: a) Pressure and shear sensor developed to monitor the stump-socket interface of amputees; b) white light scanner being used to image the shape of residual limbs; c) Aspen cervical collar design to enhance comfort and safety.

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

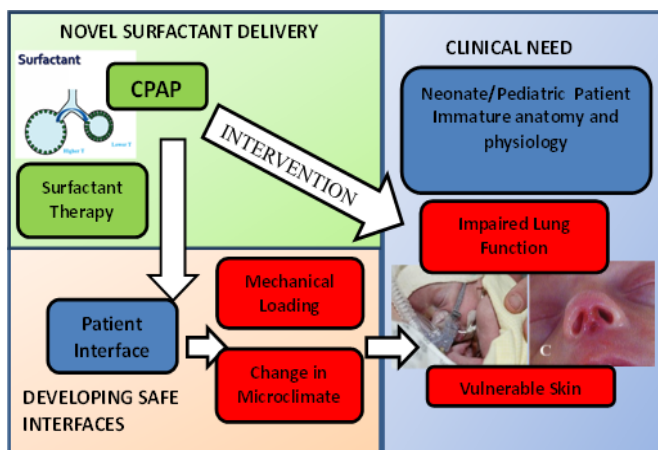
Functional medical devices are prescribed for children for a host of situations ranging from respiratory devices (nasal cannula, continuous positive airway pressure masks and medical tape) in neonatal and paediatric intensive care units to orthotics for movement disorders.

Given the immaturity in structure and function of skin, particularly in pre-term and term infants there can be mechanical-induced damage which is directly attributed to these medical devices.

Working with WoundTec HTC and clinical partner Professor Howard Clark, Professor of Child Health at the University of Southampton, the MDVSN was successful in a bid for a NIHR Paediatric Healthcare Technologies award titled “The design of respiratory medical devices to enable effective drug delivery and minimise traumatic damage to vulnerable paediatric tissues” (Figure 4).

The Paediatric Theme proposal specified two distinct Work Packages motivated by expert clinical opinion:

- 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 practice in the Thames Valley & Wessex Neonatal Operational Delivery Network to establish current clinical practice in the prevention and management of medical device related skin injuries in neonates. 56 responses were returned, the majority of which (64%) were from staff with over 10 years' clinical experience.

Figure 4: Schematic of research strategy for Paediatric Healthcare Technology award

The results of the survey, as presented at the EPUAP 2015 conference in Belgium, indicated that although staff were aware of methods to minimise damage, many of the available resources e.g. device sizes were inappropriate for the neonatal population. The incidence of skin damage was perceived to be high, with 26% of participants stating that they encountered damage daily. The survey showed that staff struggle to protect skin health in neonates due to constraints in training and availability of appropriate prophylactic resources. This has motivated a study investigating the prevalence and incidence of device-related skin damage in neonates. This multicentre study will involve three large acute trusts within the Thames Valley & Wessex Neonatal Operational Delivery Network (Southampton, Portsmouth and Oxford).

As part of the research programme, the team will evaluate of skin maturation in premature neonates. This study involving measurements of skin function in pre-term infants will be conducted at the Princess Anne Hospital in Southampton. We are currently working with the medical and research nurse team to develop the protocol for this study. We have already recruited a senior registrar to undertake the project (Dr Anushma Sharma) and have identified the measures that will be taken (ultrasound imaging, trans-epidermal water loss, pH and inflammatory cytokine screening). Ethics will be sought in May 2016, with an aim to start the project by July 2016.

KEY ACTIVITIES

Our second Sandpit and Workshop Meeting was held in Southampton on 8th October 2015. Exploring the clinical problem associated with the application of diverse medical devices from respiratory masks to cervical collars and penile clamps, the event attracted over 80 delegates including academics, clinicians and industrialists from all over the UK with a few international attendees (Figure 5).

The event also incorporated two engagement workshops, which proved extremely popular with delegates. The first workshop asked delegates to discuss the barriers and facilitators to improving clinical practice and raising awareness of medical device related injuries, creating new/novel medical devices and applying research into the field of medical devices and vulnerable skin.



a



b

Figure 5: Presentations at the 2015 MDVSN Sandpit Meeting of a) Prof Michael Clark, from the Welsh Wound Innovation Centre and b) Prof Lisette Schoonhoven of the University of Southampton

In the afternoon clinical session, clinical colleagues presented examples of medical device related injuries including incontinence devices associated with vulnerable skin, the design of respiratory medical devices to enable effective drug delivery and minimise traumatic damage to vulnerable paediatric tissues, skin injuries resulting from respiratory masks in a High Dependency Unit and device related pressure ulcers in trauma patients.

During the second workshop, delegates were asked to discuss how they can work together to:

- find solutions to the specific clinical problems
- establish which scientific/technological improvements could be made for the design/application and monitoring of medical devices
- effectively report the problems of medical device related injuries
- identify the Governing bodies/funders who can support the work

The discussions at the workshops proved very popular with delegates coming together to discuss new collaborations and potential projects, which could attract support from the MDVSN. Indeed, we welcome any applications involving proof of concept studies. Additionally, a suggestion was made that the inherent damage of medical devices should be highlighted within the Tissue Viability Society. This was followed through by Bader in organising a MDVSN Workshop at the Annual Tissue Viability Society Conference in Cardiff in April 2016.

GRANT/FINANCIAL INCOME

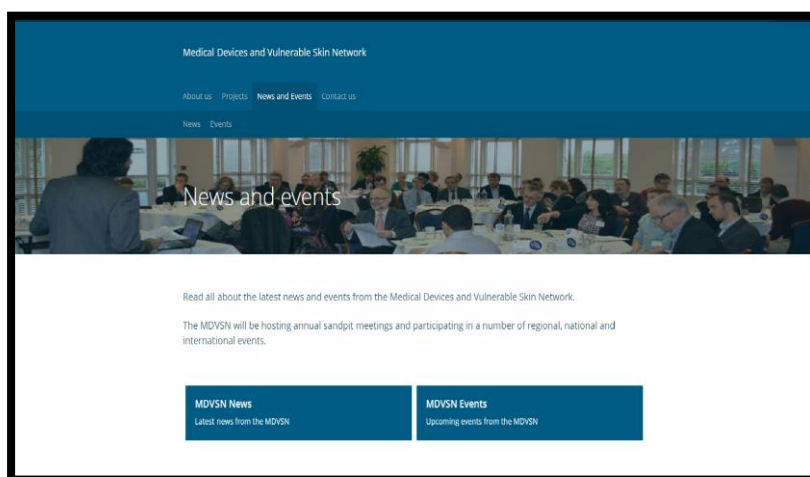
In addition to the NIHR paediatric call award (see WP6), the Network was also successful in securing funding from the EPSRC-NIHR HTC Partnership Award 'Plus' - MDVSN^{PLUS} Intelligent sensing to promote self-management. The new grant will start on 1st July 2016 for three years and will overlap with the current EPSRC-NIHR HTC Partnership Award: Medical Devices and Vulnerable Skin: Optimising safety in design, for 12 months.

The global aim of the MDVSN^{PLUS} is to bring disruptive technologies to the medical device market to promote sustainable evolution and long-term healthcare improvements by coordinating a multidisciplinary team of academics, healthcare practitioners and industrialists. More information and a calls update will be announced at our autumn sandpit.

We have also 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 mattresses 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 and Scarletred, as well as being awarded an EPSRC Case PhD Studentship with Sumed as partners.

MDVSN DISSEMINATION AND LOBBYING

In addition to the Sandpit event, 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 6 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.



In the period of February 2015 to March 2016, the Medical Devices and Vulnerable Skin Network received over 5,200 visits from 4,500 users.

Figure 6: MDVSN website www.southampton.ac.uk/mdvsn

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.

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 interface.

We have been invited to present MDVSN activities at various 2015 meetings including:

- European Wound Management Association (EWMA), incorporating the TVS, London
- International Society of Prosthetics and Orthotics World Congress Lyons, France,
- European Pressure Ulcer Advisory Panel (EPUAP) Annual Scientific Meeting, Gent, Belgium,
- “Prosthetics rehabilitation following war injury” Technology in Medicine Section, London
- “Current evaluation of support surfaces” British Health Trade Association (BHTA), Wellingborough

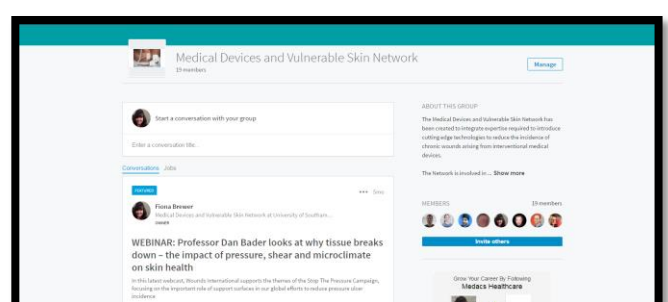
The team continue to engage closely with the Thames Valley & Wessex Neonatal Operational Delivery Network, the respiratory Biomedical Research Unit in Southampton and Welsh Wound Innovation Centre with Profs Harding and Clark. We have recently engaged with Technology Innovation Transforming Child Health (TITCH), where we 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. He also co-presented a Webinar for Wounds International to support the 'Stop The Pressure Campaign 2015', focusing on the important role of support surfaces in the global efforts to reduce pressure ulcer incidence. In the webinar, he detailed current knowledge on:

- the mechanisms of tissue breakdown
- the impact of pressure, shear and microclimate on skin health
- the importance of using an effective support surface.
- the important features to consider when selecting support surfaces for individual patients to optimise care.



a



b

Figure 7: 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

We have also delivered keynote presentations introducing MDVSN projects at over 15 International conferences, events, workshops including:

- 5th Annual Thames Valley & Wessex Neonatal ODN Multi-professional Clinical Day – Feb. 2015,
- Ortho Europe CAD/CAM event - August 2015,
- Prosthetic Rehabilitation, Royal Society of Medicine, London - September 2015,
- Incontinence: The Engineering Challenge X, Institute of Mech. Engin., London - Nov. 2015,
- College of Podiatry Annual Conference, Harrogate – Nov. 2015
- Cardiff Institute of Tissue Engineered Repair – Feb. 2016.
- Skin Workshops – Skin damage and tolerance levels during vigorous sporting activities
- 3rd EPUAP Scientific Focus meeting “The Role of Skin and Tissue Maturation and Aging in Pressure Ulcer Research and Practice” in Berlin - April 2016
- Workshop at the Tissue Viability Society conference in Cardiff – April 2016.

FUTURE PROSPECTS FOR THE MDVSN

With the new grant from EPSRC-NIHR HTC Partnership Award 'Plus' - MDVSN^{PLUS} Intelligent sensing to promote self-management, we will be extending our multidisciplinary team of academics, healthcare practitioners and industrialists, to produce cost-effective functional medical-device and sensing technologies to improve patient safety. It will fund a series of feasibility studies aligned with our core aims and target one or more of three EPSRC Grand Challenges; (i) Optimising Treatment (ii) Frontiers of Physical Intervention (iii) Transforming Community Health and Care. Each potential proposal will be reviewed by an independent innovation panel and assessed based on the clinical need and feasibility to translate the research findings to clinical practice. It benefits from two expert 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 provide 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 the textile or smart bandage. This offers the potential to detect early signs of damage resulting from prolonged use of medical devices.

To complement the emerging UK expertise (Worsley, Dickinson), collaborators with world-leading 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 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*), the stump-socket interface of amputees.

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 estimation 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 in their predictive value 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 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 industry.

Sustainability of the network will be ensured by its integration into an International Skin Health research group with links with the Welsh Wound Innovation Centre (Professor Keith Harding) and further associations with other EPSRC/NIHR funded Networks e.g. IMPRESS, NewMind etc. During the funded period we will aim to generate intellectual property and establish spin off companies associated with the manufacturing of novel medical devices and sensing technologies.

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:

Peacocks Medical Group	Dr Jari Pallari
Fripp Design	Steve Roberts
Activa Healthcare	Jeanette Muldoon
Intersurgical	Mike Hinton
Medstrom	Michael Clancy
Hill-Rom	Thierry Flocard
Frazer Nash Consultancy	Dr Andrew Moore
Sumed International UK	Graham Collyer
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
University of Leeds (IMPRESS Network)	Dr Peter Culmer
University of Manchester (NewMind Network)	Professor Chris Taylor
National Physical Laboratory (NPL)	Professor Graham Machin, Dr Rob Simpson
University of Southampton	Professors Mandy Fader, Lisette Schoonhoven, Howard Clark and Liudi Jiang, Drs Georges Limbert and Alex Dickinson
Institute of Life Sciences (IfLS)	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
University of Surrey	Professor Graham Cookson
University College London	Professor Alan Cottenden, Margaret Macaulay
Tel Aviv University	Professor Amit Gefen
Eindhoven University of Technology	Professor Cees Oomens, Twan Rooijackers

Clinical partners include:

Wound Tech HTC	Professors Peter Vowden, Steven Jeffrey, Hussein Dharma
D4D HTC	Dr Nicola Heron, Professor Wendy Tindale
TITCH	Nathaniel Mills
Southern Healthcare	Gina Winter-Bates, Paul Clarkson
Solent Healthcare	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
Great Ormond Street Hospital NHS Foundation Trust (GOSH)	Dr Anna Martinez, Dr Jemma Mellerio, Nicky Jessop, Jackie Denyer

SELECTED RESEARCH OUTPUT FROM THE MDVSN

- 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): 166-174.
- Oomens CW, Bader DL, Loerakker S, Baaijens FP (2015) Pressure Induced Deep Tissue Injury Explained. *Ann Biomed Eng.*, 43(2): 297-305
- 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. *Ann Biomed Eng.*, 43(2): 336-347
- Herniman J, Thornhill R, Worsley PR, Bader DL, Langley G (2015) The analysis of sweat biomarkers in mechanically-loaded tissues using SFC- MS. ASMS, St Louis, USA
- Laszczak P, Jiang L, Bader, DL, Moser D, Zahedi S. (2015) Development and validation of a 3D-printed interfacial stress sensor for prosthetic applications. *Medical Engineering & Physics*, 37(1): 132-137.
- Laszczak P, McGrath M, Tang J, Gao J, Jiang L, Bader DL, Moser D, Zahedi S. (2016) A pressure and shear sensor system for stress measurement at lower limb residuum/socket interface. *Medical Engineering & Physics*, 38(7):695-700.
- 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
- Warwick D, Shaik A, Stokes M, Worsley PR, Bain D, Tucker A, Gadola S. (2015) Microcirculation in the foot is augmented by neuromuscular stimulation via the common peroneal nerve in different lower limb postures: a potential treatment for leg ulcers. *International Angiology*, 34(2): 158-65

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 of Anaesthesia*, 110(6): 896-914
- Gefen A, Chen J and Elad D (1999) Stresses in the normal and diabetic human penis following the implantation of an implantable prosthesis. *Med. Biol. Eng. Comput.*, 37: 625-31
- Linder-Ganz E, Gefen A, Elad D and Chen J (2007) A 3D model of the penis for analysis of tissue stresses during normal and abnormal erection *Annals of NY Acad. Of Sciences*, 1101: 464-76
- Oomens et al (2013) A numerical study to analyse the risk for pressure ulcer development on a spine board. *Clinical Biomechanics* 28, 736-42
- Oomens CWJ, Loerakker S, Bader DL (2010) The importance of internal strain as opposed to interface pressure in the prevention of pressure related deep tissue injury *Journal of Tissue Viability*, 19: 35-42
- Chai CY (2011) Can Interface conditions be modified by support surfaces to minimize the risk of pressure ulcer development? PhD Thesis, *Queen Mary University of London*.



Medical Devices and Vulnerable Skin Network UNIVERSITY OF Southampton

- Optimising Safety in Design

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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

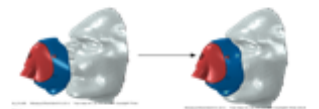
Support surface devices



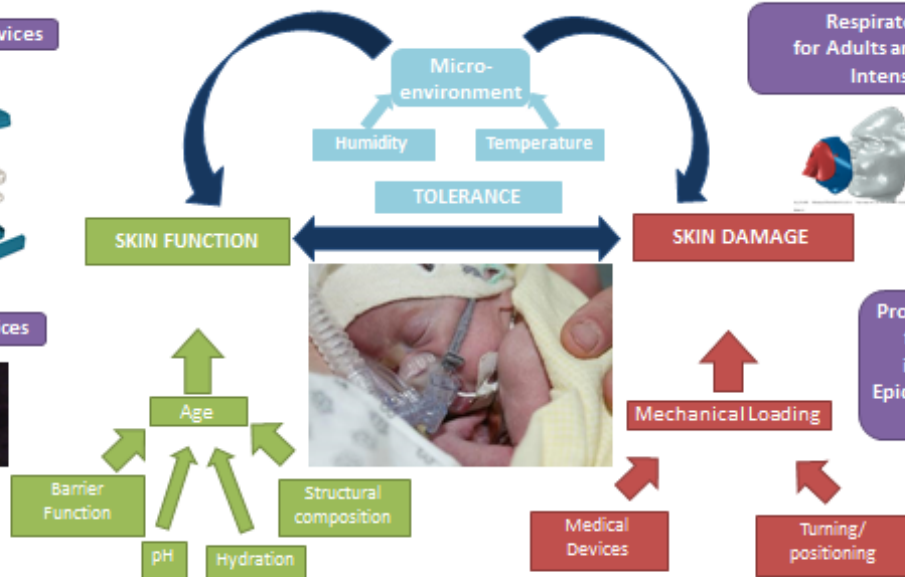
Incontinence devices



Respiratory devices for Adults and Neonates in Intensive Care



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



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