Health Sciences



Medical Devices and Vulnerable Skin Network

Annual Report: Year One | 2014 - 2015



INTRODUCTION

It is my pleasure to introduce the first Annual Report (2014-2015) for the Medical Device and Vulnerable Skin Network (MDVSN). The report aims to summarise the Network's key achievements over the initial 12 months and our future plans and aspirations.

The Network represents an EPSRC-NIHR HTC funded partnership led by the University of Southampton (Bader and Worsley) and King's College London (Grocott), with support from the NIHR Healthcare Technology Co-operatives (HTCs) associated with Wound Prevention & Treatment and Devices for Dignity (D4D) and named academic and industrial collaborators. 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.

Its global aim is to provide a technological platform for novel designs of medical devices incorporating matched interface materials and manufacturing capability, which will protect vulnerable skin tissues from mechanical-induced injury. This requires the coordination of a multidisciplinary team of academics, clinicians and industrialists, each providing expertise to fulfil a series of management, scientific, technological and clinical objectives.

Over the past 12 months, we have held our first sandpit event, funded exploratory collaboration meetings with industrial, academic and clinical colleagues and established a dedicated website to disseminate the impact of our projects. We have also attended a number of events and conferences, introducing the aims and objectives of the MDVSN to new audiences and forged new relationships with partners to collaborate on projects that will deliver the maximum impact for the Network.

The success of the MDVSN will be the result of multidisciplinary research by ourselves and our partners collaborating on projects that are delivering novel translational solutions including embedding research knowledge and innovation into our partner HTCs to satisfy their mid- and long-term goals of, for example "global leader in wound avoidance".

We encourage partners, with an interest in the area of medical devices and their impact on vulnerable skin, to engage with us and work together to raise the profile of chronic wounds arising from interventional medical devices to all stakeholders.

For regular updates on the work of the Network, please see our website: <u>www.southampton.ac.uk/mdvsn</u>

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

THE CLINICAL CHALLENGE

Overall chronic wounds, as typified in the development of pressure ulcers (PUs) and diabetic foot ulcers, represent a burden to both individual sufferers, impacting on their Quality of Life and the health services. As an example, UK incidence rates for PUs are unacceptably high with associated treatment costs of £4 billion per annum, **representing 3% of out-time expenditure in the NHS.**

The Darzi report places quality and patient safety at the heart of the NHS agenda, with pressure ulcer prevention a key safety initiative. Also PUs, many of which are preventable, encompass quality of care initiatives and patient awareness campaigns. Thus effective preventative strategies are critical for adoption within the NHS to achieve the overall goal of wound avoidance and, by implication, recurrence. Each year, the European Pressure Ulcer Advisory Panel (EPUAP) supports a 'Stop Pressure Ulcer Day' to help publicise pressure ulcer issues and bring them to the attention of the public, professionals and politicians. In addition, the EPUAP in conjunction with the organisations in the US (NPUAP) and the Pan-Pacific Pressure Injury Alliance have published their 2014 Guidelines entitled "Prevention and Treatment of Pressure Ulcers".

Medical devices are often based on traditional polymeric materials, which are secured onto the skin with tape and strapping. This creates pressure and shear forces as well as an altered microclimate at the device-skin interface. Indeed, evidence has revealed medical devices as a causal mechanism for PUs, with a third of hospital PUs medical device-related, termed MDRPUs (*Black et al. 2010*). These cases of soft tissue damage are observed in a large number of clinical settings, for example, respiratory masks in intensive care units (Fig. A), and the stump-socket interface of amputees (Fig. B). In addition, device-skin conditions can lead to pain and device rejection. Factors implicated in MDRPUs are:

- Devices are based on generic designs and do not accommodate patient variability.
- Devices employ materials which are relatively stiff and do not match the compliance of skin.
- Inadequate guidance is given regarding device application.
- Many individuals exhibit skin with impaired tolerance to loading.





This has led to the following research question to be addressed by the MDVSN: Can the safety of medical devices be improved with novel designs incorporating matched interface materials and enhanced clinical guidance?

There are a host of measurable extrinsic factors associated with soft tissue breakdown, including mechanical and environmental parameters such as pressure, shear, temperature and humidity. In addition, intrinsic factors can influence soft tissue tolerance to loading which can lead to individual vulnerability. Activity within the MDVSN is focused on providing benefits to patient-centric Quality of

Life. In particular, improving device design will maintain appropriate function, while reducing discomfort and minimising the occurrence of lifelong scarring and disfigurement injuries.

Effective designs will also enable the NHS to reduce costs associated with the treatment of medicaldevice related skin damage and their recurrence and the healthcare industry can develop a range of safe devices with novel materials with associated financial benefits. Accordingly activities within MDSVN are designed to extend the success of UK plc in the advanced would dressing market, which currently embraces over 20% of the global market in the wound prevention or avoidance market.

OUR CURRENT PROJECTS

Current medical devices are based on designs employing traditional materials which are relatively stiff/rigid and do not match the compliance of fragile skin tissues. To date, the MDVSN has been addressing the research question with a number of feasibility studies spanning four key research themes. Each work package will be measured against specific objectives, namely,

Objectives	Ref	Key Targets
Scientific	S1	To understand how damage mechanisms occur in loaded fragile skin.
	S2	To develop a series of models which can predict how medical devices
		perform in association with fragile skin
	S3	To provide a template of design features, including material
		properties which minimise the risk of damage to fragile skin
Technological	T1	To introduce novel design features to medical devices
	T2	To establish new polymer materials to interface with skin safely
	Т3	To develop a series of robust biosensors providing point-of-care
		diagnostics and early detection of skin damage
Management	M1	To provide an environment in which basic science and technology
		knowledge can be translated into novel designs of medical devices
		with full engagement of industrial partners and clinical colleagues
	M2	To fill gaps across the wider community, by linking partners with a
		focus on device management relevant to NHS practice and patient needs
Clinical	C1	Facilitate discussion to address clinical problems associated with
	01	device related injuries to skin and soft tissues
	C2	To design out device features, which result in iatrogenic injuries
	C3	To provide safe guarding for vulnerable patients who rely on medical
	00	devices both in the acute and community setting.

WP1 Respiratory devices

Respiratory devices for adults and neonates in Intensive Care (S1, S2, T3, M1 and C)

Respiratory masks are often prescribed to individuals who require breathing support or medicinal interventions such as oxygen therapy. These devices are used on a range of hospital patients from neonates with immature lungs, to elderly individuals with chronic respiratory problems.

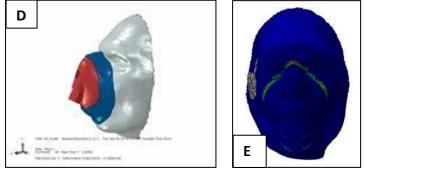
Recent research has shown that respiratory support devices such as masks and nasal prongs can cause damage to the skin and underlying soft tissues when used for prolonged periods. Indeed, lesions on the bridge of the nose account for a large portion of mask complications, occurring in 5-30% of patients (*Carron et al. 2013*).

The development of skin abrasions or necrosis is one factor that can limit the tolerance and duration of wearing the mask. Progressive tightening of the harness, increasing the air volume in the mask cushions, and increasing inspiratory pressure are factors that promote nasal pressure ulcers.



A combination of experimental studies and computational modeling, matched to clinical experiences, has been adopted to evaluate existing mask designs. This has involved collaboration with clinical (Solent NHS Trust, University Hospital Southampton NHS Trust), academic (University of Southampton) and industrial (Intersurgical, Frazer-Nash Consultancy) partners. Our research aims to establish key design features and materials which could be a causal factor in MRPUs in individuals who wear masks for prolonged periods (Fig. C). In order to fulfil

these aims we are adopting computational modelling techniques to introduce novel designs which can safely interface with vulnerable skin tissues. A finite element model was created using a Magnetic Resonance Imaging (MRI) data set, where skin, soft tissue and bone tissues were defined (Fig. D). Boundary conditions from experimental studies and clinical guidance were used to apply a CAD mask model onto the face. Results showed high contact pressures on the bridge of the nose and these translated into high strain values in the underlying skin and soft tissues (Fig. E). These high contact pressures corresponded with areas of skin damage observed in clinical practice (Fig. F).





Research output has been developed through collaboration with Frazer-Nash Consultancy to employ a summer intern to develop the face-mask model. Results have shown that contact pressures on the bridge of the nose are high and this has translated into high strain values in the underlying skin and soft tissues. Sensitivity analyses are currently being performed to establish optimal material modulus of the mask, in order to minimise tissue strains whilst maintaining device functionality.

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. (T1, T3 and M1)

PUs can occur in any situations where people are subjected to sustained mechanical loads, but are particularly common in immobile and insensate subjects who are bedridden or confined to chairs for much of their waking day (Fig. G). Thus, common sites of damage include the sacrum, heel, ischial tuberosities (ITs) and the back of the head. The benefits of some form of pressure relief and/or redistribution have been well established for many subject groups deemed to be at high risk of developing pressure ulcers.



It can be provided by a number of management strategies ranging from regular turning of the patient, which is labour intensive, to active support surfaces including a number of commercial alternating pressure air mattresses (APAMs). The use of APAMs is based on the premise that such systems, which are used in both hospital and community settings, reduce the effects of prolonged load-induced ischaemia on soft tissues overlying bony prominences, such as the sacrum and heels. For financial reasons, they are generally reserved for

use with subjects deemed to be at high risk of developing pressure ulcers.

There is a well-established collaboration between researchers at the University of Southampton and health care companies manufacturing support surfaces. This has expanded within the MDVSN. In addition, there is considerable industrial interest in developing material systems, which control the microclimate at the loaded skin interest. This matches research expertise within the MDVSN in monitoring temperature and humidity in both physical models and clinical situations.

WP3 Prophylactic devices

Prophylactic hand devices to delay disease progression hand deformities for infants, children, adults suffering from Epidermolysis Bullosa (C1, C2, C3, T1, T2, M1, M2)

Generation and evaLuation Of hand therapy deVices for Epidermolysis – GLOVE Project (Grant Ref: II-LB-0813-20002).



Epidermolysis Bullosa (EB) is an inherited lifelimiting condition. It affects a small population (1 in 17,000 live births; 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. People with EB require disproportionately large healthcare resources because of the severity and progressive nature of EB. 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. 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. (Fig. H). Current devices are not tolerated; the resulting webbing and contractures require repeat surgery to maintain hand function. This project is based upon the experiences of adults with EB from the WEB (Woundcare for Epidermolysis Bullosa) project, which was awarded the 2013 Guardian University Award for 'outstanding research impact' (http://www.guardian.co.uk/higher-education-network/university-best-practice).

WEB is collaboration between patients with EB, clinical academics, a clothing designer, manufacturers and electronic data capture companies.

At the patients' request WEB developed dressing retention garments (Skinnies WEB[™]) as alternatives to bandages. The patients and clinicians observed the Skinnies gloves aided post-operative recovery from surgery to release webbing, and delayed webbing, extending the time between repeat surgery. Two more devices are required to manage wounds and delay contractures, a dressing glove and splint glove, which are compatible with the web-spacer glove. 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 lining to aid healing of blisters and post-operative wounds; 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.

Prophylactic device retention systems for neonates in intensive care including infants suffering from Epidermolysis Bullosa (S1, S2, C1, C2, C3, T1, T2, M2)

For neonates in intensive care airway management with devices such as masks, oro- or nasopharyngeal airway insertion, can damage skin, lips, tongues and mucous membranes. Nutritional status is affected and trauma to nasal passages must be avoided with nasalgastric tubes. Current equipment and retention tapes can cause pain and skin damage.

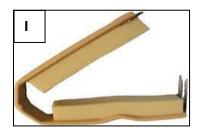
Partners within the MDVSN, King's Health Partners and the Craft Council are in the process of setting up an investigation into features of neonates and EB skin affected by devices with a particular focus on device positioning and attachment, the microclimate and the sources of mechanical loading. Expertise is being drawn from clothing designs, innovative materials, 3D imaging of skin deformation and body shape and seamless knitwear manufacturing, to identify materials, designs and manufacture of affordable device attachment systems.

Pre-clinical investigation and modelling of designs and materials is being conducted in terms of fluid and moisture management and impact on the skin, coupled to surrogate tests of designs. This approach can be translated to others with fragile skin e.g. adults in intensive care, those with stomas and other external devices which need to be attached to the skin.

WP4 Incontinence devices

Clamps for males with persistent urinary incontinence (S1, S3, T1, T3, M2 and C2)

Although a range of devices for men with urinary incontinence exist, some lead to soft tissue damage, ulceration, pain and discomfort and this limits their use. Recent research indicates that penile clamps are preferred by active males due to its ease of use and lack of leakage.



However, the clamp is not clinically recommended because if applied with excess force, the fragile soft tissues of the penis can be damaged (Fig. I and J).



This motivates the design and development of improved designs and materials to match the internal pressures in which the soft tissues will remain viable.

In this area, the MDVSN benefits from an established research team in Southampton, led by Professor Fader, funded by Prostate Cancer UK, to develop effective and comfortable penile compression devices. They are recording the experiences of patients and conducting tests to evaluate the device impact on soft tissues.

The MDVSN has been adding value by providing pre-clinical simulation of penile clamp designs using Finite Element Analysis (FEA) approach, with boundary conditions provided by biomechanical and physiological responses from lab testing.

Of the few published computational models of the penis to examine various physiological functions and disease processes, Gefen and colleagues (1999, 2007) predicted the internal mechanical state of the internal structures, in the form of local Von Mises stresses, at different levels of blood pressures up to 13.3kPa. Accordingly, in collaboration with Prof Gefen from Tel Aviv, we are simulating the external conditions imposed on the model by the application of a number of selected clamp designs used to manage male incontinence. The use of realistic boundary conditions will enable the examination of the effects of design features on the internal mechanical state of the tissues and vessels within the penis, with particular reference to threshold levels of tissue tolerance. The model has also been used to predict novel designs of clamps, which demonstrate functional competence and minimise trauma to the vulnerable soft tissues.

TRANSLATION

As new design features of medical devices are identified within the programme of research, the MDVSN will target the pathways to translation and impact by providing a forum for collaboration to identify health research priorities, determined on a clinical need basis. Once these ideas are established it will seek advice from the relevant stakeholders in the medical device industry, governing organisations (MHRA), market representatives (NHS) and patient groups. This will be achieved through invitations and involvement in the annual sandpit meetings and planned engagement within the Network.

Once these ideas and designs are established we will seek expertise to establish clinical trial designs, funded through a range of funding agencies (NIHR, TSB, Research Councils e.g. MRC, industry and charities).

ACTIVE NETWORK PARTNERS

Successful collaborations within the MDVSN and beyond will facilitate multidisciplinary research and provide a platform for novel, translational ideas. The associated spidergram is illustrated in Fig. K.

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	lan Shurville

Industrial Partners include:

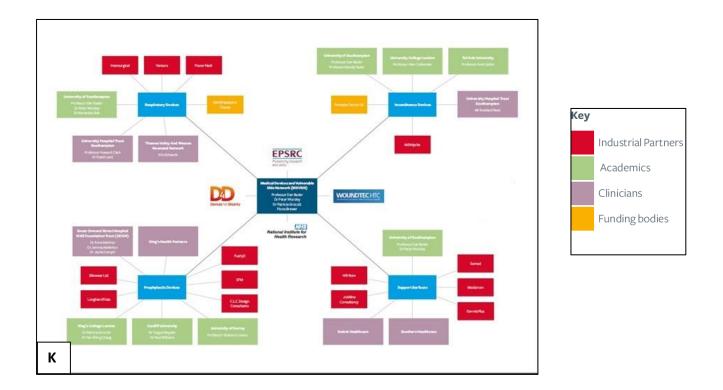
Fuel 3D	Andrew Smith
Longhand Data Limited	Roger Young
Skinwear Limited	lan Davenport
SFM Limited	Matt Stratton
C.L.C. Design Consultants Limited	Alex Currie

Academic Partners include:

University of Newcastle	Professor Kenneth Dalgarno, Dr Javier Munguia
University of Nottingham	Professor Stephen Morgan
Queen Mary University of London	Professor Ton Peijs
National Physical Laboratory (NPL)	Professor Graham Machin
University of Southampton	Professors Mandy Fader, Lisette Schoonhoven,
	and Howard Clark, Dr Georges Limbert
Institute of Life Sciences (IfLS)	Professor Peter Smith
Kings College London	Dr 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
Tel Aviv University	Professor Amit Gefen
University College London	Professor Alan Cottenden

Clinical partners include:

Southern Healthcare	Gina Winter-Bates, Paul Clarkson
Solent Healthcare	Marjolein Woodhouse, Pam Woods
University Hospital Trust Southampton	Mr Rowland Rees, Dr David Land
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, Jane Clapham
Sheffield Teaching Hospitals NHS Foundation	Professor Chris Chapple
Trust	
Great Ormond Street Hospital NHS Foundation	Dr Anna Martinez, Dr Jemma Mellerio, Nicky
Trust (GOSH)	Jessop, Jackie Denyer



KEY ACTIVITIES

On the 26th November 2014, the MDVSN held its first sandpit event, attended by 45 delegates with an interest in the latest research and developments in medical devices and their impact on vulnerable skin. The meeting was designed to promote exchange of ideas and techniques between academics, industrialists, clinicians, and key government agencies to foster collaborations with focus on a series of clinical exemplars.



Lectures at the Sandpit meeting: Hussein Dharma of the WoundTec and Prevention HTC (Fig. L) and Prof Steve Morgan of the University of Nottingham (Fig. M)

In the morning session, keynote presentations were given by Dan Bader and representatives from our partner NIHR HTCs. The afternoon session provided an open forum to discuss research opportunities within four key themes:

- Computational Modelling to predict Device Performance (led by University of Southampton)
- Physiological Sensing of Skin Tissues (led by University of Nottingham)
- Measurements to Improve Wound Management (led by the National Physical Laboratory)
- Medical Device Design (led by University of Newcastle)

There was an encouraging response from delegates including:

"Thank you for organising and inviting me to this Sandpit Event, I found the day very useful, and thought you had a very good mix of excellent presentations." Sally Mounter, Senior Medical Device Specialist at MHRA

"It was a tremendously helpful and interesting day and I feel that the Network has got off to a fantastic start." **Rory O'Connor, Senior Lecturer in Rehabilitation Medicine, University of Leeds**

From this event, we have identified a number of potential projects and have been collaborating with multidisciplinary colleagues to develop these ideas into the possibility of implementation.

GRANT/FINANCIAL INCOME

Working with WoundTec and Prevention HTC and clinical partner Professor Howard Clark, Professor of Child Health at the University of Southampton, the MDVSN has recently been 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".

The MDVSN has also generated additional funding through collaborative projects with selected industrial partners including manufactures of support surfaces, Medstrom and Hill-Rom. It will be actively pursuing funding calls and competitions from UK Research Councils and NIHR.

MDVSN DISSEMINATION AND LOBBYING



During 2014/2015 we have been very active in raising the awareness of medical device-related injury.

We have recently launched the MDVSN website (*ww.southampton.ac.uk/mdvsn and Fig. N*) to be used as part of our strategy to attract other academics to offer additional expertise to the innovation platform in the form of methodological or theoretical techniques and to engage partners within the Network.

The MDVSN website is designed to disseminate project activities and information related to upcoming meetings, conferences and sandpits of relevance to the multidisciplinary community.

It will also be used to broadcast our activities to a wider academic and clinical audience, acting as a repository for research findings, information, a platform for two way discussions and a driver for news e.g. bulletins.

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 have represented the aims of the Network at key workshops, conferences and international events including:

- Conference of the European Wound Management Association in cooperation with Tissue Viability Society (TVS) London, UK, 2015,
- ISPO World Congress Lyons, France, 2015,
- EPUAP Annual Meeting (European Pressure Ulcer Advisory Panel Gent, Belgium, 2015,
- European Tissue Repair Society & the Wound Healing Society, Copenhagen, Denmark, 2015.
- EPSRC/NIHR HTC Partnership Awards Network Workshop, Birmingham, 2015

Throughout the year we have also hosted a number of exploratory partner project meetings to investigate mutual areas of expertise. Research output from the MDVSN will be published in specialised peer reviewed journals and targeted conferences. Information will also be published via clinical journals, networks e.g. TV nurses and policy makers within the NHS. Exemplars of targeted groups with their associated meetings would include: EPUAP, UK Tissue Viability Society and European Wound Management Association, International Continence Society, DEBRA and Neonatal Society.

FUTURE PROSPECTS FOR THE MDVSN

As we look to the second year of activity, the MDVSN will aim to consolidate on the initial successes that we have made and to forge new partnerships in emerging research themes areas area such as amputee research, orthotics and the diabetic foot. These themes will also provide the focus of our next MDVSN sandpit event, to be held on Thursday 9th October 2015 at the Chilworth Manor Hotel on the University of Southampton Science Park. At the event, we will be exploring the clinical problem and medical device management issues and the technical assessment of the effectiveness of technology solutions to solve them. As research projects start to deliver impact, the findings will be disseminated to appropriate stakeholders via papers, website and engagement at events.

SELECTED RESEARCH OUTPUT FROM THE MDVSN

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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

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Grocott P, Blackwell R, Weir H, Pillay E. (2012) Living in dressings and bandages: findings from workshops with people with Epidermolysis bullosa. *International Wound Journal*, 10 (3): 274–284.

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