Institution: University of Southampton		
Unit of Assessment: 03 Allied Health Professions, Dentistry, Nursing and Pharmacy		
Title of case study: 03-05 Advancing technologies to maintain skin health and improve pressure ulcer prevention in vulnerable patients		
Period when the underpinning research was undertaken: January 2011 – December 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s):	**Role(s) (e.g. job title):**	**Period(s) employed by submitting HEI:**
Dan Bader	Professor of Bioengineering and Tissue Health	January 2011 – present
Lisette Schoonhoven	Professor of Nursing Science	January 2012 – April 2018
Peter Worsley	Associate Professor	January 2011 – present
Liudi Jiang	Professor of Materials and Electromechanical Systems	August 2006 – present
Alex Dickinson	Associate Professor, Bioengineering	May 2010 – present
Period when the claimed impact occurred: June 2014 – December 2020		
Is this case study continued from a case study submitted in 2014? N		

1. Summary of the impact

The Skin Health Group at the University of Southampton has led a multidisciplinary consortium to evaluate and optimise cutting-edge technologies to improve the safety of interventional and therapeutic medical devices and minimise skin damage in vulnerable patients. The resulting commercialised devices have had an impact on patient care, leading to pressure ulcer prevention and effective wound healing; the research underpinning them has shaped new international clinical guidelines. Working with the NHS, the Group has pioneered the use of sensing technologies to reduce pressure ulcer risk, resulting in improved patient experience and adoption by four NHS trusts. The economic impact of co-developed medical products is seen through the use of one mattress system in six NHS sites, generating revenues of GBP500,000 for a UK company, the sale of 20,000 therapeutic mattress products by a US company across 20 countries, and the creation of a spinout company attracting external investment and creating jobs. The research has changed national policy – for the first time, device-related pressure ulcers are part of routine reporting practice across 200 NHS sites – and the team have influenced the design of new international device standards.

2. Underpinning research

Skin damage, in the form of chronic wounds, is a major global healthcare challenge, resulting in pain and reduced quality of life in vulnerable patients. Chronic wounds are associated with an estimated annual cost of GBP5bn in the UK alone. Despite national and international directives, the incidence of chronic wounds such as pressure ulcers (PUs) has remained unacceptably high. There are many situations where PUs occur, ranging from immobile individuals spending prolonged periods in a bed or chair, to those in critical care environments where therapeutic or interventional medical devices are attached to skin and can cause damage. Individuals of all ages can be affected, leading to greater care dependency and longer hospital stays.

Translational research by the Skin Health Group has explored the mechanisms of skin damage and developed novel sensing technologies to reduce the incidence of mechanical-induced damage in vulnerable patient groups. This was achieved through a multidisciplinary approach, involving nursing scientists (Schoonhoven), allied health professionals (Worsley) and bioengineers (Bader, Jiang, Dickinson). Our key research findings have included the characterisation of the skin response to representative clinical scenarios e.g. prolonged lying [**3.1**-**3.4**] and the application of medical devices [**3.5**-**3.7**]. This research was enabled through leading a first-in-kind NIHR-EPSRC international network entitled “Medical Devices and Vulnerable Skin” (2014-2019), focused on two primary aims: i) Optimising safety in device design and ii) Developing intelligent sensing to promote self-management.

Optimising Safety in Design

The team have worked with a number of commercial partners to evaluate the performance of existing medical devices and co-develop novel features to improve skin health. This has involved studies on volunteer cohorts to simulate relevant clinical scenarios, using standard test methods to characterise device interactions and, in particular, specific skin responses. The team has also used physical models and computational simulations to assess the relative effects of different material interfaces and device designs. These approaches were used to assess a range of medical devices, including support surfaces (mattresses and cushions) [**3.1**-**3.3**], respiratory masks [**3.5**] and prosthetics sockets [**3.6**, **3.7**]. The group have established an international track record of evaluating the scientific efficacy of medical devices, attracting collaborations from companies worldwide (e.g. US, Sweden, UK, Japan). This has been achieved using a purpose built suite of laboratories (since 2011) where skin physiology can be monitored with an array of bioengineering tools. Our research has led to medical device design optimisation, ensuring patient safety while maintaining device functionality. This research has been successfully translated to impact on patient care and is associated with sales of device products.

Intelligent Sensing to Promote Self-management

The team have employed a range of sensing technologies to evaluate the interactions between an individual and a medical device, enabling monitoring of pressure ulcer risk. Sensing technologies have involved pressure arrays, shear sensors and microclimate monitoring. The effects of these loads on skin health have been established using robust biophysical and biochemical markers [**3.1**, **3.2**, **3.5**]. The team have worked with industrial collaborators to develop novel sensors, including an innovative flexible pressure and shear sensor that can be integrated within a prosthetic device for amputees (MRC Biomedical Catalyst grant with Blatchfords, UK, 2014-2016). This provides real-time patient feedback regarding the interface conditions, used to monitor risk of skin damage [**3.6**]. Members of the team have also employed commercial sensing systems and advanced data processing to monitor individuals' posture and mobility in the acute and community clinical settings (Health Foundation support QI study with Cornwall Foundation Trust, 2017-2020). Here novel algorithms based on machine learning are used to estimate key indicators which are clinically relevant for personalised patient care [**3.4**]. These technologies are providing the platform to improve self-management and enable efficient care for vulnerable individuals.

3. References to the research

3.1 Chai CY, Sadou O, **Worsley PR, Bader DL**. Pressure signatures can influence tissue response for individuals supported on an alternating pressure mattress. J Tissue Viability. 2017 Aug;26(3):180-188. https://doi.org/10.1016/j.jtv.2017.05.001

3.2 Worsley PR, Parsons B, **Bader DL**. An evaluation of fluid immersion therapy for the prevention of pressure ulcers. Clin Biomech (Bristol, Avon). 2016;40:27-32. https://doi.org/10.1016/j.clinbiomech.2016.10.010

3.3 Worsley, PR. and **Bader, DL**. A modified evaluation of spacer fabric and airflow technologies for controlling the microclimate at the loaded support interface, Textile Research Journal, 2019. 89(11), pp. 2154–2162. https://doi.org/10.1177/0040517518786279

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

3.5 Worsley PR, Prudden G, Gower G, **Bader DL**. Investigating the effects of strap tension during non-invasive ventilation mask application: a combined biomechanical and biomarker approach. Med Devices (Auckl). 2016;9:409-417 https://doi.org/10.2147/MDER.S121712

3.6 Laszczak P, McGrath M, Tang J, Gao J, **Jiang L, Bader DL**, Moser D, Zahedi S. A pressure and shear sensor system for stress measurement at lower limb residuum/socket interface. Med Eng Phys. 2016 Jul;38(7):695-700. https://doi.org/10.1016/j.medengphy.2016.04.007

3.7 Steer, J. W., **Worsley, P.R.,** Browne, M., **Dickinson A.S.** (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

Key underpinning grants and research quality

The fundamental research and translation of novel devices has been achieved through funding from Research Councils, NIHR, charities and industrial collaborations totalling around GBP3m since 2014. These include the NIHR-EPSRC Medical Device and Vulnerable Skin Network (2014-2019, EP/M000303/1, EP/N02723X/1), EPSRC Global Challenge Research Fund (2017-2020, EP/N02723X/1), MRC Biomedical Catalyst grant (2014-2016, MR/L013096/1), Prostate Cancer UK grant (2016-2019) and a Health Foundation Scaling Up grant (2017-2020).

The quality of the research has been acknowledged with a number of prestigious international awards, including a European Pressure Ulcer Advisory Panel (EPUAP) experienced investigator award for Schoonhoven (Sept 2018), EPUAP novice investigator for Worsley (Sept 2018) and a BioMedEng legacy award for Bader (March, 2018).

4. Details of the impact

Through industry collaborations, multidisciplinary research by the Skin Health Group has optimised the design of medical devices, ensuring patient safety while maintaining device functionality and delivering further commercial opportunities. It has led to the development of novel monitoring technologies, national policy changes and new international clinical guidelines, all of which have improved pressure ulcer prevention.

Healthcare impact: Optimising device performance to improve patient outcomes

The Skin Health Group's research (conducted 2014, published 2016) recommended that a modification was required in the range of internal air pressures associated with a fluid immersion mattress system (Dolphin FIS, Jeorns Healthcare, USA), to optimise device performance and patient safety [**5.1**]. The study underpinning [**3.2**] led to changes in the default internal pressure settings of Medstrom's Dolphin Therapy FIS mattress system and its clinical user guidance [**5.1**]. These changes were defined in 2014 and are now commercially available in all countries in which Dolphin Therapy is distributed, including the USA, Canada, UK and Netherlands [**5.1**]. Medstrom describes Dolphin as a reactive system that allows full immersion and envelopment, significantly reducing pressure, and shear and tissue deformation. Independent evaluations have demonstrated its clinical efficacy for the provision of effective pressure redistribution for individuals both at high risk of pressure ulcers and with existing wounds. A review of 1000 patient outcomes with complex medical conditions (2015-2018) showed that Dolphin was 99% effective at prevention of skin damage in the most complex of patients and 55% of patients experienced a degree of wound healing. Anonymised comments from caregivers included: '*Heals faster and is more effective than other air mattresses used within the Trust*'; '*Patient normally has red marks on all surfaces…no marks since on Dolphin*'; '*Dolphin Therapy improved comfort levels prior to end-of-life*' [**5.2**].

Healthcare impact: uptake of intelligent pressure monitoring in NHS community settings

Since 2017, the Skin Health Group has collaborated with Cornwall Partnership NHS Foundation Trust on a quality improvement initiative, Pressure Reduction through Continuous Monitoring in the Community Setting (PROMISE). Funded by the Health Foundation, the project deployed the intelligent pressure monitoring sensors (ForeSitePT, XSensor Technology Corp, Canada) that the Group optimised [**3.4**] for patients' evaluations. Sensors in mattresses and chairs were used to help patients and carers to better understand the positions that are likely to reduce the risk of pressure ulcers, and clinicians were able to monitor patients remotely over prolonged periods for the first time. Using the Group's advanced understanding of data processing and analysis using Continuous Pressure Monitoring, they trained health professionals on how to use the sensor system, supported clinicians to interpret the pressure monitoring data and provided clinical advice to patients [**5.3**]. By the end of the impact period, the technology had been adopted by four NHS trust sites in Cornwall, Devon and Somerset. It had been used by 88 individuals in their homes; 66% of patients with chronic pressure ulcers had healed or were healing within nine months of using the sensors [**5.3**]. An independent evaluation commissioned by the Cornwall Trust revealed *'a significant impact on patient care and clinical decision-making'*. A Tissue

Viability (TV) nurse in Somerset was quoted as saying: *'It gave me the ability to identify which piece of pressure relieving equipment wasn't working. We hadn't been able to do this before and couldn't have done this without PROMISE.'* A patient said: *'This Promise thing has been one of the best things we could have got involved in and we'd be in a very different place now if we weren't.'* [**5.3**].

Healthcare impact: shaping new national and international clinical guidelines to support pressure ulcer prevention and minimise skin damage

Based on their research expertise, the Skin Health Group has taken a leading role in developing international guidelines published by the National Injury Ulcer Advisory Panel (NPIAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) in both 2014 (Schoonhoven) and 2019 (Worsley). The *Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline* is available in 14 languages and represents the leading international consensus to standardise and improve pressure ulcer prevention. Full text guidelines of the latest version (2019) have been downloaded over 6,500 times by healthcare providers around the world (31 countries) [**5.4**]. The Group's research '*had a significant impact on the evidence cited in the guidelines to inform practice'*, used widely throughout the guidelines (n=48 citations), in a number of key sections e.g. aetiology, support surfaces and medical devices. The Group has used research insights developed through **3.3** (impact of respiratory masks on facial skin health) to inform key aspects of rapidly released NHS guidelines relating to personal protective equipment (PPE) and Covid-19 [**5.5**]. Published in April 2020 by NHS England and NHS Improvement to protect clinicians from pressure injuries, the guidelines, titled *Helping prevent facial skin damage beneath personal protective equipment*, include recommendations from the Group on the use of a barrier skin wipe, mask fitting (e.g. do not over-tighten), regular inspection and regular breaks from mask wearing (every two hours).

Economic impact: providing the clinical evidence base for commercial products

Medstrom states that research papers published by the Skin Health Group (including specific mentions of **3.3**) have provided '*the critical evidence to support our mattress sales*' [**5.1**]. As well as the Dolphin FIS mattress system, this applies to the company's Aerospacer range, the therapeutic mattress product described in section 2. For the Aerospacer, the physical model evaluation presented in **3.3** enabled the co-development of optimal 3D spacer textiles within a mattress construct to improve the management of microclimate (temperature and humidity at the patient interface). '*This had a direct impact on our final design specification*,' the company wrote [**5.1**]. These mattress systems came to market in May 2015 and by the end of the impact period had been used across six NHS hospital sites, resulting in GBP500,000 of revenue [**5.1**].

Commissioned research with one of the world's largest medical device providers Hillrom (headquartered in the United States) revealed novel information with respect to various mattress features designed to decrease pressure injuries, including: i) An embedded prototype sensor (SAALP™) to optimise settings based on body mass index; ii) Optimal alternating low-pressure signatures to maintain skin health [**5.6**]. Hillrom used the Group's findings, [**3.1**] '*to define technical product specifications and product architecture*' of air mattress systems, resulting in a '*direct impact on the successful commercialization and distribution of Hillrom products into new international markets*'. These products include the Duo 2 Surface, a dual-therapy low pressure mattress for patients at the highest risk of pressure ulcers, and the ClinActiv+ MCM™, a pressure redistributing therapy mattress system with optimised microclimate management. These were commercialised during the impact period in the US and 14 countries within Europe. In addition, the sensor SAALP™ (Self Adjusting Low Pressure sensor) was adapted for use with other surfaces sold in long-term and acute care departments in 20 countries (launched in 2014, now termed I-mmersion sensor™). As of the end of 2020, device features made possible by the Group's research had been incorporated into 20,000 mattress products sold throughout the world by Hillrom for the provision of optimal care to vulnerable patients [**5.6**].

The research has also resulted in a ***spin out company***, Radii Devices Ltd [**5.7**], which adopts cutting-edge engineering to support socket fitting, through the introduction of novel software [**3.7**]. Since March 2019, it has employed three staff members and attracted GBP120,000 of external investment from a University Dragons' Den event [**5.8**]. The software includes a point-

of-care tool for aiding socket design for prosthetic limbs and architecture for storing clinical data to evaluate patient outcomes. This was launched at the Consumer Electronics Show (CES) in Las Vegas, with Worsley as a co-founder. The software platform has already attracted a further GBP208,600 of funding from a leading respiratory mask manufacturer (Philips Sleep and Respiratory Care, USA) to create a complimentary face-mask model, through designing an intelligent and efficient platform to improve their device designs.

Policy impact: changing NHS policy on pressure ulcer reporting and informing new international standards for support surface manufacture

Improving the reporting of device-related skin damage is key to strengthening medical device regulation and optimising product design. The Skin Health Group has been '*at the forefront of lobbying activities aimed at improving the reporting of device related pressure ulcers*' [**5.9**]. Based on insights accumulated through the body of underpinning research, the Group worked with NHS Improvement to successfully change reporting policy in England to include device-related damage, marking the first time that device-related pressure ulcers could be documented by clinicians [**5.9**]. This reporting metric was implemented in April 2019 when it was incorporated into *Pressure ulcers: revised definition and measurement framework* [**5.9**]. It is now part of routine reporting practice in over 200 care facilities across acute, community and mental health services. The Group also worked with NHS Improvement to co-create educational videos for clinicians to support best practice for medical device selection and application [**5.9**]. Coordinated as part of the NHS Stop the Pressure campaign, the videos were viewed 3,000 times within a month of release in April 2020.

The Group have applied their evaluative research methods to work with the British Healthcare Trades Association (BHTA) and the International Organization for Standardisation (ISO) on the development of new standards for two sectors specialising in pressure ulcer prevention: seating and support surfaces [**5.10**]. They have been invited by the BHTA to disseminate their scientific evidence at support surface meetings and international symposiums in London and Las Vegas aimed at educating manufacturers on the need to improve device design. This '*has resulted in the collation of extensive data to create a better understanding of the issues of support surfaces and their interactions with human skin*' [**5.10**]. The Group has provided underpinning knowledge to international definitions, published by ISO (*ISO 21856 B.23: Forces on soft tissues of the human body, July 2019*) to aid the design of a new standard [**5.10**]. This has created the means to establish standard test methods to evaluate the relative performance of support surfaces, adopted within an ISO framework (ISO/TC 173/WG 11) for which the Group is a participating member of the related ISO committee [**5.10**].

5. Sources to corroborate the impact

5.1 Corroborating statement and economic data from Medstrom Healthcare.

5.2 Dolphin 1,000 (patients) Clinical Evaluation Summary (2015-2018), Medstrom Healthcare.

5.3 Corroborating statement re PROMISE from Cornwall Partnership NHS Foundation Trust.

5.4 Statement from the European Pressure Ulcer Advisory Panel regarding Skin Health impact on international guidelines.

5.5 Helping prevent facial skin damage beneath personal protective equipment, 9 April 2020, NHS England and NHS Improvement.

5.6 Corroborating statement and economic data from Hillrom.

5.7 Radii Devices Ltd website: www.radiidevices.com

5.8 News release from the Future Worlds Dragons' Den 2019 event: https://www.southampton.ac.uk/engineering/news/2019/05/27-dragons-den.page

5.9 Corroborating statement from NHS Improvement and NHS England.

5.10 Corroborating statement from the British Healthcare Trades Association.