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**Clinical Biomechanics**

**Title: Bioengineering considerations in the prevention of medical device-related pressure ulcers**

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***Abstract***

Background: In recent years, it has become increasingly apparent that medical device-related pressure ulcers represent a significant burden to both patients and healthcare providers. Medical devices can cause damage in a variety of patients from neonates to community based adults. To date, devices have typically incorporated generic designs with stiff polymer materials, which impinge on vulnerable soft tissues. As a result, medical devices that interact with the skin and underlying soft tissues can cause significant deformations due to high interface pressures caused by strapping or body weight.

Methods: This review provides a detailed analysis of the latest bioengineering tools to assess device related skin and soft tissue damage and future perspectives on the prevention of these chronic wounds. This includes measurement at the device-skin interface, imaging deformed tissues, and the early detection of damage through biochemical and biophysical marker detection. In addition, we assess the potential of computational modelling to provide a means for device design optimisation and material selection.

Interpretation: Future collaboration between academics, industrialists and clinicians should provide the basis to improve medical device design and prevent the formation of these potentially life altering wounds. Ensuring clinicians report devices that cause pressure ulcers to regulatory agencies will provide the opportunity to identify and improve devices, which are not fit for purpose.

*Keywords: Medical device related pressure ulcer; bioengineering; biophysical sensing; biomarkers; computational modelling.*

Highlights:

* The formation of medical device-related pressure ulcers restricts effective management in a range of patients.
* Bioengineering technologies can assess the device-skin interface conditions.
* Biochemical and biophysical sensors can evaluate tissue status during device loading.
* Computational models verified with experimental data can inform the design of safer devices.
* Multidisciplinary collaboration is required to prevent these device related injuries.

1. ***Introduction***

One study proved quite a revelation to many researchers and clinicians in the pressure ulcer (PU) community, who have long focused their attention on the mechanical-induced damage resulting in patients supported for prolonged periods in lying and/or sitting postures. The US-based study reported that over 30% of PUs acquired in hospitals were a direct result of interventional medical devices (*Black 2010*). In addition, their findings indicated that if a patient presented with a medical device, they were 2.4 times more likely to develop a PU of any kind [1].

Subsequently, the condition termed, medical device-related pressure ulcers (MDRPUs), has been defined as resulting “from the use of a device designed and applied for diagnostic or therapeutic purposes”. The resultant pressure ulcer generally closely conforms to the pattern or shape of the device [2]. There is no doubting that MDRPUs contribute to the financial and personal burden imposed on many patients with vulnerable tissues. They occur in a wide age range of patients [3], typically those managed in intensive care units (ICUs) [4], where individuals are fitted with multiple diagnostic and therapeutic devices, attached to the skin with strapping and tape. Other situations involve amputees requiring lower-limb prostheses, patients requiring orthoses for functional support and the immobilised elderly who are managed in beds or chairs. It has been well recognised by clinicians that long-term usage of a range of medical devices can cause incidences of skin irritation, pain, maceration and ulceration. Thus it is common that existing devices are often rejected, leading to inadequate intervention and wasted resources. These events can be reported by clinicians on government agency platforms, for example the US Food and Drug Administration (FDA) MAUDE website, highlighting incidences of device-related harm. This is not the case in other countries, such as the UK, where generic reporting platforms are available, but the clinical means of reporting their incidence is limited. As such, there is little evidence of specific medical devices, which commonly compromise the health of skin and sub-dermal tissues.

The topic of medical devices interfacing with vulnerable skin clearly requires a significant technological input to minimise the risk of MDRPUs. This was recognised by the UK Engineering and Physical Sciences Research Council (EPSRC), who awarded two of the authors based in Southampton (DLB, PW) funding to establish a Network activity in 2014. The global aim of this Medical Devices and Vulnerable Skin Network (MDVSN) was 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 damage. Accordingly, its research focus was to maintain the functionality of a range of these devices while adapting to changing requirements, in the form of patient variability, the clinical environment including both hospital and community settings and individuals presenting with enhanced susceptibility to skin and sub-dermal tissue damage. This was intended to lead to fewer incidences of device rejection with the associated cost implications.

The specific bioengineering factors implicated in MDRPUs are:

* Devices are based on generic designs and do not accommodate patient variability in body size and shape.
* Devices employ materials, which are relatively stiff and do not match the mechanical compliance of the skin and sub-dermal tissues.
* Inadequate guidance is provided regarding device application.
* Many individuals exhibit skin and sub-dermal tissues with impaired tolerance to loading, e.g. associated with ageing, malnutrition, neuromuscular compromise or diabetes.

Diagnostic and therapeutic medical devices that are attached to the body will create both mechanical and thermodynamic challenges at the interface with the skin and underlying soft tissues. Having a clear understanding of the load transmission and its relative effects on skin and soft tissues health is critical in the design of safe devices (Figure 1). An emerging body of research has been established to investigate this device-tissue interaction using an array of sensing technologies, physical sensors, biosensors, imaging modalities and computational modelling [5].

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*Figure 1. Device-soft tissue interactions between a residual limb of an amputee and the socket interface.*

There are both similarities and differences between MDRPUs and more traditional pressure ulcers (PUs) as summarised in Table 1.

Table 1. Overview of features associated with pressure ulcers and medical device related pressure ulcers.

|  |  |  |
| --- | --- | --- |
|  | **Pressure Ulcers (PUs)** | **Medical Device Related Pressure ulcers (MDRPUs)** |
| Aetiology | Four physiological mechanisms each of which are important at different magnitudes of strain and time [6] | Four physiological mechanisms each of which are important at different magnitudes of strain and time [6] |
| Cause of deformation-induced damage | Gravitational forces due to body weight | Due to external applied forces (strapping and tape) |
| Individual vulnerability | Immobile, insensate and areas, with previous tissue damage | Illness possibly with co-morbidities e.g. ICU patients, diabetes and others who cannot communicate discomfort or pain. Skin and soft tissues sites with previous damage. |
| Nature of Medical Devices | Support Surfaces i.e. cushions, mattresses, bedside chairs, car seats, toilet seats etc. based on individual risk | Generic designs of medical devices not matched to individual characteristics |
| Prevention strategies | Pressure redistribution, pressure relief and periodic position changes | Improved design of devices, pressure relief through alternative device application, adequately designed prophylactic dressings |
| Vulnerable tissue areas | Adjacent to bony prominences e.g. sacrum, ischial tuberosities and heels | Any body site, often loading tissues with limited prior mechanical conditioning. Commonly on the head or neck. |
| Microclimate | Affected by support surface design, ambient conditions and individuals sweat response and clothing. | Affected by device interface, including any seal the device creates with the skin, or therapeutic heating/humidity. |

The present paper provides a review of the bioengineering approaches to examine the performance of a range of these medical devices. It includes studies involving both experiments and computational models, which have been designed to identify the key parameters used to assess the performance of the medical devices in terms maintaining the integrity of skin and underlying soft tissues.

1. ***Pressure and shear at the device-skin interface***

Interface pressures are always present when medical devices are attached to the skin thereby applying forces through soft tissues or body forces, transmitted through device strapping or due to gravity. Accordingly, bioengineers have developed accurate and reliable pressure measuring systems, based on a number of physical principles involving pneumatics, electro-pneumatics, force-sensitive resistance materials and capacitance methods. These have been used in many studies, which have revealed a significant range in pressure and shear values at different device-skin interfaces (Table 2).

Table 2. Typical peak pressures and shear values at various device-skin interfaces.

|  |  |  |  |
| --- | --- | --- | --- |
| Device | Pressure (kPa) | Shear (kPa) | Source |
| Trans-tibial prosthetic Socket | 200-417 |  | Rajtukova (2014), Convery and Buis (1999) [7, 8] |
| Trans-knee prosthetic socket | 58 | 27 | Laszczak et al. (2016) [9] |
| Trans-femoral prosthetic socket | 34-95 |  | Lee et al. (1997) [10] |
| Respiratory mask | 4-21 |  | Worsley et al 2016, Brill et al 2018., Shikama et al 2018 [11-13] |
| Cervical collar  Foot orthoses | 5-23  50-250 |  | Worsley et al 2018, Tescher et al 2007, Tescher et al 2016 [14-16]  Ki et al 2008 [17] |
| Mattresses | 5-15 |  | Woodhouse et al 2015, Worsley et al 2016 [18, 19] |
| Seat Cushions | 8-22 |  | Worsley et al 2018, Li et al 2017 [20, 21] |

It is evident that the highest pressure values correspond to devices which transfer a significant proportion of body weight through the body interface, typically through prosthetic sockets with peak pressures varying considerably (34-417kPa) and at the interface under the foot (50-250kPa). In a recent study, novel tri-axial pressure and shear sensors, based on the capacitance design principles, demonstrated high levels of shear forces at the socket-skin interface in amputees [9, 22]. This combination of pressure and shear will create internal stresses/strains in the local stump tissues, thus increasing their risk of damage [23, 24]. Although respiratory masks and cervical collar devices reveal lower peak pressure values at the skin interface (4-23kPa), their locations are at sites with limited subcutaneous tissues not previously conditioned to loading. For example, with a nasal-oral respiratory mask the pressures are localised at vulnerable areas on the face, such as the bridge of the nose, chin and cheeks (Figure 2).

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*Figure 2. Individual wearing an oral-nasal respiratory mask. Peak pressures are typically observed over the bridge of the nose (annotated with circles). [11]*

Another example where sustained pressures are applied to vulnerable tissues involves newborn infants connected to life-support systems, including mechanical ventilation in the operation theatre or in NICUs. In these cases, a donut-shaped head support is often used to position and stabilize the head of the infant. The device will concentrate the weight of the head and transmit it through a narrow circular contact strip between the thin scalp tissues and the superior aspect of the support [25].

The generic design of many medical devices which are constructed of relatively stiff polymeric materials, can result in non-uniform pressure distributions. Indeed, bony landmarks are exposed to high pressure gradients at the device-skin interface e.g. bridge of nose in respiratory masks, occiput in cervical collars [11, 14] or donut supports [25] (Figure 3). The resulting contact areas are hence compromised, limiting the efficacy of the device and/or its function to distribute pressures over larger contact areas [26]. The tension in the straps of medical devices will inevitably affect the resulting interface pressures. Indeed increased applied tensions were reported to cause a 2-fold increase in interface pressures for designs of both respiratory masks and cervical collars [11, 14]. However, uncertainty remains when considering best practice. For example, clinicians often over-tighten respiratory masks to ensure their security and functional effectiveness e.g. minimise oxygen leakage but, in doing so, they may compromise tissue health and integrity at the mask-face contact regions. There have also been reports of devices (electrodes and tubes) being misplaced under patients [27], with the resulting local tissue deformations [25] presenting a high risk of ulcer formation. In order to investigate the interactions between devices and the underlying skin and soft tissues, researchers have employed an integrated experimental-computational approach, involving mannequin testing and finite element analysis (FEA) to investigate the associated boundary conditions and soft tissue strains (Figure 3).

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*Figure 3. Integrated experimental-computational work to evaluate the risk associated with an off-loading donut-shaped head support (labelled ‘donut’) which is sometimes prescribed in paediatrics surgery. The study employed (a) a head dummy of an infant with sensors to measure contact pressures applied by the weight of the head on the donut and (b) a computational model of the head resting on the donut. The modelling provides (c) interface pressures at the head-donut contact which are useful for model validation, but also, importantly, it informs about deeper tissue loads such as (d) stresses within scalp tissues near the contact sites with the donut.*

Establishing the mechanical conditions at the interface between the device and the underlying skin and soft tissues provides only a limited indication of the relative risk of damage. Indeed, the tolerance of tissues to withstand the mechanical loads is highly dependent on the characteristics and factors inherent to the individual. Such factors may include the internal anatomical structure and tissue composition, the resulting tissue stiffness, the patency of blood and/or lymphatic flow at the distorted region, presence of acute or chronic diseases which affect inflammation, repair capacities (cell proliferation, migration and differentiation) and the overall individual health status [28]. Accordingly, it is impossible to define clear thresholds for tissue exposure to pressure and shear forces, above which MDRPUs will inevitably occur. Nonetheless, it can be stated that when the body interacts with devices, the magnitude of pressure and shear forces exerted onto the skin will in many cases exceed the individual tolerance of the skin and soft tissues, as evidenced by the high incidence of MDRPUs. This is particularly the case involving tissues with no prior history of mechanical conditioning. When tissues are conditioned, as in the example of a lower limb amputee who undergoes a period of anatomical and physiological adaptation, tissues become stiffer and more load tolerant [29].

1. ***Monitoring the microclimate at the device-skin interface***

Studies have employed thermocouples, thermography and hygrometer devices to monitor the microclimate at loaded skin interfaces. They have revealed elevated temperatures and humidity values in the plantar aspects of the foot [30], the residual amputee stump-socket interface of amputees [31] and at tissues where high forces are transmitted through foot orthoses [32]. These changes will inevitably reduce the skin and subcutaneous tissue tolerance to mechanical-induced damage [33]. For example, both temperatures in excess of 35 °C and increased skin moisture have a detrimental effect on the stratum corneum by affecting its mechanical stiffness and strength [34]. Skin temperature also affects the local tissue physiology, with a 1 °C rise resulting in a 13% increase in the metabolic demand [35], which reduces the available energetic resources for cells to repair damage and hence provides additional risk to vulnerable soft tissues already compromised by local vascular and lymphatic obstructions. Conversely, an excessively dry skin is liable to damage by cracking [36]. Thus, achieving an optimal moisture level at the device-skin interface is critical for maintaining its barrier function and ability to dissipate mechanical loads through deformation.

Several technologies have been developed to control the temperatures at the device-skin interface using both passive [37] and active systems [38]. However, the nature of these interventions often necessitate a closed environment i.e. a complete seal around the device, as exemplified with respiratory masks or tracheostomy tubes, where mechanical ventilation forms part of the intervention. This results in a hot and humid microclimate at the interface, with little opportunity for the dissipation of heat or transfer of water vapour. In addition, such devices may include humidified air as a treatment, increasing the potential of fluid accumulation at the device-skin interface [39].

1. ***Early detection of device related pressures ulcers: Biochemical and biophysical marker detection***

There are several biofluids containing a selection of biomarkers, which can be collected directly at the skin surface or systemically in blood or urine. These biomarkers can be targeted to represent inflammatory processes such as C-reaction protein (CRP), cytokines and chemokines, local metabolic activity or the by product of oxygen free radical release during reperfusion. In a few studies, sweat collection using simple paper methods and analysis, represented an appropriate means to interrogate the skin-device interface. Seminal research combined this approach with transcutaneous gas tension measurements to evaluate the effects of different loading regimens on able-bodied individuals [40]. The authors revealed a significant correlation between the up-regulation of sweat lactate and reduction in TcPO2, a measure of tissue oxygenation, provided the latter exceeded a threshold value of 60% when compared to unloaded basal values. More recent analysis has revealed that there is also a temporal change in the ratio between lactate and pyruvate concentrations in sweat sampled prior to and following mechanical loading. Lactate has also been sampled from sebum released from local sebaceous glands, following a period of loaded support on a spine board. The results revealed that lactate concentrations had strong relationship with pressure exposure time on the spine board, but not with pressure magnitude [41]. More recently progress has been made using sophisticated chromatographic techniques in the simultaneous quantification of multiple metabolites in sweat [42].

Cytokines produced by active keratinocytes in the epidermis have been collected from sebum at the skin surface using commercial tapes before, during and after medical device application. The tapes are applied for short periods (2 min) and the collected sebum is extracted in a solution of saline containing non-ionic surfactant using sonication. The extracts are analyzed using commercial immunoassay test kits. The cytokine levels recovered from each tape extract are generally normalized to total protein (TP) levels [43]. This approach has been reported in several studies where skin tissues are subjected to prolonged loading via medical devices e.g. respiratory masks [11] and spine boards [41], as well as the combined effects of prescribed shear and pressure [44, 45]. To date, the aforementioned studies have examined the relative changes in inflammatory cytokine IL-1α. However, this cytokine is released from keratinocytes in response to several stimuli, acting as the primary event of inflammation. Consequently, it may have limited specificity to determine whether skin has been irritated by either mechanical or chemical insults and lacks the sensitivity to detect subtle changes to skin physiology. The analysis of secondary mediators, for example IL-8, which is associated with the promotion of dendritic cell migration and recruitment of monocytes and neutrophils during cutaneous inflammation, may provide more robust means to detect inflammation resulting from mechanical insults. However, such techniques do require adequate sample volumes and are often associated with low cytokine concentrations that fluctuate with time. As a result, longitudinal test protocols are critical if they are to be adopted into routine screening in the clinic. The advent of low cost highly sensitive portable point-of-care (PoC) testing systems based on printed electrochemical sensors could provide a means of clinical translation [46]. Although biomarkers sampled from the skin surface provide a means to examine the status of both epidermal and dermal tissues, it is less reflective of compromise to the underlying subcutaneous and muscle tissues. Indeed biomarkers for deep tissue injury, specifically concerning muscle cell damage, have been identified in blood where CRP levels were significantly raised in SCI subjects with PUs [47]. Subsequently, the potential to interrogate the status of skin and soft tissues to provide an early indicator of potential damage and inform effective intervention to prevent MDRPUs could be based, in the near future, on biochemical markers.

Mechanical loads and high moisture levels can also disrupt the barrier function of the skin. Transepidermal water loss (TEWL) represents the standard biophysical skin measurement for assessing stratum corneum integrity. Studies have revealed significant increases in TEWL following a range of skin insults including water exposure, prolonged mechanical loads and tape stripping. Studies evaluating TEWL changes following medical device application have reported significant changes following the application of respiratory masks incorporating humidified air treatment [39]. There has also been significant increases in TEWL at the pad interface of those individuals affected by incontinence [48].

Other biophysical measures provide an alternative or complementary approach to biochemical marker detection and can also be based on early detection of an inflammatory response to deformation-induced cell death. As an example, the commercial sub-epidermal moisture (SEM) Scanner (Bruin Biometrics LLC, LA, USA) detects micro-oedema by measuring the biocapacitance of tissues [49]. Changes in the SEM reading given in arbitrary units reflect the local fluid content and hence the dielectric capacity of the tissues. The portable system has been used in a few clinical studies in the early detection of PUs caused by sustained bodyweight forces at the sacrum and heels [50, 51]. It might prove a promising adjunct for detecting early damage caused by medical devices. However, the location of the device related skin damage (face and neck) could limit the practical application of such systems.

1. **Imaging device-skin interactions**

Several imaging modalities have been used to identify tissue deformations during the application of medical devices. Examples include the stump-socket interface of amputees [23], spine board [52], spinal orthosis [53] and foot orthosis [54]. In the former study, Magnetic Resonance imaging (MRI) was used to visualize the soft tissue deformations in the muscle flap of the residual limb of a trans-tibial amputee, during both donning of a prosthetic socket and load-bearing [23]. The resulting estimated strains provided a means to assess how deformations are distributed internally in the loaded residual tissues. Ultrasound imaging has also been used to visualize dermal and sub-dermal tissues following periods of mechanical loading. The latest relevant ultrasound systems are now affordable for most facilities and have been reduced to a probe connectable via software downloads to tablets or mobile phones e.g. the Philips Lumify™ system. Although this modality offers clear benefits, it is currently limited by its restricted field of view and reliance on operator expertise to interpret the acquired images [55]. In an alternative approach, laser-based surface scanners can create digital records of soft tissue shape in order to assess device fit in several settings and inform device design. Although this technology has been established for over 30 years, the adoption of computer-aided design and manufacturing (CAD/CAM) has been slow due, in part, to preference for manual casting in many countries. Nonetheless, highly accurate and reliable scanner technologies are now available to clinicians, in association with interactive software platforms [56]. Additionally, surface scanners have also been used to assess the quality of fit in generic device designs e.g. respiratory mask. Indeed, interface fit distance metrics was reported to differ for the nasal, face shield and, in particular, oronasal masks in pediatric patients [26]. The authors also reported that areas of high contact were associated with skin erythema and PUs.

1. **Computational Modelling to evaluate medical device design**

In order to improve existing device designs, bioengineers are employing a combined experimental and computational approach to understand and simulate device-body interactions, providing a robust means to estimate the internal mechanical state of soft tissues, which can be indicative of tissue risk. The computational models have been developed using imaging data, describing tissue morphology and composition, in combination with measured mechanical and thermodynamic boundary conditions, involving pressures (Figure 4), shear forces and thermal challenges. A summary of the recent studies and the relevant internal tissue stress and strain values is presented in Table 3.

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*Figure 4. (a) Finite element model of a respiratory mask attached with tension straps onto a facial morphologyface (generated from CT data). (b) Pressure values at the skin interface after the mask has been displaced on into the face model.*

Table 3. Data derived from finite element analysis (FEA) of estimated internal tissue strains or stresses resulting from the application of various medical devices.

|  |  |  |  |
| --- | --- | --- | --- |
| Medical Device | Effective stress (kPa) | Principle compressive (or shear) strain (%) | Sources |
| Residuum-socket interface of amputees | 24-860 | 31-163 | Dickinson et al 2017. [57] |
| Foot orthosis | 119-310 |  | Chen et al. 2010 [58] |
| Penile Clamps | 270 | 39 | Levy et al. 2017 [59] |
| Misplaced wire and electrode devices | 5-22 |  | Levy et al. 2017 [25] |
| Spine board |  | Up to 80 (predicted shear strain) | Oomens et al. 2013 [52] |
| Cushions | 30-102 | 50-96 | Luboz et al. 2014 [60]. Linder-Ganz et al. 2007 [61] |
| Lateral Tilting Mattress |  | 50-70 (predicted shear strain) | Oomens et al. 2016 [62] |

Indeed FEA has been used to verify the performance of a range of device designs in a virtual domain that is representative of its planned real-life application. In addition, the results provide informed recommendations for design improvement and optimization [59]. Computational modeling offers the advantage of producing rapid results of performance prior to costly prototyping and bench testing. This could reduce costs over the product development cycle. However, the application of the modeling demands high expertise to properly navigate the computational methodologies and critically appraise the resultant findings. It is also of note, that the estimations of tissue stress and strain within the models is highly dependent on the modulus assigned to the soft tissues, which is poorly defined in the literature [60]. Further, established product development strategies must be revised to integrate the modeling into the early design phase, which represents considerable effort for industry.

An example of this systematic approach involves the design of a novel prototype penile compression device (PCD). These clamps have proved popular with certain active males following prostrate surgery for controlling incontinence, although there is little evidence concerning their optimum design features. FE modeling was used to analyze existing PCD designs and compared their relative effects on underlying tissue mechanics [59]. Typical results reveal the distribution of effective stresses on the local tissues, which was highly dependent on design features of the device (Figure 5a).

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***Figure 5*** *(a) Finite Element model of penile clamp designs [59] (b) First in kind evidence based clinical guidelines for the application of penile clamps co-developed with patients.*

In a complementary experimental approach, bioengineering techniques were used to examine PCD performance on a small cohort of volunteers. The findings revealed a significant obstruction of blood flow, as measured using Laser Doppler imaging, associated with the high interface pressures applied by the various PCD designs. On PCD removal perfusion levels were restored. Penile skin was noted to be sensitive, with raised concentrations of the inflammatory marker IL-1α after 10min wear, indicating an inflammatory response, which was restored to basal levels after 40min PCD removal (paper under review). These approaches have resulted in a series of design features, which will minimize the risk of soft tissue damage while maintaining effective functionality. Accordingly, a novel prototype PCD has been designed and manufactured and is currently being evaluated with a cohort of patient volunteers. In addition, this research has informed the first evidence-based guidelines for PCD application (Figure 5b).

An additional important role of computational modelling in MDRPU prevention is in visualizing the potential consequences of sustained mechanical loads delivered by devices to the body tissues. In particular, situations where objects were mislaid under the body of an insensate, immobile patient. This was modelled using FE analysis by Levy and colleagues (2017a), who examined the internal soft tissue loads at the occiput of an infant while lying on an EEG electrode or a wire of such electrode [25]. In particular, the study demonstrated that these rigid objects inflict stress concentrations in skin and sub-dermal tissues (Table 3). It is critical that bioengineers convey this message at training/educational days to clinicians involved in the management of patients in neonatal and paediatric ICUs to alert them the potential repercussions of such accidental events. In a similar manner, patients may be left unattended on toilet seats for prolonged periods in nursing homes. This was examined in a combined computational and experimental approach. By embedding a transcutaneous oxygen electrode in a toilet seat, the authors demonstrated that in healthy subjects, the modelled stress concentrations were associated with reduced tissue oxygenation. Hence, computational modelling is pivotal not only in the analysis of tissue loads for design purposes, but also, for generating effective educational materials for training clinicians and care givers [63].

The role of computational modelling in pressure ulcer prevention including prevention of MDRPUs is emerging. Modelling can inform the design features needed to alleviate, for example, stress concentrations in skin and deeper tissues as illustrated (Figure 3, Figure 4). This aligns well with development of regulatory policies in medical devices, such as the FDA guidelines published in 2016 on reporting of computational modelling studies in medical device submissions [64]. Indeed, the FDA acknowledge that traditionally, bench testing, animal studies, and clinical trials have formed the primary sources of evidence for translating medical devices into the US market. These methods are being superseded by computational modelling methods with software platforms, embedded in medical devices, serving as clinical decision support tools. There are clear strengths and cost benefits in modelling in the medical device arena.

1. ***Summary***

This review has provided an overview of the bioengineering technologies to assess and monitor medical devices, which interface with vulnerable skin. Of the clinical studies published to date, there appears to be a significant challenge regarding the protection of skin underlying devices, particularly in the cases of patients in critical care settings. Another key clinical challenge is where the device has to support body weight interfacing with unconditioned tissues i.e. prosthetics and orthotics. Despite the emerging evidence, it appears government agencies have provided little impetus on healthcare industries improving devices designs and materials. Indeed, many devices are still based on generic shapes incorporating stiff polymer materials, which impinge on the skin and soft tissues creating high resultant strains. In order to protect individuals from device related skin and soft tissue damage, routine reporting of injuries must be adopted by healthcare institutions and their personnel. This would provide the government agencies with the critical leverage to inform companies regarding the safety of their devices. Bioengineering technologies combining experimental and computational approaches, represent an important means by which devices can be assessed in the pre-clinical environment and monitored for safety on application.

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