Proof of Concept

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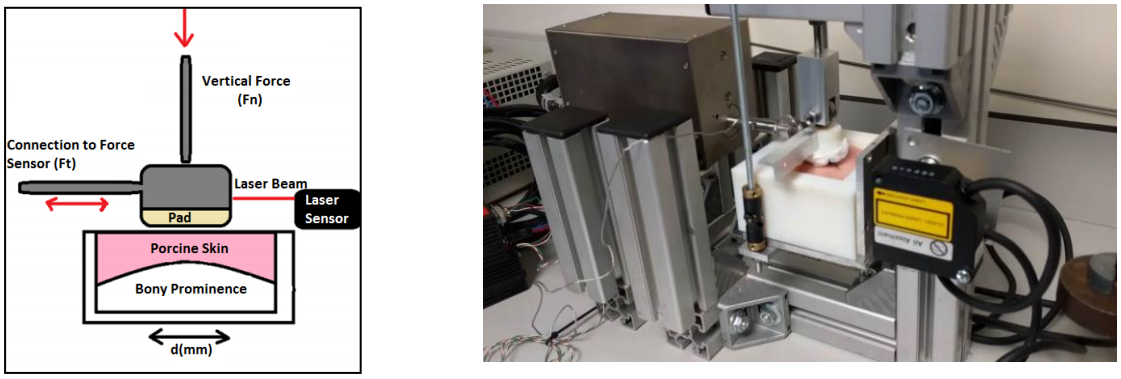
Title of Study:	**Bio-Tribology of Incontinence Management Products**
Aims and Objectives: (max 400 words)	Pressure ulcers have become a global burden in both developed and developing countries. Whilst much research has been done to study the friction of skin-textile couples; the mechanisms and interactions between contact mechanics, the emollients and lubricants used and ulcer formation are not well understood. Traditional tribological lubrication theory has been applied to many of these situations in an attempt to provide a quantitative parameter in which to assess skin-textile couples. Friction under pure sliding lubricated/un-lubricated conditions (typical sliding distance 50-100mm) is typically used as a method of quantifying the propensity of pressure ulcer formation. Yet this is not a scenario that will typically lead to ulceration; ulcers most commonly develop in individuals who are not moving about, such as being bedridden or those who are confined to a wheelchair. Questions still remain as to how the slip mechanisms and contact mechanics contribute to the formation and evolution of pressure ulcers and their interactions with system variables such as fecal or urinary matter, counter-body material and emollient systems under realistic loading conditions. This project aims to develop an activity in incontinence tribology bringing leaders in the area of engineering tribology, cellular biology and incontinence technologies together in an attempt to bridge the apparent gap. This initial PoC project will facilitate further meetings with leading academics in the area as well as some initial laboratory investigations to form the PoC for future grant application. Objectives include: • Conduct a comprehensive literature review in the area of tribology specific to incontinence management to establish the current state of the art. This will likely be published in an internationally peer-reviewed journal. • Establish a small network in the area of tribology, materials technologies and mechano-biology. • Establish an initial research activity, informed and guided by the literature review and network established. The basic interactions between tribological factors such as slip mechanism, contact pressure, material couple and microclimate will be assessed with respect to pressure ulcer formation. Initial results will be presented at the IMECHE Incontinence X conference with the view to be published in an internationally peer-reviewed journal.

Description of research work: (max 400 words)	**This project was split into three work packages (WP):** **WP1 – Comprehensive literature review (Month 1-1.5)** To date an extensive body of work has been conducted in the area of skin and tissue friction. Through this project we were able to collate this information and present a review specifically relating to incontinence technologies and the tribology associated. Possible areas for exploitation were identified and formed part of the initial work in the PoC. **WP2 – Establishment of infrastructure for bio-tribological assessment (Month 1-2)** In WP2, a network of scientists was established with the view to bridge the links between engineering and biological sciences in the area of skin technologies for future grant applications. Whilst this has relevance across multiple areas of incontinence technologies, at this stage the synergy between tribological and biological factors relating to skin and continence pad interface was of focus. Multiple meetings between scientists and clinicians were held (see outcomes) with the view to carry forward the research both in a clinical and technology context. **WP3 – Initial tribological and biological assessment (Month 2)** WP3 was concerned with initial testing to demonstrate the interaction between tribological, biological and system variables. A porcine skin model was developed (Figure 1). Variables such as contact pressure (kPa – MPa), sliding displacement (µm-mm), counter-body material and local environment (urine and/or emollient containing) were assessed through a small systematic study. The role of management system on friction and slip mechanism at the interface was identified.  **Figure 1** – Skin friction rig developed as part of this project.

Key findings:	Friction and shear are factors associated with the formation of pressure ulcers, exacerbated by the presence of urine and faeces. Whilst these mechanical processes have been identified in clinical literature, research into the exact mechanisms is not great. A bespoke skin friction test machine was developed as part of the project to assess tangential forces and nature of slip established at the skin-cream-pad interfaces. The tribological properties of commercially available absorbent pads and four commonly used skin care systems against a porcine skin model in dry and wet environment were assessed.

Frictional properties of the system were evaluated using a reciprocating sliding motion (d = 10 mm) at a contact pressure of ~5 kPa (Figure 2). For these initial tests, the friction force was taken as the average tangential force during sliding. An increase in friction was seen with the addition of moisture. The use of skin and wound care treatments further increased friction, with the addition of moisture increasing friction. Hydrogel based systems were effective at controlling friction under both dry and wet conditions. Further examination of friction data identified that the sliding nature of the contact was a composite of elastic deformation and sliding. It is hypothesised at lower displacements, elastic deformation will be dominant. Further work to understand the nature of contact and the mechanisms of sliding and shear across a wide is needed to progress the current understanding.

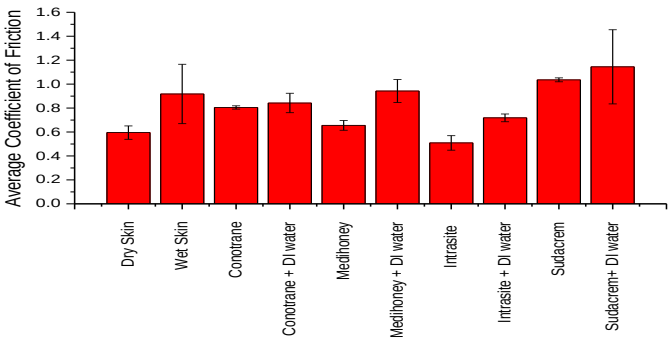


Figure 2 – Frictional results for a variety of skin-cream-pad interfaces

Further work was done to understand the nature of slip occurring at the interfaces for each system as well as in the presence of a 'bony prominence' with the view to decouple the role of friction and shear at the interface for 'fat' (approx. 12 mm) and 'thin'(approx. 6 mm) skin. This was based on the observation that skin deformation will occur when a patient slides along a surface but also a portion of the sliding will be accommodated through elastic deformation which will be dependent on the contact stiffness. In solid contact deformation, maximum shear will occur at this point until slip occurs. Analysis of tangential force vs displacement curves (Figure 3) showed that the amount of displacement accommodated for during elastic deformation varied depending upon system variables (i.e. cream or water) and the presence of a bony prominence. These results raise the question over the suitability of friction in viscoelastic systems. As can be seen in Figure 3, a variable tangential force was observed making an absolute value of friction difficult to predict. Further work to better represent the system will be carried out but this will likely use the concept of energy dissipation at the interface.

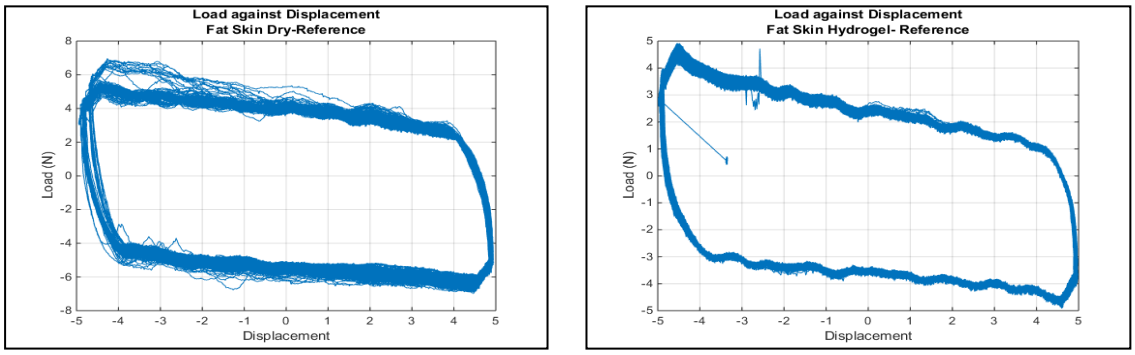


Figure 3 – Example of tangential force vs displacement curves

Outputs: e.g. publications, new links etc.	• Incontinence X poster presentation • Publication of paper in peer reviewed journal (currently being prepared) New links with Dr Parik Goswami (Leeds Non-Wovens Group) and Karen Lamb (LTHT Leeds Wounds Research and Incontinence Unit)

PROPOSED NEXT STEPS

Follow on funding Strategy:	Future funding will be sought from: • The British skin foundation project grants • EPSRC project grant • EPSRC centre for doctoral training (ie tribology or colloids)
Future research work plan:	The skin-cream-pad interface is complex and not fully understood. Our follow on work will focus on further understanding the interactions at the interfaces and the role of shear and the nature of slip on skin abrasion and susceptibility to pressure ulcer formation. Efforts to optimise the interface by engineering the skin-cream and cream-pad interface will be made. This will likely be through development of colloidal systems to give enhanced rheological properties and surface modifications of the textile surfaces. Assessment and characterisation of the surfaces at different length scales will be conducted using AFM, XPS and tribological test methods developed as part of this project. Biological assessment of tissues using histological and optical coherence tomography techniques will also be conducted to elucidate the link between mechanical damage and changes to biological architecture. A clinical strand of research has also been established with the Leeds Wounds Research Unit. Correlations between lab and clinical observation will be made. An initial study is underway to identify higher risk patient groups and current skin health as a function of management products. This study will demonstrate initial links between clinical and experimental observations as well as to provide guidelines for the effective stratification of care.

We encourage you to use diagrams and figures to illustrate your work and you may also submit additional material such as videos.