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Lessons learned in the past for a brighter future
for pressure ulcer prevention and management

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STINTS1

SILVER-CONTAINING GELLING FIBRE PRIMARY DRESSINGS: FLUID HANDLING (SORPTIVITY) AND DURABILITY PERFORMANCES TESTED ON A ROBOTIC WOUND SYSTEM

Aleksei Orlov¹, Adi Lustig¹, Angela Grigatti¹, Amit Gefen¹

¹ Tel Aviv University, Biomedical Engineering, Tel Aviv, Israel

Introduction: An adequate wound dressing should protect the wound mechanically and biologically while effectively managing the exudates. Laboratory (pre-clinical) tests of dressings are typically too simplified for capturing clinically relevant scenarios where a dressing is required to fulfil all the above roles at the same time.

Methods: A novel robotic phantom system containing 6 identical wound simulant units has been developed and employed to determine the synergy in fluid handling of two commercially available silver-containing gelling fibre primary dressings when used with a secondary foam dressing, as per clinical practice. The durability of the primary dressings post simulated use was further investigated, through tensile mechanical testing.

Results: The silver-containing gelling fibre primary dressing incorporating polyvinyl alcohol (PVA) fibres delivered greater fluid amounts for absorbency and retention by the secondary foam dressing (sorptivity), approximately 2-fold and 1.5-fold more than the comparator silver-containing primary dressing incorporating sodium carboxymethyl cellulose (CMC) fibres, after 10 and 15 hours of simulated use, respectively. The PVA fibre-based primary dressing type further demonstrated greater post-use mechanical strength that was ~4-times and ~6-times greater than that of the comparator primary dressing, when the latter dressing was tested out-of-alignment with its seams, after 10 and 15 hours of usage, respectively.

Conclusions: The PVA fibre-based primary dressing type had better sorptivity and durability than the comparator product. The present work contributes towards the development of clinically relevant testing methods for wound dressings and importantly, takes another important step forward in standardisation and automation of the performance measurements of dressings. Our work also revealed the dynamics of the fluid sharing between primary and secondary dressings, and underpinned the importance of mechanical durability of primary dressings which facilitates their safe removals.

Acknowledgement: This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No. 811965; project STINTS (Skin Tissue Integrity under Shear). This work was also partially supported by Mölnlycke Health Care (Gothenburg, Sweden).

STINTS2

STRAIN CALCULATION FROM MRI IMAGE REGISTRATION: AN APPLICATION FOR PRESSURE ULCER PREVENTION

Alessio Trebbi¹, Yohan Payan¹, Mathieu Bailet², Antoine Perrier¹

¹ Université Grenoble Alpes, Laboratoire TIMC, France

² TwInsight, Grenoble, France

Introduction: Pressure ulcers are a severe disease affecting patients that are bedridden or on wheelchair bound for long periods of time. These wounds can develop in the deep layers of the skin of specific parts of the body, mostly on heels or sacrum, making them hard to detect in their early stages. Prevention could be possible with the implementation of patient-specific Finite Element (FE) models to calculate dangerous levels of strains in the deep tissues that could trigger a pressure ulcer [1]. However, validation of such FE models is a complex task and the current implemented techniques offer only a partial solution of the entire problem considering only external displacements and pressures, or cadaveric samples [2]. In this abstract, we propose an *in vivo* technique that will be implemented for evaluating the simulations provided by a FE model of the human heel. This solution is based on the 3D non-rigid registration between two Magnetic Resonance (MR) images (one with heel at rest and the other one after applying a surface load below the heel) that is used to estimate tissue *in vivo* internal strains.

Methods: A Magnetic Resonance-compatible device has been designed to apply external loads on the heel while acquiring MR images (Figure 1). The deformation field between the undeformed and deformed configuration is computed with non-rigid registration techniques using the Elastix toolbox [3] (Figure 2). The Green-Lagrange strain field is subsequently calculated from the obtained deformation map.

Results: The MR-compatible device permitted to obtain good quality images (see figure 2) allowing for a reliable image registration. For the heel application, the location and levels of maximal strains resemble the expected results found in previous studies implementing FE models of the heel [1].

Conclusions: The implemented technique adds a useful tool for better understanding the propagation of strains in heel deep tissues that could generate pressure ulcers. This MRI compatible protocol could therefore be implemented to evaluate performances of orthotics and dressings aiming for preventing pressure injuries. Finally, strain estimations through image registration offers a promising technique for evaluating FE models for biomechanical applications.



Figure 1: MR-compatible compression device in the MR experiment.

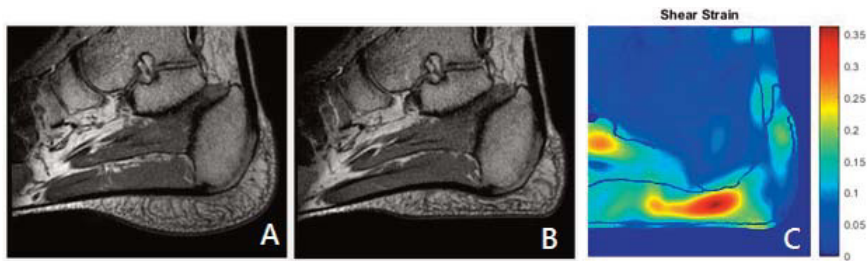


Figure 2: Image A shows the MR acquisition for a heel at rest. Image B shows the heel compressed by a plate applying 140 N of normal force. These

two images are used to run the registration and subsequently calculate the resulting shear strains shown in image C.

Acknowledgements: This project has received funding from the EU's Horizon 2020 programme under the Marie Skłodowska-Curie grant agreement No. 811965.

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STINTS3

WHAT MAKES A HYDROGEL-BASED DRESSING ADVANTAGEOUS FOR THE PREVENTION OF MEDICAL DEVICE-RELATED PRESSURE ULCERS

Angela Grigatti¹, Amit Gefen¹

¹ Tel Aviv University, Biomedical Engineering, Tel Aviv-Yafo, Israel

Introduction: The synergistic influences of geometrical, mechanical and thermal mismatches between a skin-contacting medical device and the skin may cause tissue stress concentrations and sharp temperature gradients, both of which contribute to the risk for medical device-related pressure ulcers/injuries.

Methods: In this work we developed an innovative, integrated experimental bioengineering approach encompassing mechanical stiffness, friction and thermal property studies for testing the biomechanical suitability of a hydrogel-based dressing in prophylaxis of injuries caused by medical devices. We characterized the viscoelastic stress relaxation of the aforementioned dressing and determined its long-term elastic modulus. We further measured the coefficient of friction of the hydrogel-based dressing at dressing-device and skin-dressing interfaces, using a tilting table tribometer. Lastly, we measured the thermal conductivity of the dressing, using a heat-flow meter and infrared thermography-based method. All the above measurements considered dry and moist conditions of the dressing, the latter simulating skin perspiration effects.

Results: Our results revealed that the long-term stiffness and the thermal conductivity of the hydrogel-based dressing matched the corresponding biomechanical and biothermal properties of human skin, respectively, for both dry and moist conditions. The dressing further demonstrated a relatively high coefficient of friction at its skin-facing and device-facing aspects, indicating minimal frictional sliding.

Conclusions: All the properties listed above make the currently tested hydrogel-based dressing advantageous for prevention of medical device-related injuries.

Acknowledgement: This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Skłodowska-Curie grant agreement No. 811965; project STINTS (Skin Tissue Integrity under Shear). This work was also partially supported by Paul Hartmann AG (Heidenheim, Germany).

COMPUTATIONAL MODELING OF SAGGY SKIN: THE EFFECT OF SKIN PROPERTIES ON SKIN FOLDING FORMATION

Jessica Ralvoni¹, Frank PT Baaijens¹, Sandra Loerakker¹

¹ Eindhoven University of Technology, Biomedical engineering, Eindhoven, Netherlands

Introduction: Formerly overweight patients often develop saggy skin due to massive and fast weight loss¹. This saggy/folded skin causes physical and psychosocial discomfort such as limited mobility, poor body image, and pressure ulcers (PU). The PU locate between skin folds due to unrelieved pressure, poor vascularization, and changes in the microclimate². Therefore, in post-bariatric surgery, 62.4% of patients return for body-contouring surgery to avoid the aforementioned complications¹. The occurrence of skin folding might be related to the variations in material properties and thickness of the skin among formerly overweight patients³. The goal of our study is to understand the influence of material and structural parameters on skin folding.

Methods: Using computational modeling, we investigated the influence of skin properties (e.g. stiffness ratio between dermis and hypodermis, skin thickness) on the skin folding morphology via developing a biomechanical growth model. This model was implemented in a software⁴. The bilayer system, made of dermis and hypodermis, was defined as a compressible Neo-Hookean hyperelastic material via a user-defined material subroutine (VUMAT). The hypodermis shrinkage triggers the skin folding.

Results: The stiffness ratio was varied in the range 0.7-40 to account for differences in stiffness measurements of the dermis⁵(Fig. 1). All simulations were performed for skin thicknesses of lean (1.35 mm) and formerly obese people (2.84 mm), (Fig. 1.a and .b) respectively³. Results showed large variations of the fold number and wavelength at different stiffness ratios. Generally, the number of folds decreased and the fold wavelength increased with increasing stiffness ratios. Additionally, for a ratio higher than 20, the skin folds were predicted to go deep into the hypodermis where the skin is in contact with itself. The skin thickness was also predicted to affect the surface morphology. Simulations with a thick dermis showed a lower number of folds and a larger wavelength compared to thin dermis simulations. The weight-loss percentage, at which the skin starts to buckle, decreased with increasing stiffness ratios. Particularly, for low ratios, the buckling was predicted to start at about 60% of weight loss, while this percentage dropped to 28%-23% for high stiffness ratios (20-40).

Conclusions: Our computational model predicted that large differences in stiffness between the dermis and hypodermis are associated with a higher risk of developing skin folding. The proposed model may help in the prediction of a target amount of weight loss of the patients, to prevent PU between skin folds in post-bariatric surgery.

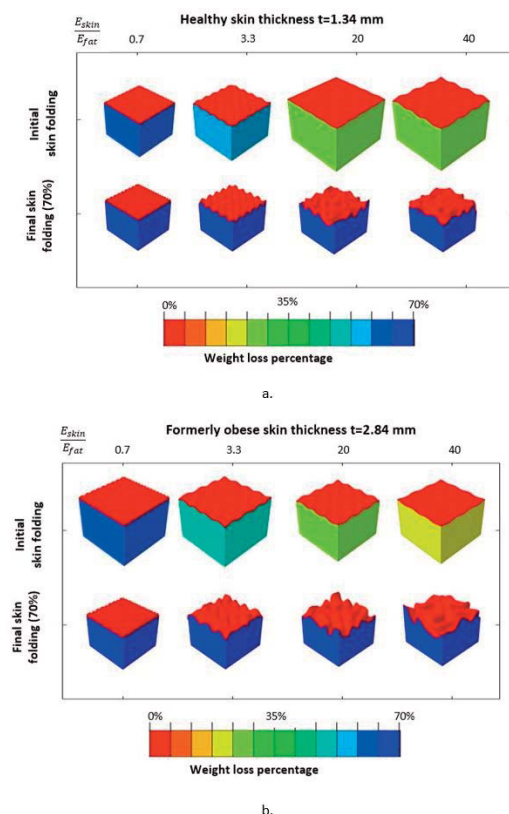


Figure 1: Skin folding representation.

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STINTS5

IN VIVO EXPERIMENTAL CHARACTERIZATION OF THE BIOMECHANICAL RESPONSE OF SACRAL SOFT TISSUES UNDER COMPRESSION USING BOTH B-MODE ULTRASOUND AND MRI: PRELIMINARY ASSESSMENT ON 2 HEALTHY VOLUNTEERS

Ekaterina Mukhina^{1,2}, Pierre-Yves Rohan¹, Nathanael Connesson², Yohan Payan²

¹ Institut de Biomécanique Humaine Georges Charpak, Arts et Métiers ParisTech, Paris, France

² Univ. Grenoble Alpes, CNRS, Grenoble INP, TIMC-IMAG, Grenoble, France

Introduction: Personalized computational models have the potential of assessing the risk of Pressure Ulcer in clinical situations and could allow the development of an individualized prevention plan. The benchmark imaging modality for the personalized Finite Element (FE) modeling is MRI 1. Yet, several barriers exist to the clinical translation of these MRI-based FE models. B-mode Ultrasound (US) imaging has shown promising results regarding the assessment of anatomical feature-related risk factors 2. The objective of this work is to experimentally characterize the response of sacral soft tissues using both B-mode US and MRI. This represents a first step to the evaluation of the relevance of using US-based FE models for monitoring internal tissue strains as an alternative to MRI-based FE models.

Methods: Two healthy male volunteers (mean: 37 y.o., BMI=27.3 kg/m²) participated in the study (MAP-VS protocol N°ID RCB 2012-A00340-43). An experimental setup was designed allowing to load the sacrum with the linear US probe of 8 MHz central frequency using the industrial US device. Setup is charged with different weights (0-1200 g), without applying the shear (Figure 1). Contact area was marked with a pen. The same acquisitions were performed with a 3 Tesla MRI using a 3D-printed copy of the US probe. Images were post-processed and Green-Lagrange shear strains were estimated using 3D image registration (Elastix library) between the unloaded and loaded MRI configurations.

Results: Preliminary evaluation of the Green-Lagrange shear strains from 3D image registration (Figure 2) showed the highest values in the skin and adipose tissues in the region of indentation above the sacral vertebra. Non-zero values at the bottom could be due to image border effects or body movement.

Conclusions: The experimental setup proposed in this contribution allowed the consecutive acquisition of the US and MRI data at the sacral region with pre-calibrated loads. 3D image registration performed on MRI data shows promising results for strains estimations. Future work will include 3D MRI-based FE modeling and validation of the simulation strain field against the field estimated with image registration. Results of the 3D simulation will be used for the evaluation of the results previously obtained with a 2D US-based FE model.



Figure1 Experimental setup at the contact

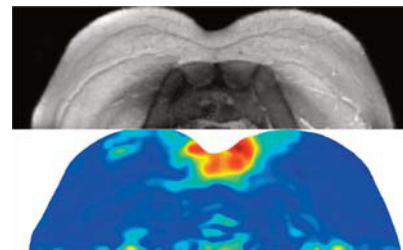


Figure2 a) Transverse plane MRI, undeformed configuration b) Green-Lagrange shear strain from image registration (on undeformed shape)

Acknowledgements: This project has received funding from the European Union's Horizon 2020 programme under the Marie Skłodowska-Curie grant agreement No. 811965.

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STINTS6

TOWARDS ULTRASOUND BASED MECHANICAL CHARACTERIZATION OF SKIN AND SKIN DISEASES

Zülal Kizilaslan¹, Marcel Rutten¹, Richard Lopata¹

¹ Eindhoven University of Technology, Biomedical Engineering, Eindhoven, Netherlands

Introduction: Studies have shown that measuring the biomechanical change of skin can be used to detect skin diseases such as Pressure Ulcer (PU) [1,2]. The objective of this study is developing an experimental setup to estimate the mechanical properties of skin based on quasi-static ultrasound (US) elastography, a technique used to investigate the biomechanical properties of tissue (such as strain, modulus) non-invasively.[3].

Methods: For an in vitro feasibility test, a 15 weight percent (wt%) Polyvinyl alcohol (PVA) phantom was created. For acoustic scattering, 3 weight percent Silicon carbide was added to the PVA mixture. Next, a linear array 10 MHz US probe was used to both compress and image the phantom simultaneously. To create an heterogeneous deformation field and measure the load, a water filled, small diameter balloon, which is attached to a pressure sensor, was positioned between the probe and the upper surface of the artificial tissue. During compression, the hydrostatic pressure that is present inside the balloon is transferred to the tissue, which was stored digitally. Ultrasound imaging was performed during compression. The displacement field in the vertical direction was estimated by analyzing the radio-frequency (RF) ultrasound data using a 2-D block matching technique, and converted into strains.

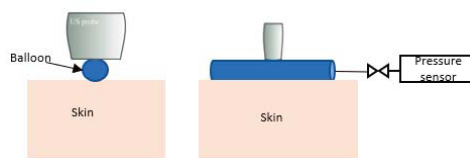


Figure 1: Schematic view of the experimental setup

Results: Figure 2 shows the undeformed and deformed state of the PVA phantom and the change on the hydrostatic pressure inside the balloon during the indentation. The blue grid overlay is based on the displacement estimation for each node. The strain field of the region of interest can be seen on the Figure 3.

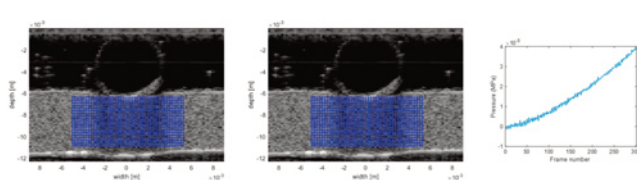


Figure 2: B-mode US images of the balloon and phantom before indentation (a) and after indentation (b). The reflection below the grid results from the plate under the phantom; c) the pressure over the consecutive US images

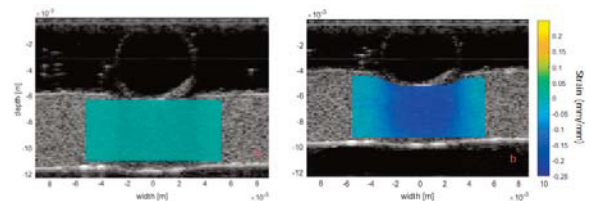


Figure 3: Strain field on phantom before indentation (a) and after indentation (b)

Conclusions: Displacement and strain field calculation, which is one of the main parameters to calculate the skin modulus, throughout the compression was succeeded. The stress, other main parameter for modulus, was acquired via pressure sensor assuming the pressure inside the balloon is equal to the pressure on the tissue. However, the result can be verified with further studies, such as mechanical tests (compression, tensile test) and Finite Element Analysis.

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STINTS7

PORTABLE PROBE TO RAPIDLY ASSESS MECHANICAL AND SENSORIAL PROPERTIES OF SKIN

Yisha Chen¹, Betty Lemaire-Semail¹, Frédéric Giraud¹, Michel Amberg¹, Vincent Hayward²

¹ Univ. Lille, Arts et Metiers Institute of Technology, Centrale Lille, Junia ULR 2697 - L2EP, F-59000 Lille, France

² ISIR, Sorbonne Université, 27063 Paris, Ile-de-France, France

Introduction: Early diagnosis of pressure ulcers (PUs) has received increased interest. Multiple studies have been performed to discover reliable indicators for skin at risk of PUs [1]–[4]. In this paper, we propose a portable probe to rapidly assess mechanical properties of skin in situ, adapted from ideas in [4].

Methods: To perform in vivo measurements, we designed a portable probe. Two piezoelectric bender actuators were employed to stretch the skin tangentially. A set of strain gauges were glued to collect feedback signals that allow skin force and displacement derivation. Figure 1 illustrates the interaction of the probe with the inner forearm. To make repeatable measurements, a control on bender displacement was implemented. In experiments, the two benders worked symmetrically and loaded the skin cyclically at 1 Hz.

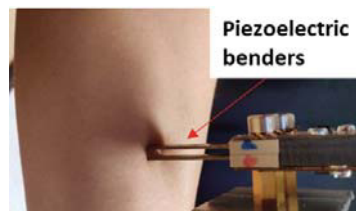


Figure 1 In vivo tests with the proposed probe.

Results: Skin responses under three displacement levels are displayed in Figure 2. The nonlinearity of skin was captured by the proposed probe, seen in the nonlinear stiffening at higher strains. Skin behaved similarly under displacement amplitudes of 100 μm and 200 μm , where the skin strain was less than 10%. For the latter, a stronger hysteresis was observed, as it corresponds to a higher rate condition. For the curve obtained under the largest vibration amplitude (400 μm), it was different from others. This may be because of the nonlinearities of the skin and those of the contact between the bender tips and the skin.

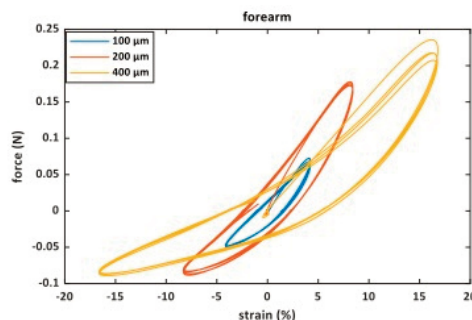


Figure 2 Skin response under cyclic loading at 1 Hz with displacement controlled. Here, strain is calculated from displacement with an initial skin length of 2.4 mm (initial distance between two bender tips).

Conclusions: Here, a portable probe is presented to characterise biomechanics of skin in situ. Skin force and displacement can be measured simultaneously through the probe. Further research will be dedicated to skin parameters extraction (stiffness, viscosity, modulus, etc), including body sites vulnerable to PUs. The highly integrated probe is beneficial to the early diagnosis of pressure ulcers.

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THE EFFECTS OF PERCEIVED SKIN SENSITIVITY ON THE PHYSIOLOGICAL RESPONSE TO MECHANICAL LOADING

Pakhi Chaturvedi^{1,2}, Peter R. Worsley², Wilco Kroon¹, Dan L. Bader², Giulia Zanelli¹

¹ Philips Consumer Lifestyle B.V., Drachten, Netherlands

² University of Southampton, United Kingdom

Introduction: It is known that skin loading can lead to tissue damage in the form of pressure ulcers ¹. Similarly, consumer products such as electrical shavers may affect skin while exerting a combination of dynamic pressure and shear loading. Such adverse skin responses could be exacerbated in individuals with enhanced skin sensitivity, e.g., due a reduced tolerance to loading, and has led to a demand for personalised prevention strategies. Many efforts have been taken to quantify skin sensitivity (SS), although evaluations have been hindered by the lack of an objective definition ². The aim of this PhD project is to evaluate the structural and physiological response of the skin to mechanical loading, in cohorts of individuals with and without perceived SS.

Methods: A review of the scientific literature regarding different parameters attributed to the loss of (facial) skin integrity and SS was conducted. Articles were screened for mechanical stimulation of the skin, with objective quantification of tissue responses. Furthermore, preliminary experiments exploring the suitability of such objective tools for characterizing local skin structure and physiology were conducted. The mechanical stimuli utilized in these experiments included tape stripping and the application of a novel instrumented shaver which measured the applied force.

Results: The review revealed that most literature to date has focussed on chemical stimuli to trigger SS and utilized subjective methods such as self-reports and visual assessment. In the few studies comparing SS and non-SS groups following mechanical stimuli, the integrity of the stratum corneum and its effective barrier function appears to be closely related with SS ^{3,4}. Thus, an array of parameters including both structural and physiological responses are required to monitor SS. Results from preliminary analysis include differences in structural parameters obtained from OCT images of the cheek and neck (e.g., thickness, roughness, blood vessel density), and changes in skin barrier properties (e.g., TEWL, hydration) following tape stripping.

Conclusions: A multimodal approach is needed to both characterize SS and monitor its relation to skins tolerance to mechanical loading. The combination of techniques including OCT images, biophysical measures of SC function, and biomarkers of skin health could provide the comprehensive parameters critical to better our understanding SS. Future studies will include evaluations of both perceived and measured skin symptoms, establishing differences in sensitivity before, during and after mechanical stimuli. The results of such studies will support the identification of individuals who may be at greater risk of developing pressure ulcers and provide the means for robust monitoring.

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STINTS9

MOLECULAR DYNAMICS APPROACH TO INVESTIGATE THE ROLE OF HYDRATION AND OTHER SURFACTANTS ON THE GEOMETRICAL AND BARRIER PROPERTIES OF STRATUM CORNEUM

Nicola Piasentin¹, Qiong Cai¹, Guoping Lian¹

¹ University Of Surrey, Chemical and Process Engineering, Guildford, United Kingdom

Introduction: Unravelling the mechanisms beneath the skin barrier and permeation properties is pivotal for a broad range of applications, ranging from skin hygiene to skin care products design. Of particular importance are changes in microclimate conditions such as temperature and hydration, which affect not only skin's barrier but also its mechanical properties and have been related to the risk of developing pressure ulcers¹. Indeed, excessive hydration makes skin fragile, reducing its tolerance to mechanical loads including pressure and shear².

Recently, molecular dynamics (MD) simulations have been reported to deliver valuable knowledge about the molecular and structural properties of inter-corneocytes lipid bilayers³. The aim of this Ph.D. is to use MD simulations to build microscopic in silico systems mimicking the SC lipid bilayers to achieve a better molecular understanding of skin health and barrier property.

Methods: The systems are being simulated via GROMACS with the CHARMM forcefield and barrier properties are predicted via MD and thermodynamical approaches. Different models are probed by changing both the lipids' ratio and their geometrical conformation. Hydration (surfactant) effects are modelled by varying the amount of water (surfactant) molecules simulated and quantified by measuring lipid structural parameters.

Results: The hydration level changes the geometrical properties of SC lipid bilayers and, consequently, the diffusive behaviour of water across them. Lipid bilayers are thinner and more disordered as the hydration level decreases, with water trapped in the polar regions of the lipids exhibiting strongly hindered diffusion. Predicted barrier properties for water compare well with experimental data, but surfactants' effects depend on the numerical implementation and the dimension of simulated system.

Conclusions: MD results compare well with experimental data for water diffusion, partition, and permeability across SC lipid bilayers. Further studies are needed to better assess the effect of surfactants and sample the mechanical properties of the SC lipid bilayers.

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LOW FREQUENCY ULTRASOUND DIAGNOSTICS SENSOR FOR PRESSURE ULCERS

Elis Marina Sales de Castro¹, Betty Lemaire-Semail¹, Frédéric Giraud¹, Michel Amberg¹

¹ Université de Lille, Arts et Metiers Institute of Technology, Lille, France

Introduction: Mechanical properties of skin are a clue for the diagnostic of pressure ulcers (PU) [1]. This project proposes a low-frequency ultrasound (LFU) device to identify the mechanical impedance (MI) of skin in different sites. The device's goal is to identify the evolution of MI of skin over time and link it with the development of PU.

In literature, studies involving LFU and PU focus on debridement through LFU cavitation [2]–[3]. Use of LFU on PU often present reduced pain and faster recovery. Although LFU for PU treatment is widely documented, the use of LFU for diagnosis is unexplored.

Thus, a Langevin transducer (LT), with 60kHz of resonance frequency is proposed for PU detection. It is a high efficiency LFU device, based on the piezoelectric effect.

Methods: A set-up consisting in a host PC, a microcontroller, power supply and a LT was implemented (Figure 1). A vector controller [4] was designed to maintain the vibration velocity controlled.

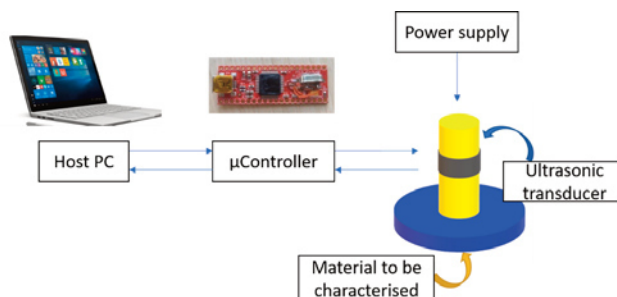


Figure 1. Set-up of the system

To achieve skin analysis, first we assessed the mechanical reaction force from skin in different body sites. Then, identified the tested skin site through this measurement, so the device can be validated as tool to characterise skin MI.

For this test, a ramp-like vibration is demanded from the device. The tests are performed at a no-load condition and in-contact condition. Due to the control, the vibration is the same for both tests. However, the effort to keep this vibration is reflected in the input voltage ($V_{(in-contact)}$ and $V_{(no-load)}$). The skin force is then calculated by the equation:

$$f_r = N(v_{(in-contact)} - v_{(no-load)})$$

Where f_r is the force imposed by the skin and N is an LT intrinsic constant.

Results: Due to the structural difference, the forearm and the palm of the hand were tested. Figure 2 presents the results from 3 subjects (1 female).

From the results, it is possible to identify the tested body spot by its response curve. Further studies are needed to validate the device.

Conclusions: The characterisation of skin by its mechanics is the initial step for this research. We hope to establish a link between these characteristics and PU, to use this device for early stage PU diagnostic.

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