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# Body numerical phantoms for estimating soft tissue pains or injuries when interacting with shoes, seats and mattresses.

M. Bucki<sup>1</sup>, V. Luboz<sup>1</sup>, A. Perrier<sup>1,2</sup>, F. Cannard<sup>1</sup>, B. Diot<sup>3</sup>, N. Vuillerme<sup>4,5</sup> and Y. Payan<sup>2\*</sup>

<sup>1</sup> TexiSense, Montceau-les-Mines, France, {marek.bucki, vincent.luboz, antoine.perrier, francis.cannard}@texisense.com;

<sup>2</sup> Univ. Grenoble Alpes, CNRS, Grenoble INP, TIMC-IMAG, F-38000 Grenoble, France, Yohan.Payan@univ-grenoble-alpes.fr;

<sup>3</sup> IDS, Montceau-les-Mines, France, b.diot@ids-assistance.com;

<sup>4</sup> UJF-Grenoble1/AGIM, Grenoble, F-38041, France, Nicolas.Vuillerme@agim.eu;

<sup>5</sup> Institut Universitaire de France, Paris, France

\* Corresponding author:

Yohan Payan

Équipe GMCAO – Laboratoire TIMC-IMAG

Université Grenoble Alpes - CNRS UMR 5525

Pavillon Taillefer

Faculté de Médecine - 38706 La Tronche cedex - France

Tel : +33 (0) 4 56 52 00 01 - Fax : +33 (0) 4 56 52 00 55

Email : Yohan.Payan@univ-grenoble-alpes.fr

## Introduction

While in interactions with external supports such as shoes, seats or mattresses, human soft tissues can suffer from discomfort that may transform into pains or tissue injuries. Indeed, the mechanical interactions between such external supports and skin tissues, usually below a bony prominence, generate shear stresses and normal pressures that can affect soft tissues integrity. To face this problem, numerous industrial products have been developed, mostly with the objective of reducing the mechanical pressure at skin surface. Shoes with dedicated insoles, mattresses with comfortable foams or customized wheelchair cushions have for example been proposed (Kim and Lee, 2013; Chenu et al., 2013; Scott and Thurman, 2014; Freeto et al., 2017). If such devices reduce discomfort for most non-disabled people, the consequences of excessive pressure at skin interface are still dramatic for people suffering from any sensory loss (from neuropathy to paraplegia) and/or peripheral vascular disease. Such persons indeed do not feel, or at least partially, the pain due to overpressures, with a healing process that can be limited because of angiopathy. It has been estimated that a foot is lost every 30 seconds in the world due to diabetes<sup>1</sup> while two-fifth of the patients being taken in charge by a reanimation or a geriatric unit will develop a pressure ulcer<sup>2</sup> (Perneger et al., 1998). Similarly, wheelchair users with impaired motor and/or sensory capacities are particularly at risk for pressure ulcers; patients with spinal cord injury (SCI) are among the highest risk

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<sup>1</sup> This trend is expected to be multiplied by four in the next 15 years with the pandemic evolution of diabetes, Shaw & Boulton, 1997.

<sup>2</sup> Pressure ulcers are defined as "*localized injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear*" (NPUAP/EPUAP 2009).

population for developing pressure ulcers. The incidence of pressure ulcers in the SCI population is indeed 25–66% (Fuhrer et al., 1993; Regan et al., 2009).

While technologies and industrial research still face these huge prevalence numbers, basic science has made substantial progress as concerns the etiology of pressure ulcer and deep tissues injuries (DTI). Mechanical compression, ischemia, lymphatic blockage and reperfusion are indeed potential factors triggering DTI (Oomens et al., 2015). Compression-induced ischemia is traditionally considered to represent the most important factor in the etiology of DTI (Daniel et al., 1981 ; Kosiak, 1959). Ischemic damage is caused by occlusion of blood vessels; tissue is deprived of oxygen and the resulting waste products accumulate in localized tissue areas. This can lead to cell death but takes several hours to develop. Direct mechanical compression results in high deformations of the subcutaneous tissue layers that can also damage tissues in a much shorter period of time (some minutes). In that case, it has been suggested recently that these high deformations gradually disrupt cells cytoskeletons with a physiological mechanism leading to cell death (Wu et al., 2016).

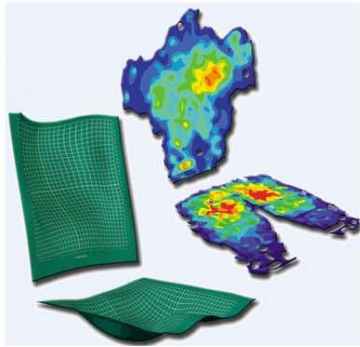
The consequence is that we are today fairly confident in what should be an efficient pressure ulcer prevention medical device. Such a device should indeed include, at least, four components:

- (1) a compliant support (shoe, seat, mattress) that optimizes the way pressure forces apply onto skin surface and that limits any stress concentration;
- (2) an on-line embedded quantitative measurement of the pressure at the support/skin interface;
- (3) an on-line estimation of the internal soft tissues deformations;
- (4) the estimation of the risk for pressure ulcer and if necessary, an alarm sent to the person.

This chapter addresses items (2) to (4) with a specific focus onto the use of personalized body numerical phantoms for estimating soft tissues internal deformations.

## **1. Pressure monitoring at the support/skin interface**

Many companies propose pressure-sensing mats allowing a quantitative measurement of the normal pressure at the support/skin interface. Figure 1 shows some commercialized devices for monitoring pressure on a wheelchair while figure 2 illustrates other devices adapted to bed and shoes. Some of these devices (e.g. Tekscan, Wellsense, Moticon or Taxisense) propose a wireless version allowing an embedded solution of the system as mentioned above. Taking into account the need for compliant pressure-sensing mats, some companies have proposed sensors based on Lycra (Vista Medical) or purely textile fibers (Taxisense).



Tekscan



Texisense



Xsensor

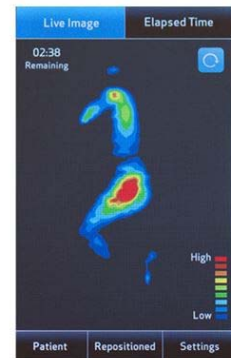


Vista Medical

Figure 1: Pressure monitoring devices for wheelchair interfaces



WellSense



Pedar Novel



F-Scan Tekscan



Moticon

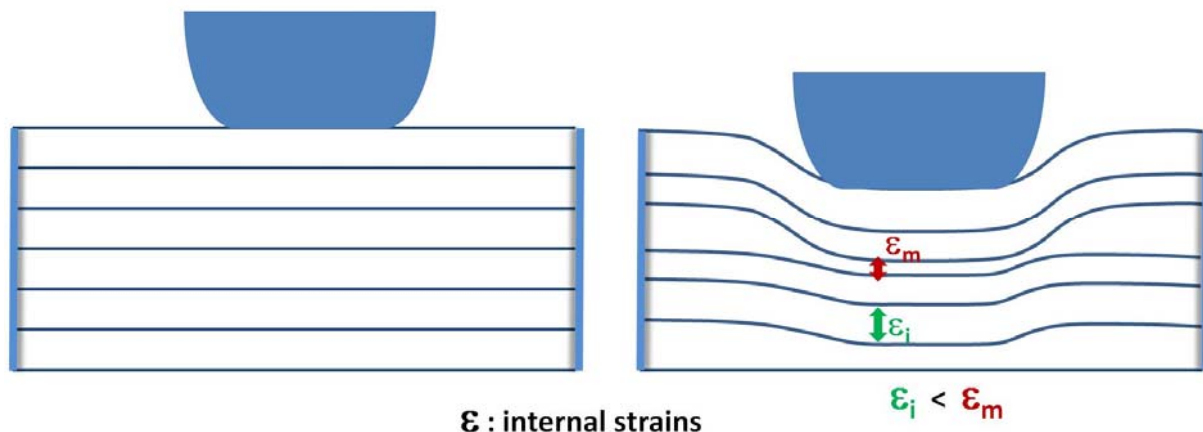


Taxisense

Figure 2: Pressure monitoring devices for bed and foot interfaces

## 2. Pressure ulcer etiology

Recent basic research results from the groups of Amit Gefen, Dan Bader and Cees Oomens (Linder-Ganz et al., 2006; Gefen et al., 2008; Loerakker et al., 2011; Slomka & Gefen, 2012; Oomens et al., 2015; Wu et al., 2016; Gefen & Weihs, 2016) have provided important clues in the understanding of pressure ulcer etiology. Indeed, these groups have demonstrated the role of the mechanical deformations (internal “strains”) in the formation of deep tissues injuries. Figure 3 explains with a simple scheme what these internal strains mean.

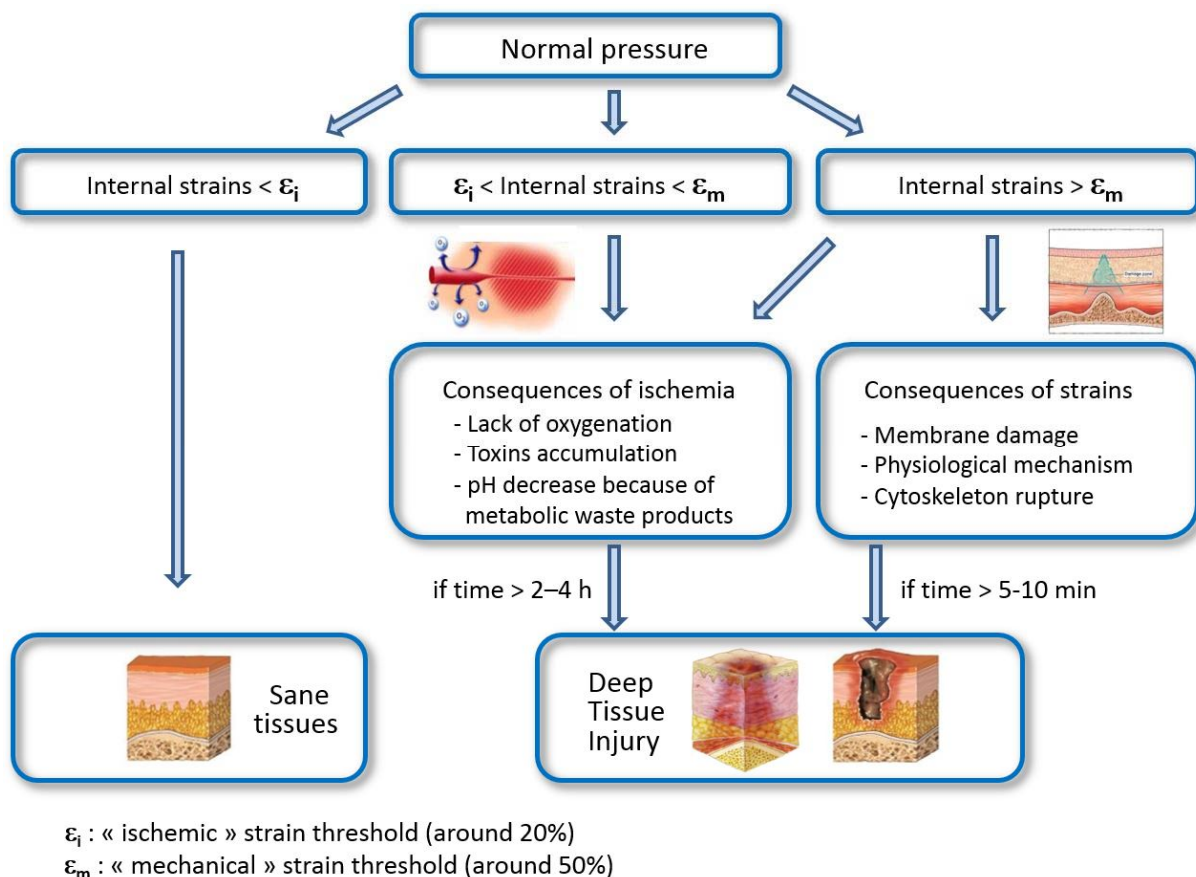


**Figure 3:** Scheme of a soft tissue deformed by a bony prominence (blue). Internal strains can vary inside the tissue depending on the mechanical properties of the different layers of soft tissues.

The global/macroscopic deformation of the soft tissues should indeed be seen as a set of local strains that depend on the boundary conditions, i.e. the shape of the support and the bony prominence, and on the heterogeneities/anisotropies of the soft tissues, i.e. the size and orientations of the skin, fat and muscular tissues, which characteristics are highly patient-specific. Therefore, as illustrated on figure 3, soft tissues that are located between the bony prominence and the support are subject to larger strains ( $\epsilon_m$ ) than the tissues located just beneath the skin surface ( $\epsilon_i$ ).

As stated by Gefen, Bader and Oomens, “it is essential to determine the tolerance of skeletal muscle cells to strains larger than 50% which represent local strains in human gluteus muscles during sitting” (Gefen et al., 2008). Unfortunately, no biomarker is available today to monitor, in real time and in an embedded configuration, the internal strains of soft tissues. Fortunately, scientists and engineer have proposed a solution from the field of Mechanics (Linder-Ganz et al., 2009): assuming that we are able to get information as concerns the morphology of the patient (sizes of the skin, subdermal and muscular tissues, shape of the bony surfaces, etc.), a numerical “biomechanical” model of these soft tissues can be elaborated and used to estimate internal strains. Such a model is a kind of virtual phantom of the patient implemented into a computer that simulates tissues deformations (and therefore estimates the internal strains) from the measured pressures at skin surface.

Thanks to animal studies, the team of Cees Oomen has provided a quantitative link between these internal strain values and the risks for deep tissue injuries (Loerakker et al., 2011; Oomens et al., 2015; Wu et al., 2016). This is illustrated on figure 4.



**Figure 4:** Relationships between tissues strains and risks for pressure ulcers (adapted from Oomens et al., 2015 and Wu et al., 2016)

According to Oomens and colleagues, two strain thresholds could be monitored inside the tissues. Such thresholds can be estimated using a biomechanical model of the soft tissues that computes internal strains (Linder-Ganz et al., 2007; Loerakker et al., 2013; Oomens et al., 2015). The first threshold, called the “*ischemic* strain threshold”, is known from clinicians since a long time and corresponds to the deformations that collapse the blood vessels and create an ischemia. Experiments and simulations from Oomens and colleagues suggest a strain threshold value  $\epsilon_i$  of the order of 20% and indicate that tissues should not be subject to such a deformation for more than two to four hours, since an ischemic pressure ulcer can appear in that case. This time scale corresponds to the advice usually provided to patients and medical staffs with SCI persons who should do regular push-up or with nurses who are asked to change the positions of lying disabled patients every two to four hours or so.

The second strain threshold  $\epsilon_m$  introduced by Oomens and colleagues (Oomens et al., 2015) is a “*mechanical* threshold” that should be much more carefully monitored since it can create deep tissue injury in a very short time scale (5 to 10 minutes). Indeed, if the pressures exerted at skin surface generate internal strains that are very high in some regions of the soft tissues, the cells located in these regions are so deformed that their cytoskeleton is degraded and their membrane broken because of physiological reasons (Wu et al., 2016) with changes in cell permeability leading to

necrosis. Biomechanical models of the compressed soft tissue have been generated to replicate animal studies thus estimating the internal strains that correspond to observed deep tissue injuries. A shear strain threshold around 50% is therefore provided by Loerakker and colleagues (Loerakker et al., 2013) assuming the use of a nonlinear Ogden constitutive material for modeling soft tissue.

Assuming that the virtual phantom of the patient is implemented into a computer that simulates tissues deformations in real time, soft tissues subject to strains higher than 20% or 50% during respective time scales larger than 2-4 hours or 5-10 minutes should therefore be considered at risks for pressure ulcers.

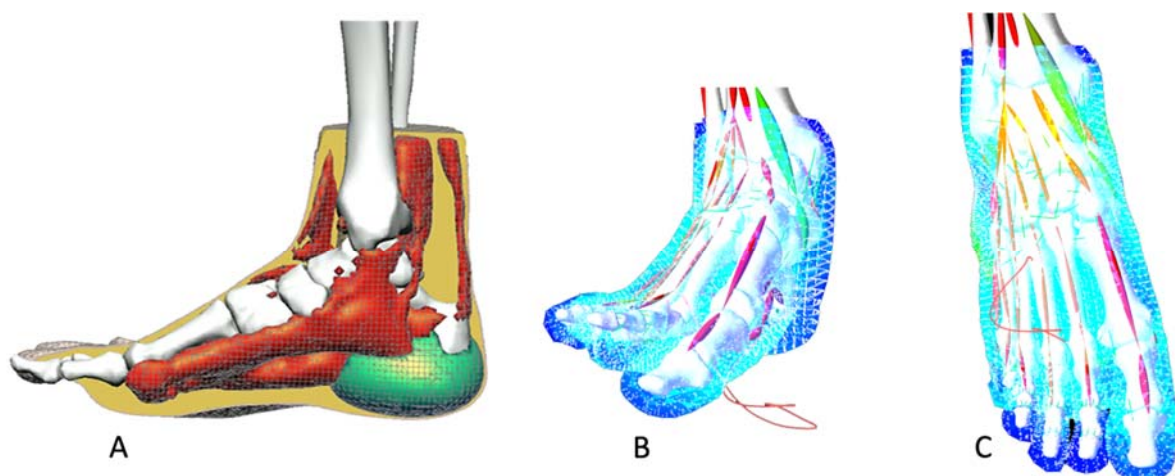
Since almost ten years, our group has designed biomechanical models of the human anatomical regions that are at risks for pressures ulcers. "Body numerical phantoms" that estimate the risks for deep tissue injuries when interacting with shoes, seats and mattresses have therefore been proposed and evaluated. Such models are described below.

### 3. Body numerical phantoms

#### 3.1 Foot model for diabetic ulcer prevention

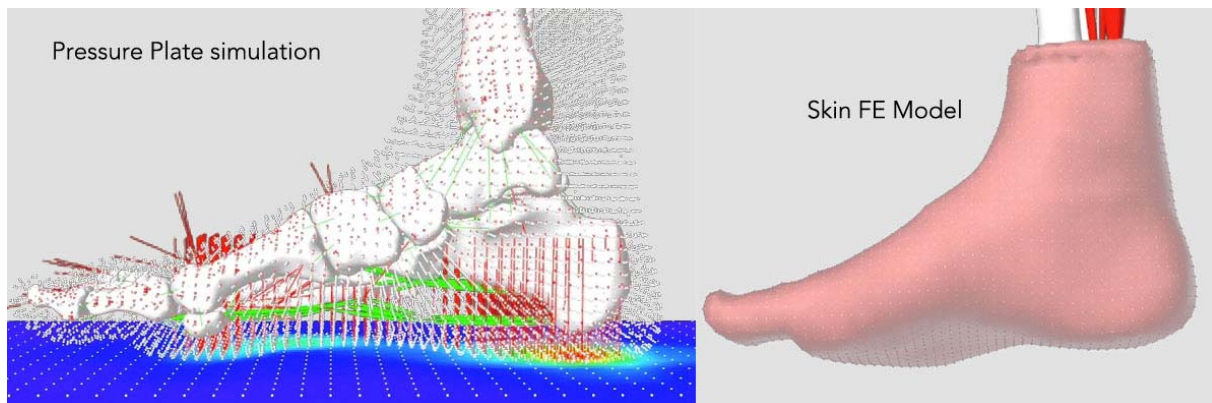
A foot model has been developed using the 3D biomechanical simulation open-source platform ArtiSynth (Lloyd et al., 2012 ; <http://www.artisynth.org>). Starting from a CT and an MRI exam of a single patient, 30 bones have been modeled as articulated rigid-bodies connected with cables that simulate the 210 segmented ligaments in their actual positions and therefore define the articulations with contacts (Perrier et al., 2015). The Aponeurosis is modeled with five parallel multipoint ligaments connected by transversal ligaments. 15 extrinsic and intrinsic Hill's model muscles have been positioned according to their anatomical course and can be independently activated in order to allow a natural movement of the foot.

A FE mesh of the soft tissues was created (Figure 5) by applying the automatic FE mesh generator TexiMesh (<http://www.texisense.com>) to the surfaces resulting from MRI and CT segmentation. The FE mesh has 142,060 elements, mainly hexahedrons, and 66,362 nodes. Three soft tissue layers with Neo Hookean materials (equivalent Young moduli, Poisson Ratio) were created to represent a 1mm skin layer (200kPa, 0.485), the fat (30kPa, 0.49) and muscle (60kPa, 0.495) tissues. A fourth layer represents the heel anatomical soft structure (100kPa, 0.4998).



**Figure 5:** Finite Element foot model (A) and its deformations (B. Abduction, C. Adduction).

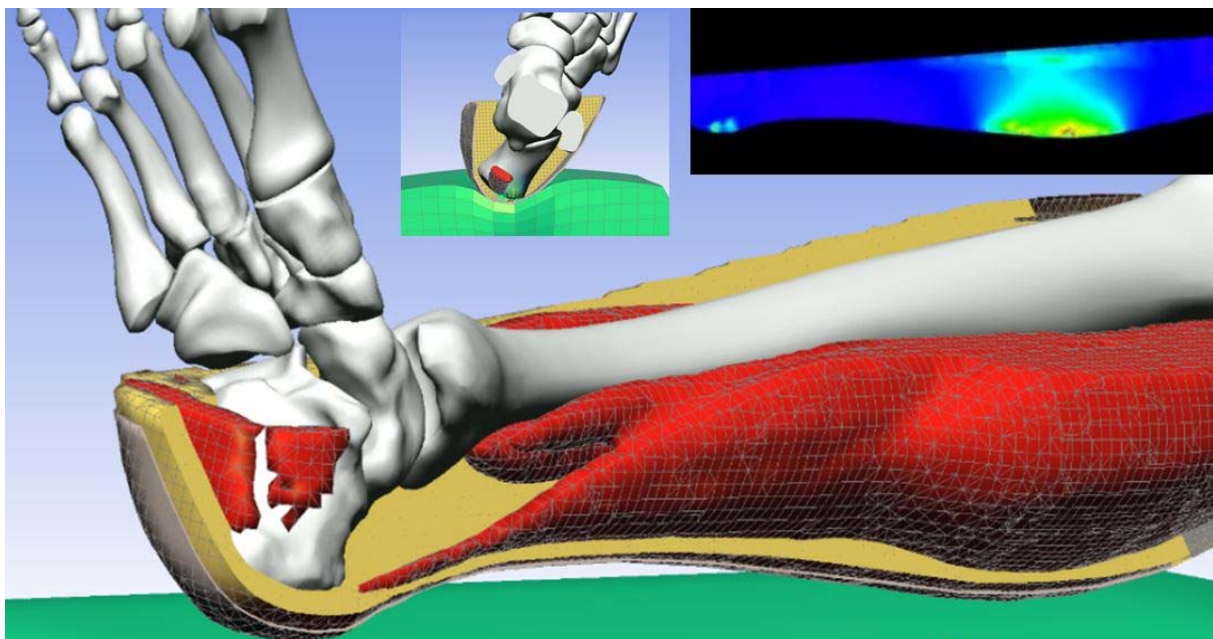
This model can then be used to compute the internal strains in a weight bearing position (figure 6) or by transferring the skin surface pressures measured with the embedded textile sock provided by Taxisense (Perrier et al., 2014 ; figure 2).



**Figure 6:** Foot model in weight-bearing position and the corresponding pressure map.

### **3.2 Lower leg model for heel ulcer prevention**

In a similar way, a model of the lower leg has been developed using the ArtiSynth simulation platform (Luboz et al., 2015). Surfaces from the lower leg's skin, muscles and bones, as well as the Achilles tendon were extracted from the Zygote database ([www.zygote.com](http://www.zygote.com)). Based on these surfaces, Taxisense's mesh generator was used to generate a mesh of the muscles, fat and skin layers with a minimum of tetrahedrons to limit the locking effect observed in quasi-incompressible assumptions while keeping a smooth and accurate boundary between the different structures using transition elements such as pyramids and wedges (figure 7). This led to a set of 18 meshes having approximately 122,000 elements, including approximately 29,000 hexahedrons, 38,000 pyramids, 28,000 wedges, and 27,000 tetrahedrons, for an approximate total number of nodes of 66,000. During the simulation, the leg lies on a cushion whose geometry represents a typical pneumatic cushion used on geriatric beds (figure 7).



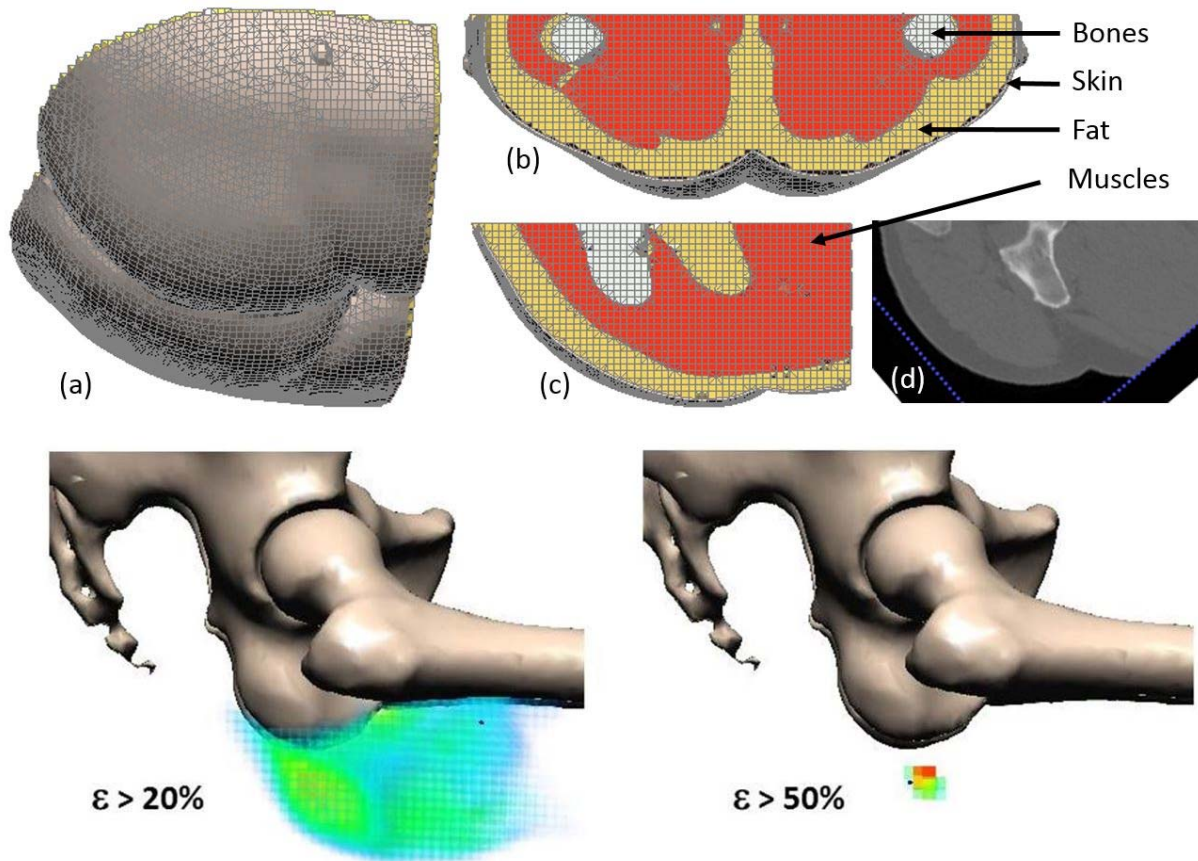
**Figure 7:** Model of the lower leg simulating interactions with a bed and the corresponding tissue strains.

### ***3.3 Buttock model to prevent ischial pressure ulcers***

An FE model of the buttock soft tissues was developed by our group (Luboz et al., 2014) and implemented within the ArtiSynth framework. This study was based on the morphology of a male subject (38 years old, 100 Kg and 1.90 m). The external surfaces of the skin, muscles and bones were semi-automatically segmented from a CT scan (image size 512x512x403, resolution 0.97x0.97x1 mm<sup>3</sup>), using the ITK-Snap snake tool (Yushkevich et al., 2006). The muscles were segmented as a single entity as they were too difficult to separate. To get non-deformed surfaces, the subject was laying on his side in the CT scan, therefore leading to one side of his buttocks not being deformed. Gravity influence was supposed to be negligible. The external surfaces of the model were then defined as a combination of this non-deformed side with its mirror side.

The TexiMesh tool provided by Taxisense Company was used to generate a three layer FE mesh, corresponding to the skin, fat and muscles. The hex-dominant mesh is composed of 27,649 linear elements (fig. 8a). The skin is a 1-element 1.5mm-thick layer of elements at the FE mesh surface. The segmented muscle surface delimits the muscle elements. Finally, the elements between the skin and muscle layers are considered as fat tissues. Figure 8b&c shows a mesh cross section after identifying these structures. In this model, the bones are assumed to be rigid. The nodes at the tissue/bone interface are attached to these bones, without any sliding.

The three soft tissues layers are modeled using a Neo Hookean constitutive material with mechanical properties inspired by (Luboz et al., 2014). Equivalent Young modulus values of 200 kPa, 30 kPa, and 100 kPa were respectively chosen for the skin, fat and muscles. A Poisson ratio of 0.49 is used for these three layers, as they are assumed to be quasi-incompressible. The pressures collected by the Taxisense mat (figure 1) are then projected onto the external surface of the buttock model, thus offering the possibility to compute the internal strains that respectively exceed 20% and 50% (figure 8, lower panel).



**Figure 8:** Buttock model and internal strains while simulating a sitting posture.

#### 4. Discussion and conclusion

There is currently no *in vivo* solution to quantitatively measure the injuries that can affect human soft tissues when put in interactions with external supports such as shoes, seats or mattresses. One solution to estimate the risks for such injuries is to use a subject-specific body numerical phantom that should compute in real time the strains inside the soft tissues, below bony prominences. Our group has proposed a clinical workflow for personalized pressure ulcer prevention (Bucki et al., 2016), based on an embedded measurement of the pressure at skin interface coupled with 3D subject-specific biomechanical modeling of soft tissues / bones interactions. For all the models presented above, proofs of concept have been provided with the computation of internal strains and the generation of alerts if high strains are maintained for a long period. The relevance of the 20% and 50% strain thresholds (and their corresponding time scales of 2-4 hours and 5-10 minutes) for deep tissue injuries is still raised and discussed. A medical device that would alert the person in case of risk for pressure ulcer should indeed not generate false alerts that would, at term, make the user reject the device.

Finally, the estimation of discomfort / pains can be related to the risk for pressure ulcer. Indeed, as mentioned above, such a risk is a function of strains values; it can therefore be hypothesized that a discomfort or a pain could also be related to strain values (Gefen, 2016; Hadid et al., 2017) with thresholds that could be ischemic (Ost et al., 2006) or mechanical (Hoff et al., 2010).

This paper has presented a proof of concept for estimating the risks for soft tissue pains or injuries when interacting with shoes, seats and mattresses. Like some other commercial solutions (e.g. Scott et al., 2014), we propose a device that measures continuously the pressure at the skin / support interface (Chenu et al., 2013). However, we have extended this device by coupling it with a personalized biomechanical model of the soft tissue able to compute the internal strains (Bucki et al., 2016). As mentioned above, this is a prerequisite to quantitatively estimate the patient-specific risks for pressure ulcers. Before implementing such a prevention technique in a clinical workflow, some aspects of the approach still require improvements. We can cite the personalization of the patient's material properties for the various soft tissues layers and the time needed to generate the patient-specific models from medical images. The approach will also require the biomechanical simulations to be run in real-time. Our group is currently investigating this question through the optimization of the simulations by using a reduced order modeling technique based on proper orthogonal decompositions of the pressure and strain fields coupled with a machine learning method (Luboz et al., 2017).

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