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Clinical workflow for personalized foot pressure ulcer prevention

M. Bucki[a], V. Luboz[a], A. Perrier[a,b,c], E. Champion[a], B. Diot[c,d], N. Vuillerme[c,e], Y. Payan[b,*]

[a] TexiSense, Montceau-les-Mines, France
[b] Univ. Grenoble Alpes & CNRS, TIMC-IMAG, F-38000 Grenoble, France
[c] UJF-Grenoble1/AGEIS, Grenoble F-38041, France
[d] IDS, Montceau-les-Mines, France
[e] Institut Universitaire de France, Paris, France

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ABSTRACT

Foot pressure ulcers are a common complication of diabetes because of patient's lack of sensitivity due to neuropathy. Deep pressure ulcers appear internally when pressures applied on the foot create high internal strains nearby bony structures. Monitoring tissue strains in persons with diabetes is therefore important for an efficient prevention. We propose to use personalized biomechanical foot models to assess strains within the foot and to determine the risk of ulcer formation. Our workflow generates a foot model adapted to a patient's morphology by deforming an atlas model to conform it to the contours of segmented medical images of the patient's foot. Our biomechanical model is composed of rigid bodies for the bones, joined by ligaments and muscles, and a finite element mesh representing the soft tissues. Using our registration algorithm to conform three datasets, three new patient models were created. After applying a pressure load below these foot models, the Von Mises equivalent strains and "cluster volumes" (i.e. volumes of contiguous elements with strains above a given threshold) were measured within eight functionally meaningful foot regions. The results show the variability of both location and strain values among the three considered patients. This study also confirms that the anatomy of the foot has an influence on the risk of pressure ulcer.

1. Introduction

It has been estimated that a limb is lost every 30 s in the world due to diabetes. This trend is expected to be multiplied by four in the next 15 years with the pandemic evolution of diabetes [22]. In addition to causing pain and morbidity, foot lesions in diabetic patients have substantial direct and indirect economic consequences [23,9]. Diabetic foot ulcers result from multiple pathophysiological mechanisms, including neuropathy, peripheral vascular disease, high foot pressures, foot deformity, and diabetes severity [25]. Several studies [17,14] recognized at least three mechanisms leading to pressure ulcer: (1) ischemia caused by increased pressure duration even for low induced strains, (2) high internal tissue strains created by increased pressure magnitude, and/or (3) tissue fatigue caused by increased number of periodic pressure loads. Time and strain have an inversely proportional contribution to ulceration [10,14,27]: high strains take a relatively short time (a few minutes) to cause ulceration whereas low strains induce lesion after a longer period (between two and four hours). Short and long term lesion inducing strain thresholds have been characterized by Loerakker et al. [14] in muscle tissues. The obtained values were around 50% of deformation for short term high strains and 20% of deformation for long term low strains. This study also showed that fat tissues have large strain variations (although not as large as muscle tissues) and they might suffer from pressure ulcer. The two strain thresholds aforementioned are therefore key values in pressure ulcer prevention.

Daily monitoring by the patient or clinical staff is the main tool to prevent foot pressure ulcers and results in an estimated reduction of foot ulcers and amputations from 50% to 80% [2]. Because early stages of ulceration are not always visible, both patient's and staff's vigilances tend to decrease over time. Unfortunately, in the case of diabetic patients, it is precisely when the first ulcers appear that serious complications develop, mainly because of the angiopathy, which severely limits healing.

It is consequently essential to introduce new monitoring tools to promote awareness and as a result, patient's autonomy in everyday life. Measuring pressure loads at the skin surface, all around the foot, and, if possible, estimating the corresponding

* Corresponding author. Tel.: +33 456 520001; fax: +33 456 520055.
E-mail addresses: marek.bucki@texisense.com (M. Bucki), vincent.luboz@texisense.com (V. Luboz), antoine.perrier@texisense.com, antoine.perrier@imag.fr (A. Perrier), eric.champion@texisense.com (E. Champion), b.diot@ids-assistance.com (B. Diot), Nicolas.Vuillerme@agim.eu (N. Vuillerme), yohan.payan@imag.fr (Y. Payan).

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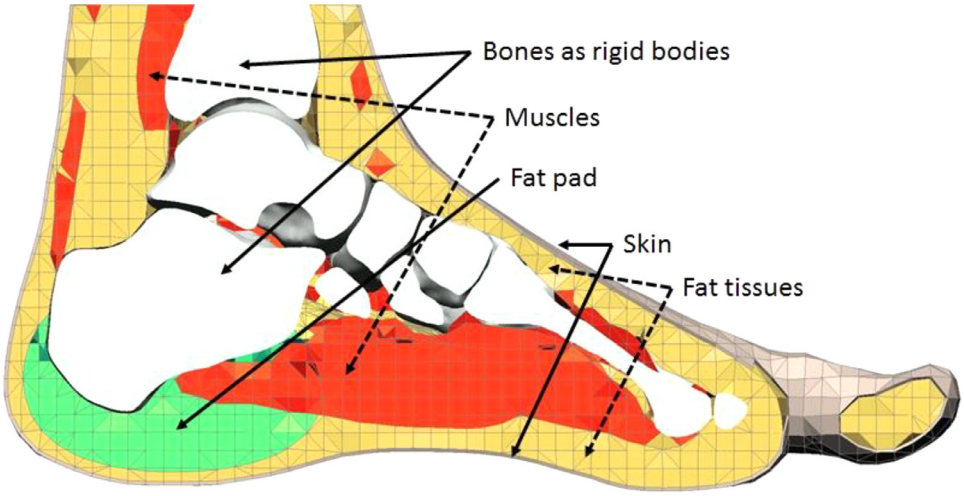

Fig. 1. Cross section of the FE mesh representing the foot soft tissues: plantar skin layer, muscle layer, and the fat in-between. The white sections represent the locations of the rigid bodies modeling the bones.

internal strains could help preventing further ulceration and facilitate wound healing [8]. Measuring interface pressures can be performed with a pressure sensor such as the ones proposed by Novel (http://www.novel.de), Tekscan (http://www.tekscan.com), Vista Medical (http://www.pressuremapping.com) or Texisense (http://www.texisense.com), however several studies established that using pressure measurements at the skin interface is not sufficient to prevent foot pressure ulcers, especially the ones starting deep in the tissues and causing substantial subcutaneous damage underneath intact skin [12,1,7]. Indeed surface measurements do not provide enough information as to predict ulcer formation in a reliable way [12]. For example, with the same pressure map, a patient with a sharp calcaneus, or a thinner heel pad, could develop a pressure ulcer while another one, with a different morphology, might not. Pressure ulcer risk is consequently highly patient-related and integrates a number of factors such as bones' curvature [16], or soft tissue thickness (in skin, fat and muscles) [8]. Monitoring internal strains is currently a consensual criterion to assess the risk of pressure ulcer and has been widely used in previous studies [12,18]. Nevertheless, measuring internal strains *in vivo* being impossible, a biomechanical model integrating the behavior of the foot internal soft tissues and bones is needed to assess internal strains and the resulting risk of ulceration. Furthermore because of inter-individual anatomical variability, personalized biomechanical models must be resorted to in order to accurately estimate internal strains and implement an adequate prevention strategy [8,16,26].

Several studies have demonstrated the use of biomechanical foot models to estimate internal strains. Most of the feasibility studies are limited to a single foot model generated for a specific patient, and seem difficult to extend in an automatic fashion to a wider group of subjects – not to mention – in clinical routine. For example, Ledoux et al. [11] modeled the soft tissues under the foot (skin, fat and muscles) as a finite element (FE) mesh with a homogeneous linear elastic material, bones as rigid FE meshes; joints were accounted for as idealized contacts between bones, and around 20 ligaments connecting the mid foot bones were modeled as cables. In another study, Chen et al. [5] proposed a more detailed FE foot model including almost all foot ligaments and using a large deformation Mooney–Rivlin constitutive law for the soft tissue bulk. Even though this model is fairly complete, it lacks computational efficiency and does not distinguish between different tissue types. These drawbacks were addressed in the model that we recently proposed [21] with foot soft tissues represented as four different Neo-Hookean materials for skin, fat, heel pad fat, and muscles respectively. In this model, bones were represented as rigid bodies connected by the most significant ligaments of the foot, modeled as cables. Nevertheless, this last model, just like the two previously cited ones, was generated from a single subject dataset and is consequently only representative of this particular morphology. In this paper, inspired by our previous study on patient-specific modeling of the calcaneus [16], we propose to use this complex foot model as an atlas – or generic model - and to generate new patient-specific models by deforming this atlas to fit the patients' specific morphology. The goal is to design a process making it possible to produce patient-specific biomechanical models in the most automated and user-friendly way possible. The proposed modeling technique could be used to study the influence of variability in morphology on pressure ulcer formation. Its further goal is to provide insight at how morphological specificities should be accounted for in the design of medical devices to optimize strain monitoring-based prevention for each individual. The following study has been carried out in a static analysis framework i.e. does not take into account the duration or repetitive mechanisms leading to pressure ulcer but only tissue compression resulting from a static stance.

2. Methods

2.1. Foot model atlas

The shape of the atlas model is based on a single subject (male, 33, healthy) and is presented in details by Perrier et al. [19,21]. The contours of the skin, heel fat pad, muscles, and bones were manually segmented from the CT scan of the right foot of this healthy subject. An automatic FE mesh generator (developed by Texisense) was run on the resulting surfaces, and produced a conforming multi-domain FE mesh containing four layers: muscles, fat, heel fat pad, and skin (Fig. 1). The meshing algorithm generates as many hexahedrons as possible in the core of the continuum to limit the locking effect observed for tetrahedral elements under quasi-incompressible assumption. Smooth and conforming boundaries between the different internal domains are defined using transition elements such as pyramids, wedges, or tetrahedrons. The meshing procedure led to a FE mesh having 44,220 elements, including 3,610 hexahedrons, 12,062 pyramids, 8,674 wedges, and 19,874 tetrahedrons, for a total of 19,574 nodes.

Finite element analyzes are carried out on the 3D simulation platform ArtiSynth [13] (www.artisynth.org). Soft tissues (skin, fat,