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3D finite element model of the diabetic neuropathic foot: A gait analysis driven approach



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ABSTRACT

Diabetic foot is an invalidating complication of diabetes that can lead to foot ulcers. Three-dimensional (3D) finite element analysis (FEA) allows characterizing the loads developed in the different anatomical structures of the foot in dynamic conditions. The aim of this study was to develop a subject specific 3D foot FE model (FEM) of a diabetic neuropathic (DNS) and a healthy (HS) subject, whose subject specificity can be found in term of foot geometry and boundary conditions. Kinematics, kinetics and plantar pressure (PP) data were extracted from the gait analysis trials of the two subjects with this purpose. The FEM were developed segmenting bones, cartilage and skin from MRI and drawing a horizontal plate as ground support. Materials properties were adopted from previous literature. FE simulations were run with the kinematics and kinetics data of four different phases of the stance phase of gait (heel strike, loading response, midstance and push off). FEMs were then driven by group gait data of 10 neuropathic and 10 healthy subjects. Model validation focused on agreement between FEM-simulated and experimental PP.

The peak values and the total distribution of the pressures were compared for this purpose. Results showed that the models were less robust when driven from group data and underestimated the PP in each foot subarea. In particular in the case of the neuropathic subject's model the mean errors between experimental and simulated data were around the 20% of the peak values. This knowledge is crucial in understanding the aetiology of diabetic foot.

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1. Introduction

The prevalence of foot ulceration (FU) among patients with diabetes mellitus ranges from 1.3% to 4.8% in the community (Boulton et al., 2005). The pathophysiology of diabetic FU is multi-factorial, but peripheral neuropathy is thought to be responsible for most cases. In the last decade several studies have highlighted that biomechanical factors play a crucial role in the aetiology, treatment and prevention of diabetic neuropathic FU. Diabetes' complications

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cause alterations in foot structure and function, subsequently leading to increased PP, which is a predictive risk factor for the development of diabetic FU (Van Schie, 2005). Some authors (Guiotto et al., 2012; Ledoux et al., 2003) demonstrated close relationships between foot morphological alterations and FU. Recently others indicated that mechanical stress concentrations in deep tissues of the plantar pad of the DNS' foot, which develop directly under bony prominences (particularly calcaneous and metatarsal heads), play a dominant role in the mechanism of DNS' foot injuries and may lead to FU (Cavanagh et al., 1993; Erdemir et al., 2005; Patil et al., 1996; Yarnitzky et al., 2006).

Some techniques have been explored to study this mechanical interaction between external and internal stresses and strains. They can be subdivided in two categories: experimental and numerical. From an experimental point of view, the motion analysis technique is one among the possibilities to quantify biomechanical variables directly measurable in-vivo. PP and ground reaction forces are largely used in gait analysis coupled with foot kinematics measurements in order to better characterize

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normal and abnormal foot function. The combination of all these data provides an exhaustive and detailed view of foot loading during gait. While experimental analyses are limited solely to measurements of interfacial variables, a reliable numerical model can provide both the interfacial pressures and insight into internal stresses and strains tolerated by the plantar tissue (Yarnitzky et al., 2006). FEMs have been used in many biomechanical investigations with great success due to their ability of modelling structures with irregular geometry and complex material properties, and the ease of simulating complicated boundary and loading conditions in both static and dynamic analyses. FEMs allow taking into account the critical aspects of the diabetic foot, namely the movement, the morphology, the tissue properties and the loads. Several recent models have used the finite element analysis (FEA) to predict the loading of the foot's components during standing and gait as they relate to foot disorders and therapeutic footwear (Actis et al., 2006; Budhabhatti et al., 2007; Chen et al., 2010; Cheung and Zhang, 2008, 2005, p. 3; Cheung et al., 2005; Erdemir et al., 2005; Fernandez et al., 2012; Gefen et al., 2000; Oosterwaal et al., 2011; Qiu et al., 2011; Thomas et al., 2004), in particular applied to diabetic foot pathology. This condition is of interest biomechanically, because custom foot insoles and surgical interventions are generally the most used approach for coping with FU. However it should be considered that state of art foot FEMs have been developed under simplified assumptions such as foot subsegments (e.g. rearfoot, forefoot), material properties, infinitesimal deformation and linear boundary conditions (Cheung and Nigg, 2008).

The aim of this study was to simulate the biomechanical behaviour of both a HS and a DNS's feet in order to predict the area characterized by excessive stresses on the plantar surface. To achieve this, a foot FEM has been developed and subjectspecific loading and boundary conditions were applied. These were experimentally measured through an integrated and synchronized kinematic-kinetic-PP acquisition set up during gait analysis trials. A subject specific FEM (case A - geometry was obtained from magnetic resonance images - MRI). Agreement between experimentally measured PP and FEM-simulated PP during different phases of the stance phase of gait was used to assess FEA validity. A secondary aim of the study was to evaluate validity of the models when driven by group gait data (10 HSs and 10 DNSs, case B) in order to investigate the possibility of applying the model to a wider cohort of subjects. Also in this case model validation focused on agreement between experimentally measured PP and FEM-simulated PP.

2. Methods

2.1. Subjects

 $\mbox{Case A}:$ one HS (HS1) and one DNS (DNS1) (Table 1) were recruited for developing the FEMs.

Case B: 10 HSs and 10 DNSs (Table 2) were recruited and their gait analysis data acquired. DNS' inclusion criteria were type 1/2 diabetes, walking ability and no history of ulcers or neurological disorders (apart from neuropathy), orthopaedic problems, lower limb surgery, cardiovascular disease. HSs were recruited among hospital personnel. All subjects gave written informed consent. The protocol was approved by the local Ethic Committee of the University Clinic of Padova.

In both cases (A and B) the following clinical screening was performed on every DNS: the neurological evaluation, the Michigan Neuropathy Screening Instrument questionnaire (Feldman et al., 1994; American Diabetes Association, 2003); physical examination as in (Sawacha et al., 2009b). HbA1c values from the preceding ten years were collected. Each patient had at least one ophthalmologic examination, a urinary albumin-to-creatinine ratio measured (0–30 mg/g normal, 30–300 mg/g microalbuminuria), a carotid artery Doppler ultrasound examination, and a 12-leads electrocardiogram in the three months preceding the study.

Table 1

Data of diabetic neuropathic and healthy subjects.

Condition	n Sex	Age	Weight [kg]	Height [cm]	BMI [kg/m ²]	Foot size	Type of foot
HS1	F	27	61	174	20.1	40	Normal
NS1	M	61	79	175	25.8	42.5	Cavus

Table 2

Demographic and clinical data of the healthy and the neuropathic subjects. #=Number of subjects.

Groups	HS		DNS		
	# or Mean	SD	# or Mean	SD	
Subjects [#]	10		10		
Sex [# of males]	7		6		
BMI [kg/m ²]	24.9	2.3	24.3	2.9	
Hypertensive disease [#]	0		8		
Age [years]	61.2	5.3	63.2	6.4	
Peripheral neuropathy [#]	-	-	10		
Diabetic retinopathy [#]	-	-	6		
Microalbuminury [#]	-	-	2		
Vasculopathy [#]	-	-	3		
Vasculopathy (peripheric) [#]	-	-	2		
Vasculopathy (TSA) [#]	-	-	5		
Vasculopathy (coronary) [#]	-	-	1		
Type of diabetes [#]	-	-	Type1: 6, type2: 4		
Hb A1c	-	-	7.97	1.28	
Years of disease	-	-	28.1	12.5	
Cavus foot [#]	6		9		
Flat foot [#]	0		1		
Valgus hindfoot [#]	3		4		
Varus hindfoot [#]	0		1		
Hallux valgus [#]	2		4		
Foot deformities [#]	4		5		
Plantar callosity [#]	1		4		



Fig. 2. 3DNSM in the Abaqus-CAE visualization. The global reference system of the model is coincident with that of the gait analysis acquisitions.

2.2. Experimental setup

The gait analysis was carried out using a 60 Hz 6 cameras stereophotogrammetric system (BTS S.r.l, Padova), 2 force plates (FP4060-10, Bertec Corporation, USA), 2 PP systems ($410 \times 410 \times 0.5$ mm, 0.64 cm² resolution, 150 Hz, Imagortesi, Piacenza). The signals coming from all systems were synchronized in post-processing (Sawacha et al., 2012). A four segments 3D foot kinematic model was adopted for the subsegments angles estimation during gait. The former was previously validated in our laboratory and it allows the 3D evaluation of ankle, hindfoot, midfoot and forefoot kinematics (Sawacha et al., 2012, 2009a) together with sub-segments forces and PP. The motion analysis acquisitions included a static trial and at least three gait cycles of each limb. For every trial, whole foot and subsegments angular displacements, ground reaction forces and pressure's curves were plotted over one stance phase of gait.

Case A: in order to cover the range of foot contact over the ground, four instants of the stance phase of gait when critical loads occurred (Gefen et al., 2000) were chosen for the 3D FEM simulations driven by the HS1 (3DHSM) and

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