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A method for subject-specific modelling and optimisation of the cushioning properties of insole materials used in diabetic footwear

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ABSTRACT

This study aims to develop a numerical method that can be used to investigate the cushioning properties of different insole materials on a subject-specific basis.

Diabetic footwear and orthotic insoles play an important role for the reduction of plantar pressure in people with diabetes (type-2). Despite that, little information exists about their optimum cushioning properties.

A new in-vivo measurement based computational procedure was developed which entails the generation of 2D subject-specific finite element models of the heel pad based on ultrasound indentation. These models are used to inverse engineer the material properties of the heel pad and simulate the contact between plantar soft tissue and a flat insole. After its validation this modelling procedure was utilised to investigate the importance of plantar soft tissue stiffness, thickness and loading for the correct selection of insole material.

The results indicated that heel pad stiffness and thickness influence plantar pressure but not the optimum insole properties. On the other hand loading appears to significantly influence the optimum insole material properties. These results indicate that parameters that affect the loading of the plantar soft tissues such as body mass or a person's level of physical activity should be carefully considered during insole material selection.

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1. Introduction

The diabetic foot disease is one of the most common complications of type-2 diabetes. Previous reports highlight that approximately 15% of people with diabetes world-wide will at some stage develop diabetic foot ulceration that could lead to amputation [1]. The complications of diabetes (type-2) are the most frequent cause of non-traumatic lower-limb amputations [1]. While in the UK up to 100 people/week have a limb amputated as a result of diabetes, it is indicated that up to 80% of these amputations could have been prevented with correct management [2].

Even though it is clear that certain areas of the foot have a significantly higher risk for ulceration (i.e. metatarsal head area, the heel and the hallux) [3] the mechanisms behind ulceration are not yet fully understood. Foot ulcers in people with diabetes are multi-factorial and linked to a variety of clinical risk factors, like peripheral neuropathy and vascular insufficiency [4], as well as biomechanical risk factors, such as increased plantar pressure [3].

Previous in-vivo studies performed with age-matched groups of non-diabetic and diabetic volunteers have found that diabetic plantar soft tissue tends to be thicker [5], stiffer [5,6], harder [7] and to return less energy after a load/unload cycle (i.e. higher energy dissipation ratios) [8]. Moreover recent in-vivo results revealed statistically significant correlations between the stiffness of the heel pad of people with diabetes (type-2) and their blood sugar and triglycerides levels [9].

One of the most common experimental techniques used to study the in-vivo mechanical behaviour of plantar soft tissues is ultrasound indentation. During the indentation test tissue deformation is measured from the ultrasound images [5,8–10] and the applied force is measured from a load sensor enabling the calculation of a force/deformation curve. This curve describes the macroscopic response of the plantar soft tissue to loading and is influenced by the morphology of the tissue as well as by the size and shape of the indenter. The effect of indenter size was numerically investigated by Spears et al. [11] to conclude that larger indenters can produce more reliable and robust measurements compared to smaller ones.

In order to produce a more accurate and objective technique for the material characterisation of plantar soft tissue, Erdemir et al. [10] combined the in-vivo indentation test with finite element (FE) modelling. Axisymmetric FE models of the indentation test were used to inverse engineer the values of the material coefficients of a simplified hyperelastic bulk soft tissue.

One of the main therapeutic objectives for the management of the diabetic foot syndrome is the reduction of plantar pressure. Although, therapeutic footwear and orthotic insoles play an important role in

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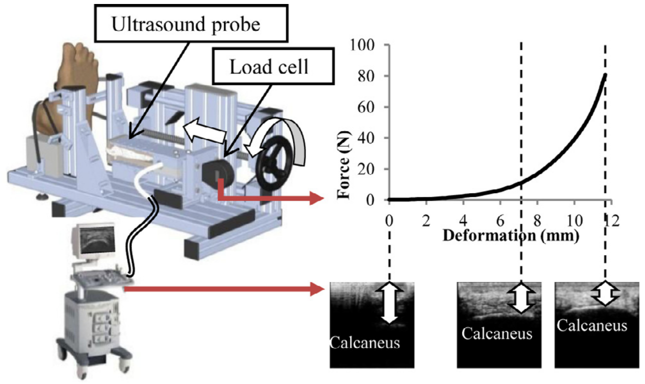

Fig. 1. The ultrasound indentation device and a schematic representation of the procedure followed to create the tissue's force/deformation curve.

redistributing the plantar load [12–15], very little information exists on the optimum cushioning properties of the materials used as foot beds, insoles or a sole. Whilst the criteria for the selection of orthotic insole materials, which were devised some time ago, identify stiffness [16] and the material's "pressure distributing properties" [17] as critical factors for selection, no quantitative method exists to identify the most appropriate material on a subject-specific basis [18,19]. As it stands there is no guideline on how "soft" or "stiff" an insole should be. Despite that, currently there are a huge number of commercially available insole materials and new ones are produced every year.

In this context the purpose of this study is to set the basis for an integrated procedure for the subject-specific FE modelling of the heel pad upon which the investigation of the mechanical compatibility between heel and insole would be possible. Such procedure would allow the optimal cushioning of the insole to be determined based on subject-specific characteristics.

2. Methods

2.1. Ultrasound indentation

A healthy volunteer (age = 38 years, body mass = 82 Kg) was recruited for the purpose of this study. Ethical approval was sought and granted by the University Ethics Committee and the subject provided full informed consent.

An ultrasound indentation device (Fig. 1) comprising an ultrasound probe connected in series with a load cell (3 kN, INSTRON) was utilised to perform indentation tests at the area of the apex of the calcaneus [9]. The instrumented probe was mounted on a rigid metallic frame that is equipped with a ball-screw linear actuator and a hand-wheel for the manual application of loading as well as with adjustable foot supports to fix the subject's foot (Fig. 1). A complete anti-clockwise revolution of the hand wheel generates 5 mm of linear movement in the forward direction. During loading and unloading the hand wheel was rotated with a target shaft angular velocity of 90 deg/s with the help of a metronome. The actual deformation rate that is imposed by the device for this target angular velocity had been previously measured during the pilot testing of the device to be equal to 0.96 mm/s ± 0.14 mm/s [9]. This measurement was based on the results of heel indentation tests from 17 healthy subjects [9].

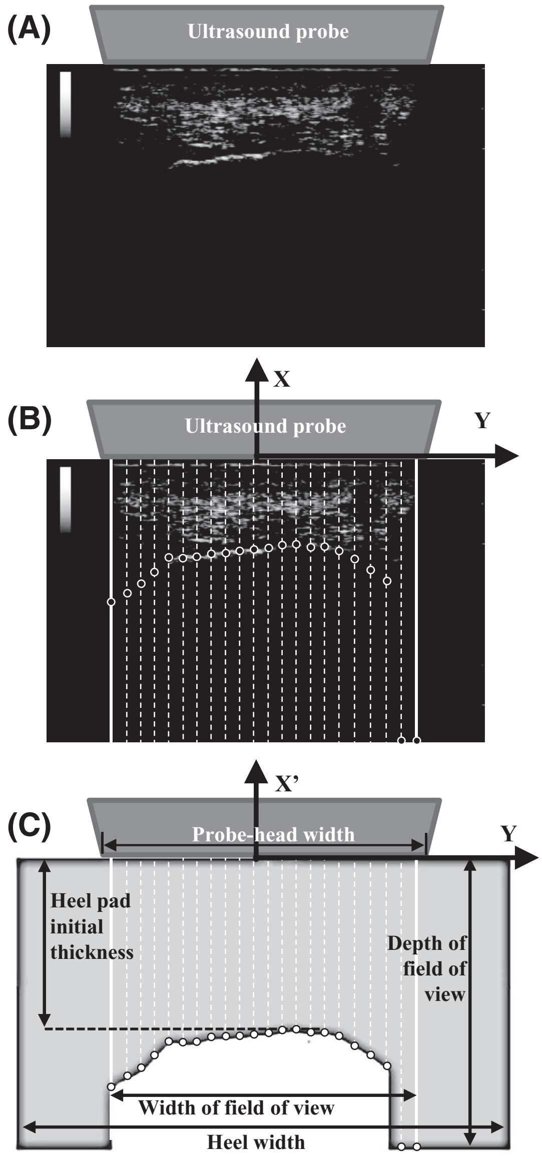

Fig. 2. (A) The frontal ultrasound image of the heel that was used for the reconstruction of the geometry of the calcaneus. (B) Using Matlab the ultrasound image is divided by a series of line segments with a relative distance of 2 mm. These lines are used as search paths to identify the transition points between bone and soft tissue. When imported into ANSYS the coordinates of these key points are utilised to create a polynomial line that outlines the calcaneus. (C) The geometry of the final FE model of the indentation test.

The tests were performed using an 18 MHz linear array ultrasound probe (MyLab25, Esaote, Italy) which is capable of imaging the entire width of the calcaneus. More specifically the footprint area of the ultrasound probe was 3.5 cm^2 and its field-of-view was 42 mm wide and 40 mm deep. Before testing, the subject's right foot was fixed on the device and the instrumented probe was carefully positioned to image the medio-lateral (frontal) plane of the apex of the calcaneus (Fig. 2A). The test's imaging plane was identified from sequential ultrasound images of the heel at different planes [9]. During loading the instrumented probe was pressed against the plantar side of the heel compressing the heel pad. More specifically, the heel of the volunteer was subjected to five preconditioning load/unload cycles followed by three measurement cycles to a maximum compressive force of 80 N. The applied force was recorded using the load cell while the initial thickness and the deformation of the heel pad was measured after the completion of the test from the ultrasound images (Fig. 1) with the help of video analysis software (Kinovea open source project, www.kinovea.org). Data were sampled at 28 Hz and utilised after the completion of the tests to create an average force/deformation curve. After the completion of the loading procedure and before releasing the subject's foot from its supports the width of the heel was also measured using a digital calliper. The measurement was taken on the ultrasound imaging plane which was identified using the ultrasound probe as a guide. The reproducibility of this simple measurement was established through a test/ re-test procedure.

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