



# The relationship between the mechanical properties of heel-pad and common clinical measures associated with foot ulcers in patients with diabetes



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## ABSTRACT

**Aim:** The present study aims at investigating the correlation between the mechanical properties of the heel-pad of people with type-2 diabetes and the clinical parameters used to monitor their health and ulceration risk.

**Methods:** A new device for the in-vivo testing of plantar soft tissues was built and pilot-tested. This device consists of an ultrasound probe connected in series with a dynamometer. Loading is applied manually using a ball-screw actuator. A total of 35 volunteers with type-2 diabetes were recruited and the thickness, stiffness of their heel-pads as well as the energy absorbed during loading were assessed. The participants with diabetes also underwent blood tests and measurements of Ankle Brachial Index and Vibration Perception Threshold.

**Results:** Pearson correlation analysis revealed strong correlations between triglycerides and heel-pad stiffness ( $r = 0.675$ ,  $N = 27$ ,  $p < 0.001$ ) and between triglycerides and energy ( $r = -0.598$ ,  $N = 27$ ,  $p = 0.002$ ). A correlation of medium strength was found between Fasting Blood Sugar (FBS) and stiffness ( $r = 0.408$ ,  $N = 29$ ,  $p = 0.043$ ).

**Conclusions:** People with type-2 diabetes and high levels of triglycerides and FBS are more likely to have stiffer heel-pads. Increased stiffness could limit the tissues' ability to evenly distribute loads making them more vulnerable to trauma and ulceration.

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## 1. Introduction

Recent reports indicate that approximately 15% of people with diabetes world-wide will at some stage develop diabetic foot ulceration (Boulton, 2000). Indeed diabetes mellitus (type-2) is the most frequent cause of non-traumatic lower-limb amputations. In the UK up to 100 people per week have a limb amputated as a result of diabetes even though up to 80% of these amputations could have been prevented with correct management (Diabetes UK, 2011). The severity of this fact becomes even more pronounced considering that eight out of ten people die within five years of having an amputation (Khanolkar, Bain, & Stephens, 2008).

Foot ulcers in people with Diabetes are multi-factorial and linked to a variety of risk factors like peripheral neuropathy, vascular insufficiency and physiological measures (Crawford, Inkster, Kleijnen,

& Fahey, 2007). Whilst, some of the epidemiological studies demonstrate that the indicators of neuropathy like impaired sensation, Vibration Perception Threshold (VPT) are predictors of ulceration (Crawford et al., 2007; Frykberg et al., 1998), other studies show that peripheral vascular disease indicated by Ankle Brachial Index (ABI), glycohaemoglobin (HbA<sub>1c</sub>) level and duration of diabetes are the main contributing factors to ulcers (Boyko, Ahroni, Cohen, Nelson, & Heagerty, 2006). Although these major risk factors are known to contribute to foot ulceration, it is not completely understood how they affect the mechanical properties of plantar soft tissue.

From previous research, it is clear that diabetes can affect the internal structure and the mechanical properties of the plantar soft tissues. Some in-vivo studies performed with age-matched groups of non-diabetic and diabetic volunteers have found that diabetic plantar tissue tends to be thicker (Chao, Zheng, & Cheing, 2011), stiffer (Chao et al., 2011; Klaesner, Hastings, Zou, Lewis, & Mueller, 2002), harder (Piaggese et al., 1999) and shows higher energy dissipation ratios (i.e. the ratio of the energy-input over the energy-return after the end of a load/unload cycle) (Hsu, Lee, & Shau, 2002; Hsu, Tsai, Shau, Lee, & Hu, 2007; Hsu et al., 2000). On the other hand Erdemir, Viveiros,

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Ulbrecht, and Cavanagh (2006) studied the mechanical behaviour of heel-pad using a novel methodology which combined in-vivo testing and finite element modelling to inverse engineer the tissue's material coefficients. The authors of that study found no statistically significant stiffness or thickness difference between age-matched groups of people with diabetes and non-diabetic volunteers (Erdemir et al., 2006).

Despite this there is a clear paucity of studies which explore the relationship between the mechanical properties of plantar soft tissue and commonly employed clinical and biochemical measures. Hsu et al. (2000) found a weak correlation between the tissue's energy dissipation ratio and the patient's neuropathy score measured based on 10 g monofilament test. These authors also indicated a strong correlation between energy dissipation ratio and the duration of diabetes.

The most popular technique for the in-vivo study of plantar soft tissues' mechanical behaviour is the combined use of ultrasonography and dynamometry. Previous research have developed different devices to perform in-vivo indentation (Chao et al., 2011; Erdemir et al., 2006; Hsu et al., 2000, 2007; Tong, Lim, & Goh, 2003; Zheng, Choi, Wong, & Mak, 1999) or bulk compression tests (Hsu et al., 2009; Rome, Campbell, Flint, & Haslock, 1998; Zheng et al., 2012). Typically, during an indentation test the plantar soft tissue is compressed between the indenting device and a bony prominence. During the test the applied force is recorded using a load sensor (i.e. dynamometer or load cell) and tissue deformation is measured from the ultrasound images.

Given this background, the overall aim of the present study is to investigate if significant correlation exists between the mechanical properties of the heel-pad of people with diabetes and the clinical parameters used to monitor their health and ulceration risk.

## 2. Patients and method

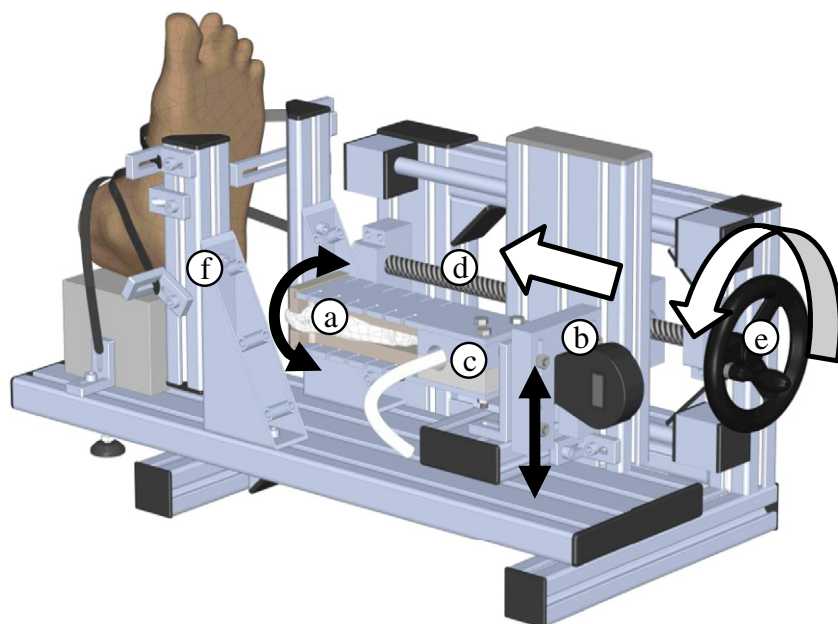
A total of seventeen (17) volunteers with no known musculoskeletal disease or diabetes (Group 1) with average age  $35.0(\pm 5.8)$  years, average height  $158.3(\pm 9.8)$  cm and average body mass  $65(\pm 14)$  kg were recruited to pilot-test the in-vivo loading procedure and produce reference data. Moreover, thirty five (35) volunteers with

type-2 diabetes (Group 2) with average age  $54.8(\pm 9.1)$  years, average height  $167.4(\pm 9.3)$  cm, average body mass  $73(\pm 16)$  kg and average duration of diabetes  $13.9(\pm 7.8)$  years were recruited at a diabetic referral centre to participate in this non-invasive study. The ethical approval was sought and granted by the Ethics committee and all volunteers provided full informed consent.

All volunteers were subjected to in-vivo mechanical tests to study the mechanical behaviour of their heel-pads. The participants with diabetes also underwent blood tests, ABI and VPT measurements. All tests were performed on the same day and besides the biomechanical measurements all clinical and biochemical tests were part of the normal treatment plan of each volunteer. The biochemical parameters measured from the blood tests included the levels of HbA<sub>1c</sub>, Fasting Blood Sugar (FBS), Post Prandial Blood Sugar (PPBS), Serum Creatinine, Serum Cholesterol and triglycerides. All participants were screened for dry skin, callosity and ulceration and were excluded from this study if they had any signs of cutaneous conditions affecting the plantar surface of the foot.

The mechanical behaviour of the heel-pad was studied using a custom made loading device (Fig. 1). This device consists of a 13 MHz linear array ultrasound probe connected in series with a dynamometer (500 N Cytec, C.I.T. Technics, Centre for Innovative Technics, Netherlands) and mounted on a rigid metallic frame. The footprint-area of the ultrasound probe is equal to  $12.7 \text{ mm} \times 47.1 \text{ mm}$ . The ultrasound probe and the dynamometer are connected with a custom made probe holder which is capable of gripping ultrasound probes of different sizes and shapes (Fig. 1c). Different sites of the foot can be tested by changing the distance of the probe from the base of the frame while different planes can be imaged by rotating the probe around its central axis. Loading is applied manually with the help of a ball-screw actuator by rotating a hand wheel. A complete anti-clockwise revolution of the hand wheel generates 5 mm of forward movement. The metallic frame is also equipped with adjustable foot supports that can rigidly fix the subject's foot.

After fixing the subject's foot on the metallic frame the ultrasound probe was rotated and pressed against the plantar surface of the heel until the calcaneus was clearly visible. The calcaneus was initially imaged in the antero-posterior (sagittal) plane. After identifying the medial process of the calcaneal tuberosity the height of the probe was



**Fig. 1.** The custom made device used for the in-vivo loading tests. (a) Ultrasound probe, (b) dynamometer, (c) probe holder, (d) ball-screw actuator, (e) hand wheel and (f) foot support.

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