Biomechanical Assessment of Plantar Foot Tissue in Diabetic Patients using an Ultrasound Indentation System

Y.P. Zheng*, Y.K.C. Choi*, K. Wong**, S. Chan**, and A.F.T. Mak*

* Rehabilitation Engineering Center, The Hong Kong Polytechnic University, Hong Kong

** Department of Prosthetics & Orthotics, Queen Mary Hospital, Hong Kong

Address for correspondence:

Prof. Arthur F.T. Mak
Rehabilitation Engineering Center
The Hong Kong Polytechnic University
Hung Hom, Kowloon
Hong Kong
Tel: (852) 2766-7671
Fax: (852) 2362-4365
Email: rcafmak@polyu.edu.hk

Running Title:

Indentation Test of Plantar Tissue

==

Submit to: ***Ultrasound in Medicine and Biology***

June 1999

Revised: ***Oct 1999***

Biomechanical Assessment of Plantar Foot Tissue in Diabetic Patients using an Ultrasound Indentation System

ABSTRACT

The biomechanical properties of plantar tissues were investigated for four older neuropathic diabetic patients and four normal younger subjects. Indentation tests were performed at four high pressure areas with three postures in each subject. The tissue thickness and effective Young's modulus were measured by an ultrasound indentation system. The system comprised a pen-size probe having an ultrasound transducer at the tip and a load cell connected in series with it. Results showed that the plantar soft tissues of the elderly diabetic patients were significantly stiffer and thinner when compared with the normal young subjects. For the diabetic subjects tested, the Young's modulus at the 1st metatarsal head was significantly larger than those at the other three sites. This site dependence was not observed in the normal young subjects. The plantar tissue became significantly stiffer in the normal young subjects as a result of posture changes. This posture dependence of the Young's modulus was not established for the elderly diabetic group.

Keyword

biomechanics, diabetic foot, indentation test, plantar tissue, ultrasound instrumentation, ulceration

INTRODUCTION

One of the complications of diabetes mellitus (DM) patients is the foot ulceration which may lead to leg amputation (Jeffcoate and Macfarlane 1995). Two of the dominant pathways leading to diabetic foot lesions are: 1) neuropathy, deformity, callus, elevated plantar pressure, and, 2) ill fitting shoes (Jeffcoate and Macfarlane 1995, Lavery et al. 1998). The DM patients who have peripheral neuropathy gradually cannot readily feel early trauma. They may also suffer from deficient motor control, clawing of toes, and limitation of joint mobility (Cavanagh et al 1993). These tend to make DM subjects vulnerable to foot ulceration. It has been documented that the diabetic ulcers frequently occur at the pressure sensitive sites, commonly the heel, bigtoe, 1st, 2nd and 5th metatarsal (Perry et al. 1995). For this reason, suitable footware to distribute plantar pressure properly in daily activities plays an important role in the prevention and treatment of diabetic foot ulceration. Various footwares for diabetic foots have been investigated for their pressure relief efficacy (Caputo et al. 1994, Wretsch et al. 1995, Perry et al. 1995, Lord and Hosein 1994).

It is expected that interfacial plantar pressure depends on the biomechanical properties of the plantar foot tissues as well as the foot geometry and the supporting surface. The bone structure can be obtained by radiograph (Cavanagh et al. 1993). The plantar tissue thickness can be measured by ultrasound technique (Gooding et al. 1985, 1986, Furumizo et al. 1990). Recently, the material properties of the plantar soft tissue were studied quantitatively (Morag et al. 1997). A motor driven apparatus with an ultrasound imaging system was developed to measure the indentation properties of heel pads. By defining a probe dimension dependent stiffness, the investigation showed a nonsignificant trend that the heel pad became stiffer with age. Few studies have been reported on the biomechanical assessment of the plantar foot tissue in diabetics.

An ultrasound indentation system with a pen size probe was developed to investigate the thickness and Young's modulus of limb soft tissues of normal subjects and prosthetic patients in various areas and with different postures (Zheng and Mak 1996, 1999). This paper reported the use of this ultrasound indentation system for the biomechanical assessment of the plantar foot tissues.

MATERIALS AND METHODS

Ultrasound indentation apparatus

The ultrasound indentation system comprised a pen-size, hand-held indentation probe (See Figure 1). An ultrasound transducer with frequency of 5 MHz and diameter of 9 mm was at the tip of the probe and also served as the indentor. A compressive load cell was connected in series with the ultrasound transducer to record the corresponding force response. The thickness and indentation depth of the soft tissue layer were determined from the flight time of the ultrasound echo signal which reflected from soft tissue-bone interface. The deflection of ultrasound echo wave due to the tissue deformation was determined with the reference of the echo peak. The sound speed in soft tissues was assumed uniformly to be 1540 m/s (Goss et al. 1980). The load signal and ultrasound signal were both digitized and collected by a computer. A program displayed in real time the response of load and indentation depth as well as ultrasound signals. The effective Young's modulus was calculated using Equation (1). This is a rigorous mathematical solution to the elastic indentation problem of a thin elastic layer bonded to a rigid half-space with a rigid, frictionless cylindrical plane-ended indentor (Hayes et al. 1972).

$$E = \frac{(1-\nu^2)}{2a\kappa(\nu, a/h)} \frac{P}{w} \qquad (1)$$

Where h is the tissue thickness, a the indentor radius, and κ a scaling factor. This scaling factor provides a theoretical correction for the finite thickness of the elastic layer, and it depends on both the aspect ratio a/h and Poisson's ratio ν. The Poisson's ratio ν was taken to be 0.45 in this study assuming soft tissue to be nearly an incompressible material. A similar assumption has been widely adopted for limb soft tissues in the literature (Zheng and Mak 1999). The ratio P/w was determined by the linear regression of cyclic load-indentation responses.

Subjects, sites, and postures

Four neuropathic DM patients (3 females and 1male) and four normal subjects (1 female and 3 males) were chosen for this study. The average age of diabetic patients was 63 (from 46 to 74), and that of normal subjects was 22 (from 21 to 24). The average year having been cared for DM for the four patients was 12 (from 5 to 24). Subjects with any plantar tissue lesions or other skin problem were excluded. The right foot was chosen for test. All the subjects tested had a good sensation at the foot. It was noted that the plantar surfaces of the diabetics were rather dry, and three patients had claw toes.

The plantar tissues covering the fist metatarsal head, second metatarsal head, bigtoe, and heel of the right foot were chosen for the investigation as shown in Figure 2. If the right foot had any skin problem or partial foot amputation, the contralateral side was tested. Ulcers commonly occur in these high pressure areas (Perry et al. 1995).

Three postures were selected for the experiment. The first posture (ankle neutral) was taken with the subject in supine lying, and with the knee flexed to 90° and ankle in neutral. A manual goniometer was used to measure angles. A proper support was provided under the lower leg and ankle so that the subject could maintain this posture. The second posture (dorsiflexion) was taken by the subject in prone lying, with the knee in full extension and the ankle at 5° of active dorsiflexion. The third posture (plantarflexion) was similar to the second one, with the exception that the ankle was kept at 20° of plantarflexion. During the experiment, we found that two diabetic patients could not maintain an active dorsiflexion and plantarflexion for a period of 17 seconds which was required for a test. Thus, passive flexions were carried out for these 2 subjects.

Procedures

Each subject was first explained about the measurement procedure before the experiment. Then, the subject was asked to lie supine on the bed with the socks removed. The sole of the right foot was examined to see whether there was any skin problem. The sensation of the foot was tested by palpating the foot at various sites and asked the subject to tell whether he/she could feel it. Afterwards, the first metatarsal head, second metatarsal head, bigtoe, and heel were identified by palpation and marked using an undelible pencil.

Before the measurement, ultrasound couplant gel was applied onto the site. Pre-conditioning of the plantar tissue was achieved by loading and unloading the probe on the testing site for a few times. Then, the probe was held in a suitable alignment to obtain a maximum ultrasound echo signal reflected from soft tissue-bone interface, and indentation test could then be started. Figure 3 shows a typical test being carried out.

During the measurement, the probe was first placed on the testing site with a minimal force. Then, the load was gradually applied manually and then released for 5 cycles in each trial. The indentation rate was approximately monitored by visual feedback of the indentation response displayed on a computer monitor. The rate was controlled approximately in the range of 1 ~ 2 mm/s. Precaution was paid to avoid slippage of the probe. The maximum indentation depth was kept to within 10 percent of the initial thickness.

The above trial was repeated five times at each testing site. Between each two trials, 2 minutes of rest were allowed for the tissue to return to the original state. The same procedure was also applied at the second metatarsal head, bigtoe and heel. After completing the measurement at the four selected sites, the subject was required to lie prone with 5° foot dorsiflexion and the knee fully extended. The entire testing procedure was repeated. Finally, the subject was requested to plantarflex the ankle to 20° and with the knee in full extension. Again, the entire testing procedure was repeated.

RESULTS

Figure 4 shows the tissue thicknesses of normal and diabetic subjects at the four testing sites. Multi-factor ANVOA (subject's type, site, and posture) showed that the tissue thicknesses of elderly DM patients were significantly ($p<0.05$) smaller than those of the normal young subjects at the four testing sites. Meanwhile, paired-t test showed that the heel had statistically thicker soft tissue layer than the other three sites in both normal and diabetic subjects.

Figure 5 shows the Young's moduli of soft tissues at the four testing sites. Multi-factor ANVOA showed that the Young's moduli of elderly DM patients were significantly larger than those of the normal young subjects at the four testing sites. Meanwhile, pair-t tests showed that the Young's modulus at the 1st metatarsal head was significantly larger than those at the other three sites in the DM patients. In the normal subjects, this was not observed, and the difference among sites was rather small. Results showed that the Young's modulus of diabetics at the first metatarsal head increased by 160% in average in comparison with that of normal subjects. This was the biggest increase among the four sites. However, the heel tissues of elderly diabetics became a little stiffer compared with that of normal young subjects, and the difference was not statistically significant. It could also be observed in Figure 4 and 5 that the site with thinner soft tissue layer seemed to possess larger Young's modulus in diabetic patients. This trend was not observed in normal subjects.

The posture dependence of the Young's modulus was shown in Figure 6 and 7. In the normal young subjects, the Young's modulus of plantar tissues in posture 1 (ankle neutral) was smaller than in the other two postures (dorsiflexion and plantarflexion). Apparently, the tissues became stiffer when the underlying muscles were engaged. The largest increase (66%) was observed at the first metatarsal head with posture changed from posture 1 (ankle neutral) to posture 2 (dorsiflexion). However, no significant posture dependence of Young's modulus was demonstrated in the elderly diabetic patients. Furthermore, the plantar tissue thickness in most cases changed slightly due to the posture change. No significant posture dependence of tissue thickness was observed in both diabetic patients and normal subjects.

DISCUSSION AND CONCLUSIONS

Many persons with diabetes may gradually lose the protective sensation due to neuropathy. Thus, a reliable tissue evaluation procedure and a proper footware are extremely important to protect diabetics from tissue ulceration and amputation. The tissue thickness and Young's modulus determined by the ultrasound indentation system might be used with the plantar pressure measurement to evaluate the danger of ulceration of diabetic foot, to help the management of ulceration, and to facilitate the design of foot orthoses.

In this study, the thickness and Young's modulus of plantar tissue of four normal young subject and four elderly diabetic patients were investigated. There was a dramatically difference of Young's moduli between the diabetic patients and the normal subjects. The plantar soft tissues of the diabetic patients were significantly stiffer and thinner than those of the unimpaired subjects. This result might be explained by the skin condition of the diabetic patients. Most diabetics show a dry skin due to the problem of glucose regulation, and this may reduce the skin flexibility and make the tissue harder and more brittle (Olefsky and Sherwin 1985). The formation of callus might explain for the increased Young's modulus in the diabetic patients. Persons with diabetes were noted to form calluses more easily than persons without diabetes (Olefsky and Sherwin 1985, Jeffcoate and Macfarlane 1995, Cavanagh et al. 1993). Moreover, age should be another effect on the change of stiffness and thickness of plantar soft tissue. A nonsignificant trend was found that the heel pad became stiffer with age (Morag et al. 1997). Concerning the tissue thickness, Gooding et al. (1986) showed that the foot pad became thinner in diabetics. Since the normal group and the diabetic group were not age-matched in this study, the effects of age as well as diabetes could not be distinguished in the present results. The plantar tissues of elderly unimpaired subjects should be included in future studies to differentiate these two effects.

It was observed that the normal young foot showed more uniform Young's moduli at the selected four sites when compared to the elderly diabetic patients. The Young's modulus of plantar tissue of the diabetic patients increased nonuniformally at different sites, and showed significant site dependence. The maximum increase (160%) was observed in the area of the first metatarsal head. Only a slight and nonsignificant increase was observed in the heel where the tissue was thickest. The significant site dependence of the stiffness in the diabetic patients might be explained as a response to the redistribution of plantar peak pressure due to the foot deformity, such as claw toe, prominent metatarsal head. The toe deformity might lead to reduce of the fat padding beneath the metatarsal head, and that region would then share higher peak pressure during gait (Olefsky and Sherwin 1985). The high pressure might induce more callus to form, and this would make the plantar tissue further stiffer (Jeffcoate and Macfarlane 1995, Cavanagh et al. 1993). This process might explain the large increase of

Young's modulus in the first metatarsal head in the diabetic patients. The peak pressures are also high on the area of the second metatarsal head and on the heel (Perry et al. 1995). However, this study showed that the Young's modulus of the elderly diabetic patients did not increase so much in these areas. It was observed that the soft tissues in these two areas were thicker than in other areas. Figure 8 shows a trend of reverse correlation between the thickness and Young's modulus of the plantar tissue of diabetics at the four testing sites. Neverthless, the correlations between the peak plantar pressure, pad tissue thickness and stiffness of diabetic feet deserve to be further investigated using a larger group of subjects. The relationship between these measurable parameters and the foot ulceration is important and valuable to the diabetic clinics.

Significant increases of Young modulus of plantar tissues were observed in the normal young subjects when the posture was changed from ankle in neutral to that of dorsiflexion or plantarflexion. This agreed with the fact that the soft tissue becomes stiffer when the underlying tissues are somewhat activated. Similar results were reported for soft tissues in the forearms and lower limbs (Zheng and Mak 1999, Zheng et al. 1999). However, no significant posture dependence of the Young's modulus was demonstrated in the elderly diabetic patients. It was not clear whether such a posture independence in diabetes was due to the weakness of their muscles or the fact that flexion was imposed passively for two of the patients who could not hold an active dorsiflexion or plantarflexion for the test. Further age-matched comparative study with a larger group size could clarify this issue. The result of such a posture dependence study might be used to evaluate the wastage of the intrinsic muscle of diabetic feet, such as toe flexor and extensor.

It was shown that the ultrasound indentation system was an effective tool for the assessment of plantar soft tissue properties. Compared with those using ultrasound imaging system to measure plantar tissue thickness technique (Gooding et al. 1985, 1986, Furumizo et al. 1990, Morag et al. 1997), this pen-size probe was of lower cost. The results of tissue thickness and Young's modulus so obtained were straightforward for interpretation. The Young's modulus of plantar tissues obtained in this study ranged from 43 to 118 kPa. For the lack of similar data in the literatures, it was difficult to compare the result of this study to those of others. Using the load-indentation data of plantar tissues provided by Morag et al. (1997), the Young's modulus extracted by Equation (1) was 65 kPa. This was comparable to the result of the current study. The Young's modulus of skin and subcutaneous tissues at other sites has been reported in the literature, such as 53 to 141 kPa (Krouskop et al. 1987), 27 to 106 kPa (Torres-Moreno 1991), 21 to 194 kPa (Mak et al. 1994) for the residual limbs, 14 to 59 kPa (Zheng et al. 1999) for the forearms. A recent in-vitro investigation (Krouskop et al. 1998) reported the Young's modulus of various excised breast and prostate tissues was in the range of 18 to 116 kPa. These values were in a similar range with the result of the plantar tissues in this study. It should be emphasized that the tissue stiffness would depend on the activation level of underlying muscle, the amount of pre-loads used, as well as maximum indentation.

It is known that soft tissues are viscoelastic. The effect of indentation rate on the extracted Young's modulus has been a common concern. From a series of tests on human forearms with 5 indentation rates ranging from 0.75 to 7.5 mm/s, we have demonstrated that the extracted Young's modulus was roughly rate independent (Zheng et al. 1999). This range of indentation rate was appropriate with manual control using the ultrasound indentation probe. Such rate insensitivity of soft tissues has also been reported by Krouskop et al. (1998). In their in-vitro study, three rates from 0.2 to 10 mm/s were used. In addition to the indentation rate, another common concern was the assumed Poison's ratio ν. The assumption of near incompressibility was made (i.e., ν was taken as 0.45) based on the fact that most of the tissue fluid would not have enough time to move within the tissue under the deformation rate (1~2 mm/s) used in this study. In this situation, the tissue together with its large water content would behave overall as a near incompressible elastic material. This assumption was consistent with the interpretation of the indentation results using the biphasic poroelastic theories (Oomens et al. 1987, Mak et al. 1987). According to this theory, the instantaneous response of a soft tissue layer was identical to that of an incompressible elastic solid ($\nu \cong 0.5$) and the equilibrium properties reflect those of the porous-permeable solid matrix. Most investigations in the limb tissue assessments have made similar assumptions for the Poisson's ratio (Mak et al. 1994).

In this study, we have concentrated more on the development of the testing protocol. Although only a relative small number of subjects were tested, many findings here were found to be significant. Further studies with a larger sample size and age-matched comparison would need to be pursued. The testing protocol developed in this study would be useful for the biomechanical assessment of the plantar tissues with respect to age, gender, years being a diabetic, and the effects of various treatments.

ACKNOWLEDGEMENT

Financial support from a Postdoctoral Research Fellowship of the Hong Kong Polytechnic University was appreciated.

REFERENCES

Caputo GM, Cavanagh PR, Ulbrecht JS, Gibbons GW, and Karchmer AW. Assessment and management of foot disease in patients with diabetes. The New England Journal of Medicine 1994; 331: 854-860.

Cavanagh PR, Simoneau GG, and Ulbrecht JS. Ulceration, unsteadiness, and uncertainty: The biomechanical consequences of diabetes mellitus. J. Biomechanics 1993; 26: 23-40.

Furumizo Sh, Cavanagh PR, and Ulbrecht JS. A new method to determine loaded and unloaded plantar soft tissue thickness in diabetic feet. Diabetes 1990; 39(1S): 156A.

Gooding GAW, Stess RM, Graf PM, and Grunfeld C. Heel pad thickness: determination by high-resolution ultrasonography. J Ultrasound Med 1985; 4: 173-174.

Gooding GAW, Stess RM, and Graf PM. Sonography of the sole of the foot: evidence for loss of foot pad thickness in diabetes and its relationship to ulceration of the foot. Invest Radiol 1986; 21: 45-48.

Goss SA, Johnston RL, and Dunn F. Compilation of empirical ultrasonic properties of mammalian tissue. J. Acoust. Soc. Am. 1980; 68: 93-108.

Hayes WC, Keer LM, Herrmann G and Mockros LF. A mathematical analysis for indentation tests of articular cartilage. J. Biomechanics 1972; 5: 541-551.

Jeffcoate W and Macfarlane R. The diabetic foot: An illustrated guide to management. Lodon: Chapman & Hall Medical, 1995.

Krouskop TA, Muilenberg AL, Dougherty DR and Winningham DJ. Computer-aided design of a prosthetic socket for an above-knee amputee. J. Rehabil. Res. & Dev. 1987; 24: 31-38.

Krouskop TA, Wheeler TM, Kallel F, Garra BS, and Hall T. Elastic moduli of breast and prostate tissues under compression. Ultrasonic Imaging 1998; 20: 260-274.

Lavery LA, Peters EJG, and Armstrong DG. Pathways to diabetic foot ulceration. Diabetes 1998; 47(1S): 19A.

Lord M, and Hosein R. Pressure redistribution by molded inserts in diabetic footwear: A pilot study. J Rehabil Res Dev 1994; 31: 214-221.

Mak AFT, Lia WM, Mow VC. Biphasic indentation of articular cartilage, Part I: Theoretical analysis. J Biomechanics 1987; 20: 703-714.

Mak AFT, Liu GHW, and Lee SY. Biomechanical assessment of below-knee residual limb tissue. J. Rehabilitation R&D 1994; 31: 188-198.

Morag E, Lemmon DR, and Cavanagh PR. An in vivo method to study the properties of the human heel pad. Proceedings of 21st Annual Meeting of the American society of Biomechanics, Clemson University, South Carolina, 1997.

Mow VC, Gibbs MC, Lai WM, Zhu WB, and Athanasiou KA. Biphasic indentation of articular cartilage, Part II: A numerical algorithm and an experimental study. J Biomechanics 1989; 22: 853-861.

Olefsky JM and Sherwin RS. Diabetes mellitus management and complications. New York : Churchill Livingstone, 1985.

Oomens CWJ, van Campen DH, Grootenboer HJ. In vitro compression of a soft tissue layer on a rigid foundation. J Biomechanics 1987; 20: 923-935.

Perry JE, Ulbrecht JS, Derr JA, and Cavanagh PR. The use of running shoes to reduce plantar pressures in patients who have diabetes. J Bone Joint Surg Am 1995; **77:** 1819-1828.

Torres-Moreno R. Biomechanical Analysis of the Interation between the Above-Knee Residual Limb and the Prosthetic Socket. PhD dissertation, University of Strathclyde, Glasgow, UK, 1991.

Wertsch JJ, Frank LW, Zhu H, Price MB, Harris GF, and Laba HM. Plantar pressures with total contact casting. J Rehabil Res Dev 1995; 32: 205-209.

Zheng YP and Mak AFT. An ultrasound indentation system for biomechanical properties assessment of soft tissues in-vivo. IEEE Transactions on Biomedical Engineering 1996; 43: 912-918.

Zheng YP and Mak AFT. Effective elastic properties for lower limb soft tissues from manual indentation experiment. IEEE Transactions on Rehabilitation Engineering 1999; 7(3) (in press).

Zheng YP, Mak AFT, and Lue BK. Objective assessment of limb tissue elasticity: Development of a manual indentation procedure. J Rehabil Res Dev 1999; 36(2).

Figure Captions

Figure 1. The pen-size ultrasound indentation probe comprising an ultrasound transducer at the tip and a load cell in series with it.

Figure 2. The four testing sites: the first and second metatarsal head, bigtoe, and heel.

Figure 3. Demonstration of the indentation test with the pen-size probe.

Figure 4. The plantar tissue thickness of the diabetic patients and normal subjects. The error bars represent the standard deviations.

Figure 5. The Young's moduli of the plantar tissues of the diabetic patients and normal subjects.

Figure 6. The posture dependence of the Young's modulus of the plantar tissues of the normal subjects.

Figure 7. The posture dependence of the Young's modulus of the plantar tissues of the diabetic patients.

Figure 8. The relationship between the thickness and the Young's modulus of the diabetic plantar tissues.

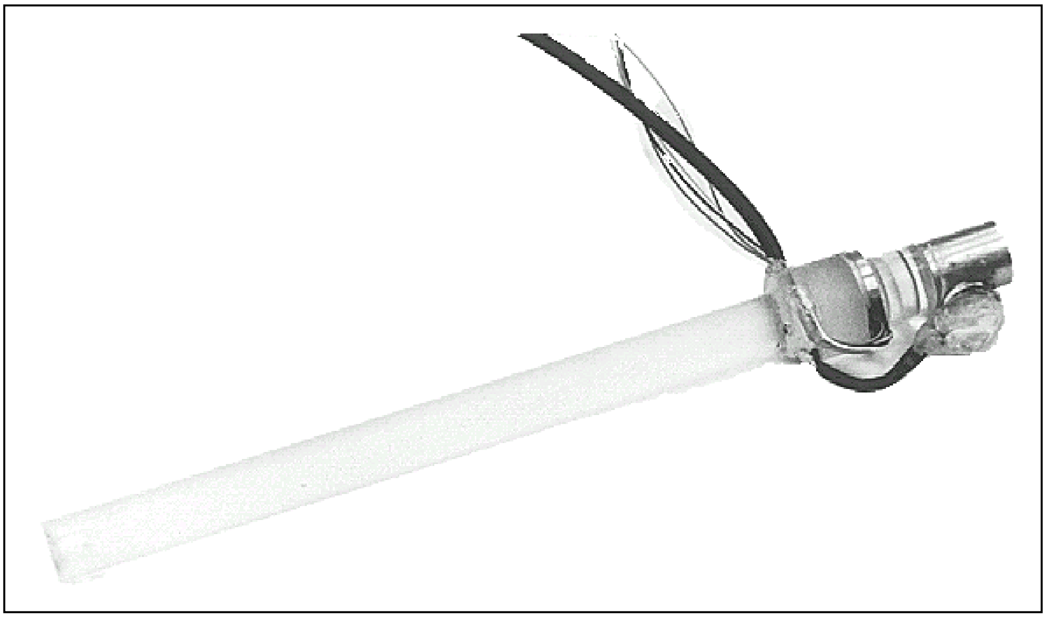

Figure 1

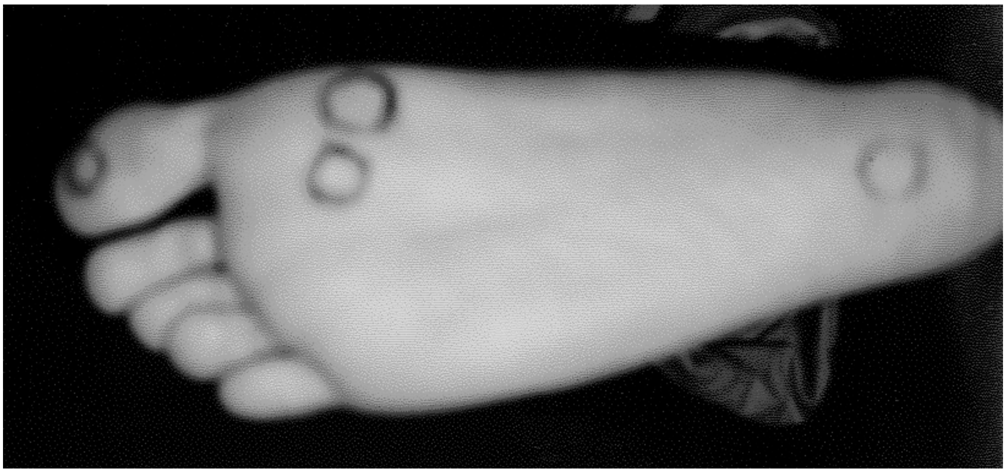

Figure 2

Figure 3

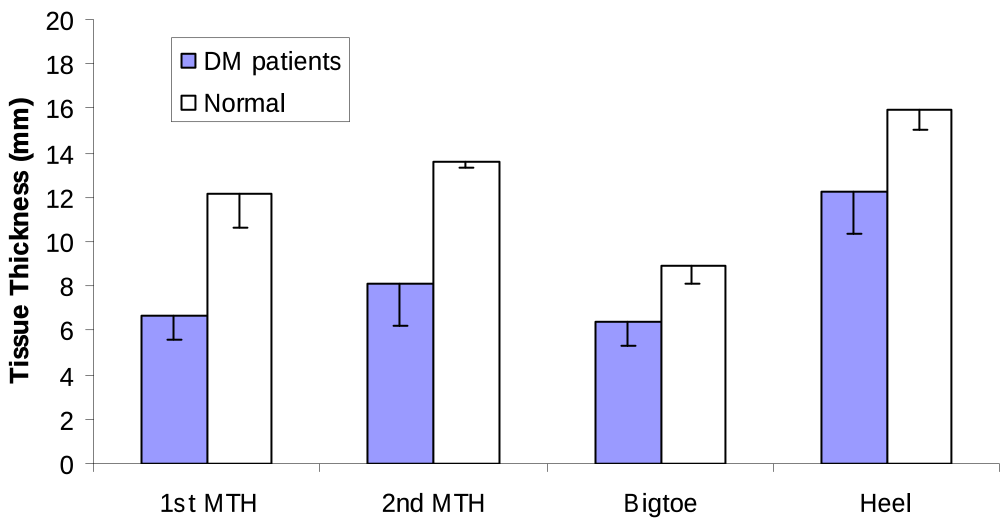

Figure 4

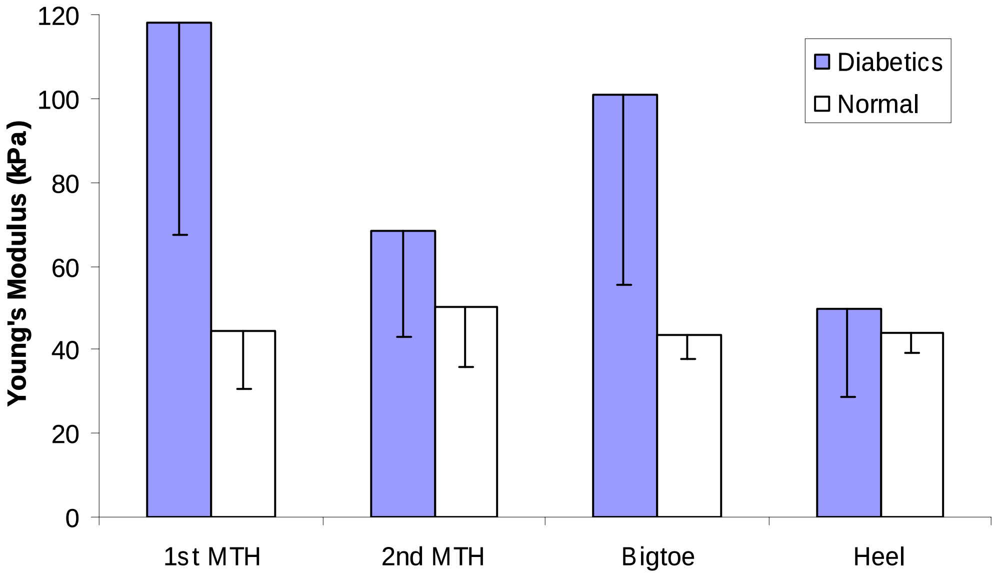

Figure 5

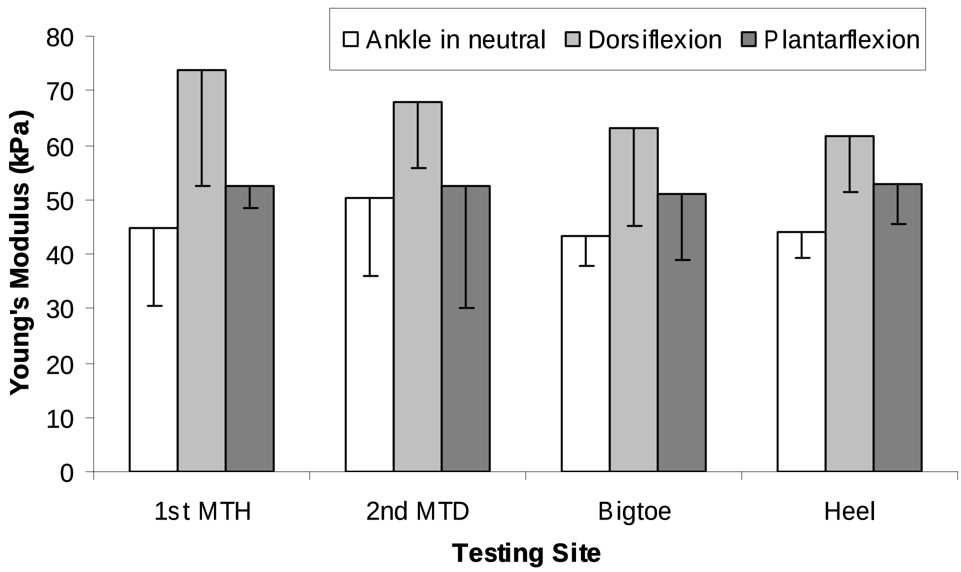

Figure 6

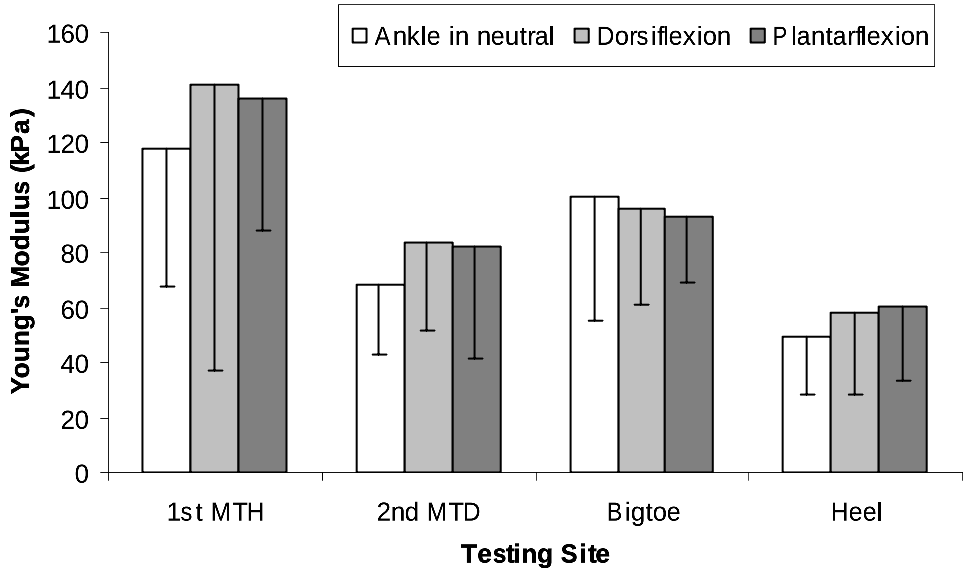

Figure 7

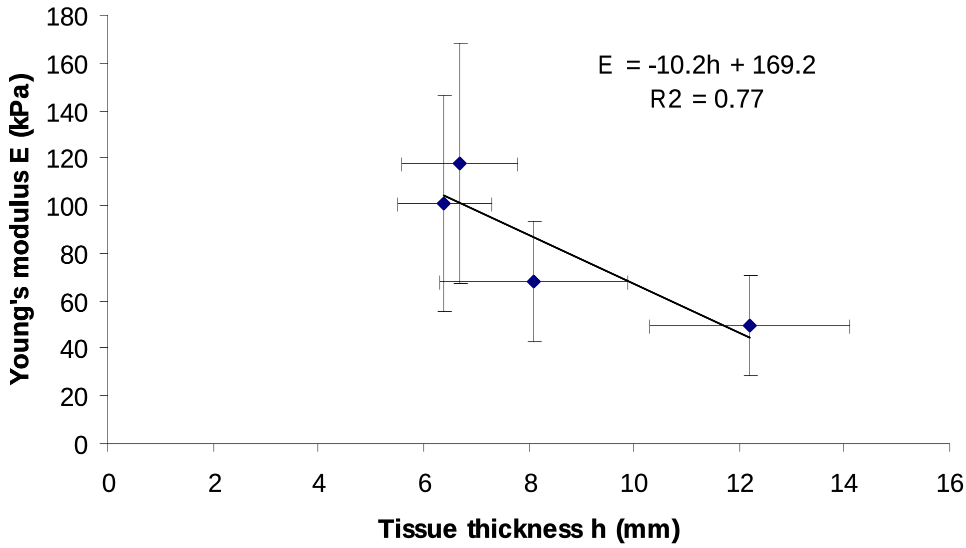

Figure 8