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**Finite Element Modelling of Radial Shock Wave Therapy for Chronic
Plantar Fasciitis**

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Summary

Plantar fasciitis is a chronic pain condition caused by the inflammation of the connective tissue along the sole of the foot (the plantar fascia). The condition affects up to 10% of the total population during the course of their lives. While non-invasive treatment methods are effective in most cases, surgical procedure is considered if the pain persists for several months. Shock wave therapy has been used as a last resort to avoid surgical intervention after other conservative treatment methods have proved to be ineffective. Radial shock wave therapy uses a ballistic method to generate high-amplitude pressure in the tissue; a metal object of 6-15 mm in diameter (an applicator) is applied superficially to the location that has to be treated. The applicator is impacted by a small cylindrical metal object (projectile) which is driven by compressed air. The understanding of the mechanical effects of shock wave therapy is not complete, and the insight into the mechanisms through which these effects may promote the healing process is at the level of speculation. The objectives of this research are to gain a better understanding of: the physical mechanisms through which the ballistic shock wave source operates; the mechanical stimuli that this method produces in the context of plantar fasciitis treatment; and the potential biological effects of these stimuli on the tissues of the foot.

A finite element model of the pressure wave source was constructed based on the geometry of an actual device. The model consisted of the applicator, the projectile, parts of the casing, and the o-rings on which the applicator is suspended in the casing. A finite element model of the foot was also constructed. The model was based on the geometry reconstructed from MRI images of a volunteer and it comprised of bones, cartilage, soft tissue, plantar fascia, and Achilles tendon. The material properties for the model components were taken from the literature. Simulations were conducted both to characterise the behaviour of the shock wave source and to simulate the effect of shock wave therapy on the foot.

When the shock wave device is “fired in the air”, the bulk movement of the applicator is in the form of highly damped oscillations with a maximum displacement of 0.2 mm and a period of about 0.5 ms. The collision between the projectile and the applicator lasts for about 10 μ s which is the time needed for the stress wave to traverse the

applicator in both directions. After the collision, there is a standing stress wave in the applicator with amplitude of the order of 10 MPa. When the device is applied to the soft tissue of the foot, pressure waves are generated that propagate in all directions. The waves consist of positive and negative pressure phases with the wave length of approximately 10 mm. The magnitude of the pressure generated in the soft tissue is of the order of several MPa, which is consistent with data reported for experiments conducted in water. The pressure amplitude at the surface of the soft tissue can be related in a simple way to the speed of the projectile and acoustic impedance of the soft tissue. The pressure magnitude and energy density decrease rapidly with the distance from the source, so that the effect of the treatment is localised to the region where the device is applied. The negative pressure at the plantar fascia origin reaches values of up to 3 MPa which should be sufficient to generate cavitation in the tissue. This result supports the hypothesis that cavitation-induced micro-trauma may be one of the mechanisms that enhance the healing process. Simulations of multiple pulses delivered at 20 Hz show that energy transferred to the foot with a pulse is not dissipated before the subsequent pulse. This result suggests that multiple pulses may lead to accumulation of energy in the foot.

Dedication

This dissertation is lovingly dedicated to my mother

Maryam Alkhaldi

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I must express my gratitude to my wife (Najla Aloudah) and my kids(Omar and Mohammed) for their love, support, and patients.

Statement of Originality

This thesis and the work to which it refers are the results of my own efforts. Any ideas, data, images or text resulting from the work of others (whether published or unpublished) are fully identified as such within the work and attributed to their originator in the text, bibliography or footnotes. This thesis has not been submitted in whole or in part for any other academic degree or professional qualification. I agree that the university has the right to submit my work to the plagiarism detection service TurnitinUK for originality checks. Whether or not drafts have been so-assessed, the university reserves the right to require an electronic version of the final document (as submitted) for assessment as above.

Zaied Alkhamaali

15th January 2014

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1 Introduction

1.1 Background

The plantar fascia is the strong, fibrous layer in the sole of the foot which originates from the heel bone and extends to the bases of the five toes. The role of the plantar fascia is to provide structural stability by acting as a tough mechanical binding for the main load-bearing bones of the foot. Another function of the plantar fascia is to absorb dynamic loads in locomotion (Herdrick 1996; Narvaez et al. 2000; Cheng et al. 2008). Since most physical activities, including normal locomotion, are dependent on the foot, this is one of the main sites for chronic injuries in the body (Roger and Grenier 1997). A common clinical problem is chronic inflammation of the plantar fascia, known as plantar fasciitis or painful heel syndrome. It is estimated that plantar fasciitis affects ten per cent of the general population during the course of a lifetime (Crawford et al. 2002; Rome and Saxelby 2005). There are many factors that are associated with the development of the condition; these include obesity, changes to the properties of the soft tissues, excessive training, and altered biomechanics of gait. Professions which require long periods of weight-bearing are also at risk of developing plantar fasciitis (Tasi et al. 1999; Rome and Saxelby 2005; Puttaswamaiah and Chandran 2007). The principal symptom of plantar fasciitis is pain at the insertion of the plantar fascia into the heel bone. Occasionally, the pain may extend to the whole foot. Characteristically the pain is strongest on the 50 first steps in the morning. Treatment or management options for plantar fasciitis include non-operative approaches (conservative) and sometimes a surgical approach (fasciotomy). Physicians start with the conservative means of treatment, which include, stretching, mechanical therapies such as strapping and orthoses, and steroid injections. Surgery is used as a last resort, if all other treatment techniques fail. The procedure consists of partial or complete release of the plantar fascia. This may potentially lead to further complications such as flattening of the foot and chronic pain. Recently, “shock wave therapy” is emerging as a new conservative treatment technique that can be used to avoid surgery. It is recommended if no improvement has occurred after six months of conventional treatment.

Shock wave therapy is a common term for therapeutic techniques that use high-amplitude transient pressure waves. It is used to treat a wide range of clinical conditions. Shock wave therapy was originally developed in the early 1980s as a non-invasive technique for breaking kidney stones (lithotripsy). Its application quickly expanded to the treatment of gall stones, pancreatic stones, and salivary stones (Storz 2003). The use of shock wave therapy for the treatment of musculoskeletal disorders is relatively new (Rome and Saxelby 2005; Rompe 2006). It originally emerged from the idea that shock waves can be used to treat tendonitis by dissolving calcifications at tendon insertions. In spite of the fact that direct fragmentation is not accomplished, it has been shown that treatment acts to eliminate or reduce the symptoms of tendonitis. Currently, shock wave therapy is used to treat a wide range of musculoskeletal disorders including: plantar fasciitis, Achilles tendinitis, calcific tendonitis of the shoulder, lateral epicondylitis of the elbow (tennis elbow), patellar tendonitis (jumper's knee). One of the methods for generating pressure waves is through the collision of two metal objects: a pneumatically driven projectile and an "applicator" placed on the surface of the skin. This type of therapy is referred to as "radial shock wave therapy". While shock wave therapy is steadily gaining ground as a treatment method of choice, the healing mechanism(s) of shock waves remains unknown (Storz 2003). Moreover, the bio-mechanical aspects of the treatments have not been fully investigated, especially in the case of radial shock wave therapy. Current research mainly focuses on clinical outcomes, while little attention has been placed on the physical aspects of the technique. Better understanding of the healing mechanisms and their relation to the physical parameters of shock wave treatment could lead to optimisation of this modality and to its further developments.

1.2 Objectives

The purpose of this work is to use computer modelling to enhance the understanding of the mechanical effects of radial shock wave therapy when applied to the foot, and to relate these effects to potential healing mechanisms. This will be achieved through the following specific objectives:

- Develop finite element model(s) of a radial shock wave source and carry out dynamic simulations to examine the mechanics of operation and to determine the minimal level of complexity necessary to reproduce the dynamics of the device in a

realistic manner. The model will be validated against experimentally determined movement of the device.

- Apply the developed model of the shock wave source to a hypothetical object of simple geometry and with uniform material properties in order to gain an insight into the pressure field generated by the device as well as the relation between the main parameters of the pressure field and intensity level settings for the device. The results will be discussed with reference to the data provided by the manufacturers and the results of independent experimental research studies.
- Develop a three-dimensional model of the foot appropriate for dynamic simulations of shock wave therapy. The model geometry will be derived from medical images and it will incorporate the main anatomical structures of the foot and the plantar fascia in particular.
- Couple the models of the radial shock wave source and the foot to simulate shock wave therapy for plantar fasciitis, for various intensity settings and device positioning, in order to characterise the physical effects of the treatment. The observed patterns of temporal and spatial stress distribution will be analysed in relation to wave propagation through the structures of the foot.
- Analyse the mechanical effects observed in the simulations with the goal of relating them to the existing hypotheses on the biological effects of shock wave therapy on the tissue.

1.3 Thesis Structure

Chapter 2 gives the background information relevant for the topic of the PhD. First, a brief account is given of the foot anatomy and biomechanics of the plantar fascia. This is followed by an overview of the plantar fasciitis in which the distribution, causes, symptoms, and treatment methods for this condition are discussed. Next, an account is given of the general principles of shock wave therapy and its clinical applications. Physical background, types of shock wave sources, and experimental studies aimed at establishing the key physical parameters of this therapeutic method are discussed. The application of shock wave therapy for the treatment of plantar fasciitis is examined in reference to clinical studies on its effectiveness and on the mechanical and biological effects that it may create. The attention then shifts to published computer modelling studies of shock wave therapy

and of the foot. A comprehensive overview of existing finite element models of the foot is given focusing on the strategies and approaches in formulating geometry, representation of the connective and soft tissue, and material models for the foot components. The relevant literature is analysed to assess the acoustic properties of the material models used in the published studies.

Chapter 3 describes the formulation and testing of the finite element model of a radial shock wave device. First, a detailed account of the modelling approach and the stages in the model creation are given. Then, the model is tested by comparing the overall dynamics predicted by the simulations to the results from an experiment performed using an actual device. Next, the details of the interaction of the model components (projectile and applicator) and the stress wave generated in the applicator are analysed. Finally, a simplified version of the model is formulated.

Chapter 4 reports the results of a series of simulations aimed at gaining general information on the physical principles of the generation and propagation of the pressure wave in soft tissue. A simplified model of the device, and a hypothetical cylindrical “soft tissue object” were used in these simulations. The specific objectives of the simulations were to: examine the performance of different material models of the soft tissue, characterise the pressure wave pattern in the soft tissue in the absence of reflections, examine the effect of projectile velocity on the pressure wave, and compare results for the key physical parameters with the published experimental results.

Chapter 5 gives an account of the creation of the finite element model of the foot. First, the reconstruction of the geometry for the various parts of the foot from the medical images is discussed; the reconstruction strategies and methods for the bones, tendons and ligaments, cartilages, and soft tissue are presented. Next, the conditioning of the geometries for each part and the creation of the finite element mesh are discussed. Finally the formulation of the finite element model, including the interaction between various components, and material properties for the model parts are given.

In Chapter 6 the models of the shock wave device and the foot are coupled to simulate shock wave therapy for plantar fasciitis; the effects of device positioning and pressure settings were considered in the simulations. All the simulation parameters including boundary and initial conditions, contacts, and loading are presented. The results are discussed in terms of the pressure waveform generated at the surface of the foot, the

pattern of the pressure wave in the foot, and the distribution of pressure amplitude and energy in the foot. Finally, the effects of shock wave therapy at larger time scales examined by simulating two successive pulses from the device.

In Chapters 7 and 8 the results from the study are discussed in reference to: relating the model performance to the results from published studies, new findings derived from the results obtained from the simulations, and possible links between the physical stimulus from the treatment and the related biological response. The limitations of the modelling reported in the study and directions for future work are also presented.

2 Literature Review

2.1 Medical Background

2.1.1 Anatomy of the Foot

The human foot is a strong and complex multi-articular anatomical structure containing bones, joints, muscles, tendons, and ligaments. Figure 2-1 shows the sagittal section of an actual foot illustrating the complexity of its structure. The foot has two main functions: weight bearing and propelling a person during locomotion. The components of the foot along with the muscles and tendons of the lower leg all work together to transmit the stress the ankle experiences when a person walks, runs, or jumps. A problem with any one of these parts can cause pain and difficulties with foot and ankle function. The foot is comprised of the bony skeleton consisting of 26 bones, the connective tissue, tendons and ligaments, the soft tissue, muscles and plantar fat.

Figure 2-1: Sagittal section of the foot (McMinn, Hutchings et al. 1982)

2.1.1.1 Bones of the foot

The bones of the foot (Figure 2-2) can be grouped into three parts based on their location. These are the hindfoot, the midfoot, and the forefoot.

The talus and calcaneus are the two components of the hindfoot. The talus has a rounded head, a neck, and a cuboidal body that are all orientated to convey forces from the foot to the leg through the ankle joint (Abboud 2002; Martin 2006). The calcaneus, or heel bone, is the largest bone of the foot. The upper surface of the calcaneus articulates with the talus. In normal standing, most of the weight is transmitted from the tibia to the talus, to the calcaneus, and then to the ground (Martin 2006). The calcaneus provides the insertion points for both the Achilles tendon and the plantar fascia.

The midfoot consists of the navicular, the cuboid, and the three cuneiforms. The navicular is located anterior to the talus. The medial, intermediate, and lateral cuneiforms articulate with the navicular. The cuboid articulates proximally with the calcaneus, distally with two metatarsals, and medially with the lateral cuneiform (Hollinshead 1976).

The five metatarsals and the toes make up the forefoot. The first metatarsal is the widest. Each metatarsal consists of a base, a body and a head. The bases articulate with the cuboid/cuneiform bones and with other metatarsals. The heads articulate with the phalanges. The second metatarsal extends beyond the first proximally. The third, fourth, and fifth metatarsals are broad at the base, narrow in the shaft, and have dome-shaped heads (Hollinshead 1976; Abboud 2002).

The phalanges constitute the digits (toes). The big toe (hallux) consists of two phalanges. The second, third and fourth toes contains three phalanges; the fifth toe may have two or three phalanges. Functionally, the toes contribute to weight bearing and load distribution and also affect propulsion during the push-off phase of gait (Abboud 2002).

Figure 2-2: Bones of the foot (McMinn et al. 1982).

- 1 Calcaneus, 2 Sustentaculum tali, 3 Talus, 4 Head of talus, 5 Navicular, 6 Tuberosity of navicular, 7 Medial cuneiform, 8 Intermediate cuneiform, 9,10,11 Base, body, and head of first metatarsal, 12,13,14 Base, body, and head of proximal phalanx of great toe, 15,16,17 Base, body, and head of distal phalanx of great toe, 18 Sesamoid bone, 19 Lateral cuneiform, 20 Cuboid, 21,22,23,24 Base, tuberosity, body, and head of fifth metatarsal, 25 Tarsal sinus

2.1.1.2 Arches of the foot

The two main functions of the foot: supporting the body while standing and acting as a lever to propel the body during locomotion, require a high degree of stability. On the other hand, the foot must adapt to standing and walking on uneven surfaces and therefore has to be flexible. This is made possible through the joints, whereby the bones are connected by ligaments and muscles to form structures termed arches. The foot is considered to have three arches: the medial longitudinal arch, the lateral longitudinal arch, and the transverse arch (see Figure 2-3). The medial longitudinal is the highest and most important of the three arches. It is composed of the calcaneus, talus, navicular, cuneiforms, and the first three metatarsals. The pillars of the arch are the calcaneus posteriorly and the heads of the medial three metatarsal bones anteriorly. The talus occupies the highest point of the arch; with its head wedged between the calcaneus and the navicular, it is the

“keystone” that holds the arch together. The lateral longitudinal arch is lower and flatter than the medial longitudinal arch, consisting of the calcaneus, the cuboid, and the fourth and the fifth metatarsal bones, with the cuboid as a “keystone”. Both medial and lateral longitudinal arches are relatively rigid in standing but become more compliant during walking, the medial arch being the more flexible of the two. The transverse arch is formed by a series of smaller arches, which exist around the metatarsophalangeal joints (joints between the metatarsals and phalanges).

Figure 2-3: Arches of the foot (Verpillot 2013).

2.1.1.3 Tendons and ligaments

There are elastic tissues (tendons) in the foot that connect the muscles to the bones. The Achilles tendon or "tendo calcaneus" is the largest and strongest tendon in the human body. It extends from the calf muscle to the calcaneus. The Achilles tendon facilitates locomotion activities such as running, walking, climbing and raising the body onto its toes. The Achilles tendon is believed to serve as the most important "reservoir of elastic energy" during the contact phase of running, thus contributing to the optimisation of energy expenditure.

Figure 2-4: Ligaments of the foot (Hollinshead 1976).

Ligaments are fibrous connective tissue whose role is to hold and to stabilize the joints. The ankle joint is reinforced by the deltoid ligament on its medial side (Figure 2-4), and with three ligaments (the anterior tibiofibular, the posterior tibiofibular, and the calcaneofibular) on its lateral side. Tarsal bones (bones of the hindfoot and midfoot) are connected with three sets of ligaments: dorsal, on the upper (dorsal) surface of the foot; interosseous, between the articular surfaces of the bones; and plantar, on the lower (plantar) surface of the foot. The plantar ligaments lying beneath the arch are much stronger than the dorsal ligaments that are on the top of the bony arch (Figure 2-4).

The plantar fascia or "plantar aponeurosis" is the longest ligament in the foot. The plantar fascia supports the medial longitudinal arch of the foot; by stretching, it allows the arch to flatten, providing balance and giving the foot strength to initiate locomotion (Abboud 2002). The plantar fascia has three components: central, lateral, and medial bands (Figure 2-5). The central band is the most prominent and structurally dominant (League 2008). It is of triangular shape with a posterior apex and an anterior base. The origin of the central part is at the calcaneal tuberosity, a lump-like posterior projection of the calcaneus at the heel. At mid-tarsal level, the central component of the plantar fascia divides in five segments that gradually diverge towards the toes, where it attaches to the plantar aspects of the proximal phalanges. A normal plantar fascia is 2 to 4 mm thick (Narvaez et al. 2000).

Other important plantar ligaments are the plantar calcaneonavicular ligament or "spring ligament" connecting the sustentaculum (lower surface) of the calcaneus with the

navicular, and the long plantar ligament that stretches between the calcaneus and the cuboid and three lateral metatarsals (Figure 2-4).

Figure 2-5: Plantar fascia (Roger and Grenier 1997).

2.1.1.4 Plantar muscles and plantar soft tissue

The muscles of the foot can be divided into extrinsic muscles, which arise from the lower leg, and intrinsic muscles, which arise within the foot itself. The main function of the intrinsic muscles as a group is to provide support to the longitudinal arch in dynamic loading situations. The intrinsic muscles can be subsequently divided into the plantar and dorsal groups (Abboud 2002). The plantar muscles, which are between the plantar fascia and the arches of the foot, form four layers. The muscles of each of the layers are shown in Figure 2-6.

Figure 2-6: Plantar muscles of the foot (Hollinshead 1976).

A: superficial (first layer). B: second layer. C: third layer.

D: the deepest (fourth) layer.

The heel pad and the ball of the foot are designed to act as efficient shock absorbers. The plantar soft tissue consists of dense strands of fibrous tissue forming circular or cone-shaped septae, which contain closely packed fat cells (Prichasuk 1994). The thickness of the heel pad at the calcaneal tubercles is between 12 and 22 mm, with an

average value of 18 mm (Kelikian 1983). Figure 2-1 shows a sagittal section of the foot with a clearly visible heel fat pad.

2.1.2 Biomechanical Function of Plantar Fascia

The plantar fascia is believed to be critical in providing the integrity of the medial longitudinal arch of the foot, which otherwise would not be able to maintain its shape. Figure 2-7 gives a simplified illustration of the structural role of the plantar fascia in maintaining the stability of the foot. Here, the foot is approximated as a truss-like structure where the talus and calcaneus form the posterior strut, and the forefoot forms the anterior strut. Both of these elements are subjected to compression. The plantar fascia is the third element of the truss that is subjected to tension (Kelikian 1983). Thus, the plantar fascia plays a significant load-bearing role in standing and locomotion. It is believed that, similar to the Achilles tendon, the plantar fascia plays the role of an elastic energy reservoir in the stance phase of running (Bartold 2004).

Figure 2-7: Schematic explanation of the structural function of plantar fascia (Kelikian 1983).

Similar reasoning can be used to explain the role of the plantar fascia in a "windlass" mechanism through which the longitudinal arch of the foot is raised and the tarsal joints are locked together by dorsiflexion of the toes (flexion towards the dorsal side of the foot). This is illustrated in Figure 2-8. The head of the metatarsal acts as the drum of the windlass, the phalanx is the handle, and the plantar fascia is the cable wound onto the drum. The dorsiflexion of the toes winds the plantar fascia around the metatarsal head,

reducing its length and raising the height of the arch (Kelikian 1983). The windlass mechanism is important as it reduces the requirement on the plantar muscles in maintaining arch stability during the propulsive phase of walking.

Figure 2-8: Schematic explanation of the windlass mechanism (Kelikian 1983).

2.1.3 Plantar Fasciitis

Plantar heel pain syndrome or plantar fasciitis is the most common cause of heel pain. Plantar fasciitis results from a degenerative process in the central part of the plantar fascia (Puttaswamaiah and Chandran 2007). The condition is generally considered to be "self-limiting" in the sense that the symptoms may eventually disappear even without any medical intervention. However, the pain may persist for months; the longer it persists, the harder it is to treat.

2.1.3.1 Distribution, aetiology, and history

Plantar fasciitis is estimated to affect 10% of the population during the course of their lives (Crawford and Thomson 2003). It affects a wide sample of the community but it is most commonly seen in those with weight bearing occupations. There is a general agreement in the literature that plantar fasciitis occurs mostly after the fifth decade of life, which has been attributed to the atrophy of the fat pad associated with ageing (Bartold 2004). Obesity also appears to be a factor leading to the condition. Plantar fasciitis is also common in the athletic population affecting mostly runners (both short and long distance), but also basketball, football, and tennis players (Bartold 2004).

The aetiology of plantar fasciitis is not entirely clear. Current evidence suggests that it is initiated by either repetitive micro-trauma or by degenerative changes to the plantar fascia (Rome and Saxelby 2005). Mechanical overload is generally believed to be the main factor leading to the condition (Puttaswamaiah and Chandran 2007). Excessive loading of the plantar fascia causes micro-tears that are followed by inflammation (League 2008). The extrinsic factors potentially leading to plantar fasciitis include, errors in sport training, running on unyielding surfaces, and improper or worn-out footwear. The intrinsic factors include obesity, foot structure, reduced flexibility of plantar muscles, and tightness of the Achilles tendon (Cornwall and McPoil 1999). Heel spurs, small protrusions on the plantar part of the calcaneus, have now been discarded as a cause of plantar fascia. However, it is possible that they can aggravate the painful condition once it is present (Puttaswamaiah and Chandran 2007).

The main symptoms of plantar fasciitis are pain, difficulty in walking, and in some cases swelling (Puttaswamaiah and Chandran 2007). The pain is usually localised over the origin of the central part of the plantar fascia towards the inner (medial) side of the heel. However, it can sometimes spread to the whole foot. The onset of the condition is gradual and it worsens over a period of weeks or even months. The pain is most severe with the first few steps in the morning or after a period of rest and it is experienced as a sharp stabbing. This is believed to be due to the accumulation of inflammatory by-products during rest. The pain lessens and becomes dull after a short period of walking (Bartold 2004; League 2008).

2.1.3.2 Treatment

Conservative (non-surgical) treatment of plantar fasciitis aims to alleviate the symptoms through, reducing tissue stress, restoring flexibility and muscle strength, and reducing pain and inflammation (Cornwall and McPoil 1999). A brief overview of conservative methods is given below:

- Various forms of stretching are used as a treatment to increase/restore flexibility (Cornwall and McPoil 1999). The most recommended form is the stretching of calf muscles and Achilles tendon (Figure 2-9 A). Stretching of the plantar structures of the foot, plantar muscles and plantar fascia, is also recommended (Figure 2-9 B, C).

- Orthoses have been in use for the treatment of plantar fasciitis based on the assumption that they may reduce tissue stress. The orthoses come in a variety of forms including: heel cuffs, visco-elastic heel pads, and accommodative inlays. In many cases the principal reason for using orthoses is to prevent excessive foot pronation (movement of the foot in which the heel bone angles outwards), which has been associated with plantar fasciitis by some authors (Bartold 2004).
- Night splints are orthoses used to hold the plantar fascia and Achilles tendon in the position of stretch during the night.
- Specific foot taping techniques have been developed for the treatment of plantar fasciitis (Figure 2-9 D). Again, the main goal of the method is to prevent excessive foot pronation (Cornwall and McPoil 1999).
- Non-steroidal anti-inflammatory drugs can be taken orally for pain relief and to reduce inflammation. Steroid injections, alone or with local anaesthetic, can be administered (Singh et al. 1997). Corticosteroids injected into the origin of the plantar fascia provide the most focused delivery of anti-inflammatory medications. However, this comes at a risk of fascia rupture or fat pad atrophy (League 2008).

Figure 2-9: Forms of conservative treatment for plantar fasciitis (Bartold 2004).

A: stretching of calf muscles. B: stretching of plantar fascia. C: strengthening of intrinsic foot muscles. D: taping of the foot.

Surgical management of plantar fasciitis (fasciotomy) is used as a last resort, if the conservative treatments fail to yield results and the condition persists for 6-12 months (Singh et al. 1997; Cornwall and McPoil 1999; Puttaswamaiah and Chandran 2007). The procedure can be performed either as open or as endoscopic surgery. Open fasciotomy involves partial or total plantar fascia release. If the heel spur is present, it can be removed at the same time. An endoscopic procedure is less invasive and is not combined with heel spur removal. The published studies on the effectiveness of surgical methods report a high level of success (Cornwall and McPoil 1999), but some authors maintain that high level of evidence from randomised trials is still lacking. Potential complications include collapse of the arch, nerve damage, and persistent or recurrent pain (League 2008).

Shock wave therapy (SWT) is a relatively recent form of conservative therapy. It is usually used when the more conventional conservative methods listed above do not yield

results as the last attempt to avoid the highly invasive fasciotomy. Shock wave therapy will be given full attention in the next section.

2.2 Shock Wave Therapy

This section gives a brief overview of the background of SWT and the physical parameters used to characterise the SWT technique. This is followed by an overview of various SWT sources, their principles of operation, and their typical physical parameters. Finally, the use of SWT in the treatment of plantar fasciitis is discussed in terms of typical clinical procedures, therapeutic effectiveness, and potential biological effects and their underlying physical mechanisms.

2.2.1 Physical Background

Shock waves are high amplitude sound waves that originate from a transient pressure disturbance. This disturbance steepens as it propagates in three dimensions to form a high pressure region at the wave front (Ogden et al. 2001). Strictly speaking, shock waves only occur if the velocities of particles in a disturbed medium are of the same order of magnitude as the speed of sound in that medium. However, in medical literature the term shock wave therapy is also used for techniques that rely on high-amplitude pressure waves. These fall short of being shock waves in the true sense of the word as they do not involve non-linear effects such as steepening of the initial waveform or movement of the particles at speeds close to or higher than the speed of sound.

The speed of sound in a solid medium (c) depends on the mechanical properties of the medium and it can be expressed as:

$$c = \sqrt{\frac{K + \frac{4}{3}G}{\rho}} \quad 1$$

where ρ is the density of the medium and K and G are the bulk and shear moduli of the medium, respectively (Cleveland and Sapozhnikov 2005).

For fluids $G=0$, and the formula reduces to:

$$c = \sqrt{\frac{K}{\rho}} \quad 2$$

Another important property is the acoustic impedance of the medium defined as (McClure and Dorfmueller (2003)):

$$Z = \rho c \quad 3$$

When an initial (incident) pressure wave travelling through a medium characterized by a certain acoustic impedance (Z_1) encounters another medium with a different acoustic impedance (Z_2), part of it will be transmitted across the interface (the transmitted wave) and part of it will be reflected back (the reflected wave). The ratio of the pressure amplitudes of the reflected and incident waves is given by (Weinberg and Ortiz (2009)):

$$\frac{p_r}{p_i} = \frac{Z_2 - Z_1}{Z_1 + Z_2} \quad 4$$

If Z_1 and Z_2 are similar, the reflected wave will be weak and most of the incident wave will be transmitted across the interface. On the other hand, if Z_2 is either much smaller or much larger than Z_1 , most of the incident wave will reflect off the boundary. In the case where Z_2 is smaller than Z_1 , the reflected wave will be of the opposite sign to that of the incident wave. Table 2-1 summarises speeds of sound and acoustic impedances of tissues and other materials of interest in SWT. It can be seen that water and soft tissues have very similar acoustic impedances. Bone, kidney stone, and metal have much higher impedances, which is of importance for the mechanisms through which kidney stones are broken using SWT. On the other hand, air (including the air in the lungs) has a much lower acoustic impedance than water and soft tissue. As a consequence, it is important to avoid air gaps between the shock wave source and the skin surface to ensure that the shock wave is transmitted from the device to the body and delivered to the affected area. This is usually achieved by using coupling gels which have similar acoustic properties as water/soft tissue.

Table 2-1: Acoustic Properties of Tissues (Ogden et al. 2001)

	Velocity of sound (m/s)		Density (kg/m ³)	Acoustic Impedance (kg/s*m ²)*10 ⁶	
	Min	Max		Min	Max
Lung	650	1160	400	0.26	0.464
Fat	1476		928	1.37	
Air	330	343	1.3	0.000429	0.000446
Water	1492		998	1.489	
Kidney	1570		1040	1.633	
Muscle	1545	1630	1060	1.638	1.728
Bone marrow	1700		9700	1.649	
Bone	2700	4100	1800	4.86	7.38
Kidney stone	4000	6000	1900-2400	7.6	14.4
Iron	5100	5800	7900	40.29	45.82

In solids the sound waves are also known as: a) compression waves, as they involve changes in volume, b) longitudinal waves, since the particles move in the same direction as the wave propagation, or c) P-waves (primary waves), as they are the fastest type of waves. It is customary to denote the speed of longitudinal waves as c_L . The other type of waves in solids are shear waves, also known as transverse waves as they involve the movement of particles in the direction perpendicular to that of wave propagation, or S-waves (secondary waves) (Dragoset 2005). The speed of shear waves in solids (c_S) depends on the shear modulus and density of the solid and is given by the following formula (Cleveland and Sapozhnikov 2005):

$$c_s = \sqrt{\frac{G}{\rho}} \quad 5$$

Shear waves generated by a SWT technique are rarely mentioned in the literature on shock wave therapy except in the context of kidney stone fracture (Cleveland and Sapozhnikov 2005). Instead, the emphasis is almost entirely on the pressure field from the longitudinal waves. Figure 2-10 gives a more complete insight on what happens when an incident P-wave encounters an interface of two media with different acoustic properties. The incident wave will split into transmitted waves and reflected waves of both P and S type. Also, the transmitted P-wave will experience change in direction.

Figure 2-10: Reflection and transmission of an incident P-wave at an interface (Dragoset 2005).

A shock wave technique is characterized by the pressure field that it creates and by the energy that it delivers to the tissue. Pressure in the tissue generated by a medical shock wave device is a function of time and space. The pressure waveform is a short transient pulse of a duration measured in microseconds and with both negative and positive phases. The pressure magnitude is of the order of 1-100 MPa, depending on the SWT source and application. The key parameters used to characterise the pressure waveform at a point in the medium are: a) the largest positive value (P_+), b) the largest negative value (P_-), c) the rise time (time needed to reach P_+ from zero), and d) the total duration of the pulse. These parameters are illustrated in Figure 2-11 showing a typical shock wave pressure transient.

Figure 2-11: Typical pressure trace of the therapeutic shock wave generated from a focused SWT source (Ogden et al. 2001).

The spatial distribution of pressure is often characterised by defining a "-6 dB" zone, which is a region in which P_+ is equal or greater than one half of the maximal pressure generated with a pulse. The size and location of a -6 dB region depends on the type of the shock wave source. The energy of SWT refers to the total acoustical energy per released shock wave and it can be determined from the temporal and spatial distribution of the pressure profile (Ogden et al. 2001). It is also possible to define the energy of the treatment as energy released with each pulse multiplied by the number of pulses delivered over the treatment. However, knowing the net energy does not tell us how that energy is distributed in the zone of treatment. A more useful physical parameter related to SWT is the energy flux density or energy flux. Energy flux (EFD) at a specific point is defined as the energy per unit area that is being released by a single pulse at that point (Ogden et al. 2001). In the context of SWT, energy flux is usually expressed in the unit of mJ/mm^2 . Energy flux at a certain location can be directly related to the pressure waveform measured at that point ($p(t)$) as (McClure and Dorfmueller 2003):

$$\text{EFD} = \frac{1}{\rho c} \int p^2(t) dt \quad 6$$

Depending on the levels of EFD generated, it is customary to classify shock wave treatments as (Chung and Wiley 2002):

- low energy ($\text{EFD} < 0.08 \text{ mJ/mm}^2$)
- medium energy ($0.08 \text{ mJ/mm}^2 < \text{EFD} < 0.28 \text{ mJ/mm}^2$), and
- high energy ($\text{EFD} > 0.6 \text{ mJ/mm}^2$)

Note that according to this classification it is not clear whether treatment with $0.28 \text{ mJ/mm}^2 < \text{EFD} < 0.6 \text{ mJ/mm}^2$ is medium or high energy. Many authors choose to classify SWT treatment at an EFD of over 0.28 mJ/mm^2 as high energy.

Similar to pressure, the transmission and reflection of energy depends on the acoustic impedances. The transmission/reflection ratio of EFD of a wave travelling from water into various tissues is summarised in Table 2-2.

Table 2-2: Effect of tissue properties on wave transmission (Ogden et al. 2001)

Transmitted and reflected EFD for a wave travelling from water into different media				
	EFD reflected (%)		EFD transmitted (%)	
	min	max	min	max
Lung	28	49	51	72
Fat	0.2		99.8	
Air	99.9		0.1	
Water	0		100	
Kidney	0.2		99.8	
Muscle	0.2	0.6	99.4	99.8
Bone marrow	0.3		99.7	
Bone	28	44	56	72
Kidney stone	45	66	34	55
Iron	86	88	12	14

2.2.2 Focused Shock Wave Therapy

Techniques that produce shock waves in the true sense of the word are based on the principle of generating an initial high-amplitude disturbance ("controlled explosion") in a fluid medium by rapid conversion of electrical into mechanical energy. The initial shock

wave is then focused onto a (small) region of treatment within the body (focused SWT). Old machines used a patient submersion system to assure good coupling as water and soft tissue have similar acoustic properties. In modern devices the shock wave is initiated in a fluid-filled "head" that has a silicone-type membrane with acoustic properties similar to water and tissue. The coupling between the membrane and surface of the skin is accomplished by using substances such as an ultrasound coupling gel. Currently, three methods are being used to generate the shock waves; electrohydraulic, electromagnetic, and piezoelectric (Ogden et al. 2001; Wang 2003). In the electrohydraulic technique, shock waves are generated by a high-voltage condenser spark discharge and then focused at the desired areas using an acoustic mirror (see Figure 2-12A). In the electromagnetic technique, a strong magnetic field is produced by passing electric current through a coil, which causes rapid movement of an adjacent highly conductive membrane, thus compressing the surrounding fluid medium to produce a shock wave. An acoustic lens is used to focus the waves on the therapeutic areas (see Figure 2-12B). In the piezoelectric technique, a large number of piezocrystals simultaneously receive a high voltage pulse. This causes deformation of the crystals, which induces a pressure pulse in the surrounding water. The focusing is achieved by precise alignment of the piezo elements (see Figure 2-12C).

Figure 2-12: methods of shock wave generations. A: electrohydraulic, B: electromagnetic, C: piezoelectric (Ogden et al. 2001).

A typical form of a therapeutic focused shock wave produced by focused shock wave sources is shown in Figure 2-11; there is an initial rise of a high peak pressure (up to 100 MPa) within less than 10ns, followed by a much smaller negative pressure (about 10% of the peak positive pressure). The total duration of the pulse is approximately

10 μ s (Ogden et al. 2001; Wang 2003). Both the primary effects, associated with the positive pressure zone, and secondary effects, associated with the negative pressure zone, are believed to have therapeutic effects. When the positive peak of a pressure wave travelling through a kidney stone reaches its end and encounters a medium of much lower impedance (tissue) it is reflected back as a tensile (negative pressure) wave. The kidney stone, which has poor resistance to tension, breaks at the point where the reflected tensile wave overlaps with the negative pressure zone of the incident wave. This is known as a "spall effect" or "spallation" (Cleveland and Sapozhnikov 2005). On the other hand, the negative phase in the pressure waveform may lead to cavitation in the tissue surrounding a kidney stone, which could provide another mechanism leading to stone fracture. Cavitation is a phenomenon related to negative pressure in liquids. It requires the existence of small gas bubbles or solid particles known as "cavitation nuclei". In the presence of a negative pressure of sufficient magnitude, cavitation nuclei grow, forming cavitation clusters that eventually collapse, releasing high pressure. Figure 2-13 displays fracture patterns of an artificial kidney stone used in experiments on fracture mechanisms from SWT (Sapozhnikov, Maxwell et al. 2007). The clear fracture due to spallation is at the distal end of the stone, whereas holes at the proximal end are caused by cavitation in the surrounding water.

Figure 2-13: Fracture patterns of an experimental model of a kidney stone (Sapozhnikov et al. 2007).

All focused SWT techniques form a focal zone in the shape of an ellipsoid. Figure 2-14 gives an example of experimentally measured distribution of P_+ in a single plane, with the elliptical -6 dB zone indicated by dark shading. The -6 dB zone should

coincide with the zone of treatment. Clinically, proper focussing in modern devices is achieved by incorporating ultrasonic and fluoroscopic devices into the SWT sources. Accurate focusing is especially important in lithotripsy, and less so in musculoskeletal applications (McClure and Dorfmueller 2003).

Figure 2-14: Spatial distribution of peak positive pressure from a focused SWT source indicating the -6 dB zone of elliptical shape (Ogden et al. 2001).

2.2.3 Radial Shock Wave Therapy

Radial shock wave therapy is a relatively new and inexpensive method used to generate therapeutic pressure waves. In contrast to focused SWT in which a sudden release of electric energy is used to initiate shock waves in fluid, radial shock wave therapy (rSWT) utilizes a much simpler "ballistic technique," which is similar to the operational principle of a jackhammer (Cleveland et al. 2007). Figure 2-15 gives a schematic explanation of the ballistic shock wave source: the projectile, a cylindrical metal object with a mass of approximately 3 grams, is accelerated by an accurately controlled burst of compressed air at a pressure between 1-4 bar (1 bar = 10^5 Pa), and propelled down a guiding tube reaching speeds between 5-20 m/s. The projectile collides with a metal object (applicator) that is suspended between two o-rings in a tightly fitted metal casing. The impact generates a small-amplitude rigid-body movement (due to elastic suspension), as well as an elastic wave in the applicator. The applicator is pressed superficially to the zone

of treatment on the skin with a force of at least 30 N and further coupled with ultrasound gel to deliver the impulse to the tissue. The pressure disturbance generated at the surface of the skin continues to spread inside the body in all directions forming a spherical “radial” wave.

Figure 2-15: Ballistic shock wave source (Wess 2008).

Figure 2-16 displays components of a DolorClast (EMS Medical, Switzerland) ballistic pressure wave source showing parts of the inner casing, guiding tube, and the standard 15 mm radial applicator that is typically used for the treatment of plantar fasciitis. The device can accommodate a number of different applicators which can be easily replaced by un-tightening the front cap. A selection of applicators that can be fitted into the same hand piece is shown in Figure 2-16C.

Figure 2-16: Components of the DolorClast radial shock wave device.

A: Rear part of the inner casing (1), front part of the inner casing (2) and front cap (3) accommodating an applicator (4), guiding tube for the projectile (5), projectile (6). B: 15 mm applicator (1) and o-rings (2). C: 36 mm planar applicator (1), 10 mm radial applicator (2), 15 mm trigger applicator (3).

2.2.3.1 Mechanics of the radial shock wave therapy source

Information on the mechanics of the ballistic pressure source operation, such as movement of the applicator and the exact speed of projectiles is not well documented, and it originates from the companies that manufacture the devices. Figure 2-17 reports the measurement of the displacement of a 6 mm diameter applicator when the device is driven at 4 bar pressure and fired in the air; the information is supplied by Storz Medical. The graph shows a bulk movement in the form of a highly damped oscillation with amplitude of about 0.2 mm and period of approximately 0.3 ms. The additional high frequency oscillations superimposed on the bulk movement are due to an elastic wave in the applicator. It is believed that both the components of applicator motion have influence on

the pressure generated in the tissue, with the overall "rigid body" movement having the dominant effect.

Figure 2-17: Displacement of a 6mm diameter applicator for handpiece pressure setting of 4 bar (Wess 2008).

In a rare independent study Benoit (2009) measured the speed of the projectile of the DolorClast handpiece for driving pressures between 1 and 4 bar using an induction coil method. He then developed a lumped-parameter mathematical model of the device to simulate its behaviour. Unfortunately, the details of the model were not reported in the document. The results displayed in Figure 2-18 indicate that the projectile speed ranges between 4 and 16 m/s, depending on the driving pressure. Also, it appears that the speed of the projectile increases as the driving pressure is elevated from 1 to 3 bar, but that further increase in the driving pressure has little effect on the projectile speed.

Figure 2-18: Velocity of the projectile for different driving pressures (Benoit 2009).

In order to further characterise the pressure waves generated by a ballistic source Benoit (2009) used the device on a "Hopkinson bar", a 1 m long aluminium bar 10 mm in diameter, suspended on ropes so that it can freely swing upon impact and instrumented with strain gauges at 86 mm, 499 mm and 995 mm from the impact end. A 15mm diameter standard applicator, the same as the one shown in Figure 2-15, was used in the experiment with different driving pressure settings (projectile velocities). The results showed that the amplitude of the stress in the bar (σ) is approximately linearly related to the speed of the projectile. The stress and speed at that point (V) were related as: $\sigma = \rho c V$, as suggested by the theory of wave propagation in longitudinal bars (Graff 1975). Also, it was found that the wave length of the stress wave in the bar is approximately equal to twice the length of the applicator (25 mm).

2.2.3.2 Physical parameters of radial shock wave therapy

In radial shock wave therapy there is no focal point within the tissue in which the wave energy is concentrated. Rather, the maximum pressure is generated at the contact between the applicator and the skin. The pressure amplitude and energy progressively decrease as the wave propagates into the interior of the body; the decrease in P_+ is proportional to the distance from the source and the decrease in EFD is proportional to the square of the distance from the source. Hence, there is a limitation of about 4 cm on the depth at which rSWT can be used effectively (Storz 2003). Radial SWT does not produce shock waves and it generates particle velocities in the medium that are well below the

speed of sound (approximately up to 10m/s versus 1500 m/s). Therefore rSWT is not a shock wave therapy in the strict sense and it is sometimes referred to as "pressure wave therapy". The main physical parameters of rSWT are much less investigated than those of focused SWT. From the limited number of in-vitro studies it is known that maximal pressures generated by this method are around 10 MPa and that the duration of pressure transients is longer than in the case of focused SWT. Figure 2-19 displays the trace of pressure in water from a DolorClast handpiece measured 1 mm away from the standard 15 mm applicator driven at maximal pressure. This data is provided by the manufacturer. The values of P_+ and P_- are approximately 10 and -6 MPa, respectively, and the pulse persists for 20 μ s. Note that although P_+ is much lower than for focused SWT, the values of P_- are actually similar for the two techniques. Therefore, it can be said that a pronounced negative pressure phase is one of the characteristics of radial SWT.

Figure 2-19: Pressure generated in the water 1mm from the applicator head by an rSWT source driven at maximal pressure (DolorClast 2009).

Figure 2-20 shows a datasheet provided by the same manufacturer as the DolorClast “Power” handpiece and several different applicator types. The graph gives a simplified relation between the driving pressure and the EFD values. From the datasheet it may be concluded that high energy treatments can be offered with this type of device. However, most rSWT treatments reported in the literature are low or medium energy. It is also very important to note that in the case of rSWT the reported values of EFD apply to a point 1 mm away from the applicator tip, as opposed to the focused SWT where EFD

relates to the focal zone of treatment. Therefore, the treatment levels of EFD reported in the literature have a different meaning depending on whether they relate to focused or radial SWT.

Figure 2-20: Datasheet for DolorClast Power handpiece for a range of applicators (DolorClast 2009).

Experimental studies

Cleveland et al. (2007) conducted an in-vitro study to map the pressure field of a ballistic source. A DolorClast source was utilised with a standard 15 mm diameter applicator. The wave was generated in a water-filled tank which had one of the sides made of a thin plastic sheet (photocopy transparency) to allow the transfer of impulses from the applicator. Pressure was mapped in the region near the tip of the applicator using a hydrophone (an underwater microphone) which could be positioned with an accuracy of 0.5 mm. The pressure trace measured 10 mm away from the applicator driven at 3 bar had the values of P_+ and P_- as 5.6 and -9.2 MPa, respectively. The EFD calculated based on the 25 μ s pressure recording was 0.234 mJ/mm², which falls into the medium energy treatment zone. The distribution of P_+ is shown in Figure 2-21. The figure shows that the -6 dB zone is concentrated in the region up to 20 mm away from the tip of the applicator. This is distinctly different from the pressure field of focused SWT, where the -6 dB zone can be focused to the zone of treatment within the tissue. Figure 2-22 displays the relation between driving pressure setting and P_+ and P_- measured at 10 mm from the applicator

head. It can be seen that the pressure levels off for driving pressures over 2.5 bar, which is consistent with the results obtained by Benoit which show that a driving pressure over 2.5 bar does not result in significant increase in projectile speed.

Figure 2-21: Pressure field generated in the water by a radial shock wave device
(Cleveland et al. 2007). The values of P_+ are normalized with respect to the maximum recorded pressure.

Figure 2-22: Variation of P_+ and P_- in water 10 mm from the applicator head as a function of pressure setting (Cleveland et al. 2007).

Benoit et al. (2009) conducted measurements of pressure generated by rSWT in biological tissue. The experimental setup is illustrated in Figure 2-23; the phantom consisted of 3 mm thick biological tissue (pork skin and fat) and of silicone rubber which has similar acoustic properties as soft tissue. A polyvinylidene fluoride (PVDF) thin-film gauge was sandwiched between the tissue and the rubber for pressure measurements. A ballistic pressure source was applied to the tissue, and the phantom was pressed against the source with 35 N force via a spring, to mimic the pre-load used in the clinical setting. A 15 mm applicator was used with projectile speeds between 9 and 15 m/s (the projectile speeds were measured using induction coils as stated earlier). Note that according to the results presented in Figure 2-18, projectile speed of 14.9 m/s corresponds to driving pressure in excess of 2 bar, whereas speeds of 12.3 m/s and 9 m/s correspond to pressures of 2 and 1.5 bar, respectively. The pressure transients at projectile speeds of 14.9 m/s, 12.3 m/s and 9 m/s are shown in Figure 2-24. The graphs show the median waveforms and quartile waveforms for each pressure setting calculated from measurements performed over a number of experimental trials. The pressure waveforms were somewhat smoother than those measured in water, but they also had a prominent negative pressure zone. The values of P_+ and P_- were lower than those measured by Cleveland et al. (2007); P_+ was just

over 4 MPa and P_- just under -2 MPa for a projectile speed of 14.9 m/s. The values of P_+ and P_- were found to be directly related to the projectile speed. It was noticed that the first positive peak of pressure was followed by a second peak of almost the same magnitude. In his thesis Benoit denotes this second positive pressure peak as P_{2+} .

Figure 2-23: Experimental setup to measure pressure generated by a ballistic pressure source in biological tissue (Benoit et al. 2009).

Figure 2-24: Pressure generated by ballistic source in a soft tissue specimen at three different projectile speeds (Benoit 2009). The thick lines give median pressure waveforms for each speed calculated from eight independent measurements. The thin lines are the quartiles, the shaded zone in the figure corresponds to results affected by reflections.

Ueberle and Rad (2012) devised an experiment similar to that of Benoit (2009) to examine pressure generated by a number of different radial shock wave sources. The experimental setup is shown in Figure 2-25. The shock wave source was applied to 5 mm thick silicon layer on a Polyoxymethylene block. The pressure transducer was sandwiched between the silicon and the block. The silicon layer was characterised with a speed of sound of 1134 m/s. The applicator was pressed against the block with a pre-load regulated by a spring and then clamped to stay in position. The applicators tested had radius of 15 mm and their mass varied between 25 and 35 gram. The devices were also tested in water and the pressure was measured 5 mm from the applicator surface with a hydrophone.

Figure 2-25: Experimental setup to measure pressure generated by a ballistic pressure source in silicon (Ueberle and Rad 2012).

The results for the pressure waveform measured in the silicon for two different applicators are shown in Figure 2-26. The driving pressure was 2 bar. The values of P_+ and P_- were about 4 MPa which is consistent with the results obtained by Benoit (2009). While the values of P_+ were essentially the same for the two applicators one of them had a much less pronounced negative phase. The pressure wave had multiple positive and negative peaks which the authors attributed to the reflections from the free surfaces of the block. The pressure traces measured in the water were very similar to those measured in silicon for the initial 10 ms, but did not have multiple peaks.

Figure 2-26: Pressure generated by two different ballistic sources in silicon. The pressure setting was 2 bar (Ueberle and Rad 2012).

2.2.4 Shock Wave Therapy for Plantar Fasciitis

Both the focused and radial shock wave therapies have been used for the treatment of plantar fasciitis and other musculoskeletal disorders. In the case of the focused SWT, both low and high energy treatments have been applied; the radial SWT typically falls into the low energy treatment category (Furia and Rompe 2007). The low energy treatment is delivered over 3-6 sessions typically spaced one week apart. In each session 1000-4000 impulses are delivered at a frequency of up to 20 Hz. The energy flux density varies between 0.02 and 0.08 mJ/mm². The typical clinical setting for the application of rSWT for the treatment of plantar fasciitis is illustrated in Figure 2-27. High energy treatment is restricted to focused SWT, which typically involves anaesthesia. The treatment is usually given in a single session involving 1500-4000 impulses delivered at 0.22-0.36 mJ/mm².

Figure 2-27: Radial shock wave treatment of plantar fasciitis (Ibrahim et al. 2010).

2.2.4.1 Clinical studies on shock wave therapy for plantar fasciitis

There have been a number of clinical studies aimed at testing whether SWT is effective in treating musculoskeletal disorders such as plantar fasciitis. These studies follow groups of patients treated with SWT (or a placebo) and assess the effectiveness of the treatment on the basis of subjective feedback from the patients. An example of a way of quantifying the success of the treatment is the "Visual Analogue Scale" (VAS) where the improvement is graded from zero to ten based on the comparison of pain before and after the treatment (Figure 2-28).

Figure 2-28: Visual Analogue Scale - "face pain rating scale" (Weil et al. 2002)

A number of clinical studies support the use of SWT as an effective method for treating plantar fasciitis. Perlick et al. (1998) examined 83 plantar fasciitis patients treated with 3000 impulses at 0.3 mJ/mm². A follow up after 12 months showed that 51 patients were pain-free and 20 patients had improved with the treatment. Ogden et al. (2001) examined the effect of shock wave therapy by following 300 patients with plantar fasciitis after three months of initial shock wave treatment received. The overall results showed that 56% of the patients were satisfied with the treatment as the pain had either decreased or disappeared completely; the study suggested that SWT should be considered before any surgical option. Rompe al. (2003) compared the result of shock wave therapy and a placebo. Two groups of patients were examined; the treatment group (22 patients) was treated with 2100 shock wave impulses at 4 Hz frequency and EFD of 0.16 mJ/mm² three times at weekly intervals. The placebo group (23 patients) was treated with only a sham treatment where a sound reflecting pad was inserted between the SWT device and the heel to absorb the shock waves. The overall results showed that over 12 months the pain was reduced from 6.9 to 1.5 on the VAS in the treatment group. In the placebo group, the reduction of pain was much smaller (from 7.0 to 4.4). Alvarez (2002) investigated the OssaTron device (the first SWT device approved by the US Food and Drug Administration) on 20 patients with plantar fasciitis. The result was that 18 patients experienced some improvement or were completely pain-free, which prompted the authors to conclude that SWT is effective for plantar fasciitis. Wang et al. (2002) examined the effect of shock wave therapy on 79 patients with plantar fasciitis. Each patient was treated with 1000 impulses of shock wave to the affected heel. The results for the whole group were as follows: 75.3% were pain-free, 18.8% were significantly better, 5.9% were slightly better, and none were unchanged or worse. Hammer et al. (2003) studied the effectiveness of SWT in patients with chronic plantar fasciitis; 24 patients were treated with 3000 shock waves at 0.2 mJ/mm² in 3 sessions at weekly intervals. In a follow up 6 months after the treatment, it was found that their pain had decreased by 6.3 on the VAS.

On the other hand, there are a number of studies which stand against the use of SWT for the treatment of plantar fasciitis, claiming that there is not sufficient proof of its effectiveness. A review of clinical studies was performed by Burton and Overend (2005) and the conclusion was that there is only limited evidence to support the effectiveness of SWT for plantar fasciitis. Boddeker et al. (2001) analysed 21 clinical studies on the

effectiveness of the SWT for plantar fasciitis. A number of principles were followed to evaluate the studies. These included: control group, randomization, clinically relevant endpoints, sample size, follow-up, and adequate data analysis. The authors concluded that there is no robust scientific evidence that proves that SWT is effective in treating plantar fasciitis.

Clinical studies have also been conducted in order to determine whether the energy and type of SWT treatment (focused vs. radial) influence the outcome of therapy for plantar fasciitis. Chow and Cheing (2007) examined the effect of EFD using the DolorClast handpiece. Forty nine subjects suffering from heel pain were divided into three groups: "fixed energy", "maximal tolerable energy" and "control". Energy density for the fixed energy group was 0.05 mJ/mm^2 , and maximal tolerable (in terms of pain) for the maximal tolerable energy group. Both of these two groups received 1000 impulses at 3 Hz with the handpiece held perpendicular to the foot surface. The control group were administered 30 impulses at 0.03 mJ/mm^2 . All EFD values were determined from the driving pressure using a conversion table provided by the manufacturer. The maximal tolerable EFD was in the range between 0.09 and 0.14 mJ/mm^2 . All three groups had three treatment sessions at weekly intervals. Both the fixed and maximal tolerable energy groups experienced improvement in terms of pain reduction in a follow-up session, whereas the control group did not experience statistically significant improvement of the condition. The results for the maximum tolerable energy group were significantly better than for the fixed energy group. The authors concluded that maximal tolerable EFD should be used for optimal results.

Chang et al. (2012) conducted an extensive literature review backed by statistical analysis of the compiled results to compare different forms of SWT treatment for plantar fasciitis. They divided SWT treatments into radial (without specifying EFD), low intensity focused ($\text{EFD} < 0.08 \text{ mJ/mm}^2$), medium intensity focus ($0.08 \text{ mJ/mm}^2 < \text{EFD} < 0.28 \text{ mJ/mm}^2$), and high intensity focused ($\text{EFD} > 0.28 \text{ mJ/mm}^2$). The results of the statistical analysis suggest that radial SWT is a more effective treatment than focused SWT and that the success rate in focused SWT is not related to the energy levels employed. Lee et al. (2013) examined the effect of EFD and total treatment energy on the treatment of plantar fasciitis. Sixty subjects were divided into two groups and treated with focused SWT at 0.08 and 0.16 mJ/mm^2 (low and medium groups, respectively). Both

groups received 1000 impulses per session. The low energy group was treated in six sessions and the medium group was treated in three sessions, so that both groups received the same total treatment energy. The results showed the same level of improvement in both groups prompting the authors to conclude that the cumulative effect of the total energy delivered in the treatment is more important than the levels of EFD.

2.2.5 Hypotheses on Healing Mechanisms of Shock Wave Therapy for Musculoskeletal Conditions

The mechanisms through which SWT may act to treat the pain in plantar fasciitis is not clear (Chung and Wiley 2002). Several biological effects of SWT that could promote the healing process have been detected through in-vivo and in-vitro experiments and are summarised in the sections below.

2.2.5.1 Biological response to shock wave therapy

Some studies suggest that SWT has a neuro-inhibitory effect, which explains why this treatment leads to pain reduction. Ohtori et al. (2001) applied low-energy focused SWT to the plantar skin of rats delivering 1000 pulses at an EFD of 0.08 mJ/mm^2 . The results showed that the number of afferent sensory fibres decreased significantly after the treatment. Maier et al. (2003) delivered 1500 high energy pulses at 1 Hz frequency and with an EFD of 0.9 mJ/mm^2 to the distal femur of rabbits. They found that the levels of substance P, a neuro-transmitter associated with inflammation and pain, decreased significantly six weeks after the treatment. Hausdorf et al. (2008) used the same experimental protocol to examine the hypothesis that SWT related long term analgesia is due to a selective loss of nerve fibres in peripheral nerves. They found that SWT resulted in selective substantial loss of un-myelinated nerve fibres, while not affecting large nerve fibres responsible for motor function. Some authors maintain that shock waves relieve pain by an effect that is not related to changes of local sensory fibres. They maintain that hyper-stimulation leads to an increased pain threshold that is mediated by the central nervous system (Wess 2008).

SWT is believed to promote the growth of new blood vessels and improve the blood supply to affected connective tissue (neovascularization). Wang et al. (2002) treated dogs with 1000 impulses of focused SWT at an EFD of 0.18 mJ/mm^2 . The shock waves were

focused at the Achilles tendon-bone junction for the hind limb. An examination performed 8 weeks after the treatment showed a significant increase in the number of capillaries at the tendon-bone junction. The same research group later performed experiments where rabbit Achilles tendons were treated with 500 impulses of shock wave at an EFD of 0.12 mJ/mm^2 . The results showed growth of new vessels in the treated animals whereas there was no vessel growth in a control group. Also, presence of biochemical factors promoting blood vessel growth was found in experimental animals exposed to SWT (Wang et al. 2003).

There is evidence that SWT creates effects at the cellular level that can promote the healing process and mediate inflammation. Chen et al. (2004) treated rats with 1000 impulses of focused SWT at an EFD of 0.16 mJ/mm^2 . Prior to the SWT treatment, Achilles tendonitis was induced in experimental animals by injecting them with collagenase, an enzyme that breaks down collagen. The healing process was found to be enhanced by the shock wave treatment. It was also found that SWT induced the proliferation of growth factors involved in the healing process. The authors attribute this proliferation of growth factors to the mechanical stimulation of mechanoreceptor cells. These are specialized cells that react to mechanical stimuli by triggering biochemical reactions. In a review article, Frairia and Berta (2011) postulate that the healing mechanism of SWT for tendinopathy is due to the mechanical stimulation of fibroblasts, mechano-responsive cells found in majority of tissues within the extracellular matrix.

In-vitro studies have been performed to examine the effect of rSWT on factors involved in an inflammatory response. The results show that rSWT could lead to a mediation of the inflammatory process. Benson et al. (2007) treated articular cartilage specimens obtained post-mortem from horses with radial waves. Up to 5000 pulses were delivered at a 10 Hz frequency with a driving pressure of 2.5 bar. The applicator was placed at 4 mm distance from the specimen with the gap filled with a coupling gel. The results showed that rSWT has a positive effect on the metabolism of chondrocytes (cells found in normal cartilage). Sugioka et al. (2010) exposed Achilles' tendon cells harvested from rats to rSWT. The applicator was placed in direct contact with cell suspension and 1000-2000 pulses were delivered at 10 Hz with a driving pressure of 3 bar. The results showed that shock waves decrease the concentration of substances that stimulate an inflammatory response.

2.2.5.2 Physical mechanisms leading to favourable biological response

Currently there is no coherent theory on the exact physical mechanism through which SWT produces biological effects in soft and connective tissue as documented in experimental studies. One mechanism that is mentioned by a number of authors is cavitation (Delijs et al. 1995; Chow and Cheing 2007; Murata et al. 2007). The occurrence and dynamics of cavitation depends on the existence and size of nuclei, the magnitude and the duration of the negative pressure waveform, and boundary conditions (McClure and Dorfmueller 2003). There is limited information on the mechanism of the formation of cavitation bubbles within the tissue and the critical negative pressure at which this occurs. Coleman et al. (1995) combined in-vivo and in-vitro experiments to determine critical levels of negative pressure at which cavitation occurs in focused SWT used for lithotripsy. The in-vivo experiments consisted of monitoring the tissue affected by shock waves during the clinical lithotripsy treatment of 30 patients. New echo clouds in ultrasound images were associated with regions of cavitation in the tissue. Next, shock waves were generated in water and the pressure was measured using a hydrophone in the regions corresponding to echo clouds observed in the patients. The measurements revealed that the minimum value of negative pressure at which cavitation occurs is between -1.5 and -3.5 MPa. As this level of negative pressure should occur routinely in rSWT, it is to be expected that this type of shock wave treatment can also induce cavitation in soft tissue. Figure 2-29 shows the pressure field of a radial shock wave source in water clearly indicating cavitation bubbles near the applicator.

Figure 2-29: Cavitation from a radial shock wave source (Schmitz 2010).

Shearing of the soft tissue is believed to be a factor in generating injury to the kidneys in lithotripsy (Weinberg and Ortiz 2009). However, this mechanism is rarely mentioned within the context of SWT treatment of musculoskeletal conditions. Nevertheless, the possibility that micro injury caused by the shearing of soft tissue in the affected region promotes the healing process cannot be ruled out.

2.3 Computer Modelling

2.3.1 Computer Modelling of Shock Wave Therapy

Relatively few computer models have been developed to examine the effect of SWT. Most of the studies focus on lithotripsy and on the mechanism through which kidney stones are fractured (Cleveland and Sapozhnikov 2005; Sapozhnikov et al. 2007). However, studies relevant to the application of focused and radial SWT for the treatment of musculoskeletal conditions have also been conducted (Benoit 2009; Fagnan 2010)

Cleveland and Sapozhnikov (2005) developed a computer model of a kidney stone and surrounding tissue to investigate the mechanisms of stone fracture in focused SWT.

The kidney stone was of idealised (cylindrical) shape and was assumed to behave as a linear elastic medium characterised by a longitudinal speed of sound $c_L=3000$ m/s. The tissue surrounding the stone was represented as a fluid having the properties of water ($\rho=1000$ kg/m³, $c=1500$ m/s). A finite difference scheme widely used for treating problems in geo-media was used to conduct the simulations. The SWT pressure pulse was modelled as an initial condition in the form of a typical pressure waveform from a focused SWT source. The results suggest that the pressure wave from the device generated shear waves at the outer edge of the stones that had a stronger effect on the fracture than the spall effect. Also, the rise time had a strong effect on the stresses generated in the stone with shorter rise times resulting in higher stresses. In a follow-up study, Sapozhnikov et al. (2007) combined experiments and numerical simulation to further investigate the mechanisms of kidney stone fracture. Cylindrical cement stones were subjected to shock waves from a focused SWT travelling through water and the experiment was also simulated via a computer model. The results pointed to the shear waves at the corners of the stone as one of the mechanisms for fracture.

Weinberg and Ortiz (2009) developed a finite element model of a kidney and the surrounding tissue to examine the causes of tissue damage related to the application of SWT to break kidney stones (Figure 2-30). Two damage mechanisms were considered: tissue shearing due to the positive pressure peak, and cavitation due to the negative pressure. A shear stress of 2 kPa was set as an injury threshold for the shearing mechanism (approximately 150 times lower than the shear modulus used for the kidney tissue). The results from the finite element model served as the input for a separate mathematical model of micro-bubble dynamics, which was used to examine cavitation-related damage mechanisms. The kidney tissue was modelled as a hyperelastic material, which is a type of material for which the stress-strain relation is derived from a strain energy density (U). This material model is well-suited for describing the behaviour of nearly incompressible materials for which the stress strain relation is not linear but it is also not dependent on the rate of deformation. Typical examples of materials that exhibit this type of behaviour are rubbers and soft biological tissue. The constants for the hyperelastic material of the kidney were determined to match the shear modulus determined from small-deformation numerical calibrations. The bulk modulus was assumed to be close to that of water. Loading conditions were derived from a typical shock wave pressure trace and were

prescribed in terms of initial node velocities at a portion of the kidney surface (Figure 2-30). The velocities were related to the pressure as: $V = p/\rho c$. It was concluded that both shearing and cavitation may occur at locations at which kidney bruising is observed, i.e., in the focal zone and immediately in front of it.

Figure 2-30: Finite element model of a kidney to examine tissue damage due to SWT (Weinberg and Ortiz 2009).

In a PhD thesis presented at the University of Washington, USA, Fagnan (2010) developed a numerical method to simulate shock formation and propagation in focused SWT. As part of a preliminary validation of the numerical method, a 2D model of an experimental shock wave generator and a model of the foot were constructed to simulate propagation of a shock wave through the tissue of the foot (see Figure 2-31). The foot was represented only partially and it consisted of bony structures and soft tissue. The soft tissue was given properties of water, whereas the bone tissue was modelled as a linear elastic material. The emphasis of the simulations was on the accurate focusing of shock waves. The results showed that anatomical structures of the treated area have a strong effect on the location of the point at which the energy of the waves is focused. The thesis provides little detail on the foot model. However, it is significant since it represents the only attempt to simulate shock wave therapy applied to the foot.

Figure 2-31: Modelling of the focused shock wave therapy: pressure contours (Fagnan 2010).

Benoit (2009) created finite element models to simulate his experiments with the Hopkinson bar and with a soft tissue phantom, which have been summarised in Section 2.2.3.2. The experiment and FE modelling were then used interactively to gain further insight into the physical aspects of radial shock wave therapy. The Hopkinson bar experiment was simulated with a highly simplified axi-symmetric model consisting of the projectile, a 15 mm applicator and a section of the Hopkinson bar, as shown in Figure 2-32. The casing and o-rings were not represented and it is not clear whether and how the applicator was constrained. The model was implemented in the ABAQUS explicit finite element package (ABAQUS Inc., Pawtucket, RI, USA). The contacts between all components were simulated using a penalty force-based algorithm. Initial conditions were prescribed in terms of the initial velocity of the projectile. Very good agreement was obtained between experimental and computer model results in spite of the simplifications used in the model. The simulations showed that 30% of the kinetic energy of the projectile is transmitted to the applicator, of which only about 10% is transmitted from the applicator to the Hopkinson bar.

Figure 2-32: Finite element model of the radial shock wave source and Hopkinson bar (Benoit 2009).

A schematic of the shock wave device and soft tissue phantom models is shown in Figure 2-33. Again, the model geometry was axi-symmetric. The model of the shock wave device consisted of the projectile, applicator, front part of the casing, and o-rings. The applicator was of the standard 15 mm radial type. The pre-load of 35 N that was applied in the experiment was not modelled. Instead, a tied contact was applied between the applicator and the soft tissue. Tied contact was also prescribed between all components of the phantom, whereas a sliding contact was applied between the o-rings and the casing. The casing was represented as a rigid object and it was restrained from moving. All components were meshed with four node elements. Initial conditions were assigned in terms of the initial velocity of the projectile. The material models of o-rings and silicone rubber were not reported. A hyperelastic material model was used for the soft tissue. For the initial projectile velocity of 14.9 m/s, the model results were highly consistent with the experiment. For lower initial projectile velocities, the computational and experimental results were consistent only for the first $4\mu\text{s}$, which roughly coincides with the first positive peak of pressure. The author attributed this discrepancy to the limitation of the material model used for the biological tissue.

Figure 2-33: Finite element model of the radial shock wave source and an experimental phantom consisting of pork skin/fat and silicon rubber by Benoit (2009).

2.3.2 Finite Element Modelling of the Foot

The finite element (FE) method has been widely used in studying different parts of the human body such as the shoulder, knee, and hip joints. However, the development of anatomically detailed FE foot models was only initiated in the late 90's (Cheung 2008; Cheung et al. 2009). A number of two-dimensional (2D) and three-dimensional (3D) finite element models have been developed since then to study and explore the biomechanics of the foot and ankle. While most of the studies focus on static or quasi-static problems related to locomotion, they are highly relevant for the modelling related to SWT, as they tackle the issues of the reconstruction of complex foot geometries, the modelling of articulations and connective tissue, and specification of tissue material properties.

2.3.2.1 Two-dimensional finite element models

Two-dimensional models of the foot have been developed to investigate problems such as the effectiveness of footwear (Nakamura et al. 1981; Lemmon et al. 1997; Erdemir et al. 2005; Cheung 2008; Covill et al. 2008; Cheung et al. 2009), mechanics of plantar soft tissue (Verdejo and Mills 2004; Spears et al. 2005; Erdemir et al. 2006; Goske et al. 2006), and the mechanics of plantar fascia (Giddings et al. 2000; Gefen 2002; Actis et al. 2006; Wu 2007). Most of the models are based on the sagittal plane sections but coronal plane models have also been developed (Goske et al. 2006).

Figure 2-34: Two-dimensional model of the foot and shoe sole by Nakamura et al. (1981)

Nakamura et al. (1981) were the first to undertake an FE analysis of the foot in 1981. They developed a 2D FE foot model of a unified bony structure of the foot; plantar soft tissue and a shoe sole. Material properties were determined experimentally from a cadaveric foot. The geometry, loading conditions and constraints are displayed in Figure 2-34. Vertical forces of 1800 N and 1200 N were applied to represent body weight and Achilles tendon, respectively; the sole of the foot was constrained to the ground. Young's modulus of the shoe sole was varied between 0.08 – 1000 MPa to determine its optimal value in terms of minimising the plantar pressure, which was found to be between 0.1 and 1 MPa.

Lemmon et al. (1997) investigated the plantar pressure under the second metatarsal head by developing a 2D model of the second metatarsal bone, plantar soft tissue, and insole. Only a small section of the foot extending from the proximal end of the second metatarsal to the metatarso-phalangeal joint was represented in the model. The model geometry was reconstructed from a video image of a post-mortem specimen. Two soft tissue thicknesses beneath the metatarsal head were considered: 12 mm to represent the normal subject and 3 mm to represent the pathological condition. The plantar soft tissue, polyurethane insole, and mid-sole were defined as hyperelastic materials, whereas the bone was assumed to be linear elastic. In order to simulate push-off, loading was applied to the metatarsal head. It was found that as the peak plantar pressure increases when the insole thickness is decreased; the insole was more effective in the case where the plantar soft tissue thickness was below its normal value. This study is significant since it introduced a

hyper-elastic material model for plantar tissue which was used in many subsequent FE models of the foot. The parameters for the plantar tissue material were determined from in-vivo force-deformation experiments performed on five subjects.

Figure 2-35: Model of the second metatarsal, soft tissue, midsole, and plug

by Erdemir et al. (2005)

Erdemir et al. (2005) introduced a slight modification to the same model to investigate the effect of plug material, geometry, and placement on plantar pressure reduction under the second metatarsal head (Figure 2-35). Thirty six plug designs, six geometries, a combination of the three materials, and two different plug insertion places were studied. Large plugs (40 mm in width) were found to be the most effective in reducing the peak plantar pressure.

Giddings et al. (2000) developed a 2D model from mid-sagittal computer tomography (CT) images to evaluate the effect of loading on the calcaneus, tendons, and ligaments for the entire gait cycle in walking and running. The model included the talus, calcaneus, midfoot, fused bony structures of the forefoot, plantar fascia, joint capsule, and Achilles tendon. The plantar fascia and ligaments were represented as tension-only spring elements. The soft tissue of the foot was not represented in the model. The measured ground reaction forces and major ankle moments were applied as loading to simulate

walking and running at speeds of 1.6 m/s and 3.7 m/s, respectively. The model predicted that the calcaneus stored the maximum strain energy at 70% and 60% of stance during walking and running, respectively.

Figure 2-36: Two-dimensional model of the foot by Actis et al. (2006).

Actis et al. (2006) developed a 2D model of the second and third metatarsal rays of the foot to study the plantar pressure distribution in diabetic patients during push-off. Models of different levels of complexity were considered. The most complex model configuration consisted of fused rearfoot and midfoot structures, three phalangeal bones, one metatarsal, Achilles tendon, plantar fascia, and soft tissue as shown in Figure 2-36. All the bones were connected by cartilage. The geometry was reconstructed from CT scans. The study concluded that the least complex model to accurately assess the plantar pressure beneath the metatarsals head should consist of toe, metatarsal, tendon, fascia and soft tissue.

Figure 2-37: Two-dimensional model of the calcaneus and heel pad by Erdemir et al. (2006).

A number of studies focused on the loading response of the heel pad using highly simplified coronal plane 2D models of calcaneus and plantar soft tissue. Verdejo and Mills (2004) studied the changes in the distribution of plantar pressure during barefoot running and running with a foamed midsole. They developed a 2D finite element model of the calcaneus and heel only, with the heel pad being assigned hyper-elastic material properties. Erdemir et al. (2006) developed a non-linear model to investigate different material properties of heel pads on 20 non-diabetic subjects and 20 diabetic subjects under vertical compression (Figure 2-37). Subject-specific heel pad tissue properties were calculated by combining FE modelling and ultrasound indentation techniques to determine the stress-strain behaviour. It was found that there is no significant difference in the heel pad thickness and stiffness between the diabetic and non-diabetic subjects. Goske et al. (2006) examined 27 shoe insole designs using a 2D finite element model of the foot. Three types of insole materials, three insole thicknesses, and three categories of conformity levels (flat, half conforming, and full conforming) were examined in the study. It was found that the most important design factor was the insole conformity and insole thickness.

The most evolved 2D models of the foot that treated the mechanics of plantar fascia are those developed by Gefen (2002) and Wu (2007). They are described in more detail below. Gefen (2002) developed 2D models of the foot to study the effect of plantar fasciotomy on the static structural behaviour of the foot. Five models were created, one for each vertical plane aligned with the five rays of the foot (see Figure 2-38). The geometries

were reconstructed from the magnetic resonance imaging (MRI) scans of a healthy volunteer.

Figure 2-38: Two-dimensional models for the five rays of the foot (Gefen 2002).

The models comprised of bones, cartilages, ligaments, plantar fascia, and soft tissue. Ligaments and plantar fascia were modelled to be of uniform thicknesses of 1.8 mm and 2 mm, respectively. The thickness of ligaments and the locations of their insertions were based on the information from the classical texts on anatomy. The space between the adjacent bones was filled with cartilage which fused the bones together. A linear elastic material was used for the bones and non-linear material models for other tissues. A pressure load was applied on the top of the talus/calcaneus to represent half a body weight (300 N), which was distributed between the five rays. In addition, a vertical Achilles tendon force of 30 N was applied at the posterior aspect of the calcaneus for each of the five rays. The models were constrained at the plantar surface. Plantar fascia release was simulated by decreasing the fascia thickness in intervals of 25% until it was completely detached. The effects of the fasciotomy were discussed in terms of the deformation of the longitudinal arch and stress in the ligaments and metatarsals. It was

concluded that total fasciotomy results in excessive stresses and deformations of the foot. The same model was later exploited to analyse plantar soft tissue loading under the metatarsals in standing for diabetic and non-diabetic subjects (Gefen 2003).

Wu (2007) presented similar but anatomically more detailed models which were used to investigate stresses and deformations in the foot due to fasciotomy and plantar ligament injuries. Two dimensional models of the second and fifth ray were constructed to represent medial and lateral longitudinal arches, respectively.

Figure 2-39: Wu's model of the second ray of the foot (Wu 2007).

1 cortical bone ; 2 trabecular bone; 3 fat pad; 4 plantar fascia; 5 flexor digitorum brevis; 6 quadratus plantae; 7 spring lig.; 8 long plantar lig.; 9 tendon of tibialis posterior; 10 tendon of peroneus longus; 11 oblique head (adductor hallucis); 12 tendon of flexor digitorum longus; 13 tendon of flexor digitorum brevis; 14 plantar interossei; 15 dorsal interossei; 16 lumbricals; 17 tendon of extensor digitorum brevis; 18 tendon of extensor digitorum longus; 19 sagittal plane joints; 20 the second toe; 21 the second metatarsal; 22 intermediate cuneiform; 23 navicular; 24 talus; 25 calcaneus (medial); 26 dorsal lig. of joints; 27 plantar lig. of joints; 28 cuboid; 29 cervical lig.; 30 interosseous talocalcaneal lig.; 31 tarsal canal lig.; 32 cartilage; 33 posterior talocalcaneal lig.; 34 Achilles tendon

The model was based on CT and MRI scans of a cadaveric foot taken at 1mm intervals, which were used to construct a three-dimensional solid model ("Virtual Chinese Female" No. 1). It is not stated in the paper how the 2D finite element models of the second and fifth ray were extracted from the 3D solid model. The model of the second ray is displayed in Figure 2-39. The model included bones, cartilage, ligaments, tendons, plantar fascia, intrinsic muscles, and fat pad. Bones were connected to each other with

cartilage. The directions and insertion points of tendons, ligaments and plantar fascia were determined using the MRI information of "Virtual Chinese Female". Eight material models, linear elastic and hyperelastic, were used in the model. Following Gefen (2002), the body weight was assumed to be distributed as 25-19-19-19-18% from the first to the fifth ray, whereas the Achilles tendon force was assumed to be distributed evenly between the five rays. The model was also loaded with the plantar pressure, whereas the top of the talus was constrained from moving. The conclusion was that plantar fasciotomy results in an increase of stress in the arches of the foot. The authors also suggested that a compensatory action of the intrinsic plantar muscles may be required to counter this effect.

2.3.2.2 Three-dimensional finite element models

A number of three-dimensional models of the foot were constructed from the mid-1990s to analyse various aspects of foot biomechanics. While early models used idealised geometries, virtually all models published since 2002 are based on realistic geometries obtained from medical images of actual human feet.

Chu et al. (1995) developed an early 3D model of the foot and orthosis to study the stress distribution in the soft tissue of the foot in walking. The foot model had a highly idealised geometry. It consisted of bones which were lumped into a single object, soft tissue, and ligaments. The ligaments were represented as tension-only truss elements. The peak stresses were found at the head and neck of the orthosis. The stress distribution in the orthosis was more sensitive to the modulus of the orthosis material than the modulus of the soft tissue material.

Jacob and Patil (1999) established a more anatomically realistic model of the foot which consisted of bones, cartilages, ligaments, and soft tissue. The foot geometry was reconstructed from x-ray scans. Only the plantar portion of the foot soft tissue was included in the model. The bones were connected together with cartilage at the joints. Simulations of heel-strike, mid-stance, and push-off were achieved by aligning the metatarsophalangeal joint angle and the associated plantar soft tissue and applying the ankle joint forces and predominant muscle forces at the points of insertion. The response of Hansen's disease with muscle paralysis was studied by reducing the thickness of the cartilages between the talus, navicular, and the cuneiforms and by neglecting the action of peroneal and dorsiflexor muscles. The highest stress level was predicted in the metatarsals

and the dorsal junction of the calcaneus and cuboid during push-off. Stress levels in the tarsal bones increased with simulated muscle paralysis. A further study was performed by the same group (Jacob and Patil 1999) to investigate the soft tissue stiffness effects on the distribution of stress in patients with diabetes. In this study, elastic moduli of normal and stiffened soft tissue were represented at 1 MP and 4 MP, respectively. The results of the study showed that the maximum normal stresses at the plantar foot tissue were higher with tissue stiffening.

Gefen et al. (2000) developed a non-linear elastic model of the foot based on a realistic geometry which included cartilage, ligament, bones and soft tissue. The geometry was reconstructed from MRI scans of the feet of a 27 year old male subject. The model consisted of a total of 17 bony elements that were interconnected by cartilage at the joints. Only the plantar portion of the soft tissue was included. Although not entirely clear from the text, it appears that only a slice of the plantar tissue (including plantar fascia) beneath the fourth and fifth metatarsals was included in the model. The ankle joint and the major muscular forces were applied to simulate six stance phases and the model structures were adapted for each stance phase. This was achieved by alternating the inclination of the foot and alignment of the phalanges and plantar soft tissue. According to the findings, the model predicted the highest stress levels in the dorsal mid metatarsals from mid-stance to toe-off.

A 3D foot model consisting of the bony structures, major plantar ligamentous structures, and soft tissue, was developed by Chen et al. (2003) to estimate the plantar foot pressure and bone stress. The geometry was reconstructed from CT images. The joint spaces of the metatarsophalangeals and the ankle joint were connected with cartilaginous structures, whereas the rest of the bony structures were merged together. Ligaments and plantar fascia were represented as tension-only trusses. The results showed that the peak stress region shifts from the second metatarsal to adjacent metatarsals in various phases of walking.

Bandak et al. (2001) developed a 3D model of the foot to investigate the mechanism of the impact response of major bones using dynamic analysis. Computer topography scans were used to reconstruct idealised geometries of the 26 bones of the foot as well as the tibia and fibula. Both cortical and trabecular bone tissues were taken into account in the model. Bones of the midfoot and forefoot were fused together and assumed

to be rigid while the rear-foot bones were assumed to be elastic. Only the plantar portion of the soft tissue was included in the model. The ligaments were represented as membranes, the Achilles tendon was represented as a tension-only truss, and the plantar fascia was not included in the model. Cadaveric feet were used for validation proposes. For velocities higher than 4.45 m/s (14.6 ft/s), the model predicted higher force and acceleration peak amplitudes than the experiments. Kitagawa et al. (2000) later used the same model to study the mechanism of the impact behaviour of the foot under compression.

A 3D model of the heel has been developed by Spears et al. (2005) based on CT scan images to investigate the relationship between the stress distribution in the heel tissue with different heel-ground angles. Only a section of the soft tissue of the foot in the heel region was represented in the model. Bones and plantar fascia were not modelled explicitly. Rather, zero displacement conditions were imposed at the surface interfaces between soft tissue and bones/plantar fascia. Force-displacement data from in-vitro experiments was used to develop the hyperelastic material model used for the soft tissue. The model predicted the greatest internal compressive stress on the heel pad underneath the calcaneus.

Since 2004 the most active research group was the one led by Jason Tak-Man Cheung. Cheung et al. published a series of studies which were based on the variations of essentially one same finite element model of the foot. The focus of the studies included: the effect of the plantar fascia stiffness on the stability of the foot (Cheung et al. 2004), sensitivity analysis for the tissue material properties (Cheung et al. 2005), the effect of socks on the biomechanics of walking (Cheung et al. 2006), foot-footwear interaction, the effect of Achilles tendon loading on the plantar fascia tension in standing (Cheung et al. 2006), and parametric design of foot orthoses (Cheung and Zhang 2005; Cheung and Zhang 2008).

Figure 2-40: A detailed three-dimensional model of the foot (Cheung et al. 2004).

As Cheung's model currently presents the state of the art in foot modelling, it will be described in more detail. The model is displayed in Figure 2-40. The geometry was based on MR images of a healthy volunteer which were taken in the coronal plane with 2 mm intervals. The images were segmented using the MIMICS software (Materialise, Leuven, Belgium) to obtain the outer surface of the bones and the soft tissue. The solid model was imported into the ABAQUS software package to form the FE model. The FE model included all 26 bones of the foot as well as distal portions of the tibia and fibula. The phalanges were fused with 2 mm thick solid elements representing the cartilage. For the other bones of the foot, sliding contacts without friction were modelled at the articulations. A total of 72 ligaments were represented by tension-only truss elements. The plantar fascia was represented using 10 tension-only truss elements. The points of attachment of the ligaments and fascia were determined using the Interactive Foot and Ankle software (Primal Picture Ltd. UK). All encapsulated soft tissue was represented as a single entity with non-linear material properties. The other components of the model were assigned linear elastic properties. The Achilles tendon was not included in the model

geometry. Rather, it was represented by five concentrated forces acting on the posterior extreme of the calcaneus.

In the two studies by Cheung et al. that focused on the plantar fascia (Cheung et al. 2004; Cheung et al. 2006), the model was constrained at the top surfaces of the tibia and fibula. The plantar surface of the foot was in contact with a flat plate representing the ground. Loading was applied to the plate beneath the center of pressure (ground reaction force equaling one half of the body weight) and at the Achilles tendon insertion (one half of the ground reaction force). The effect of fasciotomy was simulated by varying the Young's modulus of the plantar fascia from 0-700 MPa, where the zero modulus corresponded to complete plantar fascia release. The results showed that a decrease in plantar fascia stiffness led to an increase in stress in the metatarsal bones and the plantar ligament, and an increase in the deformation of the foot. However, even total release of the plantar fascia did not result in the collapse of the foot arch.

Figure 2-41: Model of the foot including a solid model of the plantar fascia (Cheng et al. 2008).

Cheng et al. (2008) presented a 3D model of the foot to analyse the effect of stretching the planter fascia. The model consisted of 26 bones of the foot, 69 ligaments, and the planter fascia. Soft tissue of the foot was not included in the model. The major novelty was that the plantar fascia was for the first time represented as a solid 3D structure. Thus, the fascia was modelled as a 2 mm thick fan-like structure with non-linear elastic material properties which extended from the calcaneal tubercle to the proximal phalanges (see Figure 2-41). Stretching by toe dorsiflexion and Achilles tendon pulling was simulated by assigning displacement of the toes and applying Achilles tendon force while the movement of the medial cuneiform and cuboid bones was constrained. The model results

were consistent with those reported in studies on cadaveric feet. One of the main conclusions of the study was that toe flexion is an effective means of stretching the plantar fascia for the purpose of treating plantar fasciitis.

Sun et al. (2012) developed a 3D model of the foot to study the biomechanical effects of different foot arches on other structures of the foot. The model consisted of bones, soft tissue, cartilage, and plantar fascia. All parts of the foot were idealised as homogeneous, linearly elastic except for the plantar fascia. Plantar fascia was modelled as truss elements with non-linear force displacement properties. The study suggests that both stress and strain of the plantar fascia were higher in a high arched foot, whereas the stresses of bony structures were higher in the low arched foot.

2.3.2.3 Analysis of modelling strategies in current FE models of the foot

Current FE models of the foot range from those that rely on fairly simple 2D idealised representations of only a portion of the foot to those that present anatomically accurate 3D geometries of the whole foot. The general trend is towards 3D foot models based on subject-specific, realistic geometries. The process of constructing such models is illustrated in Figure 2-42. First, high resolution scans of a foot are obtained through medical imaging (CT or MRI). These are then imported into a professional software package for geometry reconstruction. Geometries of various components of the foot (bones, ligaments) are extracted automatically, semi-automatically, or manually using the software. The output is in the form of CAD files (IGS, STL), one for each of the foot component. Although this is not always stated in the literature, there is often an intermediary step in which such files are further processed in another CAD package before being loaded into an FE package. Once the CAD files are imported into FE software they can be meshed and material properties, boundary conditions, and loading conditions can be defined to formulate the FE model.

Figure 2-42: Process of geometry reconstruction for subject specific finite element models of the foot (Antunes et al. 2008).

Modelling of the connective tissue, articulations, and soft tissue

In the vast majority of 3D models the connective tissue, plantar fascia, ligaments, and Achilles tendon, are represented using tension-only truss elements with linear or non-linear behaviour. In a large number of studies the Achilles tendon is omitted and its effect is accounted for by applying a load at the insertion point on the calcaneus. Some 3D models represent ligaments as shell structures; these are attached to the bones but have no direct interaction with the surrounding soft tissue. The only 3D model that represented planter fascia as a solid entity is the one presented by Cheng et al. (2008). However, this model did not include the soft tissue. To the best of the author's knowledge, there are currently no 3D models of the whole foot that represent the Achilles tendon with a realistic three-dimensional geometry. A number of 2D models do include the plantar fascia and Achilles tendon as objects embedded in the surrounding tissue.

In the current models, articulations are treated in different ways depending on their importance and the focus of the study. The articulations are sometimes neglected by fusing the adjacent bones into single entities. At the next level of sophistication the adjacent

bones are fused by filling the gap between them with a "cartilage" that "glues" them together. This is the approach taken by all 2D models and also by a number of 3D models. Finally, in some 3D models the joints, whose movement is important for the biomechanical function of the foot, are modelled by prescribing a sliding contact between the articulating surfaces of the bones forming the joint. In this case the associated ligaments play a critical role of stabilising the joint in a realistic manner.

The soft tissue of the foot is sometimes completely omitted, sometimes presented only in its plantar portion, and sometimes modelled for the whole foot. In the latter case, the soft tissue is almost always presented as a single entity that combines plantar fat and intrinsic muscles. The only model that presented significant differentiation between various components of the soft tissue is the 2D model by Wu (2007).

Material models

The material models used in current models of the foot are almost exclusively linear elastic and hyperelastic. The linear elastic materials are characterized by any two of the following four parameters: Young's modulus (E), shear modulus (G), Poisson's ratio (ν) and bulk modulus (K). In published studies linear elastic properties of tissues in the foot are usually defined via their Young's modulus and Poisson ratio. Table 2-3 summarises all combinations of relations between the linear elastic coefficients.

Table 2-3: Conversion formulas for linear elastic constants

	(K, E)	(K, G)	(K, ν)	(E, G)	(E, ν)	(G, ν)
K	K	K	K	$\frac{EG}{3(3G - E)}$	$\frac{E}{3(1 - 2\nu)}$	$\frac{2G(1 + \nu)}{3(1 - 2\nu)}$
E	E	$\frac{9KG}{3K + G}$	$3K(1 - 2\nu)$	E	E	$2G(1 + \nu)$
G	$\frac{3KE}{9K - E}$	G	$\frac{3K(1 - 2\nu)}{2(1 + \nu)}$	G	$\frac{E}{2(1 + \nu)}$	G
ν	$\frac{3K - E}{6K}$	$\frac{3K - 2G}{2(3K + G)}$	ν	$\frac{E}{2G} - 1$	ν	ν

The two hyperelastic models used in finite element models of the foot are the generalised Rivlin and Ogden models. The strain energy function for the generalised Rivlin materials is defined as follows:

$$U = \sum_{i+j=1}^2 C_{ij} (\bar{I}_1 - 3)^i (\bar{I}_2 - 3)^j + \sum_{i=1}^2 \frac{1}{D_i} (J - 1)^{2i} \quad 7$$

where I_1 and I_2 are the first and second invariants of the deformation tensor, J is the relative volume change, and $\bar{I}_{1,2} = J^{-2/3} I_{1,2}$. Constants C_{ij} and D_i are related to distortional and volumetric behaviour, respectively. The Mooney-Rivlin model is a special case of the generalised Rivlin model for which:

$$U = C_{01} (\bar{I}_2 - 3) + C_{10} (\bar{I}_1 - 3) + \frac{1}{D_1} (J - 1)^2 \quad 8$$

The simplest form of the generalized Rivlin model is the neo-Hookean model for which the strain energy function is defined as:

$$U = C_{10} (\bar{I}_1 - 3) + \frac{1}{D_1} (J - 1)^2 \quad 9$$

In the small deformation limit the constants of Rivlin hyperelastic models can be related to equivalent linear elastic parameters as follows:

$$G = 2(C_{01} + C_{10}); K = \frac{2}{D_1} \quad 10$$

The strain energy density function for the Ogden materials is given by:

$$U = \sum_{i=1}^N \frac{2\mu_i}{\alpha_i^2} \left[(\lambda_1^{\alpha_i} + \lambda_2^{\alpha_i} + \lambda_3^{\alpha_i} - 3) + \frac{1}{D_i} (J-1)^{2i} \right] \quad 11$$

Where $\lambda_i, i=1,2,3$ are the principal stretches, α_i and μ_i are constants related to distortional behaviour, and D_i are constants defining volumetric behaviour. In the current models of the foot the first order incompressible Ogden material is used such that:

$$U = \frac{2\mu_1}{\alpha^2} (\lambda_1^\alpha + \lambda_2^\alpha + \lambda_3^\alpha - 3) \quad 12$$

In this case the relations between the linear elastic and hyperelastic constants are given by:

$$G = \mu \text{ and } K = \infty \quad 13$$

An overview of material models used in current finite element models for all structures in the foot is given in the tables and text below. For brevity, only one reference is given for each of the material models reported, although some of them appear in a number of studies. For each of the reported materials, all linear elastic constants were calculated from the information given in the literature and using relations given in Table 2-3. For hyperelastic materials, equivalent linear elastic constants were determined using Equations 10 and 13. Finally, the values of the wave speeds C_L and C_S were determined for each material.

Table 2-4 summarises the material properties used for the bone tissue. A linear elastic model is assumed in all studies with E and ν used to define elastic properties of the material. Some studies differentiate between the cortical and trabecular bones, while others represent both as the same type of tissue. There is a fair level of consistency between various authors in terms of material constants. The values of C_L calculated from the

constants for cortical or "non-specified" bone tissue fall within the experimentally determined range reported in Table 2-1. However, for the trabecular bone, the values of C_L are below the values reported in Table 2-1. This discrepancy can be attributed to the fact that the living trabecular bone is a porous material consisting of a solid matrix and fluid-filled cavities (Wear et al. 2000; Cardoso et al. 2003). The bulk modulus of the combined matrix and fluid is higher than that of the solid matrix alone, which was probably used to specify constants given in Table 2-4.

Table 2-4: Linear elastic constants and wave speeds for the bone (NS: not specified, C: cortical, T: trabecular)

Type	E (Pa)	ν	ρ (kg/m ³)	G (Pa)	K (Pa)	C_L (m/s)	C_S (m/s)	Reference
NS	1.0×10^{10}	0.34	1600	3.73×10^9	1.04×10^{10}	3070	1527	(Lemmon et al. 1997)
NS	7.30×10^9	0.3	1600	2.81×10^9	6.08×10^9	2449	1325	(Jacob et al. 1996)
C	1.70×10^{10}	0.3	2000	6.54×10^9	1.42×10^{10}	3342	1808	(Shin et al. 2012)
C	1.90×10^{10}	0.3	1800	7.31×10^9	1.58×10^{10}	3724	2015	(Bandak et al. 2001)
T	5.31×10^8	0.3	500	2.04×10^8	4.43×10^8	1181	639	(Bandak et al. 2001)
T	4.45×10^8	0.3	1100	1.71×10^8	3.71×10^8	729	394	(Shin et al. 2012)

As in the case of bone, cartilage is modelled as a linear elastic material whose elastic properties are defined through E and ν . Wu (2007) is the only one who used a neo-Hookean hyperelastic model. The parameters of this hyperelastic model were determined by converting the linear elastic constants used by Jacob and Patil (1999). As can be seen in Table 2-5, there is a fair level of discrepancy between the values of parameters used by various authors. Young's moduli differ by two orders of magnitude and the Poisson's ratio ranges between 0.07 and 0.49. This is probably due to the fact that the term "cartilage" is used to denote all tissue/materials in a joint (e.g. tendons, synovial fluid) rather than cartilage tissue in the strict sense of the word. The material density is not reported in the papers, and the value of 1000 kg/m³ is used as a first approximation. The calculated values given in the Table are well below the speed of wave propagation in the bone and soft tissue, and are probably an underestimation of the real values. The calculated values of shear modulus and C_S are reasonably consistent across the studies.

Table 2-5: Linear elastic constants and wave speeds for the cartilage

E (Pa)	ν	ρ (kg/m ³)	G (Pa)	K (Pa)	C_L (m/s)	C_S (m/s)	Reference
1.00×10^7	0.49	1000	3.36×10^6	1.67×10^8	414	58	Jacob and Patil (1999)
1.00×10^7	0.4	1000	3.57×10^6	1.67×10^7	145	60	(Chen et al. 2003)
1.00×10^6	0.4	1000	3.57×10^5	1.67×10^6	46	19	(Cheung and Zhang 2008)
1.00×10^6	0.07	1000	4.67×10^5	3.88×10^5	31	22	(Cheung et al. 2006)
1.00×10^7	0.1	1000	4.55×10^6	4.17×10^6	99	67	(Actis et al. 2006)
5.00×10^6	0.1	1000	2.27×10^6	2.08×10^6	70	48	(Actis et al. 2006)
1.00×10^8	0.4	1000	3.57×10^7	1.67×10^8	460	189	(Cheng et al. 2008)
7.00×10^5	0.49	1000	2.35×10^5	1.17×10^7	109	15	(Bandak et al. 2001)
1.00×10^6	0.1	1000	4.55×10^5	4.17×10^5	31	21	(Gefen et al. 2000)
9.70×10^5	0.07	1000	4.53×10^5	3.76×10^5	31	21	(Isvilanonda et al. 2012)
1.20×10^7	0.42	1000	4.23×10^6	2.50×10^7	174	65	(Giddings et al. 2000)

In most of the studies, the plantar fascia is modelled as linear elastic with a Young's modulus $E=350$ MPa, and with a Poisson's ratio between 0.4 and 0.47, as shown in Table 2-6. Only Actis et al. (2006) used a zero Poisson's ratio for reasons that are not entirely clear. Cheng et al. (2008) used a five-constant Rivlin hyperelastic model and assumed incompressibility (Table 2-7). The equivalent linear elastic constants calculated from this material model are consistent with linear elastic parameters used in other studies (Table 2-6). The values of C_L calculated from the material parameters reported by Cheung and Nigg (2007) and Tao et al. (2009) are close to the speed of sound in water. For other reported studies the calculated values of C_L are lower (excluding the infinite wave speed for incompressible hyperelastic materials). The values of G and C_S are highly consistent across the reported studies.

Table 2-6: Linear elastic constants and wave speeds for the plantar fascia

E (Pa)	ν	ρ (kg/m ³)	G (Pa)	K (Pa)	C_L (m/s)	C_S (m/s)	Reference
3.50×10^8	0.47	1000	1.19×10^8	2.00×10^9	1465	345	(Cheung and Nigg 2007)
3.50×10^8	0.4	1000	1.25×10^8	5.83×10^8	860	354	(Gu et al. 2010)
3.60×10^8	0.47	1000	1.22×10^8	2.00×10^9	1467	350	(Tao et al. 2009)
3.50×10^8	0.42	1000	1.23×10^8	7.29×10^8	940	351	(Giddings et al. 2000)
8.50×10^7	0	1000	4.25×10^7	2.83×10^7	285	206	(Actis et al. 2006)
Linear elastic constants and wave speeds calculated from hyperelastic Rivlin parameters given in Table 2-7							
4.13×10^8	0.5	1000	1.38×10^8	∞	∞	371	(Cheng et al. 2008)

Table 2-7: Hyperelastic parameters for the plantar fascia: Rivlin model

C_{10} (Pa)	C_{01} (Pa)	C_{11} (Pa)	C_{20} (Pa)	C_{02} (Pa)	D_1 (Pa ⁻¹)	D_2 (Pa ⁻¹)	Reference
-2.22×10^8	2.91×10^8	4.73×10^6	-1.13×10^6	7.96×10^7	0	0	(Cheng et al. 2008)

In the earlier studies the soft tissue of the foot was modelled as linear elastic. More recent studies treat soft tissue as hyperelastic using either Rivlin or Ogden models. The linear elastic constants, including those calculated from corresponding hyperelastic parameters, are given in Table 2-8, Table 2-9, and Table 2-10 summarise parameters for Rivlin and Ogden materials, respectively. All linear elastic and Rivlin models are consistent in terms of (equivalent) Young's modulus. However, the wave speed C_L is underestimated by an order of magnitude. The only material model that implies a realistic value for C_L is the one by Verdejo and Mills (2004). The constants C_{01} and C_{10} for this model were derived from linear elastic parameters taken from Chen et al. (2003), whereas D_1 was chosen so that the bulk modulus is approximately the same as that of water. The studies using Ogden's hyperelastic models all assume incompressibility of the soft tissue. The equivalent elastic moduli for these materials are lower than those for linear elastic or Rivlin hyperelastic materials.

Table 2-8: Linear elastic constants and wave speeds for the soft tissue

E (Pa)	ν	ρ (kg/m ³)	G (Pa)	K (Pa)	C _L (m/s)	C _S (m/s)	Reference
1.15×10 ⁶	0.49	1000	3.86×10 ⁵	1.92×10 ⁷	140	20	(Chen et al. 2003)
1.50×10 ⁵	0.45	1000	5.17×10 ⁴	5.00×10 ⁵	24	7	(Cheung et al. 2004)
1.00×10 ⁶	0.49	1000	3.36×10 ⁵	1.67×10 ⁷	131	18	(Jacob and Patil 1999)
4.50×10 ⁵	0.45	1000	1.55×10 ⁵	1.50×10 ⁶	41	12	(Tao et al. 2009)
Linear elastic constants and wave speeds calculated from hyperelastic Rivlin parameters given in Table 2-9							
1.20×10 ⁶	0.4999	1000	4.00×10 ⁵	2.00×10 ⁹	1414	20	(Verdejo and Mills 2004)
1.58×10 ⁵	0.452001	1000	5.43×10 ⁴	5.48×10 ⁵	25	7	(Cheung et al. 2005)
1.57×10 ⁵	0.442934	1000	5.43×10 ⁴	4.58×10 ⁵	23	7	(Lemmon et al. 1997)
Linear elastic constants and wave speeds calculated from hyperelastic Ogden parameters given in Table 2-10							
3.25×10 ³	0.5	1000	1.08×10 ³	∞	∞	1	(Chokhandre et al. 2012)
4.94×10 ⁴	0.5	1000	1.65×10 ⁴	∞	∞	4	(Goske et al. 2006)
5.00×10 ⁴	0.5	1000	1.67×10 ⁴	∞	∞	4	(Erdemir et al. 2006)
4.29×10 ⁴	0.5	1000	1.43×10 ⁴	∞	∞	4	(Erdemir et al. 2005)

Table 2-9: Hyperelastic parameters for the soft tissue: Rivlin model

C ₁₀ (Pa)	C ₀₁ (Pa)	C ₁₁ (Pa)	C ₂₀ (Pa)	C ₀₂ (Pa)	D ₁ (Pa ⁻¹)	D ₂ (Pa ⁻¹)	Reference
1.00×10 ⁵	1.00×10 ⁵	0	0	0	1.00×10 ⁻⁹	0	(Verdejo and Mills 2004)
8.56×10 ⁴	-5.84×10 ⁴	-2.32×10 ⁴	3.9×10 ⁴	8.51×10 ³	3.65×10 ⁻⁶	0	(Cheung et al. 2005)
8.56×10 ⁴	-5.84×10 ⁴	-2.32×10 ⁴	3.9×10 ⁴	8.51×10 ³	4.37×10 ⁻⁶	6.81×10 ⁻⁷	(Lemmon et al. 1997)

Table 2-10: Hyperelastic parameters for the soft tissue: Ogden model.

μ_1 (Pa)	α_1	D_1 (Pa ⁻¹)	Reference
1.08×10^3	9.78	0	(Chokhandre et al. 2012)
1.65×10^4	6.82	0	(Goske et al. 2006)
1.67×10^4	6.92	0	(Erdemir et al. 2006)
1.43×10^4	7.3	0	(Erdemir et al. 2005)

Wu (2007) was the only author to represent intrinsic foot muscles separate from the rest of the soft tissue. He used an incompressible Mooney-Rivlin material with $C_{10}=120$ kPa, and $C_{01}= 60$ kPa. This corresponds to $E=1.08$ MPa and $G=36$ MPa in the linear elastic domain and is very similar to material properties used for the soft tissue by many authors.

2.4 Discussion

Plantar fasciitis is a chronic condition that affects a significant section of the general population. Shock wave therapy is emerging as an effective treatment method for plantar fasciitis in the situation when the condition persists in spite of more conventional conservative treatments and the only remaining alternative is invasive surgery. Although some doubts still remain about the efficiency of SWT for the management of musculoskeletal disorders, there is a growing body of evidence in favour of its effectiveness. In spite of that, the understanding of the biological effects of SWT on the musculoskeletal system is limited, and the exact physical mechanisms behind these effects are even less well understood.

Shock wave therapy essentially comes in two distinct forms: focused and radial. As a relatively novel low-cost variation of shock wave therapy, radial SWT is far less well explored than the more established focused SWT techniques; this applies both to the physical effects it creates in the body and to the operation of pressure wave sources. The physical mechanisms of radial and focused SWT are very different, although this is often not fully appreciated in the medical community. Radial SWT does not produce shock waves, and it cannot focus the energy of pressure waves on a region within the body.

Pressure waveforms generated by this technique have much lower positive pressure amplitudes, but approximately equal negative pressure amplitudes compared to those produced by the focused SWT. Based on the information provided by the manufacturers of rSWT devices, it appears that this method is capable of operating at medium or even high energy levels. However, energy density levels reported for rSWT relate to the skin surface and they cannot be directly compared with energy levels of focused SWT sources. Thus, it is probable that rSWT is essentially a low energy therapy where the actual affected region of treatment is concerned. In spite of that, results from recent clinical studies suggest rSWT treatment for plantar fasciitis is equally effective, if not superior to a high energy treatment that requires more highly sophisticated focused wave sources.

Computer modelling has been used to a limited extent to gain better understanding of the way in which SWT operates. The majority of these studies are concerned with focused SWT and in particular with the physical mechanisms through which kidney stones are fragmented. Nevertheless, the results from the studies investigating the side effects of SWT, such as injuries to kidney tissue in lithotripsy, can also be useful for the understanding of the effects that SWT may create in the treatment of musculoskeletal disorders. There is only one study that produced an axi-symmetric 2D finite element model of the radial SWT source. Although the results from that model appear to be consistent with experiments, many of the modelling details were not fully reported.

In contrast to computer modelling of SWT, there is an abundance of finite element models of the foot developed over the last two decades. The existing finite element models of the foot, and particularly those developed recently, serve as a good reference for the foot model to be developed and used in this study. The specific purpose of the model, i.e., simulation of short-duration dynamic loading dominated by the propagation of stress waves through foot structures, has to be taken into account when deciding on which modelling strategies should be adopted from the existing models, and whether novel features have to be introduced. A three-dimensional model geometry is necessary to be able to accurately simulate the propagation of radial (spherical) waves in the foot. This is essential since the variation of pressure amplitude and EFD with depth (distance from the source) cannot be captured accurately with a 2D model. A 3D approach for the foot geometry implies that the same approach has to be adopted when representing the shock wave source.

Since the focus of this study is on a pressure wave-based therapy for a plantar fascia condition, it is essential to represent the plantar fascia as a three-dimensional object. Furthermore, it is necessary to embed the plantar fascia into the soft tissue, since this is the medium through which pressure waves propagate from the source. This will represent a new milestone in modelling as virtually all existing foot models ignore the interaction between the plantar fascia and soft tissue of the foot. The articulations between the bones of the foot should be represented in such a way as to avoid gaps that would result in unrealistic wave reflections. With this in mind, it can be concluded that the approach where the bones are fused together or connected with cartilage should be more appropriate than applying sliding contacts at the joints. The overview of material models used to characterise various tissues in the foot revealed that from the perspective of their acoustic properties, many of the material models may be questionable. This particularly applies to the soft tissue where most of the reported material models imply unrealistically low values of longitudinal sound wave speeds. This is likely to be due to the fact that in many cases the Poisson's ratio was chosen somewhat arbitrarily, which resulted in an underestimate of the bulk modulus. This will have to be taken into account when assigning material properties for the components of the foot model.

3 Modelling and Validation of the Radial Shock Wave Device

The objective of the work reported in this chapter was to create a finite element model of the radial shock wave therapy device. This model would later be coupled with the finite element model of the foot in order to simulate shock wave therapy for plantar fasciitis. The specific type of device represented in the model was the Swiss DolorClast handpiece with a standard 15 mm radial applicator. The guiding principle in the development of the model was to achieve physically accurate behaviour with minimal complexity of the model. This was motivated by the need to keep the computational cost at a minimum, bearing in mind the complexity and size of the foot model. The assessment of the model performance was based on the information regarding the dynamics of shock wave devices reported in the literature as well as on the measurement of applicator displacement carried out as a part of this project.

3.1 Experiment to Characterise Pressure Wave Device Dynamics

An experiment was conducted in order to obtain independent information on the dynamics of the shock wave device. The device tested was the same as the one used for the computed model (Swiss DolorClast with a 15 mm diameter applicator, as described in Section 2.2.3). The parameter measured was the longitudinal displacement of the applicator. The data obtained from the experiment was used to provide guidance for choosing the input parameters for the computer model (mainly when damping of the applicator motion was concerned) and for validation of the model. The experimental setup is shown in Figure 3-1. The device was held in a custom made clamping system (Christodouloulis 2011). The system consisted of a clamp and vertical pre-load bar which were attached to a heavy metal base secured to structural beams in the laboratory for stability. The pre-load bar was machined to fit the frontal cap and had an opening to allow for the free movement of the applicator. The internal casing of the device is suspended onto a spring which serves to guide the clinician to apply a pre-load of at least 30 N (for a fully compressed spring). Prior to being secured with the clamp, the front end of the device was pressed against the pre-load bar until the spring was completely compressed. This

eliminated any movement of the inner casing of the device restricting the displacement to the applicator alone. A laser interferometer (optoNCDT 2220 high speed laser sensor, Micro-Epsilon, Birkenhead, UK) was used to measure the displacement of the applicator. The laser sensor has a linear (voltage) output, a maximum measurement range of 10 mm and a resolution of $0.15 \mu\text{m}$. The maximum sampling rate is 20 kHz which is sufficient for capturing the bulk movement of the applicator, but does not allow the measurement of displacements associated with the stress wave in the applicator. The laser sensor was clamped independently of the pressure source as shown in Figure 3-1. The pressure device was set to a single pulse mode and a driving pressure of 2 bar.

Figure 3-1: The experimental setup for measuring the displacement of the applicator. A: schematic representation. B: actual setup.

The output from the laser sensor was digitized using a data acquisition card (NI USB 6221 DAQ device, National Instruments, USA), sampled at 20 kHz and stored on a laptop for further analysis. The results showed that the applicator consistently exhibited the same displacement pattern for several experimental runs. A typical result is displayed in Figure 3-2. There is a forward motion with amplitude of just below 0.2 mm. The duration of the positive displacement phase is approximately 0.45 ms, which is followed by very weak oscillations which quickly die away. The overall pattern of movement is similar to that reported by the manufacturer for a 6 mm applicator and a 4 bar driving pressure (Figure 2-17), except that in the experiment the displacement was somewhat larger, the period was also larger, and the damping of oscillatory movement was even more pronounced. The differences in the results can be attributed to the larger mass of the applicator and the lower impact velocity of the projectile (lower driving pressure setting).

Figure 3-2: Displacement of the 15 mm diameter applicator for a single pulse and driving pressure of 2 bar.

3.2 Modelling

3.2.1 Model Configuration

The main reference for setting the configuration of the geometrically realistic model was the axi-symmetric model of a radial shock wave source presented by Benoit (2009) (Section 2.2.3). The main difference was that in this study a 3D modelling approach was adopted. The reason was that the model of the device was eventually to be coupled with the foot model for which axi-symmetry does not apply. Following Benoit, only the front portion of the device was represented in the model (Figure 3-4); there was no need

for including the guiding tube, as the process in which the projectile is accelerated by compressed air was not simulated. The front cap was modelled in detail, while the rear part of the casing was represented in a simplified form and it served mainly to keep the o-rings in place. In Benoit's model the casing geometry was set in such a way that a perfect fitting existed between the casing and the o-rings without any pre-load. However, preliminary modelling studies conducted at the University of Surrey (Fuchs 2012) suggested that this approach results in an overly stiff behaviour of the o-rings. Thus, in the model developed in this project the space for the o-rings had an initial clearance and tight fitting was achieved through pre-load (tightening of the front cap). The dimensions for the components of the shock wave source were obtained by taking measurements from an actual device which was disassembled into components as shown in Figure 2-16 (Section 2.2.3). The measurements were conducted at the machine workshop at the University of Surrey. The device was obtained courtesy of the clinicians from the Royal Surrey County Hospital, Guildford, UK with permission from the manufacturer. The geometric model of the device components was created using the ANSYS Workbench – Design Modeller (ANSYS Inc., Pittsburgh USA). The details of the model geometry for the applicator and casing are displayed in Figure 3-3. These correspond to actual parts which are shown in Figure 2-16. The front and rear o-rings have inner diameters of 14 mm and 6.8 mm, respectively, and they are both 2 mm thick. The projectile has a cylindrical shape with a length of 15.5 mm and a diameter of 6 mm.

of the time step is restricted by stability considerations; in order for the scheme to be stable, the time step has to be smaller than the time needed for the fastest wave to traverse the smallest element in the mesh. Thus, in explicit code the simulation time is determined not only by the size of the model (number of nodes and elements), but also by the element size and material properties (giving wave speed) which dictate the size of the time steps.

LS-DYNA does not include a pre-processor, meaning that the finite element mesh has to be generated using a different software and then imported into LS-DYNA. The finite element mesh for the model components was generated using the ANSYS Explicit module. Due to the complexity of the models (of the device and foot), tetrahedral elements were used to create the mesh. The main advantage of using tetrahedra is that complicated geometries can be meshed with relative ease. The disadvantage of using this type of element is that the number of elements is higher than for a hexahedral mesh with elements of the same overall size. In ANSYS Explicit, two types of tetrahedral meshes can be created: patch independent and patch conforming. In patch independent meshing, the priority is put on keeping the size of the elements roughly equal, even if geometric entities such as faces and edges are not always respected. In patch conforming meshes, geometric entities such as faces, edges, and vertices are preserved at the expense of sometimes having to use elements of very small sizes. Due to time step requirements, patch independent meshing is preferred for explicit time integration and this is the meshing approach taken in this project. The element size was set at 1 mm for all model components except the o-rings, which had to be meshed with 0.5 mm size elements in order to preserve geometric features. In total, the model comprised of 37437 nodes and 181758 elements. The finite element mesh is shown in Figure 3-4.

Figure 3-4: Finite element model of the pressure source.

In LS-DYNA the input is in the form of an ASCII file with extension “.key” referred to as a “key-file”. A key-file contains all the information needed to fully define all aspects of a model such as geometry, material properties, boundary and initial conditions, contacts and other body interactions, and result outputs. The input is specified using commands called KEYWORDS. All keyword commands start with a star sign (*) to distinguish them from the input parameters. Each LS-DYNA key-file starts with the *KEYWORD command and ends with the *END command. A keyword command is issued in a single line of the input file and is followed by lines containing input parameters related to that keyword and set in a specified format. The geometry in LS-DYNA is defined entirely via nodes and elements of the finite element mesh. Physical entities (objects) in the model are referred to as “parts” and they are defined via the *PART keyword. The *PART keyword specifies the material of the part and the element formulation used for the elements forming the part. The material and element formulations are in turn defined via *MAT and *SECTION keywords, respectively. Elements are defined using the *ELEMENT keyword which specifies the nodes of an element as well as the part to which the element belongs. Finally, the nodes are defined via the *NODE

keyword specifying coordinates of the nodes. An example of how a part is specified using a hierarchically organized set of keywords is illustrated in Table 3-1. The *PART keyword defines a part entitled “Applicator” and assigns the part identification number (pid) to be 1. The *PART keyword also specifies that the section id number for that part (secid) is 2 and the material id number (mid) is 1. The *SECTION_SOLID keyword defines a section entitled "Applicator_Elements" with id number 2. The "_SOLID" portion of the keyword specifies that this section refers to solid elements, and the element formulation (elform) number 10 means that the elements are four node constant stress tetrahedrons. The keyword *MAT_ELASTIC defines the material "Steel" with id number 1 as a linear elastic material with a density (ro) of 7800 kg/m³, Young’s modulus (e) of 200 GPa, and Poisson coefficient (pr) of 0.3. The *ELEMENT_SOLID keyword defines solid elements via two lines of parameters. The first line defines the element id number (eid), and the id number of the part to which the element belongs (pid). The second line specifies id numbers of nodes at the vertices of the element (n1... n8). For a tetrahedral element with four nodes, the id numbers of nodes n5 – n8 are the same as n4. Finally, the *NODE keyword defines the node id number (nid) and node coordinates (x,y,z).

Table 3-1: Part of the key-file defining the model of the device

*PART									
\$# title									
Applicator									
\$# pid secid mid									
1 2 1									
*SECTION_SOLID									
Applicator_Elements									
\$# secid elform									
2 10									
*MAT_ELASTIC									
Steel									
\$# mid ro e pr									
1 7800.000 2.0000E+11 0.30000									
*ELEMENT_SOLID									
\$# eid pid									
1 1									
\$# n1 n2 n3 n4 n5 n6 n7 n8									
1 5337 8132 4317 4317 4317 4317 4317 ...									
*NODE									
\$# nid x y z									
1 0.0039773 -0.0044656 0.0175500 . . .									

The model is comprised of six parts: applicator, projectile, outer casing, inner casing, rear o-ring and front o-ring. The element formulation used for all the parts was a single integration point constant stress tetrahedron. The option with additional averaging of nodal pressures was used for the o-rings. This element formulation is recommended for incompressible or nearly incompressible materials such as rubber and soft tissue in order to avoid volumetric locking (Erhart 2011). The materials used for the different components of the model are given in Table 3-2. The material for the applicator and projectile was steel whereas the material of the outer casing was aluminium. The masses of the projectile and applicator were 3.4 g and 25.7 g, respectively. The inner casing was assigned elastic constants corresponding to steel in spite of this part being represented as a rigid body. This was because the contact algorithm uses Young's modulus to calculate the penalty force between two objects. The Mooney-Rivlin hyperelastic material was used for the rubber material of the o-rings. This material model was the model of choice for all nearly incompressible soft materials in the models developed in this project. This is because this material model is supported in LS-DYNA by the element formulation with nodal pressure averaging. Other hyperelastic models such as the Ogden model are also available in LS-DYNA, but node average tetrahedrons are not supported for such a material in the current version of the software. The material constants for the Mooney-Rivlin material of the o-rings were taken from a recent study on the dynamic behaviour of o-rings by Liao, Huang et al. (2013). Other authors used similar properties for o-ring materials (Green and English 1992).

Table 3-2: Material formulations used for the components of the shock wave device model.

	Type	Parameters
Projectile	Linear elastic	$E = 200\text{GPa}; \rho = 7800\text{kg/m}^3; \nu = 0.3$
Applicator	Linear elastic	$E = 200\text{GPa}; \rho = 7800\text{kg/m}^3; \nu = 0.3$
Outer casing	Linear elastic	$E = 69\text{GPa}; \rho = 2712\text{kg/m}^3; \nu = 0.3$
Inner casing	Rigid	$E = 200\text{GPa}; \rho = 7800\text{kg/m}^3; \nu = 0.3$
O-rings	Mooney-Rivlin	$C_{10} = 1.933\text{ MPa}; C_{01} = 0.4830\text{ MPa}; \rho = 1150\text{ kg/m}^3; \nu = 0.499$

LS-DYNA provides a variety of boundary conditions, initial conditions and body interactions. Those relevant for the modelling performed in this study are briefly outlined below:

- Boundary conditions in terms of prescribed movement can be specified by assigning a time-dependent displacement or velocity to a group of nodes or to a rigid object. This type of boundary condition is set using the *BOUNDARY_PRESCRIBED_MOTION keyword. The other type of boundary condition used in this project is “non-reflective boundary”, that is, a surface over which waves propagate without any reflections. This type of boundary condition is defined using the *BOUNDARY_NON_REFLECTING keyword.
- The type of initial condition relevant for this study is the one in which initial velocity is assigned to objects (parts) or to sets of nodes. The *INITIAL_VELOCITY_GENERATION keyword can be used to define initial motion of a part by specifying translational and rotational velocity components in all three directions.
- In LS-DYNA, contact between two objects occurs only if it is specified using the appropriate keyword. There are two main types of contacts: sliding or surface-to-surface, and tied. Sliding contacts are implemented via a “penalty force” which is generated when a small penetration occurs between two interacting objects, and which acts to oppose the penetration. A tied contact between two deformable objects is implemented by locking the nodes which are on the shared surface of the two objects. The tied contact with offset assures all the nodes which are within a distance called “contact thickness” are locked together. The contact thickness can be specified as one of the parameters of the *CONTACT keyword. All contacts can be switched on and off by specifying "birth" and "death" times.
- Constraints are used to impose restrictions on the movement of two rigid objects relative to each other, or to tie a node to a “master” rigid object. The *CONSTRAINED_EXTRA_NODES keyword was used in this project to attach nodes that are physically not on a rigid object to that rigid object.

The full details of boundary conditions, initial conditions, and body interactions used in the modelling of the radial shock wave source are given in the next section.

3.2.3 Simulations

The simulations consisted of two phases. In the first "pre-load" phase, the distance between the inner and outer casing was decreased to simulate the tightening of the front cap of the device and the pre-loading of the o-rings. The second "impact" phase simulated the actual projectile impact onto the applicator. Since LS-DYNA only has the capacity to simulate dynamic problems, the pre-load phase had to be treated as a dynamic event which eventually results in static equilibrium. In order to reduce the time needed to reach the equilibrium, artificial damping was prescribed to the nodes of the model by using the *DAMPING keyword. The damping coefficient set in the *DAMPING keyword should be approximately equal to the circular frequency of the lowest mode of oscillation for the whole system so that the system is critically damped (Livermore Software Technology Corporation 2003). That frequency was determined by examining the movement of the applicator when the pre-load was implemented in the absence of any damping. The effect of damping on the time needed to reach equilibrium is illustrated in Figure 3-5 which displays the bulk displacement of the applicator during the pre-load phase, with and without artificial damping. The simulation was separated into two phases by first running the pre-load simulation, and then restarting the model from the state reached at the end of pre-load to start the simulation of impact. Restarting the model allowed the input file to be modified so that in the impact phase the results database was updated at a higher frequency. However, the simple restart procedure used in this study allowed only limited modifications to the key-file. For example, the initial conditions cannot be changed at restart. Consequently, the projectile had to be given an initial velocity at the beginning of the pre-load phase and to be positioned in such a way as to reach the applicator at the end of the pre-load phase. Also, changes in contacts were implemented by specifying "birth" and "death" times rather than modifying the key-file at restart. The summary of the simulation settings for the pre-load phase are listed below:

- The nodes at the rear surface of the front cap were constrained from any movement.
- From $t=0$ to $t=1$ ms the inner casing was prescribed constant axial speed of 0.8 m/s such that it moved by 0.8 mm in total. From $t=1$ ms onwards the rear part of the casing was constrained from moving.
- The projectile was given initial speed of 9, 12.3, or 14.9 m/s in the axial direction.

- A sliding contact was prescribed between the o-rings and both parts of the casing. A typical friction coefficient between metal and rubber of 0.8 was used in the contact (Oscar and Centeno 2009). A tied contact was prescribed between the o-rings and the applicator.
- Artificial damping with a damping coefficient of 12000 s^{-1} was prescribed for all the components of the model except for the projectile whose velocity would otherwise be affected.
- The total time was set to 2 ms.

For the simulation phase representing the impact, the settings were the same as for the pre-load phase except for the following changes:

- Damping was switched off for all components except for the o-rings.
- A tied contact was assigned between the inner and the outer casing. The contact surface corresponds to the threads by which the front cap is attached to the casing of the device.
- A sliding contact without friction was assigned between the projectile and the applicator.

3.3 Results and Discussion

The dynamics of the pre-load phase of simulation is illustrated in Figure 3-5, which shows the axial displacement of the applicator with time. The broken line shows the results in the absence of any dissipation whereas the solid line displays the results when a damping of 12000 s^{-1} was prescribed to the model components. With the addition of damping, the overshoot displacement and oscillatory motion were eliminated and equilibrium was reached more quickly. The applicator displacement levels off after approximately 1 ms, and at 2 ms (at the end of the pre-load phase) it is completely stable. At the end of the pre-load phase the applicator was displaced by approximately 0.28 mm, meaning that most of the prescribed displacement of the inner casing (0.8 mm) was absorbed by the deformation of the rear o-rings. The o-rings experienced large-scale deformation. The distribution of stress in the device and the deformation of the o-rings at the end of the pre-load phase were illustrated in Figure 3-6.

Figure 3-5: Displacement of the applicator in the pre-load phase.

Figure 3-6: Stress distribution in the device at the end of pre-load phase.

3.3.1 Overall Dynamics

The overall dynamic behaviour of the device in the impact phase as predicted by the model in the absence of any artificial damping is illustrated in Figure 3-7. Figure 3-7 A shows the “rigid body displacement” and Figure 3-7 B shows the “rigid body velocity” of the applicator after being impacted by the projectile moving at 12.3 m/s. The initial speed of the projectile corresponds to the driving pressure of 2 bar, as shown by experiments discussed in Section 2.2.3.1. During the impact, the applicator rapidly reached the velocity of 2.76 m/s. That value roughly corresponds to the value predicted by a simple theory of perfectly elastic collision which gives $V = 2m_1V_0/(m_1 + m_2) = 2.86 \text{ m/s}$, where V is the speed of the applicator after the impact, V_0 is the initial speed of the projectile, and m_1, m_2 are the masses of the projectile and applicator, respectively. Upon impact, the applicator displayed persistent oscillatory movement without a sign of amplitude decay. The amplitudes of the positive displacement (forward movement) and the negative displacement were approximately the same equalling about 0.256 mm. Similarly, the duration of the positive and negative displacement phases were almost the same, equalling approximately 0.275 ms. The displacement and the velocity were out of phase.

Figure 3-7: Overall dynamic response of pressure wave source in the absence of dissipation.

A: displacement of the applicator, B: velocity of the applicator.

The dynamics of the applicator's overall movement is further clarified by examining the energy fluctuations of the various components of the device as shown in Figure 3-8. The figure displays the total energy (kinetic + strain) of the projectile, applicator, rear o-ring, and front o-ring. The energy of the casing was negligible and therefore it is not included in the figure. Prior to the impact, the net energy of the system was almost entirely due to the movement of the projectile (kinetic energy) and the pre-loading of the o-rings (strain energy). More energy was stored in the rear (smaller) o-ring, which experienced a higher degree of deformation than the front o-ring. At the moment of impact, there is a rapid exchange of energy between the projectile and the applicator which took place over approximately 10 μ s. During that time the energies of the o-rings remained largely unchanged. Energy exchange during the impact is shown in more detail in Figure 3-9. From that point on the energy of the projectile, which bounced back upon impact, remains constant and the energy of the applicator fluctuated with its bulk movement. The energy of the applicator did not fall to zero at any point since some elastic energy was stored after the projectile impact. There was an energy exchange between the applicator and the o-rings. As the applicator moved forward from the equilibrium point, its kinetic energy was fed into the front o-ring which was increasingly deformed; the energy of the rear o-ring decreased as the deformation caused by the pre-load was relaxed. At the point of largest forward displacement, the applicator stopped and it was accelerated back by the recoil of the front o-ring. Once it passed the equilibrium point, the energy of the applicator was fed into the rear o-ring, while the energy of the front o-ring decreases.

Figure 3-8: Total energy of model components with no dissipation in the model.

Figure 3-9: Total energy of model components during the impact of the projectile on the applicator.

The results for the overall dynamics of the applicator shown in Figure 3-7 are consistent with the reported experimental results in terms of the order of magnitude of the

amplitude of movement and duration of the positive displacement phase. However, in the absence of an energy dissipation mechanism, the movement of the applicator took the form of persistent oscillations rather than being quickly damped, as happens in reality. While it is not entirely clear how the energy is dissipated in the real device, it is reasonable to assume that energy dissipation mainly involves the o-rings; the results suggest that the energy transferred to the front cap is negligible. Therefore, in order to introduce energy dissipation, damping was prescribed to the o-rings until the displacement pattern of the applicator roughly matched the experimental results. Figure 3-10 A and B show the displacement and velocity of the applicator in the case where artificial damping was added to the o-rings. The damping coefficient was set at $5.0 \times 10^6 \text{ s}^{-1}$. During the impact, the applicator reached the velocity of 2.71 m/s, which is only slightly lower than in the case where the damping was absent. However, the movement of the applicator was now in the form of highly damped oscillations; after the initial positive displacement phase the movement quickly died away. The maximum displacement from the equilibrium position was 0.17 mm and the duration of the positive phase of displacement was approximately 0.326 ms which is reasonably consistent with the experimental data shown in Figure 3-2.

Figure 3-10: Overall dynamic response of the pressure wave source with damping added to o-rings.

A: displacement of the applicator, B: velocity of the applicator.

The energy fluctuation for the model with damped o-rings is shown in Figure 3-11. The energy exchange during the impact is the same as in the absence of any damping. This is consistent with the result showing that the velocity of the applicator immediately after the impact was not affected by damping. During the positive displacement phase of the applicator motion there was an exchange of energy between the applicator and the o-rings but most of the energy received from the projectile was dissipated by the time the applicator returned to the equilibrium position.

Figure 3-11: Total energy of model components with damping added to the o-rings.

3.3.2 Impact and Stress Waves in the Projectile and Applicator

The mechanics of impact between the projectile and applicator and the subsequent stress waves in these two objects are analysed based on the results from the model without artificial damping, and with the initial velocity of the projectile of 12.3 m/s. This model configuration was chosen in order to examine the stress wave in “ideal circumstances”, where the dissipation is absent. Figure 3-12 shows the stress and velocity on the surfaces of the projectile and applicator where the contact between the two occurred. The result is shown for the period of time in which the two objects were in contact. Figure 3-12 A

displays the normal stress (in the axial direction) in an element on the area of contact in the projectile and an element on the area of contact in the applicator. Similarly, Figure 3-12 B shows the axial velocities of two nodes on the area of contact in the projectile and the applicator, respectively. The above mentioned nodes and elements were picked to be as close as possible to the axis of symmetry, although other nodes and elements on the area of contact gave almost identical results. The interaction between the projectile and applicator began at $t = 2.031$ ms (measured from the beginning of pre-load) at which time the stress started increasing simultaneously in the two objects. Until approximately $t = 2.0316$ ms, the velocities of the nodes on the contact surfaces of the projectile and applicator were not the same. This is probably due to the fact that the initial interaction between the two objects started once they were within the “contact thickness” distance, although their surfaces were not coincident. From $t = 2.0316$ ms to $t = 2.04$ ms the velocities of the projectile and applicator at their interface were the same. The stress continued increasing until approximately $t = 2.0367$ ms, at which point it reached the maximal value of approximately 580 MPa. This value is of the order of $\rho V_0 c_L$, where ρ is the density of steel, V_0 is the initial velocity of the projectile, and c_L is the speed of longitudinal waves in steel. At $t = 2.04$ ms the velocities of the projectile and applicator started diverging, while the stresses were still the same. Finally, at $t = 2.0412$ ms the interaction between the objects ended as the stresses on their contact surfaces were no longer the same. The entire duration of contact is therefore approximately 0.01 ms. This is consistent with previously discussed results (e.g. Figure 3-9).

Figure 3-12: Stress (A) and velocity (B) at the interface of the projectile and applicator during impact.

Figure 3-13, which shows the distribution of normal axial stress in a section of the device, illustrates the propagation of the stress wave during impact. At $t=2.0316$ ms, which corresponds to the moment at which the velocities at the contact surfaces become the same, the compressive stress wave reached the point at which there is an abrupt change in the radius of the applicator (see Figure 3-3). At $t=2.0338$ ms the compressive wave reached the end of the projectile and it was approximately midway through the applicator. At $t=2.0368$ ms the wave has reached the end of the applicator. Note that the stress wave did not reach the rim of the applicator at its widest part, and that due to abrupt changes in the radius of the applicator the wave was not one-dimensional. The reflected tensile wave in the projectile already started propagating from the free end toward the contact surface. At $t = 2.0412$ ms the stresses in the applicator and the projectile at their contact surfaces were both tensile and the objects separated.

Figure 3-13: Stress wave in the pressure wave source during the impact.

Figure 3-14 illustrates the effect of the projectile velocity on the stress at the contact interface between the projectile and the applicator for three different initial projectile velocities. It can be seen from the figure that the stress traces have almost identical shapes (but not amplitudes) regardless of the projectile velocity. The peak values of the normal stress are 434.9 MPa for $V_0 = 9\text{ m/s}$, 598 MPa for $V_0 = 12.3\text{ m/s}$ and 722.5 MPa for $V_0 = 14.9\text{ m/s}$. The ratio of the maximal stresses is the same as the ratio of the corresponding projectile velocities, which suggests that there is a linear relation between the contact pressure magnitude and the velocity of impact.

Figure 3-14: Stress at the interface of the projectile and applicator during the impact for three different initial velocities of the projectile.

The stress waves are further illustrated in Figure 3-15 and Figure 3-16 which show space-time plots of the stress in the elements along the axes of symmetry of the projectile and applicator, respectively. Here, the zero axial position was taken to be at the contact interface. Thus, the rear end of the projectile is at -15 mm and the front end of the applicator is at 25 mm. The data were obtained from the elements whose centroids were closest to the axes of symmetry. From the figures it can be seen that there are two distinct zones regarding the stress wave in the objects: the first zone in which the projectile and applicator are in contact with each other, and the second in which they are separated. The first zone is characterised by very high stress at the impact surface. This high stress generated by collision propagates in both directions towards the free ends of the projectile and the applicator. The magnitude of the stress decreases from the impact surface towards the free surfaces where the stress should be zero. The second zone is characterised by standing stress waves in both objects which are of much smaller amplitude than the stress generated during contact. These standing stress waves are persistent and show no sign of being quickly dissipated.

Figure 3-15: Stress on the axis of symmetry of the projectile over time.

Figure 3-16: Stress on the axis of symmetry of the applicator over time.

Figure 3-17 shows the envelope of stress amplitude along the axis of symmetry of the projectile and applicator after they have separated. Three different velocities of the projectile were considered. The curves were constructed by identifying the maximal value of stress at each location, over the whole simulated event after the impact. Maximal stress in both the projectile and the applicator is of the order of 10-100 MPa and it is somewhat larger in the projectile than in the applicator. For both the projectile and the applicator the stress is zero at the free ends which are the nodes of the standing wave. The stress distribution in the projectile has a simple shape of a half sine wave with the anti-node half way between the free ends. For the applicator, the stress distribution has a more complex shape with the maximal amplitude at approximately 5 mm from the impact end, which corresponds to the point where the diameter of the applicator increases suddenly from 5 to 11 mm. There are other local maxima at approximately 13 and 22 mm from the impact end. Also, there are local minima at approximately 10 and 18 mm. The more complex distribution of stress in the applicator is due to its more complex shape. For both the projectile and the applicator the shape of the stress envelope is the same regardless of the value of the initial projectile velocity. The stress values are on the other hand directly proportional to the projectile velocity, which is consistent with previous observations regarding the stress at the impact interface (Figure 3-14).

Figure 3-17: Stress envelope along the axis of symmetry after the separation. A: projectile, B: applicator.

As previously stated, the analysis of impact and wave propagation in the applicator and projectile was performed based on the results from the model that did not include any damping. For the model which included damping for the o-rings, the results for the stress wave did not differ significantly. This is illustrated in Figure 3-18 which shows normal stress waveforms for an element at the front end of the applicator, with and without damping. It can be seen that the waveforms are almost identical for the first fifty μs . The examination of the waveform for a full millisecond showed that there is good level of agreement for that whole period of time. This suggests that the dissipation in the o-rings has significant influence on the overall motion of the applicator but has very limited effect on the stress wave in the applicator.

Figure 3-18: Comparison of the stress waveforms at the front end of the applicator for the model with and without damping.

3.3.3 Simplified Model

The results presented in the previous sections of this chapter suggest that the mechanical response of the casing and o-rings could be approximated as a response of an arrangement of springs and dampers. This rationale is based on the fact that the bulk movement of the applicator is in the form of harmonic oscillations which are damped or un-damped depending on whether dissipation is added to the o-rings or not (Figure 3-2, 3-7 and 3-10). In this section, investigation has been performed in order to establish whether the casing and o-rings could be replaced by a simple spring-damper system without significantly affecting the results regarding the mechanical behaviour of the actual device. The advantage of using a simplified version of the model is a reduction of the computational cost of simulation. In particular, this simplified version of the model does not require a pre-load phase for the o-rings which is the most time consuming phase of the simulations. This is practical in situations where a large number of simulations have to be performed, for example when testing the effect of parameter variation on the results. The simplified model of the device is shown in Figure 3-19. The applicator and the projectile are still the same as in the original model. The o-rings were represented by a single spring

and single damper in parallel. The casing was represented by a rigid object whose only purpose was to provide an anchor for one side of the spring-damper system. Since the shape of the “casing” is irrelevant it was given the same shape as the projectile. The spring and damper use discrete elements defined via two nodes (nodes 1008682 and 1008681 in Figure 3-19). The spring and damper materials are defined via their corresponding constants. The ends of the spring and damper component were attached to the casing and applicator using the `*CONSTRAINED_EXTRA_NODES` keyword. As discussed previously, this keyword allows a node to be attached to a rigid body even when it is not physically on that body (see Section 3.2.2). Since the nodes can be constrained only to a rigid object, the outer surface of the rim of the applicator (blue surface in Figure 3-18) was overlaid with rigid shell elements. This shell served as the anchor for the other side of the spring-damper system. The location of the rigid shell anchor was chosen in such a way as to have the minimal effect on propagation of the stress wave in the applicator.

Figure 3-19: Model of the device with a spring-damper system representation of o-rings and casing.

The constants for the spring and damper elements were determined in the following way: the whole device was assumed to behave as a spring mass damper system which is given an initial velocity through the impact of the projectile on the applicator (mass). The spring constant was determined in such a way as to match either the frequency or the amplitude of the applicator displacement as predicted by the geometrically accurate model without damping. Since the spring stiffness' determined using the two different criteria were not the same, their average value was used in the model. Next, the damper constant was determined in the same way, using the previously calculated spring stiffness and comparing the frequency or the amplitude results with those of the geometrically accurate model with damping.

The simplified model of the pressure source was tested against the more geometrically accurate model by comparing results for the overall motion of the applicator and for the stress wave in the applicator. Figure 3-20 displays the results of the two models for displacement of the applicator with and without damping. It can be seen from the figure that a fairly good agreement exists between the models. However, it was not possible to perfectly match the frequency and amplitude of motion at the same time by using simple spring and damper approximation. It is possible that this could be achieved by using a more complex arrangement of springs and dampers to represent the casing and o-rings. However, due to the limited usage of the simplified model in this project, that possibility was not explored. Figure 3-21 shows the comparison of the results for normal stress and velocity which were obtained from an element and a node located on the front surface of the applicator on the axis of symmetry. There is a good general agreement between the two models especially immediately after the impact. However, the results do not match as well as those for bulk applicator displacement. In conclusion, it can be said that it would be justified to use the simplified model to perform tasks requiring a large number of simulations and aimed at acquiring general information on the pressure wave generated by the device. However, the geometrically accurate model should be used to simulate the actual shock wave therapy.

Figure 3-20: Comparison of the results for bulk applicator displacement obtained from the geometrically accurate and simplified model. A: no damping included, B: models with damping.

Figure 3-21: Comparison of the results obtained from the geometrically accurate and simplified model. A: normal stress at the tip of the applicator, B: axial velocity at the tip of the applicator.

3.4 Conclusions

An experiment was conducted in order to gain a better understanding of the bulk movement of the applicator after the projectile impact. A shock wave device was fixed in a custom-made holding mechanism and a laser interferometer was used to measure the applicator displacement for a single pulse (projectile-applicator collision). The pressure setting was 2 bar. The results showed that the amplitude and period of displacement were of the order of 10^{-4} m and 10^{-4} s, respectively, which is consistent with data reported in the literature. The motion of the applicator can be described as highly damped oscillations.

A finite element model of the radial shock wave device has also been developed. The geometry of the front part of the device (that was tested experimentally) was reproduced realistically in the model. Simulations of a single pulse were performed for the device being “fired in the air”. Two cases were examined; absence of damping and damping assigned to the o-rings. The model without damping yielded reasonably good results regarding the amplitude and period of applicator displacements, but could not accurately predict the rapid diminishing of movement observed in the experiment. The model that included damping to the o-rings was much more accurate in that sense. In both cases, the main energy flow associated with bulk applicator movement was between the projectile, applicator, and o-rings. The impact between the applicator and projectile and the subsequent applicator bulk motion happen at very different time scales; the duration of contact between the applicator and projectile is of the order of 10^{-6} s. Consequently, it can be said that the transfer of kinetic energy from the projectile to the applicator during the impact happens so fast that the applicator movement during that period is negligible. It was found that in the absence of damping the effect of the o-rings can be approximated to that of a linear spring.

The collision between the projectile and applicator generated stress waves in both objects. During the contact, the value of normal stress at the contact interface was of the order of 10^8 Pa. The compressive stress wave travels from the contact surface towards the free surfaces of the projectile and applicator where it reflects as tensile wave. In the applicator, the wave has three-dimensional character and there are reflections at locations of sudden change in the diameter. The objects separate when the stress at the interface becomes tensile. The time needed for this to happen is approximately equal to the time needed for the stress wave to traverse the applicator in both directions. After the

separation, there are standing waves in both the projectile and applicator. The amplitude of these waves is of the order of 10^7 Pa. The wave pattern is more complex in the applicator than in the projectile where it takes the form of a half-sine wave. It was found that the inclusion of damping in the o-rings has little effect on the stress wave generated by the impact.

Based on the results for the overall dynamic behaviour of the shock wave device, a simplified model was created in which o-rings and casing were represented as a spring and damper in parallel. The results from the simplified model were reasonably consistent with the results from the geometrically more realistic model.

4 Pressure Wave Modelling in Simple Systems

The objective of the work performed in this chapter was to gain a better understanding of the process of generation and propagation of pressure waves in soft tissue using the model of the radial shock wave device described in Chapter 3. At the same time, the simulations served to validate the model against the published experimental results. Finally, since the models of plantar soft tissue reported in the literature vary significantly in terms of their acoustic properties, special attention was also given to evaluating a number of soft tissue materials used in published studies.

4.1 Model Configuration

The model configuration is shown in Figure 4-1. As the tasks listed above require a large number of simulations, the simplified version of the shock wave device described in Section 3.3.3 was used so that the computational cost is reduced to a minimum. The shock wave device was applied to a hypothetical object. The object was of cylindrical shape with a diameter of 70 mm and a depth of 50 mm and represented generic “soft tissue”. The size of the object was chosen such that it was sufficiently large to allow the wave propagation pattern to be clearly followed, while avoiding excessive computational cost. Also, the size of the object was chosen to be of the same order as that of the human foot. The shape was set in such a way as to avoid the effect of wave reflections on wave propagation. The top surface of the object was shaped in such a way as to provide a perfect fitting for the tip of the applicator (see Figure 4-1 B). Otherwise, the interfacing of the device and object would have to be achieved through quasi-static pre-loading which would require large simulation times. The edges of the cylinder were given curvature in order to avoid a sharp transition between non-reflective and free surfaces, as these were found to result in unrealistic stress concentrations. All the components of the model were meshed with 1 mm patch independent 4-noded tetrahedra. A constant stress formulation with node averaging was used for the soft tissue and o-rings for the reasons explained in Chapter 3 (Section 3.3.2).

Figure 4-1: Model configuration used to characterise pressure wave generated by the radial shock wave device. A: the model setup. B: geometry and mesh for the “soft tissue object”.

The object was given the material properties of plantar soft tissue. Several material models were considered as listed in Table 4-1. These models were taken from published studies and were selected such as to represent the range of materials reported in the literature. The Ogden model by Goske et al. (2006), which is originally incompressible, was assigned the bulk modulus of water (2 GPa) to avoid infinite wave speed. In addition to the materials from the literature, a Neo-Hookean material was formulated with constants set such that they were consistent with the Mooney-Rivlin material formulation used by Verdejo and Mills (2004). This material was introduced to examine the significance of different formulations for hyperelastic models. Finally, water was also considered as this is the medium used in most experimental studies. Water was implemented in LS-DYNA as a solid with zero shear modulus using the *LINEAR_ELASTIC_FLUID key-word.

Table 4-1: Material models considered for the idealised soft tissue object

Material	Material model	Constants	Reference
Linear elastic 1	Linear elastic	$E = 1.15 \times 10^6 \text{ (Pa)}$; $\nu = 0.49$	(Chen et al. 2003)
Linear elastic 2	Linear elastic	$E = 1.50 \times 10^5 \text{ (Pa)}$; $\nu = 0.45$	(Cheung et al. 2004)
Hyperelastic 1	Mooney-Rivlin	$C_{10} = 1.00 \times 10^5$; $C_{01} = 1.00 \times 10^5 \text{ (Pa)}$ $D_1 = 1.00 \times 10^{-9} \text{ (Pa}^{-1}\text{)}$	(Verdejo and Mills 2004)
Hyperelastic 2	Ogden	$\mu_1 = 1.65 \times 10^4 \text{ (Pa)}$; $\alpha_1 = 6.82$; $K = 2.0 \times 10^9 \text{ (Pa)}$	(Goske et al. 2006)
Hyperelastic 3	Generalised Rivlin	$C_{10} = 8.56 \times 10^4$; $C_{01} = -5.84 \times 10^4$ $C_{11} = -2.32 \times 10^4$; $C_{20} = 3.9 \times 10^4$ $C_{02} = 8.51 \times 10^3 \text{ (Pa)}$ $D_1 = 3.65 \times 10^{-6} \text{ (Pa}^{-1}\text{)}$	(Cheung et al. 2005)
Hyperelastic 4	Neo-Hookean	$C_{10} = 2.00 \times 10^5 \text{ (Pa)}$ $D_1 = 1.00 \times 10^{-9} \text{ (Pa}^{-1}\text{)}$	
Water	Linear Elastic	$K = 2.0 \times 10^9 \text{ (Pa)}$	

For all the simulations performed, the boundary conditions were as follows: the casing was constrained from moving while the rigid shell at the outer rim of the applicator was allowed to move only in the axial direction; Non-reflective boundary conditions were set at all surfaces of the object except on its top surface on which the device was applied; The projectile was given an initial velocity of 9, 12.3 or 14.9 m/s. A sliding contact was assigned between the projectile and the applicator and a tied contact was assigned between the applicator and the object.

4.2 Results and Discussion

4.2.1 Pressure Waveform and the Effect of Soft Tissue Material Properties

Figure 4-2 and Figure 4-3 show the pressure waveform in an element at the surface of the soft tissue object located just beneath the applicator tip. The projectile speed used was 12.3 m/s (2 bar driving pressure). Due to the very different pressure (and time) scales for two groups of material models, the results are presented in two separate figures. From Figure 4-2 it can be seen that using hyperelastic models 1, 2, and 4 results in almost

identical pressure waveforms. This is in spite of the fact that these materials are based on different hyperelastic models (Mooney-Rivlin, Ogden, and Neo-Hookean). Generally, the magnitude of the predicted pressure and wave shapes are consistent with experimental results discussed in Chapter 2 (Cleveland et al. 2007; Benoit et al. 2009; DolorClast 2009); the maximum and minimum pressures (P_+ and P_-) are of the order of 1 MPa and the duration of positive and negative pressure phases are approximately 2-3 μs . The results for water are consistent with those of hyperelastic materials in terms of P_+ and the duration of positive/negative phases. However, the waveform shape is somewhat different and P_- is less pronounced.

Figure 4-2: Pressure waveform at the surface of the soft tissue object for material models predicting realistic pressure magnitudes.

When linear elastic materials 1 and 2, and hyperelastic material 3 were used, the predictions for the pressure amplitude were well below the experimentally obtained values. This is illustrated in Figure 4-3. Note also that the duration of the positive phase of the pressure waveform is much larger than in the experimentally obtained results reported in the literature. In particular, hyperelastic material 3, which is currently one of the most common models for plantar soft tissue, led to predictions of exceptionally low pressure amplitudes. Material linear elastic 2 led to almost identical predictions as material

hyperelastic 3. Both materials were introduced and used by the same group of authors, mostly for analysing static or quasi-static types of situations (Cheung et al. 2004; Cheung et al. 2005). On the other hand, material linear elastic 1 is representative of most early finite element models of the foot, which were also mainly restricted to static analyses.

Figure 4-3: Pressure waveform at the surface of the soft tissue object for material models predicting unrealistically low pressure magnitudes.

The common feature of the materials that led to realistic predictions for pressure waveforms is that the speed of longitudinal waves was approximately equal to the speed of sound in water (see Table 2-8 for more details). On the other hand, the materials that led to unrealistically low pressure results were characterised by longitudinal wave speeds which were much lower than the speed of sound in water. Since the shear modulus is low for all material models considered, it follows that the critical parameter for obtaining realistic results for the generated pressure is the bulk modulus which should be almost equal to that of water. Note that materials hyperelastic 1 and 2 have shear moduli which differ by one order of magnitude but still give almost identical predictions for the pressure waveform. Using zero shear modulus (water) did lead to somewhat different results but predicted the same levels of pressure amplitude.

4.2.2 Pressure Wave Pattern in the Soft Tissue

Figure 4-4 illustrates the general pattern of the pressure field generated in the soft tissue. The figure shows the distribution of pressure in a plane of symmetry of the applicator and soft tissue object for six different moments in time. In order to clearly denote zones of positive and negative pressures, the cut-off limits of the colour bar were deliberately kept at values of ± 0.1 MPa that are much lower than the amplitudes of the positive and negative pressures. The results were obtained using a projectile velocity of 12.3 m/s and material model hyperelastic 1. The same material model has been used to obtain the results discussed in the remainder of this chapter. This material was chosen over materials hyperelastic 2 and 4 since it is based on a material formulation supported by node averaged pressure element, and because it has been used in published studies.

Figure 4-4 A shows the moment at which the pressure wave propagating through the applicator is about to reach the soft tissue. Figure 4-4 B-D show the formation of initial positive and negative pressure zones. Figure 4-4 E corresponds to the time at which the pressure wave has reached the bottom of the soft tissue object. Finally, Figure 4-4 F shows pressure distribution at the moment where the initial positive and negative pressure zones have just propagated past the bottom surface of the soft tissue. It can be seen that the general pattern of the pressure field in the soft tissue is that of a train of positive radial pressure waves each of which is followed by a negative pressure wave. The pressure waves in the soft tissue originate from the stress wave in the applicator which is generated from the projectile impact. The combined thickness of the initial positive and negative pressure zones in the soft tissue is about 12-13 mm. The positive and negative pressure waves that follow the initial wave are thinner as shown in Figure 4-4 E. This may be because reflections at the sudden changes of diameter eventually result in a shorter wave length of the stress wave in the applicator. Also, the three-dimensional wave effects in the applicator become more pronounced after several reflections of the initial wave from the ends of the applicator. This is supported by the fact that in Figure 4-4 A-D pressure throughout the applicator is either positive or negative, whereas in Figure 4-4 E and F there are zones of both positive and negative pressure in the applicator. Finally, it should be noted that the stress wave in the applicator is not one-dimensional. For example, in Figure 4-4 F the pressure in the central part of the applicator front surface is negative whereas it is positive on the corners.

Figure 4-4: Pressure field in the soft tissue object and applicator at different moments in time.

A: $t=3.1 \times 10^{-6}$ s, B: $t= 8.6 \times 10^{-6}$ s, C: $t=10.4 \times 10^{-6}$ s, D: $t=18.0 \times 10^{-6}$ s, E: $t=37.4 \times 10^{-6}$ s, F: $t=49.0 \times 10^{-6}$ s.

The wave pattern in the applicator and the soft tissue can be further analysed by examining space-time plots along the axis of symmetry. Here, velocity (of nodes nearest to the axis of symmetry) was chosen as the variable to be displayed. This is because the magnitude of the velocity is the same for the applicator and soft tissue whereas the pressure is much higher in the applicator than in the soft tissue. Again, the projectile velocity was 12.3 m/s. The velocity along the axis of symmetry is displayed in Figure 4-5. The origin of the spatial coordinate is at the interface between the applicator and soft tissue so that the rear end of the applicator is at -0.025 m. The figure shows successive waves in the applicator that travel in both directions. When an incident wave reaches the soft tissue, some of the wave is transmitted and travels towards the bottom of the soft tissue object. Most of the wave is, however, reflected and travels back as the acoustic impedance of the soft tissue is much smaller than that of the steel. When the reflected wave reaches the rear end of the applicator, it is again (fully) reflected and the process is repeated. There are also wave reflections in the applicator itself due to changes in diameter (at 6.5 and 11.5 mm from the impact end) which further complicates the wave pattern. As a wave is transmitted from the applicator into the soft tissue the slope in the space-time plot suddenly changes because of the much lower speed of sound in the tissue. A forward travelling wave needs about $5\text{ }\mu\text{s}$ to traverse the whole length of the applicator (25 mm) and about $35\text{ }\mu\text{s}$ to traverse the whole length of the block (50 mm). This is consistent with wave speeds of about 5000 m/s and 1400 m/s in the steel and the soft tissue, respectively. Waves in the soft tissue lose intensity with distance travelled as the energy spreads in all directions. When they reach the edge of the soft tissue object, they travel through the non-reflective boundary and leave the object. Waves in the applicator lose only a small amount of energy each time they reach the interface with the soft tissue so that the wave pattern in both the applicator and the tissue persists for a considerable amount of time (approximately 0.5 ms).

Figure 4-5: Velocity on the axis of symmetry of the applicator and soft tissue. The zero distance coordinate corresponds to the contact surface between the applicator and soft tissue.

In order to further examine the importance of the elastic wave in the applicator on the pressure field in the soft tissue, a version of the model was run in which the applicator was represented as a rigid body. The results from that model are shown in Figure 4-6 and Figure 4-7. Figure 4-6 shows the pressure field at the moment where the initial wave reaches the bottom of the soft tissue object and it corresponds approximately to Figure 4-4 E for the steel applicator. It can be seen that the initial positive and negative pressure zones are also present when the applicator is rigid, but they are not followed by a train of positive and negative pressures. This is further illustrated in Figure 4-7 which compares pressure waveforms at the impact surface of the soft tissue for a rigid and steel applicator. It can be observed that for the rigid applicator there is only one positive and one negative pressure peak. Also, the pressure amplitudes are lower than in the case of the steel

applicator. Finally, the pressure waveform starts earlier since there is no time lag between the impact of the projectile on the rear end of the applicator and the movement of the applicator tip.

Figure 4-6: Pressure field in the soft tissue object at the moment where the wave reaches the bottom end. The results were obtained using a rigid body applicator.

Figure 4-7: Comparison of the pressure waveforms on the contact surface of the soft tissue obtained with a steel applicator and a rigid applicator.

4.2.2.1 Pressure field and energy flux density

The variation of pressure amplitude and energy flux density with the distance from the pressure source was examined by analysing pressure waveforms in the elements along the axis of symmetry of the soft tissue object. The results for the distribution of the positive and negative pressure amplitudes (maximum value recorded over the whole simulated time) are shown in Figure 4-8. It can be seen from the figure that there was an exponential drop in the amplitude with the distance from the source. Both the positive and negative pressure amplitudes drop to less than half of their values recorded at the contact surface at a distance of 10 mm from the source. Close to the source, the relation between the distance and the pressure amplitude is not completely smooth, and the rate at which the amplitude diminishes with distance is lower than that further away from the source.

Figure 4-8: The distribution of the positive (P_+) and negative (P_-) pressure amplitudes along the axis of symmetry of the soft tissue object.

Figure 4-9 shows the distribution of the energy flux density along the axis of symmetry of the soft tissue object. It can be seen from the figure that the decrease in EFD with distance from the source is even more pronounced than in the case of the pressure amplitude. This is consistent with the theory of radial wave propagation which states that the pressure amplitude drop is proportional to the distance and the drop in EFD is proportional to the square of the distance. Two curves are displayed in the figure. One is

obtained by integrating pressure results over the whole simulated period ($80\text{ }\mu\text{s}$ after the impact); the other is obtained by integrating over the period of $25\text{ }\mu\text{s}$ which is the period typically used in experimental studies (Cleveland et al. 2007; DolorClast 2009). The values obtained with an integration period of $25\text{ }\mu\text{s}$ are consistent with the data sheet reported by the manufacturer (Figure 2-20), whereas integration over $80\text{ }\mu\text{s}$ gives higher values of EFD. From the data reported in the literature, it is not clear why most authors used pressure signals in the duration of $20\text{--}25\text{ }\mu\text{s}$ to calculate energy flux density, since the experimentally obtained pressure waveforms do not seem to completely diminish after that time (e.g. Figure 2-19).

Figure 4-9: The distribution of the energy flux density along the axis of symmetry of the soft tissue object.

4.2.2.2 The effect of projectile speed on the pressure wave

The effect of projectile speed on the pressure wave generated in the soft tissue is illustrated in Figure 4-10 and Figure 4-11. Figure 4-10 shows the axial component of the velocity of the node on the contact surface between the applicator and soft tissue which is closest to the axis of symmetry. The velocity waveforms of adjacent nodes were not exactly the same but they were similar in terms of shape and amplitude. It can be seen from the figure that the waveforms for three different projectile speeds have the same shape and

only differ in magnitude. The magnitudes of the first positive peak were 5.55 m/s for $V_0 = 14.9$ m/s, 4.55 m/s for $V_0 = 12.3$ m/s and 3.34 m/s for $V_0 = 9$ m/s. In each case, the magnitude of the first positive peak was 37% of V_0 which suggests that there is a linear relation between the magnitude of the waveform and the projectile speed.

Figure 4-10: Axial speed of a node on the contact surface between the applicator and soft tissue for three different projectile velocities.

A similar situation, where the projectile speed affects the magnitude but not the shape, was observed for pressure as shown in Figure 4-11. The results were obtained from the element on the contact surface which was closest to the axis of symmetry. The magnitudes of the first positive peak were 7.4 MPa for $V_0 = 14.9$ m/s, 6.3 MPa for $V_0 = 12.3$ m/s and 4.6 MPa for $V_0 = 9$ m/s, suggesting that there is a linear relation between the projectile speed and the magnitude of the generated pressure. Also, the magnitude of the first peak in the pressure waveform was almost exactly equal to the magnitude of the first peak in the velocity waveform times the acoustic impedance of the soft tissue ($Z = \rho c = 1.414 \times 10^6 \text{ kg m}^{-2} \text{ s}^{-1}$). Since the first velocity peak at the applicator was about 40% of the projectile speed, it can be concluded that the first pressure peak at the surface of the soft tissue was roughly equal to 40% of the projectile speed multiplied by the acoustic impedance of the soft tissue.

Figure 4-11: Pressure waveforms on the contact surface of the soft tissue for three different values of projectile velocity.

4.3 Conclusions

The simplified model of the shock wave device was integrated with a soft tissue object of simple geometry in order to gain understanding of the factors that influence pressure wave initiation and propagation. It was found that the speed of movement of particles at the tip of the applicator was about 40% of the projectile speed (for the type of applicator examined). The pressure in the tissue at the contact surface with the applicator was of the order of particle speed multiplied by the acoustic impedance of the tissue. Regarding the material models for the plantar soft tissue used in published studies, it was found that the materials with bulk modulus of around 2 GPa lead to results consistent with experimental data reported in the literature. On the other hand the material models that underestimate the bulk modulus of the soft tissue lead to unrealistically low predictions for the pressure levels generated in the tissue. The pressure pattern observed in the soft tissue object took the form of alternating positive and negative radial waves with wavelength of

the order of 10 mm. The wavelength of the initial positive and negative waves was larger than the wavelength of the waves that followed, and it was observed both for the applicator made of steel and the applicator modelled as a rigid body. The subsequent pressure waves were present only for an applicator made of steel. These results suggest that the pressure waves in the tissue that follow the initial wave are directly related to the elastic wave in the applicator which persists for up to 0.5 ms. The pressure amplitude and energy flux density diminished quickly with the distance from the source as is expected from the theory and experiment. The EFD values were consistent with published data when they were calculated by integrating pressure over the period of 25 μ s which is a typical time interval used in experimental studies. However, when the integration was performed over a longer period of time, (much) larger values of EFD were predicted from the results.

In terms of modelling the results point to the fact that it is crucial that the acoustic properties of foot component materials have to be accurate in order to obtain realistic results for the pressure wave generated by shock wave therapy. Also, it is important to represent the projectile and the applicator as elastic (deformable) objects in order to capture the transmission of the stress wave from the applicator to the soft tissue of the foot.

5 Development of a Three-Dimensional Finite Element Model of the Foot

The objective of the work reported in this chapter was to create a three-dimensional finite element model of the human foot. This model would later be coupled with the finite element model of the shock wave therapy device described in Chapter 3 in order to simulate shock wave treatment for plantar fasciitis. The choice for the model configuration was driven by the nature of the problem to be simulated, i.e. propagation of pressure waves through various mediums representing different anatomical structures and tissues of the foot. Since the therapeutic waves are radially propagating in all three dimensions, the model of the foot needs to be three-dimensional. The geometry was meant to be sufficiently realistic to represent a generic human foot but did not have to accurately reproduce all geometric details of a specific human foot. This is because the aim of the simulations was to investigate the general case. The approach used to achieve such a geometry was to start from medical images of a specific person, and to allow for a high level of smoothing in order to eliminate small geometric details and so facilitate the model creation and simulations. In particular, the elimination of very small geometric features was necessary to avoid the need for very small elements which would drive down the time-step used in the simulations. Also, the use of a smoother geometry helped in avoiding any unwanted “voids” between the anatomical structures in the foot which would otherwise affect wave propagation. Regarding the specific anatomical components of the foot, the modelling strategy was as follows: all the bones of the foot were constructed, including the tibia and fibula. However, simpler configurations were also considered by fusing some or all of the previously reconstructed bones of the foot.

The plantar fascia, which is the focus of this work, was fully reconstructed as a three-dimensional object. Only the central portion was considered as this is the main load carrying component as well as the component affected by fasciitis. Although not immediately relevant for this project, the Achilles tendon was also reconstructed as a 3D object with potential future model applications in mind. Both the plantar fascia and Achilles tendon were embedded in the surrounding soft tissue in order to be able to simulate the transmission of pressure waves from the shock wave source, through the soft

tissue, to the connective tissue and bones. To the best of the author's knowledge, this direct interaction of the plantar fascia and Achilles tendon with the soft plantar tissue has not been represented in other existing models of the foot. The strategy for modelling the joints was influenced by the fact that the focus was on the transmission of pressure waves through the articulations rather than on accurately simulating the kinematics of joints in the foot. Therefore, it was decided to fill the articulations with cartilage tissue which provided stability and continuity of wave transmission. Consequently, no ligaments were represented in the model. This approach has been used in other current models of the foot as discussed in Chapter 2. All the soft tissue of the foot, including the plantar fat pad and muscles, was modelled as a single entity. This is justified as the acoustic properties of all soft tissue in the foot are very similar, as discussed in Chapter 2.

Figure 5-1: The process of creation of a finite element model of the foot based on a realistic geometry. The steps are shown in a clockwise direction from the upper left image: Subject; MRI imaging; Stack of MR images; Segmentation and processing of the MR images; 3D geometry of the foot; Finite element model of the foot.

The model was created in several stages and using three software packages. The process of the model creation is illustrated in Figure 5-1. Starting with the upper left figure and moving in a clockwise direction: a foot of a volunteer was scanned using an MRI

scanner to obtain a stack of medical images; these images were processed using 3D geometry reconstruction software to obtain geometries of the anatomical components of the foot; these geometries were exported in CAD format to a finite element package for further processing and meshing; and finally, the finite element mesh was exported to another finite element package, where material properties and body interactions were assigned to different components of the foot. Details of all these steps are reported in the following sections.

5.1 Reconstruction of the Foot Geometry from Medical Images

The foot geometry was reconstructed from the MR images taken from the right foot of a healthy female, 32 years old (height, 167cm; weight, 60kg). The images were obtained using a Siemens Avanto MRI device, 1.5 T at Royal Surrey County Hospital, Guildford. The images were scanned at intervals of 0.8 mm in the sagittal plane. During the MRI screening the subject was supine and the scanned foot was in the neutral unloaded position. The MRI scans are illustrated in Figure 5-2.

Figure 5-2: MRI scans of the foot in the sagittal and transverse planes used for the geometry reconstruction. The anatomical structures indicated by numbers are as follows: 1 Tibia, 2 Talus, 3 Achilles tendon, 4 Calcaneus, 5 Bones of the midfoot, 6 Metatarsals, 7 Phalanges, 8 Intrinsic muscles, 9 Plantar fascia, 10 Plantar fat pad.

A commercial package was used to extract the 3D geometries from the MRI scans. Simpleware 3.2 (Simpleware Ltd., Exeter, UK) was the software of choice for this project. Simpleware comprises of two modules: Scan IP and Scan FE. Scan IP is used to import images (stacked 2D images or “slices”) and it provides a range of image processing and geometry reconstruction tools. These processed images can be exported in a CAD format such as STL or IGES. Scan FE was used to produce finite element models (mesh, based on the reconstructed geometry), which can be exported in formats compatible with major finite element packages such as ANSYS, ABAQUS, and LS-DYNA.

Figure 5-3 shows the Scan IP user interface: there are three windows showing imported images in three different planes, as well as a 3D preview window showing the reconstructed geometry. In the slice views, the cursors (red, green and blue lines in Figure 5-3) allow the user to locate an area of interest in all three planes. The box on the left hand side of the user interface contains various tools for 3D reconstruction.

Figure 5-3: The full screen of Scan IP; A: sagittal plane, B: coronal plane, C: transverse plane, D: 3D preview, E: tools for 3D reconstruction.

The process of reconstructing a 3D entity or “mask” is referred to as segmentation. Segmentation is a semi-automatic process that is achieved using various techniques. The main segmentation tools are: *painting*, *thresholding*, *flood-filling*, and *confidence connected region growing*. *Painting* is a manual tool which allows the user to select or delete individual pixels. *Thresholding* allows the user to select a window of greyscale pixel values within the total range between 0-255 brightness values. *Flood-filling* is a more

sophisticated tool that is based on a region growing algorithm where a threshold value is used as a measure of similarity and connectivity. *Confidence connected region growing* allows the user to select the area of interest by creating an initial “seed point” which then grows in successive iterations according to a statistical algorithm based on greyscale intensity. *Painting* can be used only on specific slices, whereas the other methods can be used on a single slice, a selection of slices, or all slices. The segmentation techniques of choice depend on the specific structure to be reconstructed. Most of the time a combination of techniques is necessary. Masks reconstructed using the above mentioned techniques have to be further processed in order to eliminate small unconnected objects, voids, and unnecessary small geometric features. This is achieved through various filters such as island removal filters, cavity fill filters, smoothing, and noise removal filters. Boolean operations such as union and subtraction can be used to create or modify masks using other existing masks. More details on how these techniques were used to create the foot geometry are explained in subsequent sections.

5.1.1 Overview of the Reconstruction Methods Used for the Bones

For the bones of the foot, the main segmentation method of choice was *confidence connected region growing*. As mentioned before, this method can be used on a single slice or all slices. It was found that using this technique on all slices did not produce satisfactory results because it was not possible to restrict segmentation to a single bone. Therefore, the segmentation was performed in 2D going through one slice at a time. This process is illustrated in Figure 5-4 which shows the growth of the selected region in three successive iterations. The figure depicts reconstruction of the cuboid bone which will be used as an illustration of the bone reconstruction process. The other tools used to complement *confidence region growing* were manual *painting* and sometimes *flood-filling*.

Figure 5-4: Confidence connected region method for reconstruction of bones. From top to bottom: the bone is gradually reconstructed by filling each slice by clicking the cursor on the selected area.

The reconstruction had to be performed interactively in all planes. It was found useful to reconstruct slices in three different planes to get a general understanding of the 3D shape of the object at an early stage of the reconstruction process. This is illustrated in Figure 5-5 which shows selected slices of the cuboid bone in three different planes as well as the corresponding 3D object. Also, the slice view cursors were extremely useful as a means of assuring that a selected area belongs to the reconstructed object by accurately determining its position in 3D.

Figure 5-5: Confidence level method applied to slices in three different planes and resulting 3D shape.

Figure 5-6 shows the 3D shape of the cuboid bone after the segmentation process has been completed. It can be seen from the figure that the surface is rough, containing lots of small geometric features. There is also “noise” in the form of small unconnected islands (circled in red) and small cavities within the 3D entity. The first step in conditioning the geometry is to remove cavities and islands which can be achieved using cavity fill and island removal filters, respectively. This effect of using these filters is illustrated in Figure 5-7.

Figure 5-6: The 3D bone geometry from confidence connected region reconstruction applied to all slices.

Figure 5-7: The process of eliminating small gaps and islands from unprocessed 3D bone geometry (circled in yellow and red, respectively). A: initial mask containing both cavities and islands, B: island removed with cavity-fill filter, C: islands removed with island removal filter.

Once the noise is removed from the mask, the next step is to eliminate small geometric features and smooth the outer surface of the geometry. The smoothing was achieved using a 3D recursive Gaussian filter which smoothes and attenuates the contours of an object. The extent to which the object geometry is smoothed depends on the width of the standard deviation (sigma parameter) of the Gaussian filter expressed in mm. For the purpose of reconstructing the bones of the foot, the Gaussian sigma parameter was in the range between 1-3 mm depending on the specific bone geometry. One of the disadvantages of using smoothing filters is that they decrease the size of the original geometry. In order to overcome this effect, morphological filters were applied before using the smoothing filters. Morphological filters process digital images based on mathematical morphology. The filters perform two basic operations: dilate, which makes the region grow, and erode, which makes the region shrink. The two basic operations can also be combined in any order. The strategy was to dilate the geometry using a morphological filter and then smooth it using a recursive Gaussian filter. This process had to be performed interactively with different filtering parameters until the satisfactory result was achieved. During the filtering process, the mask was monitored against the MR image at different slices using the transparency mode for the mask, so that the overlap between the mask and the edges of the image contour can be monitored. The whole process is illustrated in Figure 5-8. The final geometry for the bones of the foot is displayed in Figure 5-9.

Figure 5-8: The process of filtering and smoothing of the cuboid geometry; transverse plane (left) and 3D geometry (right). A: initial geometry, B: geometry after morphological filter is applied, C: geometry after recursive Gaussian smoothing filter with $\sigma = 2$ mm is applied.

Figure 5-9: Reconstructed geometries of all bones in the foot.

5.1.2 Overview of the Reconstruction Methods Used for the Plantar Fascia and Achilles Tendon

The plantar fascia and Achilles tendon were reconstructed using the same approach as for the bones. The main difference was that segmentation for the plantar fascia had to be performed almost entirely using manual painting. This is because it was far more challenging to identify the plantar fascia than any other foot structure. The process of

manual rendering of the plantar fascia was monitored by two surgeons from the Royal Surrey County Hospital with expertise in ankle and foot surgery. The reconstructed geometry of the plantar fascia and Achilles tendon is shown in Figure 5-10. The top left corner of the figure shows the sagittal plane view of the MR image with masks for the plantar fascia, Achilles tendon and the calcaneus. The filtering process was also conducted following the procedure used for the bones. In this case, however, more iterations had to be performed to avoid substantial shape change as the plantar fascia has a small thickness and filtering can introduce unwanted gaps. Also, morphological dilation can result in massive increases in the plantar fascia thickness if not used carefully.

Figure 5-10: Reconstructed plantar fascia and Achilles tendon. Figure in the top left corner illustrates the segmentation process.

5.1.3 Overview of the Reconstruction Methods Used for Cartilages

As mentioned at the beginning of the Chapter, the strategy for modelling joints was to fill the articulations between the bones with cartilage tissue. The sequence of steps conducted to create cartilages is illustrated in Figure 5-11, using the example of the joint between the talus and navicular bones. In the first step, the masks of the bones articulated with the joint to be reconstructed were duplicated and joined into a single mask using the Boolean unite operation (Figure 5-11 A). In the second step, the morphological “close” filter was used to physically connect the two bones; the close operation in morphological filtering is equivalent to dilate followed by erode. This operation is appropriate since it fills the space between the bones without enlarging the bones themselves (Figure 5-11 B). Manual conditioning of the resulting geometry at each slice had to be performed in order to fill larger gaps that may have remained following the close operation. In the third step, the mask containing both bones and cartilage fused together was subtracted from each of the original bones using the Boolean subtract operation (Figure 5-11 C). The resulting cartilage mask had a rough surface containing small geometric details. In order to smooth the cartilage geometry, the morphological dilate operation was used followed by a smoothing recursive Gaussian filter. The resulting smoothed geometry again had to be subtracted from the original bones to achieve a good fit of contact surfaces (Figure 5-11 D). All the reconstructed cartilages in the model are shown in Figure 5-12.

Figure 5-11: The process used for the reconstruction of cartilages. A: duplicate related bone masks, B: bone masks merged together, C: Booleans used to subtract bones from the duplicate masks, D: cartilage after smoothing and filtering.

Figure 5-12: Reconstructed geometries of all cartilages in the foot.

5.1.4 Overview of the Reconstruction Methods Used for the Soft Tissue

The strategy used to reconstruct the soft tissue of the foot was to first create a mask containing all the structures of the foot and then use Boolean operations to subtract all other masks to create the soft tissue mask. In the case of the soft tissue, rendering was initiated using the thresholding method applied to all slices at the same time. This was possible because the initial mask contained almost all the pixels with brightness values over zero in the MRI scans. Figure 5-13 illustrates the effect of using thresholding with a lower cut-off pixel brightness of 35 and a higher cut-off of 254. It can be seen from the figure that by performing a single thresholding operation, most of the geometry was captured with some gaps and unconnected islands. Large unwanted features were removed manually using the painting tool or flood-filling on a slice by slice basis. Noise was removed using cavity fill and island removal filters as described earlier in this Chapter (see section 5.1.1).

Figure 5-13: Using 35-254 pixel brightness range to initiate creation of the soft tissue mask.

Figure 5-14 A shows the rendered initial geometry of the soft tissue. This geometry was filtered using morphological and smoothing filters following the similar procedure used for other structures of the foot. The smoothed geometry is shown in Figure 5-14 B. In the final step, the bones, cartilages, plantar fascia, and Achilles tendon were subtracted from the soft tissue mask to obtain the final soft tissue geometry (Figure 5-14 C and D).

Figure 5-14: Reconstructed geometry of the soft tissue. A: soft tissue after thresholding, B: soft tissue after smoothing and filtering, C and D: geometry after Boolean subtraction of all other parts of the foot.

5.1.5 Model Configurations

As stated previously, simplified model geometries with some or all of the bones fused together were also created. Figure 5-15 shows the different model configurations. The most detailed model is shown in Figure 5-15 A. This model was used as a starting point for creating models with simplified geometries. The model configuration shown in Figure 5-15 B is the simplest configuration. It was constructed by fusing all the bones and cartilages from the most detailed model into a single mask using the Boolean unite operation. The mask representing the fused bones was then filtered to create a smoother geometry. The geometry shown in Figure 5-15 C was obtained by fusing the bones and cartilages of the forefoot and midfoot, while keeping the rest of the bones as separate entities. Also, a new single “cartilage object” was created to connect all the bones in the model. That object is shown in Figure 5-16.

Figure 5-15: Three different configurations of the model. A: full detailed model with all bones and cartilages, B: all bones and cartilages fused into one single object, C: bones of the forefoot and midfoot fused.

Figure 5-16: The “cartilage object” used in model configuration with fused forefoot and midfoot bones.

5.1.6 Exporting of the Reconstructed 3D Geometry

The reconstructed geometry has to be used to create the mesh (nodes and elements) of the finite element model. Since Simpleware has built-in tools for mesh creation directly from the masks, the creation of the finite element model using Simpleware was investigated as one possible approach. As previously mentioned, finite element models created in Simpleware can be exported to formats compatible with commercial finite element packages. In the case of LS-DYNA, the model is exported as a key-file whereas in the case of ANSYS, the model is exported as a CDB file which is an ASCII file containing ANSYS commands giving full information about the model. However, this approach proved to be impractical for a number of reasons. For example, there was little control over the mesh quality, which resulted in a very coarse mesh in some regions and very small elements elsewhere in the model, especially at the interfaces between different parts. Also, the size of the exported finite element files was extremely large so that it was almost impossible to import such files into desired finite element packages. Finally, when the mesh was created in Simpleware, the masks have to be assigned in order of priority. This priority order directly affects the quality with which the shape of an object is reproduced in the mesh. The object with the highest order of priority is reproduced accurately whereas the geometry of a low priority object can be severely distorted. This is illustrated in Figure 5-17 which shows the talus bone and cartilage between the talus and calcaneus. In Figure 5-17 A, the talus was given highest priority whereas the cartilage was assigned to be low priority. In Figure 5-17 B, the opposite was the case. It can be seen from the figure that the high priority object preserves high quality geometry, whereas the geometry of the low priority object is corrupted.

Figure 5-17: Mask priority effect on the quality of CAD files for talus (cyan) and associated cartilage (violet) exported from geometry reconstruction software. A: talus was first priority and cartilage was last priority, B: talus was last priority and cartilage was first priority.

Various combinations of the order of mask priority were investigated but none of them gave satisfactory results as some of the objects were always overly distorted. It was therefore decided to export geometry as IGES files (defining volume objects bound by triangulated surface) and process them in another software package. Thus the IGES files were imported into the ANSYS Design Modeller module which was used to perform final processing of the geometry and to create the finite element model. The IGES files exported from Simpleware also follow the mask priority order regarding the quality of mask geometry. This issue was overcome in the following way: highest priority was set for a mask, the whole model was then exported in IGES format, and all masks except the one with the highest priority were discarded. The same process was repeated for all the masks in the model. While it was also possible to export each mask separately, it was found that this led to inaccurate positioning of the parts in the model. The IGES files obtained by the exporting strategy discussed above are shown in Figure 5-18, which displays parts of the foot geometry with a single cartilage object and fused forefoot and midfoot bones.

Figure 5-18: Geometries of foot model components in IGS format. A: soft tissue, B: cartilage object, C: calcaneus, talus, tibia, and fibula, D: bones of the forefoot and midfoot.

5.2 Construction of the Finite Element Model

The consequence of exporting each mask in IGES format with first priority was that the perfect interface between objects sharing surfaces was not reproduced accurately. For this reason, the geometry imported in the ANSYS Design Modeller had to be further processed. It was decided that the most practical option was to use the geometry with fused bones, as it was judged that the small cartilages in the forefoot and midfoot should not significantly affect wave propagating patterns in the foot. The chosen geometry was the one with lumped forefoot and midfoot, and with a separate representation of the remaining bones of the foot (Figure 5-15 C and Figure 5-18). This geometry was chosen over the one with all bones fused because it allows the examination of pressure wave propagation through soft tissue, bone, and cartilage interfaces, along the main anticipated direction leading through the calcaneus, talus, and tibia. The geometry conditioning process is described in the next section.

5.2.1 Conditioning of the Geometry Imported from Simpleware

The soft tissue mask had to be exported from Simpleware as a whole lumped foot (see Figure 5-18 A) and the Boolean operations to create its interior geometry had to be redone in ANSYS. This process is illustrated in Figure 5-19. The highlighted green areas represent the contact surfaces between the foot structures and the soft tissue after the Boolean operations. First, all the bones were subtracted one by one from the soft tissue (Figure 5-19 A). Next, the cartilage object was subtracted (Figure 5-19 B). Finally, the Achilles tendon and plantar fascia were subtracted (Figure 5-19 C and D, respectively). After each Boolean operation, the soft tissue was inspected to make sure that the operation did not result in the creation of unwanted small objects or unconnected contact surfaces. In order to achieve that, it was found necessary to scale up the plantar fascia and cartilages by 1%. Also, the plantar fascia and Achilles tendon were translated by 0.5 mm towards the bones that they are connected to. These operations created a small overlap between the bones on one side and the plantar fascia, Achilles tendon and cartilages on the other side, and eliminated any voids that resulted from the IGES exporting process.

Figure 5-19: Boolean subtraction of foot components from the soft tissue. Contact surfaces created by the operation are highlighted in green. A: all bones, B: cartilage, C: Achilles tendon, D: plantar fascia.

In the next step, the overlap between the bones and other structures of the foot were eliminated by using Boolean subtraction. The bones were always used as a tool body which preserves its shape whereas the other objects were target bodies. This is illustrated in Figure 5-20. The figure shows the contact surfaces between the bones and cartilage (Figure 5-20 A), between the bones and plantar fascia (Figure 5-20 B), and between the calcaneus and Achilles tendon (Figure 5-20 C).

Figure 5-20: Boolean subtraction to create contact surfaces with the bones. A: cartilage, B: plantar fascia, C: Achilles tendon.

In the simulations to be conducted using this model, zero displacement boundary conditions need to be applied to part of the foot to render it statically stable during the pre-load phase (pressing of the shock wave device against the heel pad). The top surface of the tibia is an obvious choice. However, imposing zero movement at that location would prevent the transmission of pressure waves through the tibia. Therefore, it was decided to extend the tibia so that the zero displacement boundary is further away from the main area of interest. This was achieved by first merging all the areas on the top side of the tibia (Figure 5-21 A) to form a single face which was then extruded by 10 cm upward (Figure 5-21 B).

Figure 5-21: Creation of the tibia. A: areas forming the top surface of the original tibia are fused into a single surface, B: the unified top surface is extruded by 10 cm.

5.2.2 Meshing

Meshing was performed in the ANSYS Mechanical module. In the meshing tool, the preference was set for explicit dynamic problems. All the components of the model were meshed with 4-noded tetrahedral elements and using a patch independent method. Each object in the model was meshed separately. The mesh, with element size set to 2 mm for all objects, is shown in Figure 5-22. The number of nodes and elements for this mesh were 307,938 and 1,621,452, respectively. A version of the mesh was also created where the element size for the soft tissue and plantar fascia was set to 1 mm. This configuration was found to be of a limited practical use since it resulted in a very large number of elements, which hugely increased the demands on computational resources.

Figure 5-22: Finite element mesh for the foot model.

5.2.3 Exporting of the Finite Element Mesh

The mesh for each part of the foot was exported to ANSYS APDL from which it was converted into an input file in LS-DYNA keyword format. The conversion was performed using in-house scripts written in APDL macro-commands. Each of the created key-files contained information on the nodes and elements of the object, node and segment sets needed to define boundary conditions. For the bones in the model, the APDL “esurf” command was used to create shell elements overlaying the outer surface of the bone. These shell objects were also exported to serve as a representation of the cortical shell of the bones. Segment sets and node sets to be used to define boundary conditions in LS-DYNA were also defined in ANSYS APDL and included in the key-files for the associated object. Segment sets are sets of triangular or rectangular patches overlaying the outer surface or a portion of the outer surface of an object. As LS-DYNA does not recognise any geometric objects beyond the finite element mesh, segment sets have to be used to define an area. Figure 5-23 shows a segment set which was used to define boundary conditions on the top surface of the soft tissue.

Figure 5-23: Segment set on top surface of the soft tissue (in purple).

The key-files for each of the objects forming the foot were imported into a single master key-file using the LS-Prepost pre-processor. The remaining keyword commands were implemented using the LS-Prepost user interface. Figure 5-24 shows the foot model after importing all the parts into LS-DYNA.

Figure 5-24: Wireframe of the whole foot model imported into LS-DYNA.

5.2.4 Body Interactions

All the objects exported into LS-DYNA were meshed independently and thus were not connected via shared nodes. Therefore, tied contacts had to be introduced to connect different parts of the foot. This was achieved using the `*TIED_SURFACE_TO_SURFACE_ CONSTRAINED_OFFSET` keyword. The “OFFSET” option allows the nodes to be tied if they are within a certain distance (offset) from the contact surface. The contact surface thickness was set between 0-0.2 mm to assure that the objects are properly connected. The CONSTRAINED option means that the nodes of the “slave object” are locked to the “master object” at the interface surface

between the two, using a constraint type algorithm. In contrast to the “penalty force” approach, where the nodes of the slave object within the offset tolerance are physically moved to the master surface, here the nodes are locked without being moved. Figure 5-25 shows the tied contact between the calcaneus and the cartilage object. Cartilage is the slave object and calcaneus is the master object. Green dots signify nodes of the slave object which are constrained to the surface of the master, whereas the red dots are the nodes of the slave object which are outside the offset range and are therefore not tied. The following tied contacts were defined in the model: between the tibia extension and the original tibia bone; between the soft tissue and all other parts of the foot, except the tibia extension; between the cartilage object and all the bones; between the Achilles tendon and calcaneus, and between the plantar fascia and bones (calcaneus and lumped bones).

Figure 5-25: Tied contact between the calcaneus and cartilage. The constrained nodes of the cartilage are displayed in green.

5.2.5 Element Formulation and Material Properties for Model Parts

There were 10 parts in the foot model. The cortical shells of the bones were originally included, representing (five) additional parts. However, it was decided to discard these parts for reasons that will be discussed later in this section. For all the parts in the model, constant stress tetrahedral elements were used. The element formulation with the averaging of nodal pressures was used for the soft tissue, plantar fascia, and Achilles tendon which are characterised by nearly incompressible materials. The reason for choosing this element formulation is discussed in Section 3.2.2.

The material properties for model parts were based on the data reported in published studies. The material models used were a linear elastic model, and the Mooney-Rivlin and neo-Hookean hyper-elastic models. The bones were the only parts for which linear elastic materials were used. It was initially considered to separately represent the cortical and cancellous bone tissue. However, the material models for the cancellous bone used in most studies result in an inaccurate representation of its acoustic properties; preliminary simulations carried out with the cancellous bone with Young's modulus of 445 MPa (Shin et al. 2012) resulted in a pressure wave in the bone propagating slower than in the soft tissue, which is not realistic. In order to accurately model the acoustic behaviour of the cancellous bone, it would be necessary to represent this tissue as a poro-elastic material. Since the focus of this study was not on the effects of shock wave therapy on bone tissue, it was decided to use a simpler approach in which no distinction was made between the cortical and cancellous bone tissue. This approach has been implemented in other published studies from which material parameters for the bone tissue were adopted (Jacob and Patil 1999). The choice for the soft tissue material model was largely based on the results of the analysis performed in Chapter 4. This analysis showed that the bulk modulus is the most important parameter in terms of accurate predictions of pressure wave formation and propagation in the tissue. While more than one material model performed adequately, the practical issue of material model compatibility with node averaged pressure formulation required that a Mooney-Rivlin model be used (Verdejo and Mills 2004). The cartilage was represented as a neo-Hookean hyperelastic material following the procedure used by Wu (2007), who implemented this material in a 2D foot model where cartilage was used to connect the bones and to give structural stability to the foot. However, the hyperelastic constants were determined to match Young's modulus of 100 MPa used by

Cheng et al. (2008) so that the speed of longitudinal waves in the tissue is of the same order of magnitude as in other materials in the model. The material properties for the plantar fascia and Achilles tendon were based on linear elastic models reported in the literature (Cheung and Nigg 2007), but were re-interpreted as neo-Hookean hyperelastic materials whose constants were calculated to match linear elastic parameters; the same approach was used by Wu (2007) to calculate hyperelastic constants for cartilage. The bone tissue had density of $1.6 \times 10^3 \text{ kg/m}^3$, and all other materials were assigned density of $1.0 \times 10^3 \text{ kg/m}^3$. The material models for the tissues represented in the model and their parameters are given in Table 5-1. For hyperelastic models, both the Poisson ratio and compressibility constant D_1 are reported for convenience, although they are not mutually independent parameters.

Table 5-1: Material models used in the foot model

Tissue	Material Model	Constants
Bone	Linear elastic	$E=7.3 \times 10^9 \text{ Pa}$; $\nu=0.3$
Cartilage	Neo-Hookean	$C_{10}=1.67 \times 10^7 \text{ Pa}$; $\nu=0.49$; $D_1=1.2 \times 10^{-9} \text{ Pa}^{-1}$
Plantar fascia	Neo-Hookean	$C_{10}=6.0 \times 10^7 \text{ Pa}$; $\nu=0.47$; $D_1=1.0 \times 10^{-9} \text{ Pa}^{-1}$
Achilles tendon	Neo-Hookean	$C_{10}=2.1 \times 10^8 \text{ Pa}$; $\nu=0.45$; $D_1=4.0 \times 10^{-9} \text{ Pa}^{-1}$
Soft tissue	Moony-Rivlin	$C_{01}=C_{10}=1.0 \times 10^5 \text{ Pa}$; $\nu=0.4999$; $D_1=1.0 \times 10^{-9} \text{ Pa}^{-1}$

5.3 Conclusions

A three dimensional finite element model of the foot has been constructed. The model consisted of the bones of the foot, Achilles tendon, plantar fascia, cartilage, and soft tissue. The geometry was reconstructed from MRI scans of an actual foot using dedicated software. The strategy for geometry construction was to start from the most complex (and realistic) representation of foot structures, and then simplify the geometry keeping the only features which are relevant to the specific application for which the model was designed. The reconstructed geometries of the foot components were exported as IGES files which were imported into ANSYS software for further processing and creation of the finite element mesh. The generated meshes of all the foot components were exported as LS-DYNA key-files. The material properties and contacts between the foot components were assigned using appropriate LS-DYNA keyword commands. The material properties for the tissues of the foot were based on the data reported in the literature. The main novelty of this model is in the fact that the plantar fascia and Achilles tendon are represented as three-dimensional objects which directly interact with the surrounding soft tissue.

6 Simulation of Shock Wave Therapy for Plantar Fasciitis

The models of the radial shock wave source and the foot were coupled to simulate the mechanical effects of shock wave therapy. Three different positions for the shock wave source and three different projectile speeds were considered. The stress and energy fields in the foot were examined for all variations of simulation input parameters. The parameters of the pressure field were then discussed in the context of possible effects that they could generate in the tissues of the foot.

6.1 Method

The following section gives an overview of the model configurations, initial conditions, boundary conditions, and contact settings used for the simulation of shock wave therapy.

6.1.1 The Model

Figure 6-1: Model of the shock wave device and foot. The device is in the Position 1.

The finite element model used in this chapter is shown in Figure 6-1. The model combined the shock wave device model described in Chapter 3 and the model of the foot described in Chapter 5. The combined model comprised of 16 parts: projectile, applicator, front o-ring, rear o-ring, inner casing, outer casing, soft tissue of the foot, plantar fascia, Achilles tendon, calcaneus, talus, lumped bones of forefoot and midfoot, tibia, fibula, cartilage, and tibia extension. The mesh, material properties, and contacts for the device parts and the foot parts were as described in Chapters 3 and 5, except that now the front cap of the device was represented as a rigid object. Three possible positions were considered for the shock wave source. In Position 1 the front surface of the applicator was placed in such a way that its perimeter was below the insertion of the plantar fascia into the calcaneus, so that its axis of symmetry was going through the most affected region of plantar fascia. The axis of symmetry of the device was perpendicular to the surface of the sole of the foot. This position corresponds to positioning of the device shown in Figure 2-27. In Position 2, the axis of symmetry of the applicator intersected the attachment of plantar fascia to the calcaneus and it was perpendicular to the surface of the soft tissue. The third position was such that the axis of symmetry of the applicator went through the concave surface at the lower part of the calcaneus. Position 1, was the “default” position which was assumed to be the most preferred choice. Position 2 was chosen to assess the effect of directing the main direction of the pressure wave through the bone. Position 3 was chosen to assess the effect of wave reflection from the bone surface on the pressure field. The three positions used for the device are shown in Figure 6-2.

Figure 6-2: Positions of the applicator used in simulations. A: Position 1, B: Position 2, C: Position 3.

6.1.2 Simulations

The simulations consisted of three phases: two pre-load phases and one impact phase. The first pre-load phase was to pre-load the o-rings in the device and it was performed in the same way as described in Section 3.2.3. The second pre-load phase was performed in order to simulate the procedure where the clinician presses the device against the foot with a force of at least 30 N before activating it. This procedure is to assure proper contact between the applicator and the foot. In the context of modelling, this phase was crucial in order to achieve realistic interfacing of the applicator and the foot. The impact phase simulated the actual collision of the projectile and the applicator and the propagation of stress waves in the foot. The pre-load phases were simulated as dynamic events with numerical damping added to reach the equilibrium as quickly as possible. The duration of the first pre-load phase was 2 ms, and the duration of the second pre-load phase was 23 ms, giving 25 ms in total. The duration of the impact phase was much shorter (0.2-1 ms). For all three phases of simulation, the top surface of the tibia extension was restricted from movement and a non-reflective boundary was set at the top surfaces of the soft tissue cartilage and fibula (Figure 6-3).

Figure 6-3: Boundary conditions for the foot.

The initial condition was set in terms of the initial projectile speed. This initial condition was set at the beginning of first pre-load phase. Three projectile speeds were considered, 9 m/s, 12.3 m/s, and 14.9 m/s. The projectile had to be positioned in such a way as to reach the applicator at the beginning of the impact phase (Figure 6-1). The other boundary conditions, loading conditions, damping settings, and contacts between the device and the foot for the three phases of simulation are summarised below.

- First pre-load phase:
 - Outer casing was constrained from moving.
 - Inner casing was prescribed a constant velocity in the axial (y) direction of 0.8 m/s, from 0 to 1 ms, and then constrained from moving in all other directions. After 1 ms the inner casing was constrained from any movement.
 - Artificial damping coefficient for all parts of the shock wave device except the projectile was set at 12000 s^{-1} .
- Second pre-load phase:
 - Outer casing and inner casing were tied together and allowed to move in an axial direction while constrained from moving in any other direction.
 - A force of 50 N was applied to the inner casing in the axial direction. The force magnitude was ramped from zero at 2 ms to its full value at 4 ms, and then held constant.
 - Sliding contact without friction was set between the applicator and the soft tissue of the foot until 20 ms, at which time the contact was changed to tied. This ensured that the tied contact between the applicator and the foot was activated only when a good interface was established between the two objects. The other possibility where the sliding contact was maintained throughout all phases of simulations was also considered.
 - An artificial damping coefficient of 12000 s^{-1} was kept for all components of the shock wave device except the projectile. Also, an artificial damping coefficient of 1000 s^{-1} was set for all parts of the foot model.

- Impact phase:
 - The inner casing and the attached outer casing were constrained from any movement.
 - The contact between the applicator and the soft tissue was implemented as either tied or sliding; the tied contact was the default setting.
 - The damping was deactivated for all parts except for the o-rings for which a damping coefficient of $5 \times 10^6 \text{ s}^{-1}$ was set.

6.2 Results and Discussion

6.2.1 Pre-load Phases

The dynamics of the two pre-load phases is illustrated through the displacement of the applicator shown in Figure 6-4. The results were obtained for the applicator in Position 1. During the first pre-load phase, which simulated pre-loading of the o-rings, there was a gradual increase in applicator displacement from zero to approximately 0.28 mm over the first millisecond. Once the rear casing movement stopped, the displacement settled down until the beginning of the second pre-load phase. During the first pre-load phase, there was no contact between the applicator and the soft tissue. With the onset of the second pre-load phase there was a substantial movement of the applicator from approximately 3 ms until approximately 10 ms. At about 8 ms, there was a slight overshoot and the displacement just exceeded 3.5 mm. The displacement then gradually decreased and at 10 ms it settled at 3.3 mm. There was no observable movement of the applicator when the contact between the applicator and soft tissue was changed from sliding to tied contact at 20 ms.

Figure 6-4: Rigid body displacement of the applicator during the pre-load phases of a simulation.

Figure 6-5: Section in the plane of the second ray of the foot.

Figure 6-5 shows the section through the model which is used for the most part to display the results for the distribution of parameters of interest in this section and throughout this chapter. The section passes through the Achilles tendon, insertion of the plantar fascia into the calcaneus, and the second metatarsal bone. It corresponds to the “plane of the second ray of the foot” used by Gefen (2002).

Figure 6-6 shows the distribution of stress in the model at the end of the pre-load phases. Figure 6-6 A gives the normal stress in the y direction (the direction in which the pre-load force acts). The limits for the stress contours are set at a relatively low value of ± 0.1 MPa in order to better visualise the main direction of loading. There is a negative (compressive) stress region starting from the applicator-soft tissue interface, and spreading through the posterior (back) portion of the calcaneus, cartilage, talus, and tibia. On the other hand, the stress at the anterior (front) part of the tibia is positive. This stress distribution can be attributed to the fact that the pre-load force causes bending of the tibia resulting in tension on its anterior side. The pressure distribution is shown in Figure 6-6 B. The positive pressure zone corresponds to the negative y-stress zone. However, the values of pressure are higher in the soft tissue and cartilage than in the bones, except for the tip of the calcaneus and tibia extension. Also, the portion of plantar fascia near the insertion is under negative pressure since it experiences tension. From the distribution of von Mises stress shown in Figure 6-6 C it can be seen that the region with the highest loading is the portion of the calcaneus and plantar fascia near the insertion point. The maximal value of stress at that point is 2.9 MPa.

Figure 6-6: Stress distribution at the end of pre-load. The applicator was in the Position 1. A: normal y stress, B: pressure, C: von Mises stress.

In the forefoot, the region of highest stress was in the metatarsals. The distribution of the x stress (approximately in the direction of the plantar fascia) shown in Figure 6-7 reveals that the stress in the metatarsal was positive on the inferior (bottom) side, and negative on the superior (top) side. This suggests that the metatarsals were also exposed to bending due to the load being transferred through the soft tissue.

Figure 6-7: Normal x stress distribution in the forefoot.

Figure 6-8 shows the distribution of normal y stress at the end of pre-load for the applicator Positions 2 and 3. For Position 2 (Figure 6-8 A), the effect of bending in the bones was even more pronounced than for Position 1 (Figure 6-6 A). This was especially the case in the tibia extension which had prominent zones of positive and negative stress. On the other hand, for the Position 3 (Figure 6-8 B) the bones were all in compression since the line of action of the pre-load force was moved towards the long axis of the tibia, thus reducing the bending effect. Compared to Position 1, the stress in the metatarsals was lower for Position 2 and higher for Position 3, which is consistent with the assumption that the metatarsals are bent by the load transferred from the soft tissue. The results for von Mises stress for Positions 2 and 3 were similar to those for Position 1 in terms of stress distribution and magnitude. Again, the region of highest stress was at the insertion of the plantar fascia into the calcaneus with the maximum stress of 2.2 MPa for Position 2 and 2.3 MPa for Position 3.

Figure 6-8: Normal y stress distribution for Positions 2 and 3. A: Position 2, B: Position 3.

6.2.2 Impact Phase

6.2.2.1 Pressure waveform

The impact of the projectile on the applicator resulted in a pressure wave which was transmitted into the foot. The highest pressure was generated at the interface between the applicator and the soft tissue.

Figure 6-9: Region of contact between the applicator and soft tissue (red). The circle indicates the zone of highest pressure. The black dot indicates the position of the element picked to present a typical pressure waveform.

That region is indicated by red colour in Figure 6-9 which shows pressure distribution in the foot for the applicator in Position 1 just before the impact. The pressure waveforms for all the elements within the black circle for the projectile speed of 12.3 m/s are shown in Figure 6-10. It can be seen from the figure that the waveforms are similar for all the neighbouring elements. The maximal positive and negative pressure values were approximately 7 MPa and -6 MPa respectively. This is consistent with the results previously obtained using a simple “soft tissue object” (Section 4.2.1). The difference was that for the foot the pressure slightly shifted towards positive values, and that the pressure magnitude dropped somewhat following the initial positive and negative peaks. The shift towards the positive values was due to pre-load. The pressure magnitude drop after initial waves was probably because of the fact that the interface between the applicator and the foot was less ideal than in the case of the simple soft tissue object. However, the pressure waveform did persist over 0.5 ms following the impact.

Figure 6-10: Pressure waveforms in the zone of highest pressure at the surface of the soft tissue. The zone is circled in Figure 6-9.

The black dot in Figure 6-9 indicates the position of the element which was chosen to display a typical waveform for a certain applicator position and projectile speed. The location corresponds to the point where the pressure reaches the maximal negative value. Also, the value of the peak positive pressure at that point was only slightly below the maximal value, which was recorded in a nearby element in the zone shown in Figure 6-9. Figure 6-11 shows pressure waveforms for the applicator in Position 1 for three different speeds of the projectile. The time is set to zero at the moment at which the pressure wave reaches the soft tissue, so that all three waveforms start at the same time. Only the first 30 microseconds are shown to make the comparison easier. It can be seen that the waveform shapes are independent of the projectile speeds. The ratio of pressure amplitude is linearly related to the projectile speed in the same way as observed in Section 4.2.2.2 so that the first peak of pressure is approximately 40% of the projectile speed, multiplied by the acoustic impedance of the soft tissue.

Figure 6-11: Pressure waveforms for three different projectile speeds and applicator in Position 1. The position of the element from which the pressure was taken is indicated with a black dot in Figure 6-9.

Figure 6-12 compares the results for the case where the applicator was tied to the tissue and the case where the applicator was in sliding contact with the tissue. In both cases the applicator was in Position 1 and the projectile speed was 12.3 m/s. The figure shows that the first positive peak is almost the same for the two cases, with the amplitude being somewhat smaller for the sliding contact. However, after that point the two waveforms differ considerably. In the case of the sliding contact the amplitude of the pressure falls rapidly with time and the negative pressure is far less pronounced than in the case of the tied contact. This is not in agreement with published experimental data which show that there are more than one negative and positive pressure peaks of similar magnitude.

Figure 6-12: Pressure waveforms for tied and sliding contact between the applicator and soft tissue. The applicator was in Position 1 and projectile speed was 12.3 m/s. The position of the element from which the pressure was taken is indicated with a black dot in Figure 6-9.

Figure 6-13 compares pressure waveforms for the three different applicator positions. The projectile speed was kept at 12.3 m/s. The locations of the pressure waveforms shown were chosen based on the criterion of maximal negative pressure and

they did not coincide for the three cases examined. However, the point of choice was always located on the surface of the soft tissue near the centre line of the applicator. The waveforms show a great deal of similarity, both in terms of shape and pressure magnitude, and especially in the region of the first positive peak. For Position 3, the magnitude of the second positive pressure peak was almost as high as the magnitude of the first peak, which was not the case for Positions 1 and 2. Generally speaking, for Position 3 the pressure magnitude did not decrease immediately after first positive and negative peaks. For this applicator position, the maximal negative pressure actually occurred at 36 microseconds after the impact. This result suggests that wave reflections may have played a significant role in the formation of the pressure waveform.

Figure 6-13: Pressure waveforms for Positions 1, 2, and 3. The projectile velocity was 12.3 m/s. The pressure waveforms with the highest value of negative pressure were picked for all three positions.

Table 6-1 summarises the values of maximal positive and negative pressures recorded for all positions, projectile speeds, and contact types. The results suggest that the applicator positioning had only a minor effect on the values of maximal P_+ and P_- . There is

a simple linear relation between projectile speed and the values of maximal P_+ and P_- . The sliding contact between the applicator and soft tissue resulted in the maximal value of P_+ , which was only slightly lower than in the case of the tied contact, whereas the values of maximal P_- were substantially lower than for the tied contact.

Table 6-1: Maximal values of P_+ and P_- for all combinations of projectile speeds, applicator positions, and types of contact between the applicator and soft tissue

Position	1	1	1	1	2	3
V_0 (m/s)	9	12.3	14.9	12.3	12.3	12.3
Contact	Tied	Tied	Tied	Sliding	Tied	Tied
P_+ (MPa)	5.25	6.97	8.36	6.11	6.81	6.99
P_- (MPa)	-4.16	-5.77	-7.14	-3.66	-6.21	-5.84

6.2.2.2 Stress wave pattern in the foot

Figure 6-14 illustrates the general pattern of the pressure field generated in the foot for the reference model configuration with the applicator in Position 1 and with the projectile speed of 12.3 m/s. The section presented in this figure is the plane of the second ray of the foot. The focus is on the region around the heel, where the pressure source was applied. The limits for the pressure contours are set at a relatively low value of ± 0.1 MPa in order to easily identify zones of positive (red) and negative (blue) pressure and to gain a clear picture of the pressure wave propagation pattern. Figure 6-14 A shows pressure distribution at 2 μ s after the impact (0.02527 s from the beginning of the pre-load phases). At that point in time the stress wave had been generated in the applicator and the projectile but it still had not propagated into the soft tissue of the foot. At 10 μ s after the impact, the first positive pressure wave had been generated in the soft tissue and reached the plantar fascia, as shown in Figure 6-14 B, and also in Figure 6-15 A which gives a coronal plane section through the device and the foot. The wave still had not progressed into the calcaneus bone at that point in time. At 16 μ s after the impact, the first negative pressure wave had been generated in the tissue, and the positive wave started penetrating the

calcaneus. This is shown in Figure 6-14 C. Figure 6-14 D and Figure 6-15 B show the moment when the negative wave reached the plantar fascia at 20 μ s after the impact.

It can be seen from the figure that the pressure wave in the bone progressed faster than in the soft tissue and that it also took a slightly different direction. Due to the low cut-off limits of the pressure contours, the figure does not give information on the exact magnitude of pressure in the bone as compared to the surrounding soft tissue. This will be discussed in subsequent sections. At 35 μ s after the impact the initial positive pressure wave had reached the boundary between the calcaneus and the cartilage, which separates the calcaneus from the talus, as shown in Figure 6-14 E and Figure 6-15 C. The figure also shows a train of alternating positive and negative pressure waves that followed the initial waves. It is clear from the figure that waves propagated through the bone faster than they did through the soft tissue. Figure 6-14 F shows pressure distribution at 63 μ s after the impact, when the initial wave reached the top surface of the foot. Due to the loss of pressure magnitude with distance travelled, that wave is not clearly seen in the figure. The pressure distribution at that point was more complex due to multiple reflections, and continuous trains of positive and negative pressure waves generated by the device.

Figure 6-14: Pressure field in the foot and the device for different moments in time. The results are displayed in the plane of the second ray of the foot. The time interval after the impact: A: $t=2 \mu\text{s}$, B: $t=10 \mu\text{s}$, C: $t=16 \mu\text{s}$, D: $t=20 \mu\text{s}$, E: $t=35 \mu\text{s}$, F: $t=63 \mu\text{s}$.

Figure 6-15: Pressure field in the foot and the device for different moments in time. The results are displayed in the coronal plane passing through the axis of symmetry of the applicator. Time interval after the impact: A: $t=16 \mu s$, B: $t=20 \mu s$, C: $t=35 \mu s$.

Figure 6-16 shows a three-dimensional view of the pressure wave pattern focusing on the plantar fascia, bones, and other connective tissues. Figure 6-16 A shows pressure distribution at $16 \mu s$ after the impact, at which time the initial positive pressure wave spread through the plantar fascia and started penetrating the calcaneus. This corresponds to the situation shown in Figure 6-14 C. Figure 6-16 B shows pressure distribution at $20 \mu s$ after the impact when the initial negative pressure wave spread through the plantar fascia. This corresponds to the situation shown in Figure 6-14 D and Figure 6-15 B. Finally, Figure 6-16 C shows pressure distribution at $35 \mu s$ after the impact at which point the pressure wave had reached the interface between the calcaneus and cartilage. This corresponds to the situation shown in Figure 6-14 E and Figure 6-15 C. It can be seen from the figure that the calcaneus and the segment of the plantar fascia near the insertion absorb most of the pressure wave. In the region where the plantar fascia becomes wider, the magnitude of the pressure wave was lower.

Figure 6-16: Pressure field in the bones and connective tissue of the foot for different moments in time.
Time interval after the impact: A: $t=16\ \mu\text{s}$, B: $t=20\ \mu\text{s}$, C: $t=35\ \mu\text{s}$.

Figure 6-17 shows the pressure distribution for the applicator in Position 2. Figure 6-17 A gives the pressure field at $16\ \mu\text{s}$ after the impact, which corresponds to Figure 6-14 D for Position 1. It can be seen that the results for Position 1 and Position 2 are very similar, apart from the fact that for Position 2 the penetration of the first positive pressure wave into the bone is somewhat higher since the distance between the applicator and the calcaneus is smaller. Figure 6-17 B shows the pressure field at $35\ \mu\text{s}$ after the impact and it corresponds to Figure 6-14 E for Position 1. Again, the pressure field for the two positions is similar with the positive pressure zone near the surface being more emphasized for Position 2.

Figure 6-18 shows pressure distribution for the applicator in Position 3 at $16\ \mu\text{s}$ and $35\ \mu\text{s}$ after the impact (Figure 6-18 A and Figure 6-18 B, respectively). Compared to the equivalent results for Position 1, there is much less penetration of the first positive pressure

wave into the bone at $16\text{ }\mu\text{s}$ after the impact. Also, at $35\text{ }\mu\text{s}$ after the impact, the pressure field in the calcaneus consists of a single positive and single negative pressure zone. The pressure field in the tissue surrounding the calcaneus has a shorter wave length and there are multiple positive and negative pressure zones. This suggests that only the initial positive and negative pressure waves are propagated into the calcaneus while the subsequent waves are mainly reflected.

Figure 6-17: Pressure field in the foot for the applicator in Position 2. Time interval after the impact:
A: $t=20\text{ }\mu\text{s}$, B: $t=35\text{ }\mu\text{s}$.

Figure 6-18: Pressure field the foot for the applicator in Position 3. Time interval after the impact:
A: $t=20\text{ }\mu\text{s}$, B: $t=35\text{ }\mu\text{s}$.

Figure 6-19 shows the pressure distribution for the applicator in Position 1, but with sliding contact between the applicator and soft tissue. Again, Figure 6-19 A and Figure 6-19 B show the pressure distributions at $16\ \mu\text{s}$ and $35\ \mu\text{s}$ after the impact, respectively. At $16\ \mu\text{s}$ after the impact, the pressure distribution was very similar with the results obtained with the applicator tied to the soft tissue. The main difference is that with the sliding contact there was no second positive pressure wave whose onset can be seen in Figure 6-14 D. At $35\ \mu\text{s}$ after the impact the pressure distribution was markedly different compared to the results obtained with the tied contact; the negative pressure zone in the calcaneus was very weak, and so were the pressure waves following the initial positive and negative waves.

Figure 6-19: Pressure field in the foot for sliding contact between the applicator and soft tissue. Time interval after the impact: A: $t=20\ \mu\text{s}$, B: $t=35\ \mu\text{s}$.

More information on the pressure wave propagation and the magnitude of pressure in different regions of the foot can be gained by examining pressure fluctuations over time in a certain direction. The principal direction of wave propagation can be associated with the axis of symmetry of the applicator as the source of the pressure wave. Therefore, the pressure fluctuations over time were examined for the elements located on a line aligned with the axis of symmetry of the applicator and stretching from the surface of the foot to

50 mm within the foot. For all three positions the line passes through the soft tissue and the calcaneus and it ends near the top portion of the calcaneus. For Position 1 and Position 3 the line also passes through the plantar fascia. The elements used to analyse wave propagation for all three applicator positions are shown in Figure 6-20. The other direction examined was in the plantar fascia along the line of the second ray of the foot (see Figure 6-5), starting from the insertion into the calcaneus and stretching 50 mm towards the phalanges.

Figure 6-20: The elements along lines aligned with the axis of symmetry of the applicator.

The pre-load values of pressure were subtracted from the results in order to clearly differentiate the pressure due to the wave generated through the impact. The results for the three positions of the applicator are shown in Figure 6-21. The zero distance in the figure is at the surface of the foot. For all three positions the maximal pressure was at the surface. The pressure amplitude diminishes with distance, initially in an exponential way, and then abruptly. The abrupt drop in pressure amplitude coincides with the point where the wave encounters the calcaneus. This is most pronounced for Position 2 where the applicator was placed beneath the insertion of the plantar fascia (Figure 6-21 B). For this position the initial exponential drop in pressure is not clearly visible indicating that wave reflection from the calcaneus may have played a role in pressure amplitude distribution. For the Position 3, where the applicator was further away from the bone, the abrupt pressure drop is the least pronounced (Figure 6-21 C). Position 1 (Figure 6-21 A) is somewhere between the other two positions showing both the initial exponential pressure drop and the abrupt drop at the bone interface.

Figure 6-21: Pressure in the foot in the direction of the axis of symmetry of the applicator extending 50 mm into the foot from the surface. A: Position 1, B: Position 2, C: Position 3.

Figure 6-22 shows pressure fluctuations in the plantar fascia along the line of the second ray of the foot. For all three applicator positions there is a zone immediately above the applicator where the pressure amplitude is fairly constant at up to 2 MPa positive and negative pressures. Also, in that zone the time delay between pressure waveforms at different points is not clearly visible. The zone is about 15 mm wide for Position 1 (Figure 6-22 A) and about 10 mm wide for Position 2 (Figure 6-22 B). For Position 3, the width of the zone is up to 20 mm (Figure 6-22 C). Outside of the zone above the applicator, the pressure amplitude decreases exponentially with distance and there is a clear time delay between different points. This suggests that the pressure wave reached a region of the plantar fascia almost at the same time and from there it spread to the remaining part of the plantar fascia.

Figure 6-22: Pressure in the plantar fascia in the direction of the second ray extending 50 mm from the insertion into calcaneus. A: Position 1, B: Position 2, C: Position 3.

Another stress measure examined was von Mises stress. Figure 6-23 shows the distribution of von Mises stress in the plane of the second ray of the foot for the applicator in Position 1 and with the projectile speed of 12.3 m/s. Figure 6-23 A shows stress distribution at 20 μ s after the impact which corresponds to the moment when the pressure wave started to penetrate the calcaneus, as shown in Figure 6-14 D. The von Mises stress was highest in the plantar fascia and calcaneus near the point of plantar fascia insertion (red colour). Compared to the stress distribution at the end of the pre-load phase shown in Figure 6-6 C, the region of high stress (>0.1 MPa) in the calcaneus was larger; in the plantar fascia von Mises stress remained the same. Figure 6-23 B shows stress distribution at 35 μ s after the impact which corresponds to the moment when the pressure wave reached the top part of the calcaneus, as shown in Figure 6-14 E. The region of high von Mises stress spread mid-way through the calcaneus but did not reach the top as the pressure wave did. There were no changes in stress distribution in the plantar fascia. Figure 6-23 C shows y stress distribution at 63 μ s after the impact which corresponds to the moment when the pressure wave reached the top surface of the foot, as shown in Figure 6-14 F. von Mises stress in the calcaneus had a more complicated pattern and there was also a high stress region at the bottom part of the talus. Again, there was no observable change in the stress distribution in the plantar fascia. For the soft tissue, von Mises stress was low for all the time increments discussed.

The explanation for the observed dynamics of the von Mises stress distribution could be as follows. When the pressure wave reached the calcaneus, it generated a shear wave in the bone tissue which is characterised by a high shear modulus compared to soft tissue and plantar fascia. That shear wave resulted in high von Mises stresses. Since the shear wave is slower than the pressure wave ($C_S=1325$ m/s compared to $C_L=2449$ m/s for the bone material used in the model), the von Mises stress spread through the bones at a slower rate than the pressure. In soft tissue the shear wave is so slow compared to the bone ($C_S=20$ m/s) that changes in von Mises stress distribution cannot be observed on time scales examined in Figure 6-23.

Figure 6-23: Von Mises stress field in the foot and the device for different moments in time. The results are displayed in the plane of the second ray of the foot. The time interval after the impact: A: $t=20 \mu\text{s}$, B: $t=35 \mu\text{s}$, C: $t=63 \mu\text{s}$.

6.2.2.3 Pressure field and energy flux density

As stated in Section 2.2.1, the mechanical effect of pressure wave therapy is usually presented in terms of pressure and energy fields. These represent the spatial distribution of maximal positive/negative pressures reached over the whole duration of the shock wave pulse (P_+ and P_- , respectively) and of the energy flux density. The pressure and energy fields were determined from the simulation results during the $100\ \mu\text{s}$ period after the impact. The model configuration considered was the one with the applicator in Position 1, and with the projectile speed of $12.3\ \text{m/s}$. Pressure waveforms for all the elements comprising the foot model were exported as ASCII files and processed in the Matlab software package (Mathworks inc. USA) using an in-house code to determine P_+ , P_- , and EFD for each of the elements. The values of P_+ , P_- , and EFD for each element were then imported back into LS-DYNA to present the results. In addition, the maximal value of von Mises stress reached over the whole duration of the shock wave was also determined for every location in the foot. The values of P_+ , P_- , and maximal von Mises stress included pre-load values, whereas the EFD was determined from pressure waveforms from which pre-load values were subtracted.

Figure 6-24: P_+ field in the foot. The results are displayed in the plane of the second ray of the foot.

Applicator was in the Position 1 and V_0 was $12.3\ \text{m/s}$.

Figure 6-24 shows the P_+ field in the foot. It can be seen that the region of highest P_+ was in the soft tissue above the point where the applicator was applied. The area in red colour represents the region in which P_+ was above 1 MPa; that region stretches from the surface of the soft tissue to the boundary of the calcaneus. It also includes a short portion of the plantar fascia near the insertion. Beyond the limits of the calcaneus, the values of P_+ were negligible.

Figure 6-25: P_- field in the foot. The results are displayed in the plane of the second ray of the foot. Applicator was in the Position 1 and V_0 was 12.3 m/s.

The distribution of P_- is shown in Figure 6-25. Again, the region of the highest negative pressure was in the soft tissue above the applicator. The area in blue colour represents the region of P_- below -1 MPa. This region was somewhat narrower and deeper than the region of P_+ higher than 1 MPa. Also, a longer stretch of the plantar fascia was in the zone of the highest P_- compared to the stretch of plantar fascia in the zone of highest P_+ . This may be in part due to the negative pressure generated by the pre-load phase in the region of plantar fascia near the insertion into the calcaneus (see Figure 6-6 B).

Figure 6-26 shows the distribution of EFD in the foot. The upper limit of the contour plot is set at 0.08 mJ/mm^2 , which is the lower limit of the medium energy level

(see Section 2.2.1). It can be seen from the figure that apart from the immediate vicinity of the point where the applicator was applied the EFD was negligible. The area in red colour, which represents the region where the EFD was in the medium or high energy level, was limited to the soft tissue and a very small portion of the plantar fascia.

Figure 6-26: EFD field in the foot. The results are displayed in the plane of the second ray of the foot. Applicator was in the Position 1 and V_0 was 12.3 m/s.

Figure 6-27 shows the distribution of the maximal von Mises stress in the foot. It can be seen from the figure that the region of high von Mises stress was in the calcaneus and in a portion of the plantar fascia near the insertion. The highest value of maximal von Mises was in the calcaneus and it equalled 3.78 MPa. The stress over 1 MPa, which is shown in red colour, was concentrated in the region near the insertion of the plantar fascia into the calcaneus. In the soft tissue, the von Mises stress was negligible everywhere except immediately above the applicator. This is in contrast with the P_+ , P_- , and EFD fields in all of which the zones of maximum pressure/energy were located in the soft tissue. This is probably due to the high shear stiffness of the bone tissue.

Figure 6-27: Maximum von Mises stress field in the foot. The results are displayed in the plane of the second ray of the foot. Applicator was in the Position 1 and V_0 was 12.3 m/s..

In order to obtain more quantitative information on the pressure and energy in the foot, their distribution was examined in more detail along the two specific directions defined in the previous section, i.e., along the axis of symmetry of the applicator, and along the second ray section through the plantar fascia. The pressure and energy fields were examined up to a depth of 25 mm; past that point the pressure amplitudes were very low.

Figure 6-28: Pressure field parameters in the direction of the applicator axis of symmetry for different projectile speeds. Applicator was in the Position 1. A: P_+ and P_- , B: energy flux density.

Figure 6-28 shows the distribution of P_+ , P_- , and EFD along the direction of the axis of symmetry of the applicator for three different speeds of the projectile. The values of P_+ and P_- decreased smoothly with distance up till about 13 mm depth at which point the wave traversed the plantar fascia, as seen in Figure 6-28 A. Past that point, initially the pressure values slightly increased as the wave again travelled through a short stretch of the soft tissue, but then they fell rapidly when the wave encountered the calcaneus at the distance of approximately 18 mm. As expected, from previous results regarding the effect of projectile speed, the pressure amplitude values were linearly related to the speed. The distribution of EFD shown in Figure 6-28 B was calculated from pressure traces from which pre-load values were subtracted. A time interval of $80 \mu\text{s}$ was used to perform the calculations. At the surface (zero distance) the values of EFD were 0.19 mJ/mm^2 for $V_0 = 9$ m/s, 0.36 mJ/mm^2 for $V_0 = 12.3$ m/s, and 0.53 mJ/mm^2 for $V_0 = 14.9$ m/s. Therefore, the EFD level at the surface can be classified as medium-to-high. The values of EFD decreased with distance in an exponential way up to the depth of about 6 mm, but then levelled between 6 – 10 mm before continuing to diminish with increasing distance. There was a local increase in EFD between the plantar fascia and the calcaneus, as for P_+ and P_- .

Figure 6-29: Pressure field parameters in the direction of the applicator axis of symmetry for different types of contact between the applicator and soft tissue. Projectile speed was 12.3 m/s. Applicator was in the Position 1. A: P_+ and P_- , B: energy flux density.

Figure 6-29 gives the comparison of P_+ , P_- , and EFD for tied and sliding contacts between the applicator and the soft tissue. In both cases, the applicator was in Position 1 and $V_0 = 12.3$ m/s. It can be seen from Figure 6-29 A that P_+ was not strongly influenced by the type of contact, but that P_- was much lower for the sliding contact. This is probably due to the fact that with the sliding contact negative pressure (tension) cannot be transferred from the applicator to the tissue. The type of contact had a very strong effect on EFD which was much lower for the sliding contact, as shown in Figure 6-29 B. This is consistent with the fact that with the sliding contact pressure waveforms died away much faster than with the tied contact as shown in Figure 6-12.

Figure 6-30: Pressure field parameters in the direction of the applicator axis of symmetry for different applicator positions. The projectile speed was 12.3 m/s. A: P_+ and P_- , B: energy flux density.

Figure 6-30 gives the comparison of P_+ , P_- , and EFD along the direction of the axis of symmetry of the applicator for different applicator positions. The graphs of P_+ and P_- are similar for all three positions for a distance of up to 10 mm as shown in Figure 6-30 A. However, at a distance of approximately 14 mm, the values of P_+ and P_- for Position 2 dropped suddenly as the waves encountered the calcaneus. Graphs for Position 1 and Position 3 remain similar throughout. For the first 10 mm, the values of EFD are similar for all three Positions. Similar to the situation with P_+ and P_- , at the distance of 10 mm, the EFD for Position 2 dropped suddenly whereas the EFD for Position 1 and Position 3 stayed close together, as shown in Figure 6-30 B.

Figure 6-31 show the distribution of P_+ , P_- , and EFD in the plantar fascia along the direction of the second ray of the foot for three different projectile speeds. As for the other parameters, P_+ and P_- are linearly related to V_0 . The maximal value of P_+ was 1.03 MPa for $V_0=9$ m/s, 1.29 MPa for $V_0=12.3$ m/s, and 1.61 MPa for $V_0=14.9$ m/s, and they all occurred at the distance of 4 mm from insertion into the calcaneus. The maximal value of P_- was -1.79 MPa for $V_0=9$ m/s, -2.27 MPa for $V_0=12.3$ m/s, and -2.68 MPa for $V_0=14.9$ m/s, and they all occurred at 2 mm distance from insertion into the calcaneus

(see Figure 6-31 A). Note that pre-load values of pressure contributed significantly to the P_{+} values. The values of P_{+} and P_{-} decreased gradually with distance past 4 mm from the insertion. The graphs for EFD are consistent with those for P_{+} and P_{-} with the maximal values reached at 2 mm distance. Since EFD is proportional to the square of pressure, the difference between EFD values for different projectile speeds was even more pronounced than in the case of pressure. The maximum values of EFD were 0.027 mJ/mm^2 for $V_0=9 \text{ m/s}$, 0.051 mJ/mm^2 for $V_0=12.3 \text{ m/s}$, and 0.076 mJ/mm^2 for $V_0=14.9 \text{ m/s}$ which can all be categorised as low energy levels. It is worth noting that the maximum level of EFD for $V_0=14.9 \text{ m/s}$ is just marginally below the threshold for medium energy level. As shown in Figure 6-31 B, the EFD does not decrease smoothly with distance, rather the values of EFD drop suddenly at 8 mm distance, and then again at 14 mm distance. The zone of high EFD coincides with the section of plantar fascia immediately above the applicator and thus directly exposed to the pressure wave.

Figure 6-31: Pressure field parameters in the plantar fascia along the second ray section of the foot. Applicator was in the Position 1. A: P_{+} and P_{-} , B: energy flux density.

Figure 6-32: Pressure field parameters in the plantar fascia along the second ray section of the foot for different types of contact between the applicator and soft tissue. Projectile speed was 12.3 m/s.

Applicator was in the Position 1. A: P_+ and P_- , B: energy flux density.

The effect of the contact type between the applicator and soft tissue at the level of the plantar fascia is shown in Figure 6-32. The values of P_+ are similar for the two contacts apart from the region between 0 and 6 mm distance, as shown in Figure 6-32 A. On the other hand, the type of contact has a strong effect on P_- which is substantially lower for the sliding contact than for the tied contact. Figure 6-32 B shows that the effect of contact type on the EFD is even more pronounced with the values obtained with the sliding contact being several times smaller than those obtained with the tied contact.

Figure 6-33 shows the results for P_+ , P_- and EFD at the level of the plantar fascia for three different positions of the applicator. It can be seen from Figure 6-33 A that the graphs for P_+ and P_- are similar for Position 1 and Position 2 with the values of P_- being slightly lower for Position 1. For Position 3, on the other hand, P_+ and P_- reach their maximal values further away from the insertion at the distance of approximately 12 mm, which is in line with where the applicator is applied. Regarding the values of EFD shown in Figure 6-33 B, the shape of the curves for Position 1 and Position 2 are again similar,

but the levels of EFD are somewhat lower for Position 2. On the other hand, for Position 3 the peak level of EFD is roughly the same as for Position 1, but the maximal value is reached at the same point as the maximal values of P_+ and P_- , i.e., at the distance of 12 mm. This position results in the largest region of plantar fascia being exposed to EFD levels of at least 0.02 mJ/mm^2 .

Figure 6-33: Pressure field in the plantar fascia along the second ray section of the foot for different applicator positions. The projectile speed was 12.3 m/s. A: P_+ and P_- , B: energy flux density.

6.2.3 Energy Transfer and Behaviour at Longer Timescales

The fluctuation of energy for the model components was examined to determine the level of energy which is delivered to the foot by the radial shock wave device. Figure 6-34 shows the energy exchange between the projectile, applicator, o-rings, and foot immediately before and after the impact. The results were obtained for the reference case with the applicator in Position 1 and $V_0=12.3 \text{ m/s}$. The graphs are similar to the case when the device was “fired in the air” (see Figure 3-11, Section 3.3.1). The main difference is that the front o-ring absorbed less energy during the forward displacement of the

applicator, since some of that energy was absorbed by the foot. At the end of the pre-load phase the total energy in the foot equalled 41 mJ. After the impact, the energy of the foot quickly rose to 71 mJ at the moment when the applicator energy was at its minimum and the applicator was in the forward-most position. Given that the initial energy of the projectile equalled 256 mJ, approximately 12% of the projectile energy was delivered to the foot. After reaching its peak, the energy in the foot decreased slightly and then stayed almost constant at the level of 64 mJ, i.e, 23 mJ more than at the end of the pre-load phase.

Figure 6-34: Total energy of model components during the impact.

In the foot, the bulk of the energy was stored in the soft tissue, followed by the plantar fascia and the calcaneus. The remaining components of the foot stored negligible amounts of energy. Figure 6-35 shows energy fluctuation in the plantar fascia and calcaneus. It can be seen from the figure that the energy fluctuation pattern for the plantar fascia was similar to that of the whole foot. The energy increased from 0.8 mJ just before the impact to 1.9 mJ just after the impact and then remained largely constant at 1.7 mJ. Taking into account the initial energy of the projectile, this means that 0.4 % of the

projectile energy was delivered to the plantar fascia. The energy fluctuation pattern for the calcaneus was different. After a rapid increase of energy from 0.13 mJ just before the impact to 1.4 mJ just after the impact, the energy quickly dropped to 0.3 mJ. Therefore, about 0.5 % of the projectile energy was delivered to the calcaneus.

Figure 6-35: Total energy of the plantar fascia and calcaneus during the impact.

Since the results suggested that after the impact a certain amount of energy may remain stored in the foot, simulations were carried out to examine the effect of more than one impact. Thus, the second projectile was introduced, and it was positioned in such a way that it collided with the applicator 50 ms after the first projectile impact. This corresponds to the 20 Hz frequency of shock wave pulse delivery, which is the maximal rate used clinically. The results for the pressure at the soft tissue surface, total energy of the foot, and total energy of the plantar fascia are shown in Figure 6-36. The pressure trace shown in Figure 6-36 A indicates that the pressure at the surface of the foot quickly dissipated after each impact. The pressure waveforms for each impact were essentially the same. In contrast, there was a cumulative effect of impact on the total energy of the foot

and plantar fascia, as shown in Figure 6-36 B and Figure 6-36 C, respectively. Between two impacts, the energy of the foot decreased very slowly, whereas the energy of the plantar fascia experienced minimal increase. These results can be explained by the fact that the only dissipation in the model was due to the damping in the o-rings. Energy was also lost when the waves propagated through the non-reflective boundary at the top surface of the foot. Once the energy was delivered to the foot with an impact, it spread both via fast propagating pressure waves and via slowly propagating shear waves in the soft tissue. Only a small amount of the energy left the foot through the non-reflective boundary. Thus, most of the stored energy remained until the second impact. In reality, visco-elasticity of the tissue may dissipate some or all of the energy delivered by an impact before the next impact occurs. Consequently, these results should be regarded as a preliminary finding.

Figure 6-36: Two impacts: A: pressure waveform at the surface of soft tissue, B: total energy of the foot, C: total energy of the plantar fascia.

6.3 Conclusions

The finite element model of the radial shock wave source and the finite element model of the foot were coupled to simulate the mechanical effects of radial shock wave therapy. The interfacing between the applicator and the soft tissue was achieved by pressing the device with a force of 50 N, as achieved clinically. Three different applicator positions and three different speeds of the projectile were considered. Also, two different types of contact between the applicator and the soft tissue were examined: tied contact and sliding contact without friction. The former represented perfect interfacing between the applicator and the foot and the second represented the situation where the coupling was compromised by inadequate use of coupling gel.

The pre-load resulted in stresses of up to several MPa being generated in the bones and the plantar fascia. The positioning of the applicator had only a moderate effect on stress distribution in the pre-load phase. The impact of the projectile on the applicator resulted in a pressure wave being generated in the foot. The highest level of pressure was found at the surface of the soft tissue where the applicator was applied. Pressure waveform patterns were consistent with the results obtained using a simple model for soft tissue: pressure amplitudes were directly related to the projectile speed and acoustic impedance of the soft tissue; there was a train of positive and negative pressures whose amplitudes were of the same order of magnitude. The values of negative pressure were sufficiently high to potentially trigger cavitation in the soft tissue and plantar fascia. When the tied contact was set between the applicator and tissue, pressure persisted for longer periods of time; when the sliding contact was used, pressure died away quickly. The pressure wave propagation pattern was complex due to different material properties of the foot components which resulted in reflections and propagation at different speeds. The magnitude of the pressure wave was much lower in the bone than in the soft tissue. In contrast, von Mises stress generated by the impact was much higher in the bone (calcaneus) than in the soft tissue. This may be due to the fact that the pressure wave travelling in the soft tissue splits into a longitudinal and shear wave when it reaches the calcaneus. The von Mises stress was also high in the plantar fascia, but mainly due to the pre-load. The energy flux density generated at the surface of the foot was of medium to high level. The zone exposed to highest levels of EFD was between the surface of the soft tissue above the applicator and the calcaneus. The energy flux density generated at the plantar fascia was of low to

medium level. Positioning of the applicator had a limited effect on pressure amplitudes as well as on the level and distribution of EFD. It was found that the most effective positioning is the one where the bulk of the generated pressure wave reaches the plantar fascia before colliding with the bone. The lack of tied contact between the applicator and tissue of the foot resulted in a dramatic reduction of the EFD. The results showed that only a small fraction of the energy carried by the projectile is transferred to the foot with a single impact. However, there is a possibility that energy could be accumulated with multiple impacts.

7 Discussion

Plantar fasciitis is a chronic pain condition that affects a large section of the general population. In cases where the conventional treatment fails to yield satisfactory results, plantar fasciitis is sometimes treated using shock wave therapy. Radial shock wave therapy is a relatively novel method for the treatment of connective tissue inflammation. There is a growing body of evidence from clinical studies that this therapeutic method is effective in the management of conditions such as plantar fasciitis. However, the understanding of the physical stimuli generated through shock wave treatment, and their potential biological effects is limited. Published data on the mechanics of the radial shock wave source and on the pressure generated by this type of device mainly originates from the manufacturers (Wess 2008; DolorClast 2009; DoroCalst 2009). Only a small number of research studies were conducted in which the pressure field generated by the radial shock wave sources were measured in water-filled containers or simple experimental phantoms (Cleveland et al. 2007; Benoit et al. 2009; Ueberle and Rad 2012). Computer modelling studies of radial shock wave therapy are even less common; there is only one published finite element model of the shock wave device applied to an experimental phantom (Benoit et al. 2009). Experimental or modelling-based research studies on the effects of radial shock wave treatment on the human body have not been performed to date. The aim of this work was to bring further insight into the bio-mechanical effects of radial shock wave therapy in the context of plantar fasciitis management. The approach was to use finite element modelling as the principal research tool.

7.1 Modelling

A three-dimensional finite element model of the Swiss DolorClast shock wave source with the 15 mm standard applicator was created based on the measurements obtained from an actual device. While to some extent informed by an existing axi-symmetric model presented by Benoit et al. (2009), the current model went further in terms of realistic geometric representation of an actual device. Also, the pre-loading of the o-rings on which the applicator is suspended was addressed in this model as this has a significant effect on the bulk motion of the applicator. The foot model was created based on an anatomically realistic geometry reconstructed from the MRI images of a female

volunteer. In this model the plantar fascia was a three-dimensional object that was fully embedded in the surrounding tissue. The same modelling approach was adopted for the Achilles tendon. The model configuration was created to fit the purpose of simulating the propagation of short duration pressure waves through the anatomical components of the foot. Features such as joint kinematics were considered a low priority. Consequently, the bones of the forefoot and midfoot, which are remote to the site where the pressure source was applied, were represented as a single object and the remaining bones were connected with cartilage. This modelling approach ensured continuity of the media through which pressure waves propagate. A comprehensive literature review was conducted to assess the material models for the foot components. The material models and constants were chosen so that the acoustic properties of the tissues are consistent with the published experimental data. Numerical experiments conducted using a soft tissue object of a simple shape showed that the correct acoustic impedance of the medium is the critical parameter which determines whether the model will accurately predict the pressure wave generated by the pressure wave device. Some of the material models widely used for the soft plantar tissue in the published papers (Lemmon et al. 1997; Jacob and Patil 1999; Chen et al. 2003; Cheung et al. 2004; Tao et al. 2009) led to completely unrealistic results in terms of the main parameters of the pressure wave.

7.2 Dynamics of the Radial Shock Wave Source

The results for the bulk movement of the applicator obtained from the finite element model of the shock wave device were consistent with the published data and with the results of an experiment set to determine applicator movement for a single projectile impact. The movement of the applicator can be described as highly damped oscillations, where the o-rings act as a spring-damper. The characteristic timescale of the applicator oscillation is of the order of 10^{-4} s. The collision between the projectile and the applicator lasts for about 10 μ s and results in a stress wave in both objects. After the separation, there is a standing stress wave in the applicator with amplitude of the order of 10 MPa and with a characteristic timescale of the order of 10^{-6} s. The pattern of the standing wave is complex and it is influenced by the applicator shape. The overall dynamics of the applicator has little effect on the stress wave. Therefore, it can be concluded that the way in which the applicator is suspended should have only a minor effect on the effectiveness of

the device. On the other hand, the shape of the applicator may have a significant influence on the generated pressure. This is consistent with the experimental findings obtained by Ueberle and Rad (2012) who found that applicators of the same diameter, but of different shapes, generated significantly different pressure waveforms.

7.3 Pressure Field Parameters in the Absence of Reflections

The model of the device was coupled with a soft tissue object with the boundary conditions set in such a way as to eliminate the effect of wave reflections. The results for the pressure traces at or just below the front surface of the applicator were in good agreement with the experimental results obtained by Cleveland et al. (2007), Benoit et al. (2009), and Ueberle and Rad (2012). The positive pressure amplitude in the tissue at the interface with the applicator was equal to the product of the speed of the movement at the applicator tip and the acoustic impedance of the soft tissue. The speed of the particles at the tip of the applicator was in turn equal to approximately 40% of the initial speed of the projectile. This means that the speed of the projectile is a critical parameter that determines the level of pressure generated by the device. For applicators of roughly the same diameter and mass, the shape could be another factor that can influence the pressure generated by the device. The shape that maximizes the movement at the tip of the applicator should result in highest pressure. In terms of the pressure waveform duration, the results suggest that they may persist for up to 0.5 ms even in the absence of any wave reflections. Therefore, the successive peaks of pressure observed experimentally by Ueberle and Rad (2012) in a silicone phantom may not be entirely due to wave reflections as concluded by the authors.

The pressure wave pattern in the soft tissue object was in the form of successive radial waves of positive and negative pressure with the wave length of about 10 mm. The wave length of the initial pressure wave was somewhat larger than the wave length of the following waves. When the applicator was modelled as a rigid object, only the initial pressure wave was formed and it had the same wave length as when the applicator was made of steel. This suggests that the initial pressure wave is not directly related to the stress wave in the applicator. Thus, the wave length of the initial pressure wave may be determined by the material properties of the soft tissue and probably by the diameter of the

applicator. On the other hand, the subsequent pressure waves are directly related to the stress wave transmitted from the applicator.

The pressure amplitude and the energy flux density (EFD) decreased proportionally with distance from the applicator. The values of the EFD determined from the pressure traces were consistent with the data reported by the manufacturers (DolorClast 2009) providing that the standard interval of $25\ \mu\text{s}$ was used for the calculations. However, when the EFD was calculated using a larger time interval, much higher values were obtained. This discrepancy may be due to the fact that in the model, perfect interfacing between the applicator and the soft tissue resulted in pressure waveforms that persisted for well over $25\ \mu\text{s}$. On the other hand, it is possible that experimentally obtained pressure waveforms used for calculating the EFD are truncated at $25\ \mu\text{s}$ in order to eliminate the influence of wave reflections, thus underestimating the real values.

7.4 Pressure Field Parameters in the Foot

When the model of the shock wave device was coupled with the model of the foot, the results for the pressure waveforms at the interface with the applicator were similar to the results obtained using the soft tissue object of simple shape. The values of P_+ and P_- for the maximal projectile speed of 14.9 m/s were 8 MPa and -7 MPa, respectively. This suggests that experiments performed on simple phantoms are useful for predicting pressure generated at the surface of the soft tissue. However, when the pressure wave propagated into the interior of the foot, the pattern was much more complicated due to the complex shape of the foot components and their different material properties. The pressure wave moved through the interface between the soft tissue and plantar fascia without much influence, but the interface between the bone and the soft tissue strongly affected wave propagation. At the plantar fascia, the values of P_+ and P_- for the maximal projectile speed of 14.9 m/s were 1.6 MPa and -2.7 MPa, respectively. The results showed that the pressure amplitude falls considerably when the wave propagates into the bone. This is contrary to the prediction of a simple theory of sound propagation, according to which the amplitude increases when the wave moves into a medium of higher impedance. The explanation may be that the incident longitudinal wave reaching the bone splits into longitudinal and shear waves with the transmitted shear wave carrying much of the energy. This effect was

reported by Cleveland and Sapozhnikov (2005) whose modelling study predicted the formation of strong shear waves in a kidney stone treated with shock waves. This conclusion is also supported by the fact that the von Mises stress in the calcaneus increases as the pressure wave reaches the bone and then it spreads at a speed lower than the speed of longitudinal waves. Consequently, von Mises stresses generated by the pressure wave are highest in the calcaneus.

7.4.1 The Effect of Applicator Positioning, Contact, and Multiple Pulses

Small variations in the positioning of the applicator consistent with clinical practice did not have a significant effect on the pressure waveforms at the surface of the soft tissue, and they had only a limited effect on the pressure field at the level of the plantar fascia. The main conclusion regarding the applicator positioning is that the optimal position is the one for which the bulk of the pressure wave reaches the plantar fascia before encountering the calcaneus. On the other hand, the contact between the applicator and the soft tissue significantly affected the pressure waveform; for the sliding contact the amplitude of the negative pressure was much lower than for the tied contact, and the pressure waveform was of much shorter duration. This result emphasizes the importance of achieving the proper interface between the device and the foot. Pressure waveforms obtained using the tied contact are in better agreement with the published experimental data than those obtained using the sliding contact. The levels of the EFD at the surface of the soft tissue calculated using a time interval of 80 μ s were in the medium to high energy zone. At the plantar fascia, the levels of the EFD were at the low energy level. The effect of the contact between the applicator and the foot had an even more pronounced effect on the EFD than on the pressure amplitude; with a sliding contact the values of the EFD were exceptionally low.

The effect of multiple pulses was examined by simulating two successive projectile impacts spaced at a 50 ms interval (20 Hz frequency). The results showed that while the pressure wave dissipated long before the second hit, the (strain) energy in the foot stayed almost constant between the pulses. Thus, the second pulse added an additional amount of energy to the foot. This leads to the conclusion that multiple pulses delivered in clinical treatment sessions may have a cumulative effect on the strain energy stored in the foot. This energy is most probably associated with shear waves in the soft tissue of the foot.

While it is questionable whether this observation would still hold if energy dissipation mechanisms such as viscoelasticity of the tissue were taken into account, the energy accumulation mechanisms still deserves attention in the future.

7.5 Possible Mechanical Stimuli Leading to Healing

The results suggest that the magnitude of negative pressure at the plantar fascia is beyond the lower threshold for the onset of cavitation of -1.5 MPa suggested by Coleman et al. (1995). Therefore, cavitation could be one of the main mechanisms through which shock wave therapy enhances the healing process. The predicted values of negative pressure are of the same level as those that may be generated by focused shock wave therapy. In addition, the duration of exposure to negative pressure is longer than in the focused shock wave therapy, and the zone exposed to negative pressure is larger. Therefore, radial shock wave therapy may be more effective in inducing cavitation than the focused shock wave therapy. This may explain why some clinical studies conclude that low energy radial wave therapy is more effective in treating plantar fasciitis than focused shock wave therapy (Chang et al. 2012).

It is also worth noting that the pre-load used to achieve proper interfacing between the applicator and the foot may generate considerable tensile stress in the plantar fascia near its insertion into the calcaneus. Considering that stretching is one of the main conservative treatments for plantar fasciitis, it cannot be ruled out that the pressing of the device against the foot may have some therapeutic effect.

8 Conclusions and Future Work

A finite element study has been conducted to gain a better understanding of radial shock wave therapy and its use for the treatment of plantar fasciitis. To the best of the author's knowledge, this is the first attempt to simulate the effect of radial shock wave therapy on the human body using finite element modelling. New modelling features have been introduced in both the model of the device and the model of the foot. Most importantly, this is the first foot model with 3D plantar fascia and Achilles tendon embedded into the soft tissue. In the future, the same model can be exploited for investigating other applications of shock wave therapy such as the treatment of Achilles tendonitis. The results obtained from the model are consistent with the published experimental data which are very limited in scope. The model of the shock wave device was also validated against an experiment conducted as a part of this study. However, further validation is highly recommended. Ideally, ex-vivo experiments on cadaveric feet should be carried out to test the predictions obtained from the model.

The results from the study point to the fact that the amplitude of the generated pressure can be related to the projectile speed in a simple way. The pattern of the pressure waveform, on the other hand, is affected by the shape of the applicator. In this study only one type of applicator was examined. In the future, other existing applicator designs could be incorporated into the existing model of the shock wave device. In addition, it would be worth conducting a parametric study in order to optimise the applicator design.

The results point to the fact that interfacing between the applicator and the soft tissue has a major effect on the pressure and energy delivered to the body. For an ideal tied contact between the applicator and the tissue, multiple positive and negative pressure peaks are transmitted effectively. The other extreme case considered was a sliding contact without friction which resulted in much less effective transmission of stress from the applicator to the tissue. In reality, the interfacing is achieved using a coupling gel. Further studies are necessary to examine the coupling achieved by this approach in a more realistic fashion.

The values of negative pressure predicted by the model should be sufficient to generate cavitation in the affected region of the foot. A more precise prediction for the

onset and effects of cavitation requires further experimental and modelling effort. For example, the finite element model could be coupled with a mathematical model of cavitation bubble formation and stability. This approach has already been used for the modelling of adverse effects of shock wave therapy on kidney tissue. Another possible mechanical stimulus detected from this study may be related to the pre-load phase of treatment in which large tensile stresses may be generated in the plantar fascia. It should be said that due to the simplifying approach adopted in representing bone articulations, these results should be subjected to further scrutiny. Finally, there is a possibility that energy in the foot can be accumulated by delivering a large number of shock wave pulses, as is normally done in clinical practice. What exact biological effect this energy accumulation could generate is not clear, since the energy is not associated with high pressure. However, it cannot be ruled out that this effect is related to a healing mechanism.

The model predicts that, apart from the soft tissue and plantar fascia, the calcaneus is the foot structure exposed to the highest levels of stress. The effect that this stimulus may have on the bone has not been given attention as this was not the focus of this study. However, this is a result that merits further investigation, especially because shock wave therapy has been used for the treatment of bone non-unions. Also, adverse side effects of shock wave therapy on the bone tissue cannot be ruled out. If this type of analysis is to be carried out, the model would have to be modified to incorporate more realistic representations for the material properties of the bone tissue. The trabecular bone needs to be modelled as a poro-elastic material in order that its acoustic properties are represented accurately. A medical imaging-based non-homogeneous material consisting of a bone matrix and fluid-filled voids could be a possible approach.

The main remaining challenge for the understanding of the healing mechanism of shock wave therapy in the treatment of musculoskeletal disorders is the lack of a solid theory that connects mechanical stimulus to the biological response in the tissues. Thus, a full understanding of the limitations and further possibilities of this therapeutic method requires coordinated efforts from researchers with expertise in the different fields of engineering and biomedical sciences.

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Appendix 1 Publications

A1.1 Conference Publications (oral)

- Alkhamaali,Z., Cirovic,S., Maggi, G., 2012. Modelling of the radial wave therapy for the treatment of connective tissue inflammation. In: 18th Congress of the European Society of Biomechanics. Foot and Ankle Biomechanics. Lisbon, Portugal, 1st- 4th July 2012.
- Alkhamaali,Z., Cirovic,S., 2012. Three dimensional model of the foot and pressure source to simulate radial wave therapy. In: 19th Congress of the European Society of Biomechanics. Foot and Ankle Biomechanics. Patras, Greece, 25th – 28th August 2013.

MODELLING OF THE RADIAL WAVE THERAPY FOR THE TREATMENT OF CONNECTIVE TISSUE INFLAMMATION

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Introduction

Radial wave therapy has been increasingly used for the treatment of a variety of conditions including the management of pain related with the inflammation of the connective tissue in the foot (plantar faciitis and Achilles tendonitis). While this therapy is relatively widespread, there is no conclusive clinical proof that it is effective. Also, at this point in time the understanding of the exact mechanism through which the method may work is at the level of speculation. In the open literature, radial wave therapy is often confused with the focused shock wave therapy. However, the two methods are very different in terms of the way that the pressure wave is generated and distributed to the body. In the focused shock wave therapy, a high amplitude pressure wave (up to 100MPa) is generated outside of the body and the entire wave energy is focused via a spherical reflector to a point inside of the body. The waves that are "supersonic" may be used to break a kidney stone through shearing and cavitation. In the radial wave therapy, a metal object of 6-15mm in diameter (an applicator) is applied superficially to the location that has to be treated. Pressure pulses are generated with a frequency of up to 20Hz when a pressure driven projectile hits the applicator, giving it a velocity of 1-2m/s. These pressure waves propagate in all directions. While the pressure wave generated in the shock wave therapy has been well investigated, there is little information on the waves generated by radial pressure therapy [McClure *et al.*, 2003]. We used finite element models to gain information on the pressure pulse that is generated by a pressure wave device for various thicknesses of soft tissue. Next, the calculated pressure pulse was used as the input to a two-dimensional model of the foot.

Methods

A simple model of the pressure wave device was constructed using the OVE-ARUP, LS-DYNA finite element package. The applicator was modelled as a rigid object suspended on a spring-damper system. A purely elastic collision between the applicator and projectile generated the initial velocity of 2m/s. The applicator was in contact with a solid block representing the soft tissue whose thickness and material models were varied to

examine their effect on the generated pressure pulse.

A two-dimensional model of the foot was constructed based on MRI images in the sagittal plane. The material properties for the bone, soft tissue, plantar fascia and cartilage were taken from Wu [2007]. A single pressure pulse was applied at the point beneath the insertion of the plantar fascia into the calcaneus.

Figure 1: Two consecutive pressure pulses generated by impact with a soft tissue.

Figure 2: 2D model of the foot

Results and Discussion

The simulation of the pressure generator shows that amplitudes of the pressure pulses strongly depend on the soft tissue thickness. A possible implication of this result is that excessively high pressures may be generated when treating Achilles tendon inflammation.

The results from the foot model suggest that the wave propagating through the foot may cause the stretching of the plantar fascia as a secondary effect to the initial pressure loading.

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THREE-DIMENSIONAL MODEL OF THE FOOT AND PRESSURE SOURCE TO SIMULATE RADIAL WAVE THERAPY

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Introduction

Radial wave therapy has been increasingly used for the treatment of a variety of conditions including the management of pain related with the inflammation of the connective tissue in the foot (plantar fasciitis and Achilles tendonitis). While this therapy is relatively widespread, there is no conclusive clinical proof that it is effective. Also, at this point in time the understanding of the exact mechanism through which the method may work is at the level of speculation. In the open literature, radial wave therapy is often confused with the focused shock wave therapy. However, the two methods are very different in terms of the way that the pressure wave is generated and distributed to the body. In the focused shock wave therapy, a high-amplitude pressure wave is generated outside of the body and the entire wave energy is focused on a single point inside the body. In the radial wave therapy, a ballistic pressure source is used; a metal object of 6-15mm in diameter (an applicator) is applied superficially to the location that has to be treated. Pressure pulses are generated when a pressure driven projectile hits the applicator. These pressure waves propagate in all directions. While the pressure wave generated in the shock wave therapy has been well investigated, there is little information on the waves generated by radial pressure therapy. We created finite element models of the foot and of the ballistic pressure source to simulate the mechanical effects of the treatment.

Methods

A simplified model of the pressure wave device consisting of only the applicator and projectile was constructed using the ANSYS finite element package. The applicator was modelled as a rigid object suspended on a spring-damper system representing the constraint from the casing. The parameters of the spring-damper system were determined experimentally.

A three-dimensional geometry of the foot was reconstructed using the Simpleware Software and based on MRI images of the foot of a 32 year old female. The foot model comprised of bones, soft tissue, plantar fascia, and Achilles tendon, which were all represented as three-dimensional objects. The calcaneus, talus, tibia, and fibula were represented as separate objects, whereas the rest of the bones were lumped together. The adjacent bones were connected with cartilage. All the bones had a cancellous core and a cortical outer shell. The material properties for the bone, soft tissue, plantar

fascia and cartilage were taken from [Wu, 2007]. Meshing was performed using the ANSYS Workbench. The FE model was then exported into the LS-DYNA software which was used for the simulations of a single pressure pulse which was generated when the projectile moving at 15-20m/s collided with the applicator.

Figure 1: The finite element model.

Figure 2: Stress distribution in the plane of the second ray of the foot at 1ms after the impact.

Results and Discussion

The simulation shows that in the soft tissue the pressure wave is mainly confined to the heel pad. Once the wave reaches the stiff structures in the foot it rapidly propagates through the bones and connective tissue, whereas in the soft tissue it is quickly dissipated. The highest stress values are observed in the plantar fascia and cortical bone at the plantar fascia insertion point. However, high stresses are also observed in the cortical region of the calcaneus which could indicate that this region may be affected by the treatment.

References

L. Wu, Clinical Biomechanics, 22:221-229, 2007.