**Cadaveric experiments to evaluate pressure wave generated by radial shockwave
treatment of plantar fasciitis**

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Abstract

Background: Shockwave treatment is increasingly used for plantar fasciitis and Achilles tendinopathy. To be effective it is believed that high pressure must be achieved in the tissues. We report on the first human cadaveric experiments to characterize pressure from radial shockwave therapy (rSWT) for plantar fasciitis.

Methods: The pressure from rSWT was measured in two cadaveric feet using a needle hydrophone. Maximal pressure and energy flux were calculated from the measurements.

Results: The pressure persisted longer than supposed, for up to 400 microseconds. The peak negative pressure was up to two Mega Pascal. The predicted energy in the tissue strongly depended on the time interval used in calculations.

Conclusions: The measured pressure may be sufficiently high to cause cavitation in the tissue, which is one of the proposed healing mechanisms associated with rSWT. The results suggest that the energy is imparted to the tissues for much longer than previously thought.

Keywords

Radial shockwave therapy; Pressure waves; Plantar fasciitis; Chronic pain

1. Introduction

Shockwave therapy (SWT), the therapeutic use of high-amplitude transient pressure waves, is an increasingly popular treatment method for plantar fasciitis as well as other forms of musculoskeletal disorders such as Achilles and patellar tendonitis [1-4] . There are two forms of SWT: focused and radial. In focused shockwave therapy (fSWT), a shockwave is generated in a fluid-filled cuff and its whole energy is concentrated (focused) to a very small treatment zone. In radial shockwave therapy (rSWT) the pressure is generated through the

collision of two metal objects: a projectile driven by compressed air and an applicator which is in contact with the body. The impact from the projectile generates a stress wave in the applicator which then spreads into the tissue in all directions as a "radial wave" that eventually reaches the affected zone. In comparison with fSWT the rSWT has a much simpler operating principle, it is less expensive and it can be administered without anaesthesia. On the other hand, the pressure magnitude and energy of the rSWT are usually much lower than those of the fSWT [5, 6].

Clinical studies indicate that both forms of SWT are successful in managing plantar fasciitis and other musculoskeletal disorders [4]. However, the mechanisms through which the pressure waves act to enhance the healing process is still unknown [4]. One of the leading current hypothesis is that the healing mechanism(s) may involve cavitation-induced micro-injury promoting neovascularisation [7-9]. In order to produce cavitation in the tissues (with micro-injury and subsequent healing) the shockwave must firstly generate high positive pressure in the tissue. As this pressure falls it "recoils" below resting pressure and this negative pressure is credited with causing the cavitation. The mechanism has been compared to a bullet hitting a target, with a small entry hole but large exit hole and cavity. The minimal suggested threshold for the onset of cavitation in the soft tissue is -1.5 Mega Pascals [10] (one Mega Pascal (MPa) is ten times the atmospheric pressure, i.e., 10 bar). Other potential mechanisms have also been proposed such as biological response at the cellular level [11], and pain management through the reduction of afferent sensory fibre function [12]. These depend not only on the pressure magnitude, but also on net energy delivered by the pressure wave. Pressure transferred from the shockwave equipment to, for example the calcaneal attachment of the plantar fascia, is therefore critical to the therapeutic effect. This has never before been measured in human tissue.

The standard way of assessing the pressure field generated by shockwave devices is via water bath experiments (IEC standard 61846). Water is chosen as the working medium since it has similar acoustic properties to those of soft tissues. The tip of the applicator is directly submerged, and the device is fired to generate a pressure wave that spreads through the water. It is argued that the pressure measured in the water at some distance from the shockwave source is representative of the pressure generated clinically in the tissues at that same distance. The parameters used to characterise pressure waveform are the maximal values of positive and negative pressure (P_+ and P_- respectively) and the net energy received per unit area, i.e., Energy Flux Density (EFD). The energy is calculated by "integrating" the measured pressure waveform using a standard formula [5]. In order to get the net energy delivered by one pulse, the pressure waveform should be integrated over its entire duration. However, it is customary that only the initial part (the first 20 to 30 microseconds) of pressure waveform is considered in the calculations in order to avoid the influence of reflections from the walls of the water container [13]. The typical values of the pressure range (maximum to minimum) measured in-vitro near the tip of the applicator are up to 10 MPa. This produces Energy Flux Density of 0.05 to 0.5 milli Joules per square millimetre (mJ/mm^2). Both pressure and energy diminish rapidly as the measurements are taken further from the shockwave source [5, 14]. While water bath experiments are a useful first approximation, they do not give an entirely accurate account of the pressure field generated in clinical practice. For example, the pressure wave generated at the skin on the surface of the heel in plantar fasciitis treatment travels through different tissues (e.g. skin, soft tissue, fascia and bone), which affects its progression. Also, the interfacing between the applicator and the plantar surface is achieved via a coupling gel which may result in less effective transmission of waves from the device than when the applicator is directly submerged in water. It is therefore necessary to directly measure pressure in the treated area of the body in

order to obtain a more accurate account of the actual pressure generated by the rSWT treatment. In-vivo experiments in animal models have already been performed to measure pressure generated by the fSWT treatment of kidney stones [15]. However, the measurement of the pressure field from rSWT sources has been mainly restricted to water baths [13, 14, 16], and simple silicon experimental models [17, 18]. In this study we conducted the first in-vitro measurement of the pressure generated by rSWT plantar fasciitis treatment in human cadaveric feet.

2. Methods

The aim of the experiment was to measure the pressure generated by a radial shockwave at the point of insertion of the plantar fascia onto the calcaneus. The medial calcaneal tuberosity is the site of attachment of the central band of the plantar fascia. This is the largest of the three component parts and the part of the structure that most commonly becomes thickened and maximally tender to palpation in cases of recalcitrant plantar fasciitis. This area is therefore the typical treatment zone in the management of plantar fasciitis. A needle-type transducer capable of capturing high-amplitude pressure at a fast rate (hydrophone) was used for the measurements. This type of device is primarily designed for the measurement of transient pressure waves in fluids (e.g. water baths) and it can be easily damaged if exposed to any kind of physical force, such as the force applied when pressing the applicator against the sole of the foot to achieve a good interface. Therefore, special attention was given to devise a method for its placement into the foot. The probe was inserted into the foot from superior to inferior via a bone tunnel drilled in the calcaneus with only its pressure-sensing tip protruding just outside of the bone.

2.1 Specimen preparation

Two cadaveric feet were used in the experiment (referred to hereafter as Foot 1 and Foot 2). These were obtained from a commercial supplier (ScienceCare, Phoenix, AZ) through our regulated Surgical Training Centre (MATTU, Post Graduate Medical School, University of Surrey, Guildford, UK). The specimens were appropriately disposed of at the end of the experiments. Prior to testing, the frozen specimens were thoroughly defrosted for 48 hours and then kept refrigerated. On the day before testing, they were removed from the refrigerator and allowed to reach room temperature. The talus was removed by sharp dissection to expose the posterior facet of the subtalar joint on the superior surface of the calcaneum. This was then carefully cut in the axial plane to produce a flat surface of cancellous bone, enabling the specimen to be secured within the custom jig. A sharp 2.5 mm drill was used to drill the hole and subsequently enlarged to accommodate the dummy probe. Great care was taken to avoid the drill penetrating the soft tissues distal to the cortical bone. After drilling, the hole was gently washed to remove debris without forcing irrigation fluid into the soft tissues.

2.2 Experimental setup

The experimental setup is schematically depicted in Figure 1. The foot was secured between two horizontal plates mounted on threaded rods. Both the lower and the upper plate had openings to allow the application of the shockwave source, and of the pressure probe, respectively. The shockwave source used in this study was the Swiss DolorClast Classic (E.M.S. Electro Medical Systems S.A., Nyon, Switzerland) with a standard 15 mm applicator. The shockwave device was clamped to a supporting frame which could be freely moved on the base of the rig to position the tip of the applicator onto the treatment zone. Once the applicator was placed in the proper position it was pressed against the foot with the recommended force of 35 N and the clamp was firmly tightened to prevent any further movement. The pressure was measured using a 0.2 mm needle hydrophone (Precision Acoustics, Dorchester, UK). The probe was inserted into the tunnel and therefore measured

pressures at the deep surface of the plantar fascia where it attaches to the medial calcaneal tuberosity. A bespoke precision positioning mechanism with six degrees of freedom was used to accurately position the probe. This had very fine adjustments in order to ensure that the fragile hydrophone was not damaged during placement. The signal from the pressure probe was fed to a digital oscilloscope (Tektronix 1001B, Tektronix Inc., Beaverton, OR) to monitor the signal and to store measurement data.

2.3 Experimental procedure

The pressure probe was positioned in the following way: First, a dummy probe, an aluminium cylinder of the same length as the actual hydrophone, was aligned with the tunnel in the calcaneus and positioned so that its tip just protruded through the plantar cortex of the calcaneus. The accurate alignment of the dummy probe was achieved using the positioning mechanism. Placement of the dummy probe was confirmed with an ultrasound scan. At the same time the ultrasound scanner was used to measure the distance between the skin on the plantar surface of the specimen and the tip of the probe. The dummy probe was then removed using a single degree of freedom movement aligned with the tunnel. Next, the tunnel was fully filled with distilled water to avoid air gaps and to assure continuity of pressure wave propagation. Finally, the hydrophone was inserted using the same direction of movement and distance used to remove the dummy probe.

The shockwave source pressure setting of 2 bar was chosen for the experiment. This pressure setting is typically used in clinical practice when treating plantar fasciitis. A single shockwave pulse mode was used in all experimental trials. After running preliminary trials to assess the duration of a typical pressure waveform and determine the required resolution of the signal, the measurements were repeated 10 times for each foot. For each measurement the pressure data was acquired with a sampling interval of 0.2 μs over a period of 400 μs .

2.4 Data analysis

For both feet the pressure traces from 10 experimental runs were averaged to obtain a representative waveform. Also, standard deviations across the experimental trials were calculated for each point in the pressure trace to examine the consistency of the results across the experimental runs. The values of P_+ , P_- and EFD (the energy transmitted per square millimetre) were determined from the averaged pressure traces. The EFD was calculated for time intervals (T) ranging between 40 and 400 microseconds (μs) from the onset of the pressure pulse.

3. Results

A representative pressure waveform from preliminary trials is shown in Figure 2. The measurement was obtained in Foot 1 with a sampling interval of 4 μs capturing a signal of 1000 μs in duration. The pressure trace shows multiple positive and negative peaks of the order of MPa which persisted for up to 400 μs . The spectral analysis of this signal revealed that the pressure waveform frequency band was between 50 and 300 kHz with the dominant peak at approximately 120 kHz.

The pressure waveforms obtained from 10 experimental runs were very consistent for both feet. This can be seen from Figure 3 (a and b) which shows the averaged pressure waveforms $\pm$ the standard deviation for each of the points in the data (shaded area). Only the first 25 μs of the signal is shown so that the pressure waveform features are clearly visible. It can be seen from the Figure that the pressure traces measured in the two feet have a very similar shape, especially for the first 10-15 μs of the signal; the first positive pressure peak occurred at 2.5 μs approximately but this was not necessarily the most pronounced peak in the signal. The maximum negative pressure peak occurred at about 8 μs following a very

mild first negative peak at approximately 5 μ s. The subsequent alternating positive and negative pressure peaks diminished in magnitude as the time progressed. However, strong pressure peaks could be found as far as 50 μ s into the signal. For example, the highest positive pressure value for Foot 1 was obtained at 14 μ s from the start of the pulse. In both pressure traces the maximum negative pressure was larger than the maximum positive pressure. While the shapes of the pressure traces for Foot 1 and 2 were very similar, the magnitude was markedly different; for Foot 1, P_+ was 1.2 MPa and P_- was -2.0 MPa, whereas for Foot 2, P_+ was 0.6 MPa and P_- was -0.9 MPa. This difference in the magnitude of the generated pressure is probably due to the difference in the thickness of the plantar tissue. The distance between the plantar surface of the foot and the insertion point of the plantar fascia into the calcaneus was 10 mm for Foot 1 and 16 mm for Foot 2.

For the first 300 μ s the predicted values of EFD strongly depended on the time interval T used in the calculations (Figure 4). However, increasing T over 300 μ s made little difference to the calculated values of EFD. This means that the bulk of the energy is delivered to the tissue in the first 300 μ s from the onset of pressure pulse. There was a marked difference between the EFD levels calculated for the two feet, which is consistent with the fact that the amplitude of the pressure waveform was much higher for Foot 1. For both feet the EFD was in the low region. The calculated values using $T=400$ μ s were 0.023 mJ/mm^2 for Foot 1 and 0.004 mJ/mm^2 for Foot 2.

4. Discussion

The results from the repeated experimental runs show that the generated pressure waveforms have a highly repeatable pattern. The measured pressure waveforms were consistent with the

results reported from water bath and silicon phantom experiments. However, the pressure magnitude was at the lower end of the results obtained using simple experimental phantoms. This could be due to the fact that the interfacing between the applicator and the plantar surface of the foot is less effective than the interfacing achieved in water bath experiments. The plantar fat tissue in the heel of Foot 2 was about 5 mm thicker than in Foot 1 and this resulted in a marked difference in the pressure magnitude. It is likely that in human tissue, pressure wave dissipates with distance at an even faster rate than in water. If that is the case, plantar tissue thickness should be an important factor to consider when choosing the parameters of the shockwave therapy. Further evaluation of this may improve clinical outcomes, if the shockwave settings are adjusted to account for anatomical variation.

The results show that the duration of the pressure waveforms is of the order of several hundreds of microseconds. Pressure fluctuations in the first 300 μs contribute substantially to the energy flux and their contribution should not be neglected. Ueberle and Rad [14, 17, 18] analysed the pressure waveform generated by a rSWT in a silicon phantom and suggested that pressure fluctuations beyond the first 8.8 μs may be due to the persistent stress wave in the applicator and/or due to the reflections of the initial waveform from the free surface of the phantom. They concluded that the reflections should be the dominant factor. On the other hand, a computer-based simulation of the rSWT performed by Alkhamaali et al. [19] points to the possibility that a persistent stress wave in the applicator is the main contributor to the pressure fluctuations. In the foot, strong reflections of the pressure wave will occur at the free surfaces and to a lesser extent at the soft tissue-bone interfaces, mainly reflecting from the cortical bone of the os calcis. Such multiple reflected waves would have to cover a distance of several tens of millimetres before they reach the plantar fascia. In the process they will substantially diminish in strength and are not likely to strongly contribute to the overall pressure waveform. Therefore, we conclude that the persistent pressure fluctuations most

likely emanate directly from the applicator and should be a characteristic feature of the rSWT waveform regardless of a specific clinical application.

The calculated levels of energy reaching the tissue are very low, especially when compared to the levels generated by the fSWT [7]. Similarly, the recorded values of the maximum positive pressure are at least one order of magnitude lower than those generated by fSWT. One parameter that is on a similar scale for the two methods is the maximum negative pressure. This is the negative pressure required to produce “cavitation” in the tissue, considered to be the effect that stimulates healing. Given that fSWT and rSWT both appear to be (equally) effective in the treatment of plantar fasciitis [20] it is possible that negative pressure is the main factor contributing to the enhancement of the healing process. If that is the case, cavitation is a potential physical mechanism through which this is achieved; creation of cavitation bubbles by rSWT in water have been documented in published studies [16]. This conclusion is supported by the fact that the P. of -2 MPa recorded in Foot 1 is over the minimal suggested threshold for the onset of cavitation in the soft tissue [10].

The practical issues related to the placement of the pressure probe required that the top portion of the foot be removed and that a tunnel be drilled through the calcaneus. The removal of the top portion of the foot introduced a non-anatomical boundary from which the pressure waves could reflect back into the foot. However, as discussed in the previous paragraph, that effect is not likely to be significant. On the other hand, the presence of a relatively large water-filled tunnel may have resulted in diminishing the effect of the wave reflection from the calcaneus. This is because the acoustic properties of the tissue are much more similar to those of the water than those of the bone tissue. If the probe placement method from this study is used in future experiments, we advise that the tunnel diameter be kept to a minimum. This will require the design of even more precise placement techniques. In this study we used only a single shockwave pulse mode which is not a clinically realistic scenario.

This was mainly to avoid displacement between the foot and the source which could result in damage to the delicate probe. In the future more realistic multiple shockwave applications should be considered as this could result in different key pressure wave parameters.

4.1 Conclusions

Pressure waves generated by radial shockwave treatment were measured at the calcaneal origin of the plantar fascia in two cadaveric feet. To our knowledge this is the first attempt to measure a rSWT pressure field in a human tissue specimen. The measured pressure traces were highly repeatable and of the duration of about 400 μ s. Pressure magnitude at the plantar fascia was strongly influenced by the thickness of the plantar tissue. In the foot with thinner plantar tissue, negative pressure was of the level that may initiate cavitation (and therefore enhance healing) with multiple shockwave pulses. This study is a first necessary step towards designing future similar experiments which could involve a larger number of specimens and which may look into the effect of varying shockwave device positioning and pressure settings.

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Figures **Figure 1:** Experimental setup **Figure 2:** A typical pressure waveform. The pressure was measured in Foot 1.

Figure 3: Pressure traces ensemble averaged over 10 successive experimental runs. The shaded areas give standard deviations. a) Foot 1. b) Foot 2.

Figure 4: Energy flux density calculated over time intervals between 40 and 400 μs .