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Review

Therapeutic ultrasound in soft tissue lesions

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Abstract

Therapeutic ultrasound is one of the most common treatments used in the management of soft tissue lesions, which constitute the majority of rheumatic complaints. Although many laboratory-based research studies have demonstrated a number of physiological effects of ultrasound upon living tissue, there is remarkably little evidence for benefit in the treatment of soft tissue injuries. This may be related to several confounding factors, including technical variables, the complexity and variety of underlying pathologies in soft tissue lesions, methodological limitations of clinical studies, or true lack of effect. In this review the scientific basis for the use of therapeutic ultrasound in soft tissue lesions and the existing evidence relating to its clinical effect are detailed.

KEY WORDS: Ultrasound, Evidence, Therapeutic, Soft tissue, Tendon, Healing.

It is over 70 years since the interactions between high ('ultra')-frequency sound waves and living tissue were initially studied and the use of such energy as a form of therapy was first suggested [1]. Ultrasound has since been used to treat a wide variety of disorders, from skin wounds to malignant tumours [2, 3]. It has become one of the most commonly used treatments in the management of soft tissue injuries, and it has been estimated that over a million NHS treatments annually involve its use [4]. However, although many laboratory-based research studies have demonstrated a number of physiological effects of ultrasound upon living tissue [5–16], there is remarkable little evidence for benefit in the treatment of soft tissue injuries [17–20]. In this paper, the scientific basis for the use of therapeutic ultrasound in soft tissue lesions and the existing evidence relating to its clinical effect are reviewed.

Characteristics of therapeutic ultrasound

Ultrasound consists of inaudible high-frequency mechanical vibrations created when a generator produces electrical energy that is converted to acoustic energy through mechanical deformation of a piezoelectric crystal located within the transducer. The waves produced are transmitted by propagation through molecular collision and vibration, with a progressive loss of the intensity of the energy during passage through the tissue (attenuation), due to absorption, dispersion or scattering of the wave [21].

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The total amount of energy in an ultrasound beam is its power, expressed in watts. The amount of energy that reaches a specific site is dependent upon characteristics of the ultrasound (frequency, intensity, amplitude, focus and beam uniformity) and the tissues through which it travels. Important terminology with respect to the characteristics of ultrasound and variables that may affect the dose delivered are given in Tables 1 and 2.

Therapeutic ultrasound has a frequency range of 0.75–3 MHz, with most machines set at a frequency of 1 or 3 MHz. Low-frequency ultrasound waves have greater depth of penetration but are less focused. Ultrasound at a frequency of 1 MHz is absorbed primarily by tissues at a depth of 3–5 cm [22] and is therefore recommended for deeper injuries and in patients with more subcutaneous fat. A frequency of 3 MHz is recommended for more superficial lesions at depths of 1–2 cm [22, 23].

Tissues can be characterized by their acoustic impedance, the product of their density and the speed at which ultrasound will travel through it. Low absorption (and therefore high penetration) of ultrasound waves is seen in tissues that are high in water content (e.g. fat), whereas absorption is higher in tissues rich in protein (e.g. skeletal muscle) [24]. The larger the difference in acoustic impedance between different tissues, the less the transmission from one to the other [25]. When reflected ultrasound meets further waves being transmitted, a standing wave (hot spot) may be created, which has potential adverse effects upon tissue [26]. Such effects can be minimized by ensuring that the apparatus delivers a uniform wave, using pulsed waves (see below), and moving the transducer during treatment [24].

TABLE 1. Common terminology used in therapeutic ultrasound

Term	Definition
Power	Total amount of energy in an ultrasound beam (watts)
Acoustic impedance of a tissue	The product of the density of the tissue and the speed that ultrasound will travel through it
Attenuation	Progressive loss of energy during passage through tissue
Beam non-uniformity ratio (BNR)	The variability of the beam intensity: the ratio of the maximal intensity of the transducer to the average intensity across the transducer face
Coupling medium	Substance that prevents the reflection of ultrasound at the soft tissue/air interface
Duty cycle	The percentage of time that ultrasound is delivered over one on/off cycle
Standing wave (hot spot)	Created when reflected ultrasound meets further waves being transmitted, with potential adverse effects on tissue
Intensity (common examples):	
Spatial averaged intensity (SA_I)	Intensity averaged over the area of the transducer. Calculated by dividing the power output by the effective radiating area of the transducer head
Spatial peak intensity (SP_I)	The maximum intensity over time
Temporal peak intensity (or pulsed averaged intensity)	The peak intensity during the on period of pulsed ultrasound
Temporal-averaged intensity (TA_I)	The average power during the on and off periods of pulsed therapy
Spatial averaged temporal peak intensity (SATP)	The maximum intensity occurring during a single pulse

The larger the diameter of the effective radiating area of the transducer face, the more focused the beam of ultrasound produced. Within this beam, energy is distributed unevenly, the greatest non-uniformity occurring close to the transducer surface (near zone). The variability of the beam intensity is termed the beam non-uniformity ratio (BNR), the ratio of the maximal intensity of the transducer to the average intensity across the transducer face. This should optimally be 1 : 1 and certainly less than 8 : 1 [27].

Coupling media, in the form of water, oils and most commonly gels, prevent reflection of the waves away at the soft tissue/air interface by excluding air from between the transducer and patient. Different media have different impedances. Any coupling medium should have an acoustic impedance similar to that of the transducer, should absorb little of the ultrasound, remain free of air bubbles and allow easy movement of the transducer over the skin surface [28].

Ultrasound dosage can also be varied by alteration of wave amplitude and intensity [the rate at which it is being delivered per unit area of the transducer surface (watts/cm^2)]. Machines differ with respect to the definition chosen for their intensity setting (Table 1). In addition, therapeutic ultrasound can be pulsed or continuous. The former has on/off cycles, each component of which can be varied to alter the dose. Continuous ultrasound has a greater heating effect but either form at low intensity will produce non-thermal effects.

Modified forms of ultrasound

Modified forms of ultrasound include phonophoresis and extracorporeal shock wave therapy (ESWT). Phonophoresis involves the use of ultrasound energy for the transdermal delivery of low molecular weight drugs [29]. ESWT involves high-energy, focused ultrasound energy delivered using a modified lithotripter [30]. These techniques will not be considered further in this review.

TABLE 2. Some variables that may affect the dosage of ultrasound delivered to target tissue

Ultrasound frequency
Wavelength
Intensity
Amplitude
Effective radiating area of transducer head
Beam non-uniformity ratio (BNR)
Continuous/pulsed therapy
Coupling medium
Tissue composition
Movement and angle of transducer
Frequency and duration of treatment sessions

The physiological effects of ultrasound

Ultrasound may induce thermal and non-thermal physical effects in tissues (Table 3). Non-thermal effects can be achieved with or without thermal effects. Thermal effects of ultrasound upon tissue may include increased blood flow, reduction in muscle spasm, increased extensibility of collagen fibres and a pro-inflammatory response. It is estimated that thermal effects occur with elevation of tissue temperature to 40–45°C for at least 5 min [31]. Excessive thermal effects, seen in particular with higher ultrasound intensities, may damage the tissue [24].

It has been suggested that the non-thermal effects of ultrasound, including cavitation and acoustic microstreaming, are more important in the treatment of soft tissue lesions than are thermal effects [32]. Cavitation occurs when gas-filled bubbles expand and compress because of ultrasonically induced pressure changes in tissue fluids, with a resulting increase in flow in the surrounding fluid [33]. Stable (regular) cavitation is considered to be beneficial to injured tissue, whereas unstable (transient) cavitation is considered to cause tissue damage [34]. The former can be sustained at lower

Table 3. Proposed effects of therapeutic ultrasound

Type of effect	Result
Thermal	Increase in tissue extensibility Increase in blood flow Modulation of pain Mild inflammatory response Reduction in joint stiffness Reduction of muscle spasm
Non-thermal	Cavitation Acoustic microstreaming In combination may result in stimulation of fibroblast activity, increase in protein synthesis, increased blood flow, tissue regeneration, bone healing

intensities than are required for unstable cavitation and can be suppressed by the use of very short pulses. At least 1000 cycles at 1 MHz are required to establish stable cavitation [34]. Acoustic microstreaming, the unidirectional movement of fluids along cell membranes, occurs as a result of the mechanical pressure changes within the ultrasound field. Microstreaming may alter cell membrane structure, function and permeability [25], which has been suggested to stimulate tissue repair [32]. Effects of cavitation and microstreaming that have been demonstrated *in vitro* include stimulation of fibroblast repair and collagen synthesis [5–8], tissue regeneration [6] and bone healing [9].

Most of our knowledge of the effects of ultrasound on living tissue has been gained through *in vitro* studies and animal models, and much of this research has focused in particular upon skin wounds and ulcers. It has been suggested that ultrasound interacts with one or more components of inflammation, and earlier resolution of inflammation [2], accelerated fibrinolysis [10, 11], stimulation of macrophage-derived fibroblast mitogenic factors [12], heightened fibroblast recruitment [2], accelerated angiogenesis [13], increased matrix synthesis [7], more dense collagen fibrils [14] and increased tissue tensile strength [8, 15, 16] have all been demonstrated *in vitro*. Such findings form the basis for the use of ultrasound to promote and accelerate tissue healing and repair. Although these findings are relevant to wound healing, their relevance to tendinopathies, which represent a significant proportion of soft tissue injuries, is unclear. The histopathological spectrum of tendinopathies is wide and varies from inflammatory lesions of the tenosynovium to degenerative tendinoses in the absence of an overt inflammatory response [34]. The degenerative process is poorly understood, but is considered to represent a failure of the internal tendon cells to repair and remodel the extracellular matrix after injury [35, 36]. Extensive studies of normal and degenerate human tendons have shown striking variations in matrix composition [35–38], alteration of collagen fibre type distribution, with a relative increase in type III collagen over type I collagen, and, in some tendon lesions, fibrovascular proliferation and the focal expression of type II collagen, representative of fibrocartilaginous change. After injury, an increase in matrix turnover is necessary to remove damaged matrix and to remodel scar tissue. The effects of ultrasound upon these processes, which are themselves poorly understood, are not yet known.

Alternatively, ultrasound may be used for its thermal effects in order to relieve pain and muscle spasm to increase tissue extensibility, which may be of use in combination with stretching exercises to achieve optimal tissue length [39]. Lengthening with thermal doses of ultrasound has been demonstrated in the ligament of normal knees [40] and in scar tissue [41]. Once the tissue has been heated to an adequate level (considered to be 40–45°C [34]), the opportunity to stretch the tissues lasts for up to 10 min before the tissue cools [42].

Research on the use of ultrasound specifically in tendon healing is minimal and relates only to animals, with conflicting findings. Increases in tensile strength, energy absorption, mobility, improved collagen fibril alignment, reduction in inflammatory infiltrate and scar tissue in tendons has been demonstrated in some studies [43, 44] but not others [45–46]. These studies varied significantly with respect to the regimes used.

Caution must be exercised in extrapolating these results to human tendon lesions, as differences exist between species in the types of collagen in tendon.

Ultrasound in soft tissue lesions: the evidence for clinical effect

Ultrasound is commonly used in the treatment of most soft tissue complaints, particularly lesions of tendon, ligament and bursa. Clinical studies of ultrasound in soft tissue injuries are limited by appropriate outcome measures (pain, swelling and function) and do not have the advantage of wound-healing studies, which can evaluate the lesion more closely by wound tracing.

Gam and Johanssen reviewed 293 papers published between 1953 and 1993 to evaluate the evidence of effect of ultrasound in the treatment of musculoskeletal pain [17]. Twenty-two trials were found which compared ultrasound treatment with sham ultrasound, non-ultrasound treatment or no treatment. These trials assessed a variety of disorders, including lateral epicondylitis (four studies), ‘periarthrosis humeroscapularis’ (two studies), shoulder bursitis (three studies), tendinitis of the shoulder and elbow (one study), ankle ‘distorsion’ (sprain) (two studies), and other disorders such as osteoarthritis of the knee (three studies), low back pain (two studies), myofascial pain (one study), traumatized perineum (two studies) and breast pain after delivery (one study). These studies were evaluated with respect to a list of predefined criteria and were found to be lacking with respect to description of dropouts, randomization methods, the apparatus used, mode of delivery, the size of the sound head, the size of the site treated and follow-up time. In 16 of these trials, ultrasound treatments were compared with sham ultrasound and in 13 cases data were presented in a way that made pooling possible. Two standardized effect sizes were applied to the results to enable evaluation of the effect of ultrasound treatment on pain. No evidence was found for pain relief with ultrasound treatment.

Since the review of Gam and Johanssen [17], further papers have been published on the subject of ultrasound treatment upon soft tissue lesions, but few have added any support to the use of ultrasound. In a review of 400 randomized trials of the use of physiotherapy in a variety of musculoskeletal disorders, Beckerman *et al.* identified 16 trials involving ultrasound [18]. Low methodological quality was noted in most studies, with a median methodological score of 41 (range 17–70) out of a maximum score of 100. The authors concluded that there was no evidence to suggest that the treatment was effective, and although they indicated that there may be some evidence to support its use in 'elbow disorders', they did not give further details.

Two systematic reviews found ultrasound to be ineffective in the management of pain in the shoulder [19, 20], one of the most common sites for soft tissue pain. In a systematic review of interventions in shoulder disorders, Van der Heijden *et al.* identified six trials of ultrasound [20]. However, because of insufficient blinding, dissimilar groups at baseline, inadequate sample sizes, varied outcome measures, withdrawal from treatment and inadequate follow-up, only three trials were considered to be of adequate methodological quality to be included for review. One of the three trials included subjects with rotator cuff lesions [47], one included those with subacromial bursitis (which usually occurs in the presence of a rotator cuff lesion) [48] and one included all subjects with shoulder pain [49]. It was concluded that therapeutic ultrasound is ineffective in the treatment of shoulder disorders.

Ultrasound and the stage of injury

There has been some suggestion that ultrasound may be of particular use in the early stages after injury, whereas many studies have evaluated more chronic lesions (or those of unspecified duration). This has been addressed in part by the use of delayed onset muscle soreness (DOMS) as a clinical model of acute inflammation. Again, conflicting results are reported. A reduction in pain and tenderness and increased muscle strength in DOMS has been reported [50], but this has not been confirmed by other workers [51]. There is evidence that thermal doses of ultrasound in DOMS can aggravate pain and stiffness [52].

Explaining the apparent lack of effect

It is apparent that, although ultrasound is used extensively in soft tissue injuries and there are rational theories for its use, sound evidence for its effectiveness in such conditions is lacking. While *in vitro* studies of ultrasound have demonstrated numerous effects, these have failed to translate into *in vivo* success. The absence of evidence for benefit for ultrasound in soft tissue lesions may be due to a true lack of effect, but poor study design or technical factors may play a role [53]. As has been outlined, there are many technical variables in the delivery of ultrasound treatment that may act as a source of error in such studies (Table 4). The dose of therapeutic ultrasound is determined by many factors, as described in Table 2.

Inadequate calibration of machines has also been noted [54]. Pye and Milford evaluated 85 ultrasound therapy machines in use in Lothian Region, Scotland for performance and calibration [54]. Of the machines tested, 69% had power outputs that differed by more than 30% from the expected values. Therapy machines more than 10–12 yr old and modern dual-frequency treatment heads performed particularly badly.

The design of clinical studies also may be at fault. Significant heterogeneity of study populations, with the inclusion of a variety of disorders presenting with shoulder pain, prevents a clear conclusion being made with respect to ultrasound and rotator cuff tendinopathies. It is possible that ultrasound is effective only in the earlier stages after tissue injury and there is a need for studies which specifically define not only the lesion being evaluated, but also its chronicity.

The non-inflammatory, degenerative nature of many soft tissue lesions, in particular those affecting the tendon, and the presence of more complex underlying pathologies may also contribute to the apparent lack of effect of ultrasound. Even if ultrasound is truly 'therapeutic', it is inappropriate to use it as the sole approach to the management of soft tissue lesions. Unfortunately, this situation is not uncommon, other important aspects of rehabilitation frequently being neglected in favour of the use of a machine. Failure to address other causative factors in the aetiology of the lesion and its chronicity may also lead to apparent

TABLE 4. Possible reasons for the apparent lack of effect of therapeutic ultrasound in soft tissue lesions

Study design	Insufficient blinding
	Dissimilar groups at baseline, inadequate sample sizes
	Varied outcome measures, withdrawal from treatment
	Loss to follow-up
	Inadequate duration of follow-up
	Wide spectrum of pathologies within study group
Dosage of ultrasound	Varied between studies
	Varied between treatments
	Inappropriate dose
Inadequate calibration of machinery	Inappropriate dose
Inappropriate or inadequate coupling medium	Inadequate delivery of ultrasound to injured site
True lack of effect	

ineffectiveness of ultrasound as a therapy. Other factors, such as an individual's body composition, which will affect the extent of transmission of the ultrasound waves, are more difficult to control.

Conclusions: the future

In view of the scientific rationales for the use of ultrasound in soft tissue lesions, it would be premature to abandon the use of ultrasound because of the current lack of clinical evidence for effect. Studies must include ultrasound units that are calibrated regularly and other variables, such as coupling media and transducer surface area, must be described clearly. Reliable methods of measurement for characterizing the output and performance of ultrasound physiotherapy equipment have been developed and can be used to ensure the delivery of a standard dosage of ultrasound therapy. Adequate randomized double-blind placebo-controlled clinical studies are required of the use of ultrasound therapy at specific doses in specific, closely defined soft tissue lesions.

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