Chapter 20

Ultrasound

Chapter Outline

I. FOUNDATION
   A. Definition
   B. Conventional Ultrasound
   C. Low-Intensity Pulsed Ultrasound
   D. Noncontact Low-Frequency Ultrasound
   E. Ultrasound Devices and Accessories
   F. Rationale for Use

II. BIOPHYSICAL CHARACTERISTICS
    A. Ultrasonic Wave Formation
    B. Ultrasonic Beam Projection
    C. Delivery Mode
    D. Transducer Effective Radiating Area
    E. Ultrasonic Intensity
    F. Beam Nonuniformity Ratio

III. THERAPEUTIC EFFECTS AND INDICATIONS
     A. Conventional Ultrasound
     B. Low-Intensity Pulsed Ultrasound
     C. Noncontact Low-Frequency Ultrasound
     D. Research-Based Indications

IV. DOSIMETRY
    A. Conventional Ultrasound
    B. Low-Intensity Pulsed Ultrasound
    C. Noncontact Low-Frequency Ultrasound

V. APPLICATION, CONTRAINDICATIONS, AND RISKS
    Application, Contraindications, and Risks
    Case Studies

VI. THE BOTTOM LINE

VII. CRITICAL THINKING QUESTIONS

VIII. REFERENCES

Learning Objectives

Remembering: Define and describe the biophysics of therapeutic ultrasound.
Understanding: Distinguish between conventional ultrasound (CUS), low-intensity pulsed ultrasound (LIPUS), and noncontact low-frequency ultrasound (NCLFUS).
Applying: Show the application steps for CUS, LIPUS, and NCLFUS.

Analyzing: Explain the proposed physiologic and therapeutic effects of CUS, LIPUS, and NCLFUS.
Evaluating: Formulate the dosimetric parameters associated with CUS, LIPUS, and NCLFUS.
Creating: Discuss the body of English-language, scientific evidence supporting the use of CUS, LIPUS, and NCLFUS therapy.
I. FOUNDATION

A. DEFINITION

Ultrasound, often designated by the acronym US, is sound traveling through a medium at frequencies above (hence, the prefix ultra) the upper-limit frequency of human audibility, which is measured to be approximately 20 kilohertz (kHz) (Leighton, 2007; O'Brien, 2007; Ter Haar, 2007). Sound is a form of mechanical acoustic energy, or pressure waves, that propagates through vibration in the air and in other media such as water and soft biologic tissues. Therapeutic ultrasound refers to the use of this mechanical acoustic energy for treating a variety of soft tissue pathologies, including bone fractures and dermal wounds. More specifically, its spectrum may be classified, as shown in Table 20-1, into three categories, namely conventional ultrasound (CUS), low-intensity pulsed ultrasound (LIPUS), and noncontact low-frequency ultrasound (NCLFUS).

Therapeutic ultrasound is characterized based on the following parameters: frequency, intensity, delivery mode, application method, application technique, coupling agent, effect, and indication. Traditionally associated with the use of CUS is the practice of sonophoresis, also known as phonophoresis, which is defined as the application of acoustic energy (hence, the prefix sono- or phono-) for the transfer (phoresis) of drug ions through the skin for therapeutic purposes. In other words, sonophoresis is a form of drug iontophoresis (see Chapter 13) where mechanical energy is substituted for electrical energy. Coverage of sonophoresis is beyond the scope of this chapter because the human research-based literature is limited and dated, and results are conflicting (Griffin et al., 1967; Kleinkort et al., 1975; Wing, 1982; Halle et al., 1986; Pottenger et al., 1989; Stratford et al., 1989; Holdsworth et al., 1993; Saliba et al., 2007; Nagrale et al., 2009). To learn more about the broad use of sonophoresis in medicine, dentistry, and physical medicine, readers may consult the following recent review articles (Mitragotri et al., 2004; Mitragotri, 2005; Escobar-Chavez et al., 2009; Polat et al., 2010, 2011).

B. CONVENTIONAL ULTRASOUND

This first category, clinically introduced in the early 1950s, is called conventional ultrasound because it is the oldest and most conventional therapeutic type of ultrasound used today to treat soft tissues conditions (see Table 20-1). CUS is delivered at low and high frequencies and intensities using continuous or pulsed delivery modes. Its application technique is dynamic, and application is with contact or noncontact with the skin surface. Aquasonic gel and tap water are common coupling agents placed between the applicator face-plate and the skin surface to optimize acoustic energy transmission. CUS is used primarily for its thermomechanical effects on tendon, ligament, and muscle disorders (Robertson et al., 2001; Robertson, 2002; Robertson, 2008; Armijo-Olivo et al., 2013).

C. LOW-INTENSITY PULSED ULTRASOUND

Introduced in the 1980s, low-intensity pulsed ultrasound is characterized by ultrasonic energy delivered at medium frequency (1.5 megahertz [MHz]) and at much lower intensity (0.03 watts per square centimeter [W/cm²]) than CUS (see Table 20-1). LIPUS is pulsed, and the stationary applicator makes contact with the skin surface overlying the bone fracture site. Ultrasonic gel is also required as coupling medium at the soundhead applicator-skin interface. LIPUS therapy is used for its mechanical effect on fresh and slow-to-heal bone fractures (Claes et al., 2007; Dijkman et al., 2009; Martinez et al., 2011).

D. NONCONTACT LOW-FREQUENCY ULTRASOUND

First introduced in the early 2000s, this most recent category is known as noncontact low-frequency ultrasound. It is characterized by ultrasonic energy delivered at a much lower frequency (40 kHz) with intensity in the lower range (0.5 W/cm²). NCLFUS is pulsed, and its application technique is dynamic. It uses sterile saline water contained in a bottle as a coupling medium and

Historical Overview

The development of ultrasound as a means to treat human disorders dates back to the discovery, in the 1880s, of the piezoelectric effect by two French scientists, Pierre and Paul-Jacques Curie. This effect refers to the production of electrical energy, in certain nonconducting natural and synthetic crystals, by applying mechanical pressure on them (O'Brien, 2007). The word piezo is Greek for “pressure.” In 1910, another French scientist, Paul Langevin, discovered the reverse piezoelectric effect. This effect is the production of mechanical energy in the crystals by applying electrical energy across them (O'Brien, 2007). Application of the reverse piezoelectric effect is the fundamental biophysical principle behind the manufacture of modern therapeutic, diagnostic, and industrial ultrasound devices.
TABLE 20-1  SPECTRUM OF THERAPEUTIC ULTRASOUND

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>CUS</th>
<th>LIpUS</th>
<th>NCLFUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>MF/HF</td>
<td>MF</td>
<td>LF</td>
</tr>
<tr>
<td>Mid (MF)</td>
<td>1-3 MHz</td>
<td>1.5 MHz</td>
<td>40 kHz</td>
</tr>
<tr>
<td>High (HF)</td>
<td>0-3 W/cm²</td>
<td>0.03 W/cm²</td>
<td>0.5 W/cm²</td>
</tr>
<tr>
<td>Intensity</td>
<td>LI/HI</td>
<td>LI</td>
<td>LI</td>
</tr>
<tr>
<td>Delivery mode</td>
<td>C/P</td>
<td>P</td>
<td>P</td>
</tr>
<tr>
<td>Application technique</td>
<td>D</td>
<td>S</td>
<td>D</td>
</tr>
<tr>
<td>Application method</td>
<td>C/NC</td>
<td>C</td>
<td>NC</td>
</tr>
<tr>
<td>Coupling agent</td>
<td>G/W</td>
<td>G</td>
<td>W</td>
</tr>
<tr>
<td>Effect</td>
<td>M/T</td>
<td>M</td>
<td>M</td>
</tr>
<tr>
<td>Indication</td>
<td>Muscle, tendon, and ligament disorders</td>
<td>Bone fracture</td>
<td>Dermal wounds</td>
</tr>
</tbody>
</table>

CUS, conventional ultrasound; LIpUS, low-intensity pulsed ultrasound; NCLFUS, noncontact low-frequency ultrasound.

is applied in a dynamic noncontact fashion. This ultrasonic device creates ultrasonic waves that produce and propel a gentle mist of sterile saline water to the wound bed. This water mist facilitates the transfer of ultrasonic energy to the wound bed without direct contact. NCLFUS, also known under the commercial name MIST Therapy System, is used to promote dermal wound healing through its mechanical cleansing, debridement, and antibacterial effects.

E. ULTRASOUND DEVICES AND ACCESSORIES

1. Conventional Ultrasound

Figure 20-1 illustrates a typical line-powered CUS device made of an electrical generator to which is attached, via a cable, a handheld soundhead applicator that houses a piezoelectric transducer. Soundhead applicators come in different sizes to accommodate smaller to larger treatment surface areas. The delivery of ultrasound energy requires an ultrasonic coupling agent, such as a gel, gel pad, or tap water (noncontact), placed between the applicator and the skin overlying the treatment area. When there is risk of infection, sterile ultrasonic gel may be used. Gel temperature is kept constant by using a commercial ultrasound bottle warmer. Soundhead applicators, as well as reusable gel pads, should be cleaned with an antimicrobial solution after each application to minimize the risk of cross-infection (see Fig. 20-1).

2. Low-Intensity Pulsed Ultrasound

Figure 20-2 shows a battery-powered LIpUS device. Its applicator (transducer) may be applied in-cast, on-cast, or directly on the skin overlying a bone fracture site by using a specially designed retaining and fixating system placed over the fracture site. Ultrasonic gel is also required between the applicator and the skin overlying the fracture site.

3. Noncontact Low-Frequency Ultrasound

Figure 20-3 illustrates a line-powered NCLFUS device, which consists of an electrical generator to which is attached a handheld applicator that also houses a piezoelectric transducer. Attached to this applicator is a specially designed disposable applicator assembly system holding a sterile saline water bottle. Finger pressure on the applicator control button releases an ultrasonic flow of mist water through the transducer tip and over the wound bed primarily for the purpose of mechanical wound cleansing and debridement.

F. RATIONALE FOR USE

Ultrasound, a form of mechanical energy that can be transmitted in the human body as high-frequency acoustical pressure waves, has been widely used for therapeutic, diagnostic, and surgical purposes. This chapter focuses on the application of therapeutic ultrasound. The rationale
FIGURE 20-1 Typical conventional ultrasound device (A) with soundhead applicators of various sizes (B). Aquasonic gel (C), gel pad (D), gel bottle warmer (E), and soundhead cleaning solution (F). (A, B: Courtesy of DJO Global, C–F: Courtesy of Parker Laboratories Inc.)
behind the use of CUS is to induce deep and localized thermal and mechanical effects in pathologic soft tissues, particularly in tissues rich in proteins, such as tendons, ligaments, and muscles, while inducing minimal effect on the overlying skin and subcutaneous tissues. The rationale for LIPUS therapy, on the other hand, is to promote and accelerate bone growth, through its mechanical effects, in cases of fresh and slow-to-heal bone fractures. Finally, the rationale for NCLFUS is to facilitate wound cleansing debridement through its noncontact mechanical effect, thus promoting dermal wound healing.

II. BIOPHYSICAL CHARACTERISTICS

A. ULTRASONIC WAVE FORMATION

Figure 20-4 schematizes the formation of an ultrasonic beam of energy generated by a therapeutic ultrasound device. The formation of sound, or mechanical waves, is based on the reverse piezoelectric effect, which states that when a high frequency, alternating electrical current (AC) is applied to the surface of a piezoelectric material, called a transducer, mechanical deformations of this transducer follow in the form of oscillations, or cycles of expansion and contraction. The soundhead applicator houses the transducer, which is made of a natural or synthetic piezoelectric material. The transducer converts the electrical energy applied against its surface into mechanical or acoustic energy. Attached to the transducer is the soundhead applicator metallic faceplate. The soundhead applicator transfers the acoustic energy from the transducer to the metallic faceplate interface and to soft tissues (see Fig. 20-4). The repeated high-frequency cycles of micro-expansion and micro-contraction of the transducer create an ultrasonic beam of energy described as acoustic, mechanical, or pressure waves having a sinusoidal shape and traveling in time in the medium. During the expansion phase of the transducer, high pressure develops in the soft tissues, bringing molecules closer together. During the contraction phase, however, low pressure develops, which sends molecules farther apart. Ultrasound waves are longitudinal waves because the motion of the...
molecules in the medium is parallel to the direction of wave propagation (see Fig. 20-4).

B. ULTRASONIC BEAM PROJECTION

Figure 20-5 illustrates the spatial projection of the ultrasonic beam of energy emitted from a typical soundhead applicator. The beam region closest to the transducer faceplate is termed the near field or Fresnel zone. The region that immediately follows is called the far field or Fraunhofer zone (Frizzell et al., 1990). Biophysics has shown that the near field corresponds to the less divergent, or more focused, region of the beam emitted from the soundhead. The far field, in contrast, corresponds to the more divergent, or less focused, region of the beam.

The length (L) of the near field, relative to the soundhead faceplate, corresponds to the boundary line separating these two fields or zones. This length (L) is directly related to the square radius (r²) of the transducer’s effective radiating area (ERA) and is inversely related to the ultrasonic beam’s wavelength, where $L = \frac{r^2}{\text{wavelength}}$ (Ter Haar, 1996). Acoustic waves travel in aqueous media (e.g., gel, water, human tissues) at a speed or velocity (v) of approximately 1,500 meters per second (m/s). For example, the near-field length (L) of an ultrasonic beam emitted at 1 MHz, from a transducer ERA of 10 cm², equals 21.1 cm. This L value is calculated as follows.

First, wavelength is proportional to the speed of transmission (v) and inversely related to frequency (f)—thus: Wavelength = v/f. In this example, wavelength equals 0.15 cm (0.15 cm = 1,500 m/s/1,000,000 cycles per second).
Therapeutic CUS is delivered, as illustrated in Figure 20-6, using the continuous and pulsed modes. Continuous mode refers to the uninterrupted flow of acoustic energy during the entire treatment duration (see Fig. 20-6A). Pulsed mode, on the other hand, refers to periodic interruption of acoustic energy characterized by ON (flow) and OFF (no flow) periods (see Fig. 20-6B). Pulse frequency is the frequency with which ultrasonic pulses are delivered and is calculated as follows: \( f = 1/(\text{ON + OFF}) \). For example, a pulsed frequency (f) of 1,000 Hz will result from the combination of a pulse duration (ON time) of 0.2 milliseconds (ms) followed by an interpulse duration (OFF time) of 0.8 ms (1,000 Hz = 1/0.002 s + 0.008 s).

2. ON:OFF Ratio Versus Duty Cycle
The ON:OFF ratio expresses the relationship between the ON and OFF times. In the previous example, the ON:OFF ratio is 1:4 (0.002:0.008 = 1:4). This ratio means that the time during which ultrasound energy is delivered (ON) is four times shorter than the time value during which no ultrasound energy is delivered (OFF). Duty cycle (DC), on the other hand, refers to the duration, measured as a percentage (%), during which acoustic energy is delivered and is calculated using this formula: \( \text{DC} (\%) = (\text{ON}/(\text{ON} + \text{OFF})) \times 100 \). Duty cycle related to the continuous mode is always 100% because there is no (zero) OFF time. In keeping with the example, the duty cycle related to the continuous mode equals 20%: 20% = (0.002 s/0.002 s + 0.008 s) \times 100. This duty cycle means that ultrasonic energy is delivered for a period equivalent to 20% of the total treatment duration. In other words, if the total treatment duration is 6 minutes, acoustic energy would be delivered for a total of 1.2 minutes (1.2 min = 6 min \times 20%), with delivery time being equivalent to one fifth (6 min/1.2 min), or 20%, of the total application duration. It follows from the earlier formula that the shorter the OFF time between given ultrasonic pulses (ON), the larger the duty cycle value and the larger the amount of acoustic energy delivered to the soft tissues. Duty cycle values are programmable and may range between 20% and 100% on most devices.

D. TRANSDUCER EFFECTIVE RADIATING AREA
A soundhead applicator consists of a piezoelectric transducer covered by a steel plate; together they form a handheld soundhead applicator with a steel faceplate (see Fig. 20-1A,B). The term effective radiating area, measured in square centimeters (cm²), is the area of the transducer from which ultrasound energy radiates. Transducer ERA is a key dosimetric parameter. Technically speaking, transducer ERA is always smaller (approximately 10%) that the soundhead applicator faceplate surface because the transducer is embedded in the applicator (see Figs. 20-4 and 20-5). Unfortunately, most manufacturers fail to make the distinction, when reporting technical specifications in their brochures, between transducer ERA and the applicator faceplate surface area. Most manufacturers report soundhead applicator using the term size, such as 1, 2, 5, and 10 cm². Not knowing what manufacturers refer to when reporting size (i.e., transducer ERA or soundhead applicator faceplate area), this chapter will assume, for the sake of simplifying dosimetry, that the soundhead applicator size is synonymous with transducer ERA.

E. ULTRASONIC INTENSITY
As ultrasound waves pass through soft tissues, they transport acoustic mechanical energy through them. Energy (E) is the ability to do work and is measured in joules (J). The rate of energy transport is known as power. Power (P) is the rate at which energy is transported and is measured in watts (W), where 1 watt equals 1 joule second (Js). Therapeutic ultrasound is produced in beams that are usually focused into small areas ranging from 1 to 10 cm². Intensity (I) is defined as the amount of acoustic...
power (P), measured in watts (W), per unit area of the transducer ERA, measured in square centimeters. It is expressed in watts per square centimeters based on this formula: \( I = \frac{P}{ERA} \). For example, a power output (P) of 8 W applied through a transducer ERA of 5 cm\(^2\) yields an intensity equal to 1.6 W/cm\(^2\) (1.6 W/cm\(^2\) = 8 W/5 cm\(^2\)). Because ultrasound energy is delivered using transducers with different ERAs (spatial domain), in both continuous and pulsed modes (temporal domain), the concept of intensity must be further defined in relation to these two domains.

1. **Spatial Peak Intensity (I\(_{SP}\))**
The term spatial peak intensity (I\(_{SP}\)) refers to the maximum, or peak, intensity delivered during the continuous delivery of ultrasound energy (see Fig. 20-6A). Spatial peak intensity (I\(_{SP}\)) is synonymous with spatial average temporal peak intensity (I\(_{SATP}\)).

2. **Spatial Average Intensity (I\(_{SA}\))**
Spatial average intensity (I\(_{SA}\)) refers to the mean, or average, intensity delivered during pulsed delivery of ultrasound energy (see Fig. 20-6B). Spatial average intensity (I\(_{SA}\)) is calculated by multiplying the spatial peak intensity (I\(_{SP}\)) of the device by its duty cycle (DC) using this formula: \( I_{SA} = I_{SP} \times DC \). As discussed earlier, the duty cycle, expressed as a percentage (%), is derived from the ON and OFF times: \( DC(\%) = \left( \frac{ON}{ON + OFF} \right) \times 100 \). For example, the delivery of an I\(_{SP}\) equal to 1.6 W/cm\(^2\), combined with a DC of 30%, yields an I\(_{SA}\) equal to 0.48 W/cm\(^2\) (0.48 W/cm\(^2\) = 1.6 W/cm\(^2\) \times 30%). The larger the duty cycle, the greater the spatial average intensity. Spatial average intensity (I\(_{SA}\)) is synonymous with spatial average temporal average intensity (I\(_{SATA}\)).

**F. BEAM NONUNIFORMITY RATIO**
Biophysics has shown that the ultrasonic beam delivered at the transducer faceplate is irregular, or nonuniform, meaning that the intensity is greater in the center (larger spikes) than at the edge (lower spikes) of the transducer (Dunn et al., 1990; Frizzell et al., 1990; Lehmann et al., 1990). The nonuniformity of an ultrasonic beam of energy is represented by its beam nonuniformity ratio (BNR) (Fig. 20-7). A transducer BNR is calculated as the ratio of its spatial peak intensity (I\(_{SP}\)) to its spatial average intensity (I\(_{SA}\)). In other words, it is the ratio between the peak intensity (highest spike at the center) and the average intensity of all other spikes (edges). For example, a BNR value of 5 (or 5:1) means that the spatial peak intensity generated by the device is five times larger than its spatial average intensity (5 = 5 W/cm\(^2\) / 1 W/cm\(^2\)). BNR is determined by the intrinsic piezoelectric properties of the transducer. The better the piezoelectric quality of the transducer, the more uniform the beam intensity across its ERA, and the lower its BNR value. BNR values should range between 2 and 8.

**III. THERAPEUTIC EFFECTS AND INDICATIONS**
Summarized in Figure 20-8, and discussed next, are the proposed physiologic and therapeutic effects associated with therapeutic ultrasound.

**A. CONVENTIONAL ULTRASOUND**
There is strong evidence in the literature to suggest that CUS can trigger significant thermomechanical effects on human soft tissues (see Lehmann et al., 1990; Alexander et al., 2010; Shanks et al., 2010; Tsai et al., 2011). Although the physiologic and therapeutic effects of CUS are traditionally separated into thermal and mechanical effects, there is evidence to suggest that both effects occur concomitantly, one dominating the other, depending on the dosimetry used (Erdogan et al., 2009).
1. Thermal Effect
When acoustic energy is absorbed as it penetrates soft tissues, molecules within the acoustic field are caused to vibrate under very high frequency cycles of compression waves (i.e., molecules moving closer together) and rarefaction waves (i.e., molecules moving farther apart). The higher the intensity of the ultrasonic beam and the more continuous the emission of acoustic waves, the more vigorous the molecular microvibration process. The more intense the molecular vibration, the more vigorous the microfriction effect, the more intense the cellular kinetic energy, or frictional heat, generated in the tissue (Dyson, 1987, 1995).

2. Mechanical Effect
Concomitantly with the thermal effect induced in soft tissues is the mechanical effect triggered by the absorption of ultrasonic energy. Biophysics has shown that the delivery of ultrasonic energy to soft tissues triggers two interrelated mechanical effects—namely, stable cavitation and microstreaming (Kimmel, 2006; O'Brien, 2007). The word cavitation is derived from the Latin word cavus, meaning “hollow” and refers to the formation, in fluids or solids, of empty spaces or cavities resulting from the formation of microbubbles. Ultrasonic cavitation, triggered by the absorption of sound energy, begins when minute gas pockets that infiltrate most biologic fluids, termed nuclei, develop into microscopic bubbles, thus causing cavities in these fluids and the surrounding soft tissues. Under the sustained influence of acoustic radiation, these microscopic bubbles expand and contract (pulsate or oscillate) at the same carrier frequency at which the acoustic waves are produced. Depending on the frequency and intensity level of acoustic energy, two types of cavitation can occur in soft tissues: stable and unstable. Stable cavitation occurs when the bubbles begin to pulsate—that is, compress during the high-pressure waves and expand during the low-pressure waves. This phenomenon triggers molecular movement as molecules move closer together during the compression phase and farther apart during the rarefaction phase of the acoustic waves. This movement in the fluid is called microstreaming, which is defined as localized high-velocity streams of fluids created by ultrasonic energy in a liquid (Erdogan et al., 2009). Microstreaming causes movement and transfer...
of intracellular and extracellular ions affecting cellular membrane permeability. Unstable cavitation, on the other hand, occurs when the bubbles, subjected to strong cycles of compression and expansion, collapse or implode, releasing very high temperature and pressure changes in their vicinity in the fluid. Biophysics has shown that therapeutic ultrasound devices do not have the intensity and frequency outputs necessary to produce unstable cavitation. The occurrence of unstable cavitation during CUS therapy, therefore, poses no therapeutic concern.

3. Targeted Tissues
For thermomechanical effects to occur, ultrasonic energy must be absorbed by soft tissues. Attenuation reflects on the weakening of sound energy as it propagates through a medium such as soft tissues. It results from the combined effect of absorption and scattering. Absorption is the conversion of ultrasound energy to other forms of energy, such as thermal and mechanical energy. Scattering is the reflection of sound waves in directions other than its original direction of propagation. Biophysicists express the extent of ultrasound attenuation by using attenuation coefficients. An attenuation coefficient is a measure that characterizes how easily a material or tissue can be penetrated by a beam of ultrasound energy. In other words, attenuation coefficient is a measure of the capacity of a material or tissues to absorb ultrasonic energy. The attenuation coefficient is the sum of the individual coefficients for absorption and scatter. In soft tissues, the absorption coefficient accounts for 60% to 90% of the attenuation, and scatter accounts for the remainder (Hendee et al., 2002). Consequently, the terms attenuation coefficient and absorption coefficient are generally used interchangeably in the literature. Practically speaking, the larger the attenuation coefficient of a tissue, the greater is its capacity to absorb ultrasonic energy. Biophysicists have measured the attenuation coefficients of several soft tissues when exposed to ultrasound energy delivered at 1 MHz (Frizzell et al., 1990, p. 393). The results show that soft tissue attenuation or absorption coefficients tend to increase with protein content and decrease with water content. Clinically speaking, this means that protein-rich deeper tissues, such as bones (collagen), tendons (collagen), ligaments (elastin), and muscles (actin/myosin) can absorb greater amounts of ultrasonic energy than in those more superficial tissues, such as skin and fat, both of which contain less protein and more water. Together, the thermomechanical effects of CUS are presumed to increase blood flow, cell metabolism, collagen synthesis, protein synthesis, and collagen extensibility, thus decreasing joint stiffness while enhancing connective (tendon and ligament) and muscular tissue healing (see Fig. 20-8). There is minimal to no thermal (athermal) effect because the pulsed ultrasonic beam of energy is delivered at a very low intensity (30 mW/cm²). In other words, minimal microvibration or microfriction effects occur, leading to very low levels of molecular kinetic energy that are unable to heat up soft tissues. There is strong evidence to show that the main, and only, target tissue for LI-PUS therapy is bone (Malizos et al., 2006; Griffin et al., 2008; Busse et al., 2009; Erdogan et al., 2009; Mundi et al., 2009; Watanabe et al., 2010; Kasturi et al., 2011; Bashardoust et al., 2012; Riboh et al., 2012). Why is it so? First, bone, among all human soft tissues, has the highest ultrasound absorption coefficient, which is approximately three times higher than those coefficients measured for tendons, ligaments, and muscles (Frizzell et al., 1990). This means that the application of low-level ultrasonic energy is capable of triggering physiologic effects in bone without causing any thermomechanical effect on the soft tissues surrounding it. Second, ultrasound application generates the piezoelectric effect in bone. The piezoelectric effect is the property of some materials, such as bone, to convert mechanical energy to electrical current. In the 1950s, Fukada et al. (1957) first discovered and described the piezoelectric property of bone, and Corradi et al. (1953) made the first observation that ultrasound stimulates fracture healing in humans. In 1983, Xavier (1983) and Duarte (1983), using animal models, demonstrated the effectiveness of LI-PUS for bone fractures. In the same year, Xavier and Duarte (1983) showed the benefit of using LI-PUS for the treatment of human bone fractures. As shown in Figure 20-8, the application of LI-PUS mechanically stresses the bone, thus triggering the piezoelectric effect—that is, the production of electrical potential across the bone. This effect, in turn, induces and increases bone reparative processes such as angiogenesis, chondrogenesis, and osteogenesis, which together enhance fracture healing (Ying et al., 2012).

C. NONCONTACT LOW-FREQUENCY ULTRASOUND
In contemporary wound care, a plethora of topical treatments is available that are aimed at accelerating the healing of chronic wounds (Sussman et al., 2012). Among them, cleansing and debriding procedures are critical to optimal dermal wound healing. NCLFUS, commercially known as the MIST Therapy System, is a mechanical agent that uses low-frequency ultrasonic energy to atomize saline water and deliver it as mist to the wound (Driver et al., 2011; Voigt et al., 2011; Escandon et al., 2012). The water mist generated has a relatively uniform droplet size that acts as a conduit for transmitting ultrasound energy to the treatment site. The use of NCLFUS for treating open wounds first originated in the early 2000s from the studies of Ennis and colleagues on humans (2005, 2006). As illustrated in Figure 20-8, the application of NCLFUS triggers mechanical effect...

B. LOW-INTENSITY PULSED ULTRASOUND
Contrary to the application of CUS, the delivery of LI-PUS energy to soft tissues causes only mechanical effects (see Fig. 20-8). There is minimal to no thermal (athermal) effect because the pulsed ultrasonic beam of energy is delivered at a very low intensity (30 mW/cm²). In other words, minimal microvibration or microfriction effects occur, leading to very low levels of molecular kinetic energy that are unable to heat up soft tissues. There is strong evidence to show that the main, and only, target tissue for LI-PUS therapy is bone (Malizos et al., 2006; Griffin et al., 2008; Busse et al., 2009; Erdogan et al., 2009; Mundi et al., 2009; Watanabe et al., 2010; Kasturi et al., 2011; Bashardoust et al., 2012; Riboh et al., 2012). Why is it so? First, bone, among all human soft tissues, has the highest ultrasound absorption coefficient, which is approximately three times higher than those coefficients measured for tendons, ligaments, and muscles (Frizzell et al., 1990). This means that the application of low-level ultrasonic energy is capable of triggering physiologic effects in bone without causing any thermomechanical effect on the soft tissues surrounding it. Second, ultrasound application generates the piezoelectric effect in bone. The piezoelectric effect is the property of some materials, such as bone, to convert mechanical energy to electrical current. In the 1950s, Fukada et al. (1957) first discovered and described the piezoelectric property of bone, and Corradi et al. (1953) made the first observation that ultrasound stimulates fracture healing in humans. In 1983, Xavier (1983) and Duarte (1983), using animal models, demonstrated the effectiveness of LI-PUS for bone fractures. In the same year, Xavier and Duarte (1983) showed the benefit of using LI-PUS for the treatment of human bone fractures. As shown in Figure 20-8, the application of LI-PUS mechanically stresses the bone, thus triggering the piezoelectric effect—that is, the production of electrical potential across the bone. This effect, in turn, induces and increases bone reparative processes such as angiogenesis, chondrogenesis, and osteogenesis, which together enhance fracture healing (Ying et al., 2012).
only—that is, stable cavitation and microstreaming. Ultrasound energy is used to mechanically cleanse and debride devitalized tissues covering the wound. In doing so, NCLFUS mechanically removes bacteria, fibrin, and exudates, and increases cell membrane permeability, thus increasing cellular activity leading to enhanced wound healing.

D. RESEARCH-BASED INDICATIONS

The search for evidence behind the use of CUS, LIPUS, and NCLFUS, displayed in the Evidence-Based Indications box, led to a collection of 150 English peer-reviewed human clinical studies. The methodologies and criteria used to assess the strength of evidence and therapeutic effectiveness are described in Chapter 2. Of the 150 studies, 102 studies are associated with the study of CUS, 34 studies with LIPUS, and 13 studies with NCLFUS. For CUS therapy, the results reveal 60 studies showing benefit and 42 showing no benefit. Considering all conditions treated with CUS, results indicate that the strength of evidence is moderate and therapeutic effectiveness conflicting. For both LIPUS and NCLFUS therapies, the strength of evidence is moderate and therapeutic effectiveness substantiated.

IV. DOSIMETRY

A. CONVENTIONAL ULTRASOUND

Table 20-2 lists the main dosimetric parameters considerations from which clinicians must choose to prescribe and apply CUS therapy. Let us discuss and exemplify each of them.

1. Frequency

Frequency is selected based on the depth of the lesion in relation to the skin surface overlying it. Ultrasonic energy emitted at 1 MHz penetrates soft tissues deeper because of its longer wavelength (see Ultrasonic Beam Projection section for details). In other words, the therapeutic zone (near-field length or Fresnel zone) is longer at 1 MHz than at 3 MHz because of its inverse relationship with wavelength.

2. Delivery Mode

Delivery mode is selected based on the amount of thermal effect needed for treatment. The more continuous the flow of ultrasonic energy delivered to the tissues, the greater the acoustic intensity delivered, and the larger the thermal effect. Pulsating the acoustic beam of energy, by manipulating its duty cycle, can either minimize or maximize the thermal or mechanical effect. For example, larger duty cycles will maximize thermal effect and minimize mechanical effect. Smaller duty cycles, on the other hand, will induce opposite effects.

3. Transducer Effective Radiating Area

Therapeutic soundhead applicators used to deliver CUS are available in various sizes (see Fig. 20-1C). To avoid confusion, we will assume that the term size, used in most corporate brochures, is synonymous with transducer ERA. The selection of applicator size is based on the treatment surface area under consideration. The optimal recommended ratio between transducer size and treatment surface area is 1:3. Practically speaking, this means that to treat a surface area of 15 cm², a transducer size of 5 cm² or larger should be used. Using a smaller applicator size implies longer treatment duration in order to deliver the same acoustic energy in each square centimeter of tissue as well as less thermal effect due to the recouling of previously sonated tissues during application.

4. Application Method and Coupling Medium

Both the selection of application methods and coupling media are guided by the geometry and sensitivity level of the treatment area. The contact method is recommended over relatively flat surface areas that can
## PART V  Mechanical Agents

### Research-Based Indications

#### ULTRASOUND

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<td>Svarcova et al., 1988</td>
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<td></td>
<td>Orgonenel et al., 2009</td>
<td>Therapeutic effectiveness: Substantiated</td>
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Strength of evidence: Moderate
Therapeutic effectiveness: Substantiated

| Mixed soft tissue disorders | Patrick, 1978 | Roman, 1960 |
|                            | Middlemast et al., 1978 | Soren, 1965 |
|                            | Aides, 1956 | Lundeberg et al., 1988 |
|                            | Davidson et al., 2001 | |

Strength of evidence: Moderate
Therapeutic effectiveness: Substantiated

| Epicondylitis               | Binder et al., 1985 | Haker et al., 1991 |
|                            | Aides, 1956 | Lundeberg et al., 1988 |
|                            | Davidson et al., 2001 | |

Strength of evidence: Moderate
Therapeutic effectiveness: Substantiated

| Perineal lesions            | McLaren, 1984 | Everett et al., 1992 |
|                            | Fieldhouse, 1979 | Creates, 1987 |
|                            | Grant et al., 1989 | |

Strength of evidence: Strong
Therapeutic effectiveness: Unsupported

| Post-exercise muscle soreness | Hasson et al., 1990 | Craig et al., 1999 |
|                             | Stay et al., 1998 | Plaskett et al., 1999 |
|                             | Brock | Symons et al., 2004 |

Strength of evidence: Strong
Therapeutic effectiveness: Unsupported

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**Strength of evidence: Strong**

**Therapeutic effectiveness: Unsupported**
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**Fewer Than 5 Studies**

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<td>I</td>
<td>Ebadi et al., 2012</td>
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<td>I</td>
<td>Aldes et al., 1998</td>
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<td>Ansari et al., 2007</td>
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<td>Plantar fascitis</td>
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<td>Clarke et al., 1976</td>
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<td>Tibial periostitis</td>
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<td>Smith et al., 1986</td>
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<td>Heel pain</td>
<td>I</td>
<td>Crawford et al., 1996</td>
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<td></td>
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<td>Dental pain</td>
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<td>Hashish et al., 1996</td>
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<td></td>
<td>I</td>
<td>Hashish et al., 1988</td>
<td></td>
<td></td>
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<td>Sahin et al., 2011</td>
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<tr>
<td></td>
<td>III</td>
<td>Ansari et al., 2006a</td>
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<td></td>
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<td>Congenital pseudoarthrosis</td>
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<td>II</td>
<td>Warden et al., 2001</td>
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</table>

**Strength of evidence: Substantiated**
tolerate the pressure exerted by the soundhead applicator during treatment. Apply medium pressure over the skin, considering that too much pressure will wash away the coupling medium, thus decreasing the transfer of energy; too little pressure will cause improper coupling. When dealing with irregular body surfaces, both the contact with gel pad and noncontact with tap water methods can be used. Noncontact with tap water is the method of choice with very irregular and hypersensitive treatment surface areas.

5. Application Technique

The application technique is dynamic only because maintaining the soundhead stationary over the treated area will induce hot spots causing pain and potentially tissue burn, especially when the level of intensity used is elevated, which often is the case with the use of CUS therapy. Hot spots are caused by stationary or standing waves, which are formed when two waves of equal frequency that are traveling in opposite directions collide. Practically speaking, standing waves are high-energy waves concentrated in a small area that can be avoided by the continuous displacement of the soundhead applicator over the treated surface area.

6. Dosage

Dosage is based on the desired thermomechanical effects required for treatment. It is by far the most challenging, and sometime the most confusing, parameter to determine. For the very large majority of clinicians and authors of textbooks on electrophysical agents, dosage is simply express using two parameters: intensity and duration of application. For example, to document dosage as “2 W/cm² for 8 minutes” in patient files or research manuscripts is incomplete and misleading. Why is this so? Such a dosage expression is no longer acceptable, as discussed later, because it does not reflect the dose of ultrasonic energy delivered to the sonated tissues. To calculate the ultrasonic dose, one must take into consideration two other dosimetric parameters—namely, the transducer ERA and the treatment surface area (S). The product of intensity (I), measured in watts per square centimeter (W/cm²), and application duration (T), measured in seconds (s), corresponds to the energy density per treatment (E_D), measured in joules per square centimeter (J/cm²). It is calculated using the formula E_D = I X T, where watts times seconds (W X s) equals joules. In the previous example, to report dosage as “2 W/cm² for 8 minutes” is to report that the energy density per treatment is equal to 980 J/cm². As demonstrated next, to report energy density per treatment is not to report the dose per treatment.

a. Dosage Calculation

Table 20-3 presents dosimetric examples related to continuous and pulsed applications of CUS therapy. These examples are designed to clarify the concept of dosage, which rests on the definition of dose. Dose per treatment is defined as the amount of ultrasonic energy delivered per square centimeter of tissue at the applicator–skin interface. To facilitate calculation, readers are invited to use the Online Dosage Calculator: Ultrasound.

i. Continuous Mode

Spatial peak intensity (I_SP) is calculated by dividing the device’s power (P), measured in watts (W), by the transducer faceplate effective radiating area (ERA), measured in square centimeters (cm²). It is expressed in units of watts per square centimeter (W/cm²) based on this formula: I_SP = P/ERA. In both examples shown in Table 20-3, I_SP equals 2 W/cm² (2 W/cm² = 10 W/s/cm²). Energy density is the product of intensity (W/cm²) and application duration measured in seconds (E_D = I_SP X T).
TABLE 20-3  DOSAGE EXAMPLES FOR CONTINUOUS ULTRASOUND THERAPY

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Continuous*</th>
<th>Pulsed**</th>
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</thead>
<tbody>
<tr>
<td>Power (P)</td>
<td>10 W</td>
<td>10 W</td>
</tr>
<tr>
<td>Transducer effective radiating area (ERA)</td>
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<td>5 cm²</td>
</tr>
<tr>
<td>Treatment surface area (S)</td>
<td>10 cm²</td>
<td>15 cm²</td>
</tr>
<tr>
<td>Spatial peak intensity (Isp)</td>
<td>2 W/cm²</td>
<td>2 W/cm²</td>
</tr>
<tr>
<td>Application duration (T)</td>
<td>480 s</td>
<td>480 s</td>
</tr>
<tr>
<td>Duty cycle (DC)</td>
<td>100%***</td>
<td>100%***</td>
</tr>
<tr>
<td>Energy density (Eo)</td>
<td>960 J/cm²</td>
<td>192 J/cm²</td>
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<tr>
<td>Spatial average intensity (I sa)</td>
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<td>0.4 W/cm²</td>
</tr>
<tr>
<td>Total energy (ET)</td>
<td>4,800 J</td>
<td>96 J</td>
</tr>
<tr>
<td>Dose per treatment (DT)</td>
<td>480 J/cm²</td>
<td>64 J/cm²</td>
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</tbody>
</table>

* Continuous: \( I_{sp} = \frac{P}{ERA}; E_o = I_{sp} \times T; E_T = I_{sp} \times ERA \times T; D_T = \frac{E_T}{S} \)

** Pulsed: \( I_{sa} = I_{sp} \times DC; E_o = I_{sa} \times T; E_T = I_{sa} \times ERA \times T; D_T = \frac{E_T}{S} \)

*** DC: Always equal to 100% because there is no OFF time.

In both examples, application durations are identical at 8 minutes or 480 s. Energy density is equal to 960 J/cm² in both examples (960 J/cm² = 2 W/cm² x 480 s). Total energy (E_T), measured in Joules (J), is the product of three parameters: intensity (I_{sp}), transducer effective radiating area (ERA), and application duration (T). It is calculated as follows: \( E_T = I_{sp} \times ERA \times T \) (J = (W/cm² x cm²) x T; J = W/s). In other words, this parameter refers to the total amount of ultrasonic energy delivered under the transducer during the entire application duration. In both examples, \( E_T \) equals 4,800 J (4,800 J = 2 W/cm² x 5 cm² x 480 s). As mentioned earlier, the dose per treatment (D_T) refers to the amount of ultrasonic energy delivered per square centimeter of tissue at the applicator-skin interface. The dose per treatment takes into account the total energy (E_T) delivered and the treatment surface area (S) measured in square centimeters (cm²). It is expressed in joules per square centimeter (J/cm²) based on the following formula: \( D_T = \frac{E_T}{S} \). In the first and second examples, doses per treatment equal 480 J/cm² (4,800 J/10 cm²) and 320 J/cm² (4,800 J/15 cm²), respectively. The dose per treatment is smaller in the second example because the same total energy is spread, or distributed, over a larger treatment area (from 10 to 15 cm²) within the same application duration (8 min), thus leaving less energy per square centimeter of tissue at the applicator-skin interface (see Table 20-3). Stated differently, dose per treatment (D_T) is said to be directly proportional to intensity, transducer ERA, and application duration, and inversely proportional to treatment surface area (\( D_T = \frac{(I_{sp} \times ERA \times T)}{S} \)).

ii. Pulsed Mode

When the flow of energy is interrupted or pulsed, the spatial average intensity needs to be calculated and taken into consideration. Spatial average intensity (I_{sa}) is calculated, as shown in Table 20-3, by multiplying the spatial peak intensity (I_{sp}) of the device by its duty cycle (DC), using this formula: \( I_{sa} = I_{sp} \times DC \). Recall that the duty cycle, expressed as a percentage (%), is derived from the selected ON and OFF times: \( DC = \frac{(ON/(ON + OFF)) \times 100}{} \). In both examples, DC values are set at 20%, which yield spatial average intensities (I_{sa}) equal to 0.4 W/cm² (0.4 W/cm² x 20%). Energy densities (E_o), measured at 192 J/cm², are identical in both examples (192 J/cm² = 0.4 W/cm² x 480 s). Keeping the application duration times (T) identical at 480 seconds or 8 minutes, total energy (E_T), in both examples, equals 960 J. The resulting dose per treatment (D_T) is, however, smaller than in the second example (64 J/cm²) when compared to the first example (96 J/cm²), because the treatment surface area (S) in the second example is larger (15 cm² vs. 10 cm²).

b. Summing Up on the Concept of Dosage

Dosage is defined as the amount of ultrasonic energy delivered per square centimeter of tissue at the applicator-skin interface. To express dosage as the product of intensity and application duration i.e., W/cm², which is unfortunately routinely done in clinical settings, is incomplete.
and misleading because it reflects the energy density \( E_0 = 1 \times T \), not the dose, delivered to soft tissues. To determine the dose per treatment \( (D_T) \), practitioners must take into consideration the transducer ERA (used to calculate total energy) and the treatment surface area \( (S) \), because the larger the treatment surface area for a given total energy, the smaller the dose per treatment. There is evidence to suggest that better treatment effectiveness using CUS is achieved when larger doses per treatment are delivered to soft tissues (Alexander et al., 2010).

### 7. Importance of Periodic Device Maintenance and Calibration

There is strong consensus in the literature to support the view that CUS devices are highly susceptible to decalibration after use. The extent of decalibration can have negative impacts on dosimetry and clinical effectiveness (Stewart et al., 1974; Allen et al., 1978; Stewart et al., 1980; Snow, 1982; Hekkenberg et al., 1986; Rivest et al., 1987; Chartered Society of Physiotherapy, 1990; Pye et al., 1994; Pye, 1996; Kimura et al., 1998; Artho et al., 2002; Johns et al., 2007; Straub et al., 2008). This situation may explain why different clinical outcomes are observed with seemingly identical devices and dosimetry (Holcomb et al., 2003; Merrick et al., 2003). As a result, it is strongly recommended that all CUS devices be inspected and calibrated several times a year and weekly if used frequently.

### 8. Need for Ultrasonic Coupling Media

For ultrasound energy to be effective, it must be properly transmitted to the soft tissues. The opposition to the transmission or flow of sound through a medium is called acoustic impedance. The specific acoustic impedance of a medium is defined as its density times its sound propagation velocity, and is measured in unit of newton second per cubic meter \( (N \cdot s / m^3) \). For example, because of its low density and propagation velocity, air has a very low acoustic impedance \( (413 \, N \cdot s / m^3) \) in comparison to water \( (1,440,000 \, N \cdot s / m^3) \) and steel \( (45,000,000 \, N \cdot s / m^3) \). For maximal \( (100\%) \) transmission of ultrasonic energy from one medium to the next, the acoustic impedance of the two media needs to be the same. The greater the difference in acoustic impedance at the interface between the two media, the greater the amount of energy that is reflected back. The greater the reflection, the smaller the amount of ultrasound energy transmitted at the interface. Practically speaking, to penetrate soft tissues, the ultrasound beam has to overcome the soundhead steel faceplate-air interface. Biophysics has established that approximately 99.99\% of ultrasound energy is reflected by air, meaning no transmission, because the very large difference (approximately 100,000 fold) between the acoustic impedance of steel and that of air \( (45,000,000 \, N \cdot s / cm^2) / 413 \, N \cdot s / cm^2) \). To optimize ultrasonic energy transmission, a suitable coupling medium is therefore required, to replace air at the soundhead faceplate-skin interface. Tap water is an ideal coupling medium because its acoustic impedance \( (1,440,000 \, N \cdot s / m^3) \) closely matches that of soft tissues \( (1,350,000 \, N \cdot s / m^3) \). Commercial aquasonic gels are also excellent coupling media, with transmissivity percentages ranging from 95\% to 100\% (Klucinec, 1997; Klucinec et al., 2000; Oshikoya et al., 2000; Myrer et al., 2001; Merrick et al., 2002; Casarotto et al., 2004; Gulick et al., 2005; Poltawski et al., 2007).

### B. LOW-INTENSITY PULSED ULTRASOUND

The dosimetry related to LIPUS therapy, contrary to that of CUS discussed previously, is much simpler because there is only one dosimetric protocol used for treatment (Table 20-4). All of the dosimetric parameters relate to this research-based dosimetric protocol. Clinicians need only to turn the device on, and the desired dosage is ready to be delivered at the bone fracture site. This standardized dosage is based on data gathered from both animal research and human clinical trials. LIPUS is routinely applied at very low intensity \( (0.03 \, W/cm^2) \), for 20 minutes \( (1,200 \, s) \), using a \( 4 \, cm^2 \) transducer ERA. The ultrasonic beam is pulsed with a 20\% duty cycle \((ON:OFF \, ratio \, 1:4)\). ON time (i.e., pulse duration) is fixed at \( 200 \, \mu s \), and pulse frequency is preset at \( 1,000 \, Hz \). The application is stationary with the transducer ERA covering the fracture site area \( (S) \), which is \( 4 \, cm^2 \) because it is equivalent to transducer ERA. The dose per treatment \( (D_T) \), in this case, equals \( 36 \, J/cm^2 \), \( 36 \, J/cm^2 = (0.03 \, W/cm^2 \times 4 \, cm^2 \times 1,200 \, s)/4 \, cm^2 \). LIPUS may be applied directly on the skin overlying the bone fracture site, or in-cast or on-cast situations using a specially designed retaining and fixing system. The application method is stationary because the ultrasonic intensity level is very low \( (0.03 \, or \, 30 \, mW/cm^2) \), thus posing minimal to no risk for the occurrence of hot spots. The application duration is fixed at \( 20 \, minutes \) per treatment, and treatments are applied daily until satisfactory bone healing is achieved. The device will automatically shut itself off with an audible beep when the 20 minutes is complete.

### C. NONCONTACT LOW-FREQUENCY ULTRASOUND

The dosimetry and application of NCLFUS, shown in Table 20-5, is standardized based on research data from human clinical trials. NCLFUS delivers continuous low-frequency \( (40 \, kHz) \) and low-intensity \( (0.5 \, W/cm^2) \) ultrasound energy to the wound bed via a fine mist of sterile water that acts as a conduit for transmitting the energy from the transducer faceplate to the treatment site. The applicator tip makes no contact with the wound bed and is held perpendicular to the wound surface, with its tip approximately 0.5 to 1.5 cm \((0.2 \, to \, 0.6 \, in)\) away from the wound. The application technique is dynamic, with the applicator moved vertically and horizontally across the wound using multiple passes. Application duration is variable and is directly related to wound size. The larger the wound size, the longer the application duration (Bell et al., 2008; Driver et al., 2011; Voigt et al.,
TABLE 20-4
STANDARDIZED DOSIMETRIC PARAMETERS AND PROTOCOL FOR LOW-INTENSITY PULSED ULTRASOUND THERAPY

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<tr>
<td></td>
<td>ON:OFF ratio: 1:4</td>
</tr>
<tr>
<td>Intensity (I)</td>
<td>Spatial average intensity ($I_{SA}$) = 0.03 W/cm²</td>
</tr>
<tr>
<td>Transducer ERA</td>
<td>4 cm²</td>
</tr>
<tr>
<td>Treatment surface area (S)</td>
<td>4 cm²</td>
</tr>
<tr>
<td>Application method and coupling medium</td>
<td>Contact with aquasonic gel</td>
</tr>
<tr>
<td></td>
<td>On the skin surface overlying the bone fracture site</td>
</tr>
<tr>
<td></td>
<td>In-cast or on-cast application</td>
</tr>
<tr>
<td>Application technique</td>
<td>Stationary: Transducer placed immediately over the bone fracture line</td>
</tr>
<tr>
<td>Application duration (T)</td>
<td>1,200 s (20 min)</td>
</tr>
<tr>
<td>Treatment frequency</td>
<td>Daily</td>
</tr>
<tr>
<td>Dose per treatment ($D_1$)</td>
<td>36 J/cm²</td>
</tr>
</tbody>
</table>

LIPUS, low-intensity pulsed ultrasound; ERA, effective radiating area.

2011; Escandon et al., 2012). Upon entering the wound size (cm²) on the unit console, the corresponding application time will appear. For example, duration from 3 to 20 minutes may be necessary to treat a wound size ranging from 10 to 30 cm. Treatment frequency is every second day. It is impossible to calculate the exact dose per treatment because the applicator to wound distance will fluctuate throughout the application duration, inducing water mist ERA variation, and because clinicians may spend more time debridging a certain area of wound over other areas, causing variable energy absorption per square centimeter of tissue.

V. APPLICATION, CONTRAINDICATIONS, AND RISKS

Prior to considering the application of therapeutic ultrasound, practitioners must first consider the contraindications and risks associated with it and then turn their attention to those key application steps and procedures designed to optimize treatment safety, efficacy, and effectiveness. To further facilitate and visualize the application of therapeutic ultrasound, readers are invited to view related online videos.

TABLE 20-5
STANDARDIZED DOSIMETRIC PARAMETERS AND PROTOCOL FOR NONCONTACT LOW-FREQUENCY ULTRASOUND THERAPY

<table>
<thead>
<tr>
<th>Parameters</th>
<th>NCLFUS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency (Hz)</td>
<td>40 kHz</td>
</tr>
<tr>
<td>Delivery mode</td>
<td>Continuous</td>
</tr>
<tr>
<td>Intensity (I)</td>
<td>Spatial peak intensity ($I_{SP}$) = 0.5 W/cm²</td>
</tr>
<tr>
<td>Application method</td>
<td>Noncontact</td>
</tr>
<tr>
<td>Application technique</td>
<td>Dynamic</td>
</tr>
<tr>
<td>Applicator to wound distance</td>
<td>0.5 to 1.5 cm</td>
</tr>
<tr>
<td>Application duration (T)</td>
<td>3 to 20 minutes, depending on wound size</td>
</tr>
<tr>
<td>Treatment frequency</td>
<td>Every second day</td>
</tr>
</tbody>
</table>

NCLFUS, noncontact low-frequency ultrasound.
## Ultrasound

**IMPORTANT:** Conduct a thermal skin discrimination test prior to first application. Cleanse the soundhead faceplate with cleansing solution after each use to prevent spreading of nosocomial infection (Schabrun et al., 2006). Illustrated, as examples, are the applications of conventional ultrasound (Fig. 20-9) and noncontact low-frequency ultrasound (Fig. 20-10).

See online videos.

### CONVENTIONAL ULTRASOUND (CUS)

<table>
<thead>
<tr>
<th>STEP</th>
<th>RATIONALE</th>
</tr>
</thead>
</table>
| 1. Check for contraindications. | Over malignant area—increases tumor growth  
Over hemorrhagic area—increases hemorrhagic response  
Over ischemic area—increases ischemia resulting from the vascular system’s inability to meet the increased metabolic demand induced by the induced-heat response  
Over area of thrombosis—thrombus detachment leading to embolism  
Over infected lesion—spread of infection  
Over gonad—infertility  
Over the eye—cavitation of humor fluid leading to damage to the retina  
Over the pelvic abdominal and lumbar areas of women who are pregnant—disruption of fetal development  
Over the pelvic and lumbar areas of women who are menstruating—increases menstrual flow  
Over the spinal cord after laminectomy—cavitation of cerebrospinal fluid leading to damage to the spinal cord  
Over plastic and cemented implants—heating can cause damage to plastic, cement, and surrounding soft tissues. CUS can be safely used over or around metallic implants (Gersten, 1958; Lehmann et al., 1958, 1959, 1961; Skoubo-Kristensen et al., 1982).  
Near or over all electronic implants—electronic malfunction |
| 2. Consider the risks. | Over epiphyseal plate—may alter normal bone growth (Nussbaum et al., 2006)  
With patients who have received radiotherapy—wait at least 6 months after the last radiotherapy treatment before using CUS over cancerous areas |
| 3. Position and instruct patient. | Ensure comfortable body positioning, and inform the patient that a sensation of heat may be present during treatment. |

**FIGURE 20-9** Application of conventional ultrasound over the shoulder area. (Reprinted with permission from Knight KL, Draper DO. Therapeutic Modalities: The Art and Science. 2nd ed. Philadelphia: Lippincott Williams & Wilkins, 2013.)
CHAPTER 20 Ultrasound

**STEP**  
4. Prepare treated area.  
5. Select application method.  
7. Prepare device.  
8. Estimate lesion depth and surface area.  
9. Select frequency.  
10. Select applicator size (ERA).  
11. Select delivery mode.  
12. Select application technique.  
13. Set dosimetry.  

**RATIONALE**

4. Cleanse the skin overlying the targeted area with rubbing alcohol. Shave or clip excess hair over treatment area because air bubbles tend to cling to them, thus reducing ultrasound transmission.

5. Choose between contact and noncontact methods. Noncontact is recommended when the treated surface area is too irregular or too painful for contact by the applicator.

6. For contact method: Use commercial ultrasonic gel for optimal ultrasonic transmissivity (Poltawski et al., 2006). Avoid gel and degassed water in latex gloves or condoms (Klucke, 1997). Use thinner gel pads to optimize transmissivity (Draper et al., 2010). Apply a thin layer of ultrasonic gel at the applicator/pad–skin interface. Keep ultrasonic coupling media at room temperature for optimal thermal effect (Oshikoya et al., 2000).

• For noncontact method: Immerse both body segment and applicator in a plastic bath or tub filled with tap or degassed water. Keep the soundhead faceplate at a distance of 2–3 cm from the skin overlying affected tissue, because the farther away it is, the less the temperature elevation in the tissues (Robertson et al., 1996). To compensate for thermal energy loss to water, increase dosage with distance (Draper et al., 1993b; Robertson et al., 1996). Air bubbles will accumulate on both the applicator faceplate and irradiated skin surface during treatment. Wipe off the bubbles periodically, using a stick or with a brush of one's finger, to ensure maximum transmission at all times during the application.

7. Keep ultrasound devices at least 5 m (15 ft) away from functioning shortwave diathermy devices to prevent electromagnetic interference. Plug line-powered devices into ground-fault circuit interrupter (GFCI) receptacles to eliminate the risk of electrical macroshock (see Chapter 5). Make sure that the ultrasound device is properly calibrated and that its beam nonuniformity ratio (BNR) value is between 2 and 8.

8. Estimate the depth of the lesion (in centimeters) from the skin surface as well as its surface area (in square centimeters). Information about tissue depth will guide the selection of frequency. Estimation of the lesion surface area will guide the selection of transducer effective radiating area (ERA).

9. Choose between 1 and 3 MHz. The deeper the lesion, the shorter the frequency.

10. Applicators in different sizes or ERAs are available (see Fig. 20-1B). Transducer ERA (applicator size) is directly related to the treatment surface area under consideration. Keep a ratio of less than 3 between these two surface areas, such that the treated surface area (S) is no more than 3 times greater than the transducer ERA (Chan et al., 1998). For example, the maximum surface area that can be treated with a transducer of 5-cmERA is 15 cm².

11. Choose between the continuous and pulsed modes. Theoretically, the continuous mode will always deliver more ultrasonic energy to the tissues per unit of time, and consequently more thermal effects, than the pulsed mode.

12. Use the dynamic technique because the stationary technique is likely to cause hot spots. Slowly move the applicator at low speed (2–7 cm/s), and with a light pressure, over the treatment area (Weaver et al., 2006). These movements should not be too fast, because the faster the movements, the less the absorption of ultrasonic energy into the soft tissues per unit of time. Do a series of up-and-down, side-to-side, and overlapping circular movements while attempting to cover the entire treatment surface area evenly. Keep the applicator faceplate perpendicular to the treatment surface to minimize reflection.

13. Use Table 20-2 as a guideline. See Table 20-3 for dosimetric calculation. Use the Online Dosage Calculator: Ultrasound.

14. Apply the soundhead faceplate over the treatment surface, and turn the device ON.
### LOW-INTENSITY PULSED ULTRASOUND (LiPUS)

<table>
<thead>
<tr>
<th>STEP</th>
<th>RATIONALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Check for contraindications.</td>
<td>Near or over all electronic implants—electronic interference</td>
</tr>
<tr>
<td>2. Position and instruct patient.</td>
<td>Ensure comfortable body positioning, and inform the patient that no sensation should be felt during treatment.</td>
</tr>
<tr>
<td>3. Prepare treated area.</td>
<td>Cleanse the skin surface overlying the targeted fracture site area with rubbing alcohol and dry. Clip or shave excessive hair if necessary.</td>
</tr>
<tr>
<td>4. Locate the fracture site.</td>
<td>Put an X mark on the skin overlying the bone fracture site with a dermal pen.</td>
</tr>
<tr>
<td>5. Position the retaining and alignment fixture (RAF).</td>
<td>The RAF is composed of an adjustable strap and a cap (see online video). Positioned the strap with the cap placed directly over the fracture as marked on the skin. Apply a layer of ultrasonic gel onto the transducer faceplate, place the transducer into the RAF, and snap the cap to close.</td>
</tr>
<tr>
<td>6. Set dosimetry.</td>
<td>All dosimetric parameters are preset. See Table 20-4.</td>
</tr>
<tr>
<td>7. Apply treatment.</td>
<td>The device is powered by a nonrechargeable lithium battery that can be changed after a lifetime of more than 150 treatment periods of 20 minutes each. It will deliver low-intensity pulsed ultrasound energy, run for 20 minutes, and then turn itself off.</td>
</tr>
<tr>
<td>8. Conduct post-treatment procedure.</td>
<td>Remove the RAF. Inspect the skin, and record any adverse reactions. Open cap. Remove transducer from RAF, and wipe off gel from the transducer using a soft cloth. Wipe off any gel remaining on skin with a soft cloth.</td>
</tr>
<tr>
<td>9. Ensure post-treatment equipment maintenance.</td>
<td>Follow manufacturer recommendations. Immediately report all defects or malfunctions to technical maintenance staff.</td>
</tr>
</tbody>
</table>

### NONCONTACT LOW-FREQUENCY ULTRASOUND (NCLFUS)

<table>
<thead>
<tr>
<th>STEP</th>
<th>RATIONALE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Check for contraindications.</td>
<td>Near or over all electronic implants—electronic interference</td>
</tr>
<tr>
<td>2. Consider the risks.</td>
<td>Treatment of open wounds always presents a risk of cross-contamination. The wearing of goggles, mask, gown, and gloves is highly recommended.</td>
</tr>
</tbody>
</table>
CHAPTER 20 Ultrasound 399

STEP RATIONALE

3. Position and instruct patient. Ensure comfortable body positioning, and inform the patient about the feeling of a fine water mist over the wound area during treatment.

4. Prepare wound treatment area. Expose the wound and then measure its size (in square centimeters) using a ruler or a planimeter.

5. Prepare the device. Keep the device at least 5 m (15 ft) away from functioning shortwave diathermy devices to prevent electromagnetic interference. Plug line-powered devices into GFCI receptacles to eliminate the risk of electrical macroshock (see Chapter 5). The device is composed of a generator and handheld transducer, to which is attached a single-use disposable applicator (see Fig. 20-3B and online videos). Press the applicator onto the transducer tip in one continuous motion. Place the refillable saline bottle upright into the applicator. Turn the generator ON.

6. Set dosimetry. All dosimetric parameters are preset with the exception of wound size (see Table 20-5). Enter wound size (in square centimeters) into the console. The corresponding application time will automatically appear. Larger wound beds will require longer-duration applications. When treating wounds with sizes greater than 30 cm² on the same patient, it will be necessary to refill the saline bottle, using sterile saline water, during treatment.

7. Apply treatment. Position and maintain the applicator perpendicular to the wound with the leading edge of the applicator approximately 0.5 to 1.5 cm (0.2 to 0.6 in) from the wound surface (Fig. 20-10). Depress and release the control button to initiate the saline flow. Move the applicator over the wound surface using slow vertical and horizontal multiple strokes or passes. The applicator tip must not touch the wound.

8. Conduct post-treatment procedure. Inspect the wound, and record any adverse reactions. Remove the applicator from the transducer. Discard the applicator and saline bottle. Clean and disinfect the applicator, cable, and device to ensure optimal hygiene and prevent cross-contamination between patients.


FIGURE 20-10 Application of noncontact low-frequency ultrasound to an open wound. Ultrasonic effervescence is visible in the form of a bubbling or frothing action at the wound surface. (Courtesy of Celleration.)

CASE STUDIES

Three case studies summarize the concepts, principles, and applications of therapeutic ultrasound discussed in this chapter. Case Study 20-1 addresses the use of conventional ultrasound (CUS) for a shoulder tendinosis affecting a middle-aged man. Case Study 20-2 is concerned with the use of low-intensity pulsed ultrasound (LIPUS) for the treatment of a slow-to-heal humeral bone fracture affecting a woman. Case Study 20-3 addresses the use of noncontact low-frequency ultrasound (NCLFUS) for an open infected wound affecting a man who is diabetic. Each case is structured in line with the concepts of evidence-based practice (EBP), the International Classification of Functioning, Disability, and Health (ICF) disablement model, and SOAP (subjective, objective, assessment, plan) note format (see Chapter 2 for details).
CASE STUDY 20-1: CONVENTIONAL ULTRASOUND FOR SHOULDER TENDINOSIS

EVIDENCE-BASED CLINICAL DECISION MAKING PROTOCOL

1. Formulate the Case History

A 44-year-old right-handed commercial painter, diagnosed with a rotator cuff tendinitis to his right shoulder 4 months ago, is referred for conservative treatment before considering surgery. The shoulder condition has evolved from a state of tendinitis to tendinosis. Radiologic imaging reveals no calcification. This patient has a surgical history that reveals a metallic implant associated with a past injury to his right acromioclavicular joint. His main complaint is pain during movement and at palpation and restricted right shoulder function. Goniometric evaluation reveals deficits in range of motion (ROM) of 20 degrees in abduction and 30 degrees in elevation. The affected tendons are estimated to be at a depth of approximately 3 cm from the overlying skin surface. Treatment surface area is estimated at 10 cm². Past treatments included oral and injected analgesic and anti-inflammatory drugs. This therapeutic approach gave less than satisfactory results. The patient continues taking analgesic drugs to control his chronic shoulder pain. He works 3 days a week, and with his right arm, doing only those painting tasks that are below shoulder height. His goal is to resume full-time work with no functional limitation as soon as possible and without having to undergo surgical treatment.

2. Outline the Case Based on the ICF Framework

<table>
<thead>
<tr>
<th>SHOULDER TENDINOSIS</th>
<th>BODY STRUCTURES AND FUNCTIONS</th>
<th>ACTIVITIES</th>
<th>PARTICIPATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Difficulty with painting tasks</td>
<td>Unable to work full-time</td>
<td></td>
</tr>
<tr>
<td>Decrease ROM</td>
<td>Difficulty with some shoulder activities of daily living (ADLs)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PERSONAL FACTORS

Healthy man
Outdoor character

ENVIRONMENTAL FACTOR

Home construction

3. Outline Therapeutic Goals and Outcome Measurements

<table>
<thead>
<tr>
<th>GOAL</th>
<th>OUTCOME MEASUREMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease pain</td>
<td>Visual Analogue scale (VAS)</td>
</tr>
<tr>
<td>Increase shoulder ROM</td>
<td>Goniometry</td>
</tr>
<tr>
<td>Avoid surgery and accelerate return to full-time work</td>
<td>Constant Shoulder Score (CSS)</td>
</tr>
</tbody>
</table>

4. Justify the Use of Conventional Ultrasound Based on the EBP Framework

<table>
<thead>
<tr>
<th>PRACTITIONER'S EXPERIENCE</th>
<th>RESEARCH-BASED INDICATIONS</th>
<th>PATIENT'S EXPECTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experienced in CUS</td>
<td>Strength: Moderate</td>
<td>Has no opinion on CUS treatment</td>
</tr>
<tr>
<td>Has used CUS in previous cases</td>
<td>Effectiveness: Conflicting</td>
<td>Hopes to avoid surgery</td>
</tr>
<tr>
<td>Is unsure about treatment effectiveness</td>
<td></td>
<td>Wants to return to full-time work</td>
</tr>
</tbody>
</table>
5. Outline Key Intervention Parameters

- **Treatment base:** Private clinic
- **Ultrasound device:** Cabinet-type CUS. The thermomechanical effects are expected to enhance the proliferative and maturation phase of tendon healing, thus facilitating normal function.
- **Contraindication:** None, because metallic implants are present in the right shoulder area, not metallic implants.
- **Application protocol:** Follow the suggested application protocol for CUS in Application, Contraindications, and Risks box, and make the necessary adjustments for this case. See online videos.
- **Dosimetry:** See Table 20-2, Table 20-3, and following information.
- **Frequency:** 1 MHz
- **Delivery mode:** Pulsed
- **Duty cycle:** 50%
- **Patient’s positioning:** Lying supine
- **Applicator type:** Handheld
- **Treatment surface area:** 10 cm²
- **Transducer effective radiating area (ERA):** 5 cm²
- **Application method:** Contact
- **Coupling medium:** Aquasonic gel
- **Application technique:** Dynamic
- **Spatial average intensity (I_{SA}):** 0.5 W/cm²
- **Application duration:** 420 s (7 min)
- **Energy density (E_d):** 210 J/cm²
- **Total energy (E_T):** 1,050 J
- **Dose per treatment (D_T):** 105 J/cm²
- **Treatment frequency:** 3 times per week
- **Intervention period:** 4 weeks
- **Concomitant therapies:** Regimen of shoulder flexibility and strengthening exercises. Home-based program focused on maintaining shoulder movements.
- **Use the Online Dosage Calculator: Ultrasound.**

6. Report Pre- and Post-Intervention Outcomes

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>PRE</th>
<th>POST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (VAS score)</td>
<td>4/10</td>
<td>2/10</td>
</tr>
<tr>
<td>Shoulder ROM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abduction: 20% restriction</td>
<td></td>
<td>5% restriction</td>
</tr>
<tr>
<td>Elevation: 30% restriction</td>
<td></td>
<td>5% restriction</td>
</tr>
<tr>
<td>CSS</td>
<td>45%</td>
<td>70%</td>
</tr>
<tr>
<td>Work status</td>
<td>Part-time</td>
<td>Full-time</td>
</tr>
</tbody>
</table>

7. Document Case Intervention Using the SOAP Note Format

**S:** Middle-aged male Pt presents with a moderate case of rotator cuff tendinosis to right shoulder.

**O:** Intervention: CUS at 1 MHz; Pulsed; DC 50%; applicator ERA 5 cm²; contact application with aquasonic gel; I_{SA} 0.5 W/cm²; application duration 7 min; E_d 210 J/cm²; E_T 1,050 J; dose per treatment (D_T) 105 J/cm². Pre-post comparison: Pain decrease (VAS 4/10 to 2/10); ROM increase: abduction from 20% to 5% restriction; elevation from 30% to 5% restriction; improved shoulder function: CSS score from 45% to 70%; improved work status: part-time to full-time.

**A:** No adverse effect.

**P:** No further treatment required. Pt instructed to minimize the use of his right upper limb for painting tasks above shoulder height. High risk of aggravation of his shoulder condition because of the nature of his employment (repeated use of his right upper limb for painting commercial buildings). This patient will need to strengthen his right shoulder and make judicious use (using the left upper limb more often) of his right shoulder at work. Otherwise, the need for additional CUS treatments is very likely over the months or years to come. Surgery as a last resort cannot be ruled out if further conservative treatments fail, and if the patient is then willing to accept it.

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**CASE STUDY 20-2: LOW-INTENSITY PULSED ULTRASOUND FOR NONUNION HUMERAL FRACTURE**

**EVIDENCE-BASED CLINICAL DECISION MAKING PROTOCOL**

1. Formulate the Case History

An active 57-year-old woman broke her left humerus about 11 months ago in a bad fall while skiing. Despite traditional orthopedic management and regular follow-up for her condition (surgery involving metallic rod, plates, and screws followed by cast immobilization), she is diagnosed today with nonunion of her fracture. Her main
complaint is residual pain, combined with the limited use of her upper right arm in the course of her daily activities. She is eager to resume her daily activities, including skiing. Her goal is to achieve complete union or resolution of the fracture without further surgery. To accelerate bone healing and the complete resolution of this fracture, the orthopedic surgeon refers this patient for LIPUS therapy. The purpose is to initiate treatment at the hospital and then to instruct and train her for home therapy for the remaining weeks of treatment. The patient is asked to come to the hospital for periodic radiographs to monitor the resolution of her bone fracture.

2. Outline the Case Based on the ICF Framework

<table>
<thead>
<tr>
<th>BODY STRUCTURES AND FUNCTIONS</th>
<th>ACTIVITIES</th>
<th>PARTICIPATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>Limited ability to do ADLs</td>
<td>Unable to resume skiing</td>
</tr>
<tr>
<td>Bone nonunion at fracture site</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PERSONAL FACTORS
- Healthy woman
- Athletic character
- Retired

ENVIRONMENTAL FACTORS
- Housewife
- Recreational sports
- Fitness and leisure

3. Outline Therapeutic Goals and Outcome Measurements

<table>
<thead>
<tr>
<th>GOAL</th>
<th>OUTCOME MEASUREMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease pain</td>
<td>101-point Numerical Rating Scale (NRS-101)</td>
</tr>
<tr>
<td>Achieve complete bone calcification and union</td>
<td>Serial radiography</td>
</tr>
<tr>
<td>Upper arm function</td>
<td>Patient-Specific Functional Scale (PSFS)</td>
</tr>
</tbody>
</table>

4. Justify the Use of Low-Intensity Pulsed Ultrasound Based on the EBP Framework

<table>
<thead>
<tr>
<th>PRACTITIONER’S EXPERIENCE</th>
<th>RESEARCH-BASED INDICATIONS</th>
<th>PATIENT’S EXPECTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal experience in LIPUS</td>
<td>Strength: Moderate</td>
<td>Hopeful that the treatment will work</td>
</tr>
<tr>
<td>Has occasionally used LIPUS in previous cases</td>
<td>Effectiveness: Substantiated</td>
<td>Wants to recover full upper limb function</td>
</tr>
</tbody>
</table>

Is convinced that LIPUS will be beneficial

5. Outline Key Intervention Parameters

- **Treatment base:** Hospital first and home thereafter
- **Ultrasound device:** Battery-operated LIPUS device. LIPUS is expected to promote osteogenesis, thus building the necessary callus for complete union of bone.
- **Contraindication:** There is no known contraindication to the use of LIPUS therapy.
- **Patient’s positioning:** Sitting with upper arm resting on table
- **Application protocol:** Follow the suggested application protocol for LIPUS therapy in Application, Contraindications, and Risks box, and make the necessary adjustments for this case. See online videos.
- **Dosimetry:** See Table 20-4 and following information.
  - **Frequency:** 1.5 MHz
  - **Delivery mode:** Pulsed
  - **Duty cycle:** 20%
  - **Treatment surface area:** Longitudinal fracture zone; estimated at 5 cm²
  - **Transducer ERA:** 5 cm²
  - **Application method:** Contact
  - **Applicator fixation:** The transducer is kept in place with a plastic retaining and alignment fixture strapped in position over the marking on the skin that identifies the nonunion fracture site.
  - **Fracture site identification:** Marked on the skin using a dermatologic pen.
6. Report Pre- and Post-Intervention Outcomes

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>PRE</th>
<th>POST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (NRS-101 score)</td>
<td>45</td>
<td>10</td>
</tr>
<tr>
<td>Bone healing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper arm function (PSFS score)</td>
<td>60%</td>
<td>90%</td>
</tr>
</tbody>
</table>

7. Document Case Intervention Using the SOAP Note Format

S: Female Pt presents with a case of nonunion humeral bone fracture following a skiing accident.

O: Intervention: LIPUS 1.5 MHz; Pulsed; DC 20%; applicator ERA 5 cm²; contact application with aquasonic gel; application duration 20 min; $I_{sa} 0.03$ W/cm²; $E_D 36$ J/cm²; $E_T 180$ J; dose per treatment ($D_T$) 36 J/cm².

A: No adverse effect. Pt overwhelmed with the result.

P: No further treatment required.

CASE STUDY 20-3: NONCONTACT LOW-FREQUENCY ULTRASOUND FOR RECALCITRANT DIABETIC ANKLE ULCER

EVIDENCE-BASED CLINICAL DECISION MAKING PROTOCOL

1. Formulate the Case History

A 54-year-old man with diabetes, diagnosed 5 months ago with a right ankle ischemic ulcer, is referred for treatment. The wound does not respond to treatment with multi-layered compression bandages. Physical examination reveals the presence of yellow slough, fibrin, tissue exudates, and bacteria in the wound bed. The wound has been recalcitrant to standard care (manual debridement and dressing), which has delayed healing. The therapeutic goal is for wound cleansing and debridement leading to wound healing. The ulcer is located below the medial malleolus. The wound size is irregular, with a surface area corresponding to 15 cm². The patient has difficulty wearing shoes and walking, both of which have a negative impact on his ADLs and work (no car; must use public transportation to commute to work). Pain is always present and is aggravated by ankle joint movement. The patient is anxious. He desperately wants to keep his ability to walk so that he is able to commute to work.

2. Outline the Case Based on the ICF Framework

<table>
<thead>
<tr>
<th>RECALCITRANT DIABETIC ANKLE ULCER</th>
<th>BODY STRUCTURES AND FUNCTIONS</th>
<th>ACTIVITIES</th>
<th>PARTICIPATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td></td>
<td>Difficulty walking</td>
<td>Difficulty commuting (walking) to work</td>
</tr>
<tr>
<td>Open infected wound</td>
<td></td>
<td>Difficulty with ADLs</td>
<td></td>
</tr>
</tbody>
</table>

PERSONAL FACTORS

Middle-aged man
Worker
College educated

ENVIRONMENTAL FACTOR

Home and leisure
3. Outline Therapeutic Goals and Outcome Measurements

<table>
<thead>
<tr>
<th>GOAL</th>
<th>OUTCOME MEASUREMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease pain</td>
<td>Visual Analogue Scale (VAS)</td>
</tr>
<tr>
<td>Eliminate wound infection</td>
<td>Serial bacterial counts</td>
</tr>
<tr>
<td>Increase wound healing</td>
<td>Serial digital photographs (wound surface area)</td>
</tr>
<tr>
<td>Improve walking</td>
<td>Patient-Specific Functional Scale (PSFS)</td>
</tr>
</tbody>
</table>

4. Justify the Use of Noncontact Low-Frequency Ultrasound Based on the EBP Framework

<table>
<thead>
<tr>
<th>PRACTITIONER’S EXPERIENCE</th>
<th>EVIDENCE-BASED INDICATIONS</th>
<th>PATIENT’S EXPECTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experienced in NCLFUS</td>
<td>Strength: Moderate</td>
<td>No opinion on treatment</td>
</tr>
<tr>
<td>Has used NCLFUS in previous cases</td>
<td>Effectiveness: Substantiated</td>
<td>Just wants to resume normal walking</td>
</tr>
<tr>
<td>Believes that NCLFUS can be beneficial</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5. Outline Key Intervention Parameters

- **Treatment base:** Hospital
- **Ultrasound device:** Line-powered NCLFUS system. NCLFUS is expected to cleanse and disinfect the wound through effective debridement and thus facilitate and accelerate wound healing.
- **Contraindication:** None
- **Application protocol:** Follow the suggested application protocol for NCLFUS therapy in Application, Contraindications, and Risks box, and make the necessary adjustments for this case. See online videos.
- **Dosimetry:** See Table 20-5 and following information.
- **Frequency:** 40 kHz
- **Delivery mode:** Continuous
- **Patient’s positioning:** Lying on bed with leg extended
- **Transducer ERA:** 1 cm²
- **Treatment surface area:** 15 cm²
- **Application method:** Noncontact
- **Application technique:** Dynamic—slow, even, repeated vertical and horizontal passes over wound bed
- **Applicator to wound distance:** 1 cm
- **Coupling medium:** Sterile water in a bottle
- **Spatial peak intensity (Lsp):** 0.5 W/cm²
- **Application duration:** 4 minutes
- **Treatment frequency:** Every second day
- **Intervention period:** Until wound closure
- **Concomitant therapy:** Home-based wound care

6. Report Pre- and Post-Intervention Outcomes

<table>
<thead>
<tr>
<th>OUTCOME</th>
<th>PRE</th>
<th>POST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain (VAS score)</td>
<td>6/10</td>
<td>0/10</td>
</tr>
<tr>
<td>Bacterial count</td>
<td>Present</td>
<td>Eliminated</td>
</tr>
<tr>
<td>Wound healing</td>
<td>Open wound surface area: 15 cm²</td>
<td>Wound closed</td>
</tr>
<tr>
<td>Walking status</td>
<td>Limited</td>
<td>Normal</td>
</tr>
</tbody>
</table>

7. Document Case Intervention Using the SOAP Note Format

**S:** Male Pt presents with diabetic recalcitrant leg ulcer.

**O:** Intervention: NCLFUS; 40 kHz; continuous; applicator ERA 1 cm²; noncontact—mist of sterile water; dynamic application; applicator to wound distance 1 cm; application duration 4 min; Lsp 0.5 W/cm². Pre–post comparison: Pain decrease: VAS 6/10 to 0/10; wound infection eliminated; complete wound closure; normal walking.

**A:** No adverse effect. Pt extremely pleased with the result.

**P:** No further treatment required. To prevent recurrence, the patient needs to control his diabetic condition and wear adequate shoes.
VI. THE BOTTOM LINE

- There is strong scientific evidence to show that ultrasound energy, delivered at frequencies ranging from 40 kHz to 3 MHz and at intensities up to 3 W/cm², can induce significant therapeutic thermal and mechanical effects in human soft tissues.
- Ultrasound energy is the production of mechanical acoustic waves resulting from the reversed piezoelectric property of natural or synthetic materials called transducers.
- The thermal effects of ultrasonic acoustic waves are caused by molecular microfriction.
- The mechanical effects of ultrasonic waves are caused by stable cavitation and microstreaming.
- The delivery of ultrasound energy to soft tissues requires the use of a coupling medium.
- Dosage, or dose per treatment, is defined as the amount of ultrasonic energy delivered per square centimeter of tissues at the applicator–skin interface and is measured in joules per square centimeter (J/cm²).
- To express dosage as the product of intensity and application duration—for example, “1.5W/cm² for 6 minutes”—is incomplete and misleading, and therefore no longer acceptable, because it reflects the energy density, not the dose per treatment, delivered to soft tissues.
- To determine the dose per treatment, practitioners must take into consideration four parameters: intensity, application duration, transducer ERA, and treatment surface area.
- Therapeutic ultrasound is delivered in three forms: CUS, LIPUS, and NCLFUS.
- Ultrasound energy is absorbed primarily by high protein–low water content soft tissues such as bones, tendons, ligaments, and muscles.
- CUS is used primarily for the treatment of pathologies affecting connective (tendons and ligaments) and muscular tissues.
- LIPUS is dedicated to the treatment of delayed-union and nonunion bone fractures.
- NCLFUS is used to cleanse and debride open wounds.
- The reason behind the use of CUS is conflicting, whereas that related to both LIPUS and NCLFUS is substantiated.

VII. CRITICAL THINKING QUESTIONS

Clarification: What is meant by CUS, LIPUS, and NCLFUS therapy?
Assumptions: You assume that the thermomechanical effects of CUS are frequency and intensity dependent. How do you justify making this assumption?
Reasons and evidence: What leads you to believe that the reverse piezoelectric phenomenon is responsible for the production of acoustic waves?

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Viewpoints or perspectives: How will you respond to a colleague who says that the use of LIPUS therapy is similar to using CUS therapy in its pulsed mode and at low intensity?
Implications and consequences: What are the implications and consequences of using CUS for its thermal effect on a patient wearing an implanted Medtronic neurostimulation system?
About the question: What is the difference between intensity and dose per treatment? Why do you think I ask this question?

VIII. REFERENCES

Articles
Clarke GR, Stenner L (1976) Use of therapeutic ultrasound. Physiotherapy, 62: 185-190
Fieldhouse C (1979) Ultrasound for relief of painful episiotomy scars. Physiotherapy, 65: 217
CHAPTER 20 Ultrasound


Review Articles

CONCLUSION


Low-Intensity Pulsed Ultrasound


Noncontact Low-Frequency Ultrasound


Sonophoresis


Textbooks


Internet Resource

http://thepoint.lww.com: Online Dosage Calculator: Ultrasound