1.6. Low-intensity Ultrasound Therapy
Therapeutic ultrasound for pain relief, healing, and mobility has had scientifically proven success. The latest research involves using a new approach to ultrasound application — low-intensity ultrasound (LIUS) over long durations [140-143]. LIUS enjoys much of the benefits of traditional higher-dose ultrasound therapeutic regimes but may be applied for much longer durations without danger of thermal damage. Traditionally, ultrasound is applied at 1–4 W/cm\(^2\) for 10 to 15 minutes. LIUS is applied at 30-1000 mW/cm\(^2\) (an order of magnitude of less intensity) for four (4) to six (6) hours. Longer treatment extends the pain relieving effect of ultrasound therapy while also allowing a much stronger mechano-transduction cell-signaling cascade with a variety of additional healing and pain relieving therapeutic effects.

The American Institute of Ultrasound in Medicine and United States Food and Drug Administration (FDA) have already deemed safe and approved for sale devices that provide LIUS levels below 100 mW/cm\(^2\) for continuous use [97, 98, 144]. Using the extended treatment approach, LIUS is emerging as a potent therapy for the treatment of complex bone fractures and tissue damage [145-150]. Ultrasonic stimuli have been shown to accelerate fracture healing by up to 40% and enhance tendon and ligament healing by promoting cell proliferation, migration, and matrix formation [151, 152]. LIUS treatment also induces closure of non-union fractures, at a success rate (85% of cases) similar to that of surgical intervention (68-96%) while avoiding the complications associated with surgery [146].

LIUS increases the healing rate of ACL tendons at graft-bone interfaces and, at a molecular/cellular level, has been shown to enable a more efficient ligamentization process [153, 154]. In sprain and tendon healing, LIUS has been shown to increase collagen synthesis and enhances the maturation of collagen fibrils of repairing tendons [155-157]. Researchers have reported that LIUS can facilitate tissue recovery with 1 MHz continuous ultrasound dosages, which have been used in the treatment of tendon ruptures to increase both strength and energy absorption capacity of the healing tendons [154, 158-160]. In dealing with pain relief, LIUS exposure induces non-specific and cell-mediated release of secretory proteins [161]. The enhanced release of cytokines and growth factors from macrophages is one mechanism mediating ultrasound’s beneficial effects, i.e., improved tissue healing and pain relief [162-165].

LIUS has found beneficial effects in reducing sciatica which can cause lower back pain, gluteal pain, and leg pain, and reduce the numbness and tingling that is associated with sciatica [133]. The pain of sciatica can be caused from a number of underlying conditions including but not limited to lumbar disc herniation [166], osteochondrosis of the lumbar spine [167], or a cyst or tumor [130] although lumbar disc herniation is still the most common cause of sciatica [133]. Evidence suggests compression and inflammation are the main effectors for sciatica symptoms, and that low-intensity ultrasound is an effective agent to decrease the lower back pain associated with sciatica by decreasing inflammation at the lumbar disc herniation (LDH) site, breaking the pain-spasm-pain cycle, and decreasing the size of the herniated mass [168]. LIUS has been significantly effective in minimizing low back pain associated with lumbar disc herniation and concomitant sciatica [168, 169]. Low intensity ultrasound, both pulsed and continuous, enhances sciatic nerve regeneration in rats [170-172] and has been shown to cause no nerve damage at therapeutic levels below 100mW/cm\(^2\) [173]. Ultrasound therapy is widely used and recommended for treatment of low back pain [130].
LIUS has also been used to decrease pain levels, increase mobility, and improve quality of life and mobility in patients with knee OA [174,175]. In most recent low-intensity ultrasound OA research, ultrasound treatments were found to increase the articular cartilage type II collagen in rodent and human OA models [176-178], slow the progression of OA via the activation of chondrocytes [179], and provide a potential long term non-pharmaceutical therapeutic approach. Indeed, the use of LIUS in rehabilitation holds much promise over the current treatment modalities but much work remains, particularly around the development and testing of practical, easy-to-use technologies to administer the therapy during everyday activity. ZetrOZTM will clinically evaluate the novel, wearable ultrasound treatment system TheraSonXTM to provide continuous 80-90mW/cm² ultrasound for 4-6 hrs of daily treatment. Successful completion of the studies will increase scientific understanding of the efficacy of low-intensity ultrasound treatment on musculoskeletal pain, mobility, and provide the first noninvasive, portable, transformative solution to pain control [9].
Selected References:


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