

## **Clinical Studies**

## Low Intensity Pulsed Ultrasound

This Schedule lists some examples of clinical studies that have been carried out on low intensity pulsed ultrasound systems (LIPUS) such as the EXOGEN® product. (EXOGEN® is the registered trade mark of Exogen, Inc). The studies below have not utilised a Melmak LIPUS device.

STUDY	OUTCOME MEASURES	RESULTS	TECHNICAL SPECIFICATIONS OF LIPUS DEVICE
Pilla et al, Non-invasive low-intensity pulsed ultrasound accelerates bone healing in the rabbit. <i>The Journal of Orthopaedic Trauma</i> , Vol 4, No 3, 1990: pp 246-253	Acceleration of fracture healing	Ultrasound treated bone as strong in torsion as intact fibulae, increased periosteal reaction	<ul> <li>f = 1.5 MHz</li> <li>t<sub>p</sub> = 200 μs</li> <li>REF = 1 KHz</li> <li>I<sub>e</sub> = 30 mW/cm²</li> </ul>
Walsh et al, Effect of Low Intensity Pulsed Ultrasound on Healing of an Ulna Defect Filled with a Bone Graft Substitute. Journal of Biomedical Materials Research Part B: Applied Biomaterials, 86B, 2008: pp 74–81	Rate of healing of bone defect	LIPUS resulted in more new bone growth at wk 4 and 12 compared to control and increased VEGF expression	> $f = 1.5 \pm 5\%$ MHz > $t_p = 200 \pm 10\%$ µs > REF = $1 \pm 10\%$ KHz > $t_e = 30 \pm 30\%$ mW/cm <sup>2</sup>
Walsh et al, Effects of low-intensity pulsed ultrasound on tendon-bone healing in an intra-articular sheep knee model. <i>The Journal of Arthroscopic and Related Surgery</i> , Vol 23, No 2 (February), 2007: pp 197-204	Rate of healing at tendon/bone junction	LIPUS resulted in improved ability to withstand increased load at tendon/bone junction	<ul> <li>f = 1.5 MHz</li> <li>t<sub>p</sub> = 200 μs</li> <li>REF = 1 KHz</li> <li>l<sub>e</sub> = 30 mW/cm²</li> </ul>
Siska et al, External adjuncts to enhance fracture healing: What is the role of ultrasound? <i>Injury Journal</i> . 2008 Oct.39 (10): pp 1095-1105	Effect of LIPUS on rate of fracture healing	Safe, practical and effective treatment	<ul> <li> f = 1.5 MHz</li> <li> tp = 200 µs</li> <li> REF = 1 KHz</li> <li> le = 30 mW/cm²</li> </ul>
Busse et al, The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. <i>CMAJ.</i> 2002 Feb 19;166(4): pp 437-441	Time to fracture healing	LIPUS may significantly reduce the time to fracture healing for fractures treated non operatively	> $f = 1.5 \pm 5\%$ MHz > $t_p = 200 \pm 10\%$ µs > REF = $1 \pm 10\%$ KHz > $t_e = 30 \pm 30\%$ mW/cm <sup>2</sup>

## **Melmak Ultrasound Device Specifications**

➤ Resonant Frequency f = 1.5 MHz➤ Signal Pulse Duration  $t_p = 200 \text{ µs}$ ➤ Pulse Repetition Rate REF = 1 KHz

➤ Spatial Average Intensity I<sub>e</sub> = 30 mW/cm²

➤ Waveform Puls = Pulsed



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