

Lubbert PHW, van der Rijt RHH, et al. Low-intensity pulsed ultrasound (LIPUS) in fresh clavicle fractures: A multi-centre double blind randomised controlled trial. Injury 2008;39:1444-1452.

Design: Randomized clinical trial

Study question: Does low-intensity pulsed ultrasound (LIPUS), compared to placebo LIPUS, result in more rapid healing of fresh clavicle fractures?

Population/sample size/setting:

- 101 patients (85 men, 16 women, mean age not reported, but said to be equal between treatment groups) treated for radiographically confirmed, isolated, closed midshaft clavicle fractures at 6 emergency departments in the Netherlands
- Inclusion criteria were age over 18, shaft fracture less than 5 days old, and mono-trauma
- Exclusion criteria were multiple trauma, re-fracture, pathological fracture, open fracture or imminent skin perforation, fracture in metaphysis, and no possibility for followup

Main outcome measures:

- Randomization was to LIPUS with a 30 mW/square cm, pulsed at 1 kHz (n=52) or placebo LIPUS with an identical appearing device (n=49)
- All patients had nonoperative treatment initially, with passive support using a collar and cuff as long as needed
- All patients had identical instructions for using the device at home, and were asked to apply the transducer daily for 20 minutes for 28 days
- Healing of the clavicle fracture was assessed by the patient, who received a pain diary which recorded VAS scores on a daily basis, as well as daily activities including housekeeping, work and sport in hours per day, analgesic use (acetaminophen and naproxen), and whether they felt that the fracture had healed
 - o Radiographic assessment of fracture healing was not used because of the uncertain relationship between callus formation and clinical healing
- Followup was done in the outpatient clinic at 1, 2, 4, 6, and 8 weeks after trauma, when the physician assessed fracture consolidation (pain, ROM, and local instability), and patient report concerning activity and when the patient felt that the fracture was stable

- The time to patient perception of fracture consolidation was equal between groups: a mean of 27.09 days for placebo and 26.77 days for LIPUS for the 92 patients who reported that consolidation had taken place
- 10 patients, 5 LIPUS and 5 placebo, did not report that fracture consolidation had occurred; these patients underwent open reduction and internal fixation of their fractures
- Analgesic use was also similar in the first 28 days: 32.88 tablets for the placebo group and 37.21 for the LIPUS group
- VAS scores in the 28 day diaries was also equal: a mean of 3.55 for placebo and 3.51 for LIPUS
- Resumption of work activities (15 days for placebo, 17 for LIPUS) was equal, as were housekeeping and sports activities
- The first author reviewed all medical records and x-rays at the end of one year in order to look for late complications and subsequent operations

Authors' conclusions:

- LIPUS does not influence the time to clinical healing of fresh midshaft clavicular fractures, and does not influence analgesic use or resumption of activity
- LIPUS has an unclear biological mechanism at present
- The decision not to use radiographic healing criteria was based upon the concept that healing can be monitored by the patient and the doctor; this is conceded not to be a validated measure of fracture healing, and may be a limitation of the study

Comments:

- The study displays reasonable control of bias in its randomization, blinding, and complete followup, with an adequate sample size to have good power to detect a treatment effect of LIPUS
- The lack of radiographic confirmation of fracture healing and the reliance of patient self-report of the main outcome does not necessarily lead to a biased estimate of fracture healing, since it was accompanied by functional gains in activity and by the one-year followup to detect likely manifestations of incomplete healing
- The Allman classification of clavicle fractures was used (Figure 1) and these appear to be nondisplaced midshaft fractures

Assessment: a high quality study with good evidence that LIPUS does not influence the healing of new nondisplaced midshaft clavicle fractures