



# Low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures

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www.nice.org.uk/guidance/ipg623

This guidance replaces IPG374.

#### 1 Recommendations

- 1.1 The evidence for low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures raises no major safety concerns. The current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and audit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and sudit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, consent and sudit or research. Find out <a href="https://www.what.special.governance">what special.governance</a>, white special <a href="https://www.what.special.governance">what special.governance</a>, white special <a href="https://www.what.special.governance">what special.governance</a>, white special <a href="https://www.what.special.governance">what special.governance</a>, white special.
- 1.2 Clinicians wishing to do low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information to support <u>shared decision-making</u>. In addition, the use of <u>NICE's information for the public on low-intensity pulsed ultrasound is recommended.
  </u>
- Audit and review clinical outcomes of all patients having low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures. NICE has identified relevant audit criteria and has developed <u>NICE's interventional</u> procedure outcomes audit tool.
- 1.3 The procedure should be used with other treatments for delayed-union and non-union fractures. It should be managed by specialists in treating these fractures.
- 1.4 NICE encourages further research into low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures. Further research should include details of patient selection, fracture site, and risk factors and comorbidities that delay fracture healing.

# 2 The condition, current treatments and procedure

#### The condition

2.1 Fractures are a common result of trauma, and are usually described as either closed (skin over the fracture site is intact) or open (involves an open wound). They may vary in complexity from a single break (transverse or oblique) to comminuted, in which the bone has broken into several pieces.

#### **Current treatments**

2.2 Fractures usually heal within a few weeks after treatment by closed or open reduction, and immobilisation using a cast or internal fixation.

Sometimes healing may be delayed or not happen at all (non-union).

There is no agreed precise definition of a fracture non-union but, typically, it is considered to be when there is failure of bony union 6 to 9 months after the fracture. Risk factors for non-union of fractures include: systemic medical conditions (for example, diabetes, malnutrition, osteoporosis); smoking; use of non-steroidal anti-inflammatory drugs; local factors such as infection; vascular problems; magnitude of injury (for example, fracture location and gap, traumatic fractures); advanced age; and other iatrogenic factors. Treatment of non-union may need complex and prolonged management with implications for the patient's quality of life and functional capacity.

### The procedure

- 2.3 The aim of low-intensity pulsed ultrasound is to promote healing by delivering micro-mechanical stress to the bone to stimulate bone healing. This procedure is used to treat fractures that are slower to heal than expected (delayed healing) and fractures that have failed to unite (non-union).
- 2.4 An ultrasound probe is positioned on the skin over the fracture and patients self-administer low-intensity pulsed ultrasound daily, usually for 20 minutes. If a patient's limb is immobilised in a cast, a hole is cut into the cast for the ultrasound probe. The probe delivers acoustic radiation and coupling gel is used on the skin to aid conduction of the ultrasound signal. An operating frequency of 1.5 MHz, pulse width of 200 microseconds, repetition rate of 1 kHz, and a temporal average power of 30 milliwatts per cm² is typically used. The exact treatment protocol and duration of treatment may vary.
- 2.5 Progress towards fracture healing is usually assessed radiographically.

  The duration of treatment ranges from a few weeks to several months.

## 3 Committee considerations

#### The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 6 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 1 randomised controlled trial and 1 cohort study and is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- The specialist advisers and the committee considered the key efficacy outcomes to be: fracture healing or union, functional outcomes and quality of life.
- 3.3 The specialist advisers and the committee considered the key safety outcome to be: need for subsequent reoperation.
- Three commentaries from patients who had experience of this procedure were received, which were discussed by the committee.

#### Committee comments

- The committee was informed that delayed-union and non-union fractures should be properly stabilised before using low-intensity pulsed ultrasound to promote fracture healing.
- 3.6 The evidence came from a variety of fracture types and different sites.

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# **Endorsing organisation**

This guidance has been endorsed by Healthcare Improvement Scotland.

# Accreditation

