

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

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

Broken bones are common and can take many months to heal. This procedure involves a short daily treatment using an ultrasound probe that is placed on the skin at the site of the fracture. The aim is to speed up fracture healing by stimulating bone cells to grow and repair.

The National Institute for Health and Care Excellence (NICE) is looking at low-intensity pulsed ultrasound to promote healing of delayed-union and non-union fractures. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 19 April 2018

Target date for publication of guidance: July 2017

1 Draft 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.

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 [shared decision-making](#). In addition, the use of NICE's [information for the public](#) is recommended.
- 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 is developing an audit tool (which is for use at local discretion), which will be available when the guidance is published.

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 Further research, preferably in the form of randomised controlled trials, 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 occur at all (non-union). Treatment of non-union may need complex and prolonged management with implications for the patient's quality of life and functional capacity. Several factors may influence how well fractures heal, including stability of the fracture, its blood supply and patient nutrition.

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.
- 3.2 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.
- 3.4 Patient commentary was sought but none was received.
- 3.5 This guidance is a review of NICE's interventional procedures guidance on [low-intensity pulsed ultrasound to promote fracture healing](#).

Committee comments

- 3.6 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.
- 3.7 The evidence came from a variety of fracture types and different sites.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

March 2018