

# **Understanding NICE guidance**

Information for people who use NHS services

# Helping fractures to heal using low-intensity pulsed ultrasound

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how low-intensity pulsed ultrasound can be used in the NHS to treat people with fractures. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe fractures or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

#### What has NICE said?

The evidence shows that low-intensity pulsed ultrasound is safe and can reduce fracture healing time, especially in people with fractures that heal poorly. This procedure can therefore be offered routinely as a treatment option for people with fractures provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

# Low-intensity pulsed ultrasound

The medical name for this procedure is 'low-intensity pulsed ultrasound to promote fracture healing'.

The procedure is not described in detail here – please talk to your doctor for a full description.

Fractures are a common injury that usually heal within a few weeks of treatment. They may be either 'closed' (where the skin over the fracture is not broken) or 'open' (where there is a visible wound). Open fractures can be further described using a grading system from I (minor fracture with minimal damage to surrounding soft tissue) to III (involving major damage to the soft tissue and nearby nerves and blood vessels). When bones do not heal properly after a fracture, it is called 'non-union'.

Low-intensity pulsed ultrasound aims to speed up fracture healing by stimulating bone cells to grow and repair. This involves a short daily treatment (usually about 20 minutes) using an ultrasound probe that is placed on the skin at the site of the fracture. You can do this yourself at home. Treatment may last just a few weeks, or in some cases several months.

If you are wearing a cast, a hole will be cut into the cast for the probe to reach the skin. A special gel is used on the skin to help the ultrasound to work.

# Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at a review of 13 studies plus 6 further studies on this procedure.

# How well does the procedure work?

The review of 13 studies included a total of 563 patients with new fractures or non-union of fractures. In 6 of the studies, there was an average reduction in healing time of 34% in 119 patients treated by the procedure compared with 122 patients treated by a sham procedure.

This procedure may not be the only possible treatment for fractures. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

#### What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks low-intensity pulsed ultrasound is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

### You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

A study of 67 patients with closed or open grade I fractures of the shin bone reported an average healing time of 96 days in 33 patients treated by low-intensity pulsed ultrasound and 154 days in 34 patients treated by a sham procedure.

In a study of 1317 patients treated with the procedure, the bones healed in 86% of patients with non-union of fractures and 91% of patients with slow to heal fractures.

A study of 32 patients with new closed or open grade I fractures of the shin bone (fixed with a metal rod inside the bone) reported little difference in the average healing time between 15 patients treated by the procedure (155 days) and 17 patients treated by a sham procedure (125 days).

In a study of 21 patients with non-union of fractures of the wrist treated by a bone graft, average healing time was significantly shorter in 10 patients who also received low-intensity pulsed ultrasound (56 days) compared with 11 patients who had a sham procedure (94 days).

A study of 30 patients with open or severe fractures of the shin bone reported that full weight bearing was possible at 9.3 weeks in 16 patients treated by the procedure and 15.5 weeks in 14 patients treated by a sham procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that how well the procedure works should be measured by the rate of fracture healing, need for surgery, and the time taken to return to carrying out normal daily tasks.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

### Risks and possible problems

In the study of 32 patients, acute compartment syndrome (a potentially serious side effect of fractures where pressure within the tissues builds to dangerous levels) occurred within the first few days of treatment in 1 patient in the ultrasound group and 2 patients in the sham group (all 3 patients had pressure-relieving surgery).

Mild swelling and redness at the site of ultrasound application were reported within the first 2 weeks in 4 patients in the study of 30 patients with fractures of the shin. No further treatment was needed and the patients continued to use ultrasound daily.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that, in theory possible problems could include formation of too much bone or bone in the wrong place, and causing tumours.

#### More information about fractures

NHS Choices (**www.nhs.uk**) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support.

#### **About NICE**

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance

To find out more about NICE, its work and how it reaches decisions, see

#### www.nice.org.uk/aboutguidance

This leaflet is about 'low-intensity pulsed ultrasound to promote fracture healing'. This leaflet and the full guidance aimed at healthcare professionals are available at

### www.nice.org.uk/guidance/IPG374

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2393). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.