NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Medical technology guidance

SCOPE

EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing

1 Technology

1.1 Description of the technology

The EXOGEN ultrasound bone healing system delivers low-intensity pulsed ultrasound waves with the aim of stimulating bone healing. It is thought that this is accomplished through stimulating the production of growth factors and proteins that lead to an increase in the removal of old bone, an increase in the production of new bone and an increase in the rate at which fibrous matrix at a fracture site is converted to mineralised bone.

The EXOGEN ultrasound bone healing system is indicated for use in patients with fresh fractures, fractures that have failed to unite (non-union) and fractures that are slower to heal than expected (delayed healing). Patients are suitable for treatment if a fracture is stable, well aligned and well reduced. The EXOGEN ultrasound bone healing system is not indicated for use in fractures of the skull and vertebrae or in patients who have skeletal immaturity.

The device comprises a main operating unit with a permanently connected transducer through which the ultrasound is delivered to the patient. The ultrasound probe is positioned on the skin over the fracture and held in position with a strap. The treatment is self-administered by the patient usually for 20 minutes each day. If the patient's limb is immobilised in a cast then a hole can be cut into the cast to allow access of the ultrasound probe to the skin. The duration of treatment ranges from a few weeks to several months.

Progress towards fracture healing is usually assessed radiographically with x-ray demonstration of bridging of the gap between the fractured bone ends with new bone cortex.

1.2 Regulatory status

The EXOGEN ultrasound bone healing system received a CE mark in June 1993 for healing non-union fractures and accelerating the healing of fresh fractures.

1.3 Claimed benefits

The benefits claimed by the sponsor for patients with long bone fractures and non-union or delayed healing are:

- A reduced time to healing compared with surgery.
- The avoidance of surgical intervention to achieve comparable clinical outcomes.
- A quicker return to weight bearing and normal daily living as compared with surgery.
- Improved treatment accessibility with a therapy that can be self-administered in a home environment.

The benefits claimed by the sponsor to the healthcare system for patients with long bone fractures and non-union or delayed healing are:

- Use of the EXOGEN ultrasound bone healing system may reduce the need for high cost surgical intervention.
- A reduction in cost because of a reduction in out-patient care, enhanced recovery and speedier return to work and normal living.

1.4 Relevant diseases and conditions

The conditions relevant to this scope for the EXOGEN ultrasound bone healing system are long bone fractures where there is non-union (failure of healing after 9 months) or delayed healing (no radiological evidence of healing after approximately 3 months).

Bone fractures usually result from traumatic injury and are more likely to occur when there is an underlying reduction in bone mineral density (osteoporosis). The incidence of all types of fractures (including osteoporotic fractures) in the general population is 3.6 fractures per 100 people per year in England (Donaldson et al. 2008). Non-union and delayed healing occurs in approximately 5–10% of all fractures but is more common in high energy fractures or open fractures (in which the broken bone is exposed through the skin) (source: expert adviser opinion). Some patients are at a higher risk of delayed or non-union, for example, those who smoke, are of an older age, have impaired peripheral circulation or who are receiving non steriodal anti-inflammatory medication.

1.5 Current management

Long bone fractures are usually treated by closed or open reduction (re-alignment of the bone ends) and immobilisation is achieved using a cast or by surgery with internal or external fixation.

Delayed healing or fracture non-union requires complex and prolonged treatment. Surgery is usually undertaken with internal or external fixing of the bone ends and the use of bone grafting (with harvesting from the patient's iliac crest) as necessary.

2 Reasons for developing guidance on the EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing

The Committee considered that the EXOGEN ultrasound bone healing system may provide significant benefit for patients with non-union and delayed healing fractures in whom surgical intervention may be avoided and recovery of limb function may be accelerated.

It was advised that non-union and delayed healing long bone fractures, particularly of the tibia, would be the most likely to benefit from this treatment.

The Committee considered that this technology therefore had the potential to be cost saving as compared with standard management, in this patient group and so should be evaluated as Medical Technologies Guidance.

The Committee also considered that there may be some benefit in using this technology in patients with fresh fractures. However, it considered it plausible that the value proposition for this patient subgroup might increase costs in the context of providing increased benefit. The Committee therefore requested the scope be developed for patients with non-union and delayed healing long bone fractures, taking account of the suitability of the value proposition for Medical Technology guidance, and advice it had received of the significant clinical need in this group.

3 Statement of the decision problem

	Scope issued by NICE
Population	Patients with long bone fractures with non-union (failure of healing after 9 months) or delayed healing (no radiological evidence of healing after approximately 3 months)
Intervention	EXOGEN ultrasound bone healing system
Comparator(s)	Surgical treatment • Internal fixation with or without bone grafting • External fixation with or without bone grafting (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: • Bridging on radiograph (3 out of 4 cortices bridged on radiograph) • Fracture healing time • Return to painless weight bearing • Avoidance of further surgery • Device-related adverse events
Cost analysis	Comparator: Surgical treatment (as defined above) Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters. A separate scenario analysis exploring the risk sharing scheme offered by Smith & Nephew should be presented alongside the base case analysis.
Subgroups to be considered	• Non-union fractures • Delayed healing fractures • Long bone fractures of different location
Special considerations, including issues related to equality	Because treatment with the EXOGEN ultrasound bone healing system is self-administered, some patients may need assistance in using the technology.

4 Related NICE guidance

Published

- Low intensity pulsed ultrasound to promote fracture healing. NICE interventional procedures guidance IPG374 (2010). Available from: http://guidance.nice.org.uk/IPG374.

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical advice:

- British Orthopaedic Association
- British Limb Reconstruction Society

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment and invited to register to receive a copy:

- British Limb Reconstruction Society
- British Orthopaedic Association
- British Society of Rehabilitation Medicine
- Chartered Society for Physiotherapy

5.2 Patient organisations

At the selection stage, NICE's Patient and Public Involvement Programme contacted the following organisations for patient commentary.

These patient organisations have been alerted to the availability of the draft scope for comment and invited to register to receive a copy:

- Arthritis and Musculoskeletal Alliance (ARMA)
- BRAKE
- British Orthopaedic Association Patient Liaison Group

- Brittle Bone Society
- CritPaL
- ICU
- National Osteoporosis Society
- Paget's Association
- Roadpeace
- Steps