Evidence Review

Use of EXOGEN ultrasound bone healing system in comparison to surgical treatment.

Questions to be addressed:

What is the evidence of clinical and cost effectiveness of the EXOGEN ultrasound bone healing system in long bone fractures where there is non-union (failure of healing after 9 months) or delayed healing (no radiological evidence of healing), compared to surgical treatment, in patients with stable, well aligned and well reduced fractures?

Reason for review:

NHS Birmingham and Solihull CCG and Sandwell and West Birmingham CCG, requested a rapid evidence review of the clinical and cost effectiveness of EXOGEN ultrasound bone healing system in patients with stable, well aligned and well reduced fractures. The review was requested because of recent published NICE evidence, as well as provider trust reports of the benefits to patients.

Options for commissioners:

1. Due to insufficient evidence to demonstrate that EXOGEN ultrasound bone healing system is more effective than surgical treatment, develop a commissioning policy that clearly stipulates that the intervention is not routinely commissioned, until more evidence is available.
2. Due to the lack of evidence for the clinical effectiveness for EXOGEN ultrasound bone healing system compared to surgical treatment, develop a commissioning policy that considers surgery followed by EXOGEN ultrasound bone healing system for patients with either long bone fractures where there is non-union (failure of healing after 9 months) OR delayed healing (no radiological evidence of healing) with restricted criteria.

Summary

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) and delayed healing (no radiological evidence of healing after approximately 3 months).

Background

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 [1]. 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) [1]. 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-steroidal anti-inflammatory medication.

The intervention

Ultrasound, comprising high frequency sound waves, is a form of mechanical stimulation that is delivered via a special device to the fracture site. For closed fractures (where the overlying soft tissue envelope remains intact), the device is typically placed in contact with the skin overlying the fracture site and left in position for around 20 minutes on a daily basis. [10]

It is known that bone formation and fracture healing are influenced by mechanical factors. It is possible that ultrasound might work by reproducing the effect of functional loading by inducing low level mechanical forces at the fracture site. [10]

NICE details that submissions were received from sponsor – Smith & Nephew [1]. 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].

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 [1].

Current Management

Long bone fractures are usually treated by closed or open reduction (realignment 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.

Assuming proper stabilisation and adequate blood supply, some long bone fractures achieve union within 8 weeks, although others (e.g., certain tibial shaft fractures) may take 4 to 6 months to heal. [13] Functional recovery of long bone fractures may take months beyond the point at which clinical and radiographic union occur, and the process of remodelling may not be fully complete for years.

Patients with delayed fracture healing at 3 months do not usually have surgery at this time unless the fracture is complex (for example, an unstable or misaligned fracture or an inter-fragment gap of more than 10 mm). Surgery may take place between 3 and 9 months after fracture, but clinical practice varies and decisions about the timing of surgery are made on an individual patient basis. If surgery is considered necessary, it usually involves internal or external fixation and bone grafting (with harvesting from the patient's iliac crest).

1 Context

1.1 Introduction

BMJ Best Practice lists electrical, magnetic, and ultrasonic bone stimulators as emerging treatments used to speed healing of stress fractures, delayed union, and other injuries. Other emerging treatments identified are bone grafting and bone morphogenetic proteins [18].

The EXOGEN ultrasound bone healing system (Smith & Nephew), referred to in this document as EXOGEN, 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 EXOGEN system is available as 2 disposable devices, which differ only in the number of treatments they deliver:

- The EXOGEN 4000+ is intended for use in patients with non-union fractures (fractures that have failed to heal after 9 months). The device delivers a minimum of 191x20 minute treatments (more than 6 months' treatment).
- The EXOGEN Express is intended for use in patients with delayed healing fractures (fractures that have no radiological evidence of healing after 3 months). The device delivers a maximum of 150x20 minute treatments (less than 5 months' treatment).

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.

The cost of the EXOGEN 4000+ stated in the sponsor's submission was £2562.50 (excluding VAT) and the cost of the EXOGEN Express device was £999.38 (excluding VAT) [1].

1.2 Existing national policies and guidance

- Low intensity pulsed ultrasound to promote fracture healing. NICE interventional procedures guidance IPG374 (2010). Available from: http://guidance.nice.org.uk/IPG374.
- EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. NICE Medical technologies guidance MTG12 (2013). Available from: https://www.nice.org.uk/guidance/mtg12

2 Epidemiology

Acute long bone fractures primarily result from significant trauma. Motor vehicle accidents, sport injury, falls, and assaults are among the most common causes of these injuries. Previous data for all types of fractures have shown an annual incidence of 21 fractures per 1000 people per year in the US, with a higher incidence in males than in females. [11] Similar data have been reported for Norway and the UK. [11] As implementation of orthopaedic implants has progressed, periprosthetic fracture rates have similarly risen. As more women have become more active in sport, their incidence of sport-related fractures has also increased. [11]

The tibia is the most frequently fractured long bone in humans. [11] In one study, they accounted for 6.6% of all fractures. [11] Femoral shaft fractures accounted for 4.5% of all fractures, while distal radial fractures accounted for 3.9%, distal femoral fractures 2%, and humeral shaft fractures 1.5%. [11] Upper limb fractures represented 31.5% of all fractures, while lower limb fractures were 34.3%. [11] In another study, femoral shaft fractures were found to be relatively uncommon, with a reported incidence of approximately 1 to 4 fractures per 10,000 people per year. Acute femoral shaft fractures are more common among young men, as well as women over the age of 65 years. [12]

As global standards of living and lifespan have increased, so too have osteoporotic fractures, as have fractures among those with chronic disease. In patients with chronic renal failure, risk factors include female sex, advanced age, and diabetes, whereas black people and those with increased BMI seemed to be protected. Among dialysis patients, long bone fracture is associated with increased risk of stroke, pulmonary embolism, congestive heart failure, pneumonia, and septicaemia.

3 Findings

3.1 Evidence of effectiveness

3.1.1 It is recognised that the available clinical data on the effectiveness of EXOGEN for treating long bone fractures with non-union show high rates of fracture healing and it judged them sufficient to support the efficacy and utility of EXOGEN treatment. Despite the absence of direct evidence on avoiding surgery, it has been considered that the assumptions in the cost model were plausible and that EXOGEN is cost saving compared with current management for the treatment of non-union. Overall, therefore, the case for adoption of EXOGEN in the treatment of long bone fractures with non-union was found to be supported by the evidence [1]. The case for adoption in NICE medical technology guidance is based on the intervention being effective, but this does not necessarily indicate improved clinical or cost effectiveness for the intervention compared to a specific comparator.

For long bone fractures with delayed healing, it has been considered that the clinical evidence was more limited. In addition, there were significant uncertainties about the rate at which healing progresses between 3 and 9 months after fracture, both with and without EXOGEN, and about whether or not surgery would be required if EXOGEN was not used. These and other considerations influenced the views about the most appropriate assumptions for cost modelling: the model considered to be most appropriate estimated that EXOGEN treatment would be costlier than current management. It was therefore judged that the case for adoption of EXOGEN to treat long bone fractures with delayed healing was not supported by the current evidence." [1]

3.1.2 AETMIS therefore considers that low-intensity ultrasound might be an exceptional treatment option for a very small number of patients. In submitting this report, AETMIS wishes to contribute to the advancement of an evidence-based medicine approach in orthopaedics and to provide orthopaedic surgeons and managers in Quebec's health-care system the necessary information on this technology. [2]

3.1.3 Low-intensity pulsed ultrasound (LIPUS) treatment can be an alternative to surgery for established non-union. Given that no spontaneous healing of established non-union is expected, and that it is challenging to test the efficacy of LIPUS for non-union by randomized clinical trial, findings are compelling. LIPUS may be most useful in patients for whom surgery is high risk, including elderly patients at risk of delirium, or patients with dementia, extreme hypertension, extensive soft-tissue trauma, mechanical ventilation, metabolic acidosis, multiple organ failure, or coma. With an overall

average success rate for LIPUS >80% this is comparable to the success of surgical treatment of non-infected non-union. [3]

3.1.4 Despite patients being chosen strictly according to EXOGEN® indications, only a small number of patients with non-union who underwent LIPUS therapy experienced successful treatment (32.8 %). Overall, its use resulted in a clear delay in the time of treatment, so that according to our results, the use of LIPUS should be seen critically in long bone non-union and use should be made on a case-by-case basis. [4]

3.2. Clinical effectiveness

Two systematic reviews did not find sufficient evidence to recommend routine use of ultrasound or electromagnetic fields bone stimulators. Though the available evidence suggests that electromagnetic field stimulation may offer some benefit in the treatment of delayed union and non-union of long bone fractures, it is inconclusive and insufficient to inform current practice. More definitive conclusions on treatment effect await further well-conducted randomised controlled trials. [9] [10]

SYSTEMATIC REVIEWS

1. **Low intensity pulsed ultrasound for bone healing: systematic review of randomized controlled trials [2]**

ABSTRACT

Objective: To determine the efficacy of low intensity pulsed ultrasound (LIPUS) for healing of fracture or osteotomy.

Design: Systematic review and meta-analysis.

Data sources: Medline, Embase, CINAHL, Cochrane Central Register of Controlled Trials, and trial registries up to November 2016.

Study selection: Randomized controlled trials of LIPUS compared with sham device or no device in patients with any kind of fracture or osteotomy.

Review methods: Two independent reviewers identified studies, extracted data, and assessed risk of bias. A parallel guideline committee (BMJ Rapid Recommendation) provided input on the design and interpretation of the systematic review, including selection of outcomes important to patients. The GRADE system was used to assess the quality of evidence.

Results: 26 randomized controlled trials with a median sample size of 30 (range 8-501) were included. The most trustworthy evidence came from four trials at low risk of bias that included patients with tibia or clavicle fractures. Compared with control, LIPUS did not reduce time to return to work (percentage difference: 2.7% later with LIPUS, 95% confidence interval 7.7% earlier to 14.3% later; moderate certainty) or the number of subsequent operations (risk ratio

0.80, 95% confidence interval 0.55 to 1.16; moderate certainty). For pain, days to weight bearing, and radiographic healing, effects varied substantially among studies. For all three outcomes, trials at low risk of bias failed to show a benefit with LIPUS, while trials at high risk of bias suggested a benefit (interaction P<0.001). When only trials at low risk of bias trials were considered, LIPUS did not reduce days to weight bearing (4.8% later, 4.0% earlier to 14.4% later; high certainty), pain at four to six weeks (mean difference on 0-100 visual analogue scale: 0.93 lower, 2.51 lower to 0.64 higher; high certainty), and days to radiographic healing (1.7% earlier, 11.2% earlier to 8.8% later; moderate certainty).

Conclusions: Based on moderate to high quality evidence from studies in patients with fresh fracture, LIPUS does not improve outcomes important to patients and probably has no effect on radiographic bone healing. The applicability to other types of fracture or osteotomy is open to debate.

2. **Healing of fracture nonunions treated with low-intensity pulsed ultrasound (LIPUS): A systematic review and meta-analysis [3]**

ABSTRACT

Introduction: Bone fractures fail to heal and form non-union in roughly 5% of cases, with little expectation of spontaneous healing thereafter. We present a systematic review and meta-analysis of published papers that describe nonunions treated with low-intensity pulsed ultrasound (LIPUS).

Methods: Articles in PubMed, Ovid MEDLINE, CINAHL, AMED, EMBASE, Cochrane Library, and Scopus databases were searched, using an approach recommended by the Methodological Index for Non-Randomized Studies (MINORS), with a Level of Evidence rating by two reviewers independently. Studies are included here if they reported fractures older than 3 months, presented new data with a sample N≥12, and reported fracture outcome (Heal/Fail).

Results: Thirteen eligible papers reporting LIPUS treatment of 1441 nonunions were evaluated. The pooled estimate of effect size for heal rate was 82% (95% CI: 77-87%), for any anatomical site and fracture age of at least 3 months, with statistical heterogeneity detected across all primary studies (Q=41.2 (df=12), p<0.001, Tau2=0.006, I2=71). With a stricter definition of nonunion as fracture age of at least 8 months' duration, the pooled estimate of effect size was 84% (95% CI: 77%-91.6%; heterogeneity present: Q=21 (df=8), p<0.001, Tau2=0.007, I2=62). Hypertrophic nonunions benefitted more than biologically inactive atrophic nonunions. An interval without surgery of <6months prior to LIPUS was associated with a more favourable result. Stratification of nonunions by anatomical site revealed no statistically significant differences between upper and lower extremity long bone nonunions.

Conclusions: LIPUS treatment can be an alternative to surgery for established nonunions. Given that no spontaneous healing of established nonunions is expected, and that it is challenging to test the efficacy of LIPUS for nonunion by randomized clinical trial, findings are

compelling. LIPUS may be most useful in patients for whom surgery is high risk, including elderly patients at risk of delirium, or patients with dementia, extreme hypertension, extensive soft-tissue trauma, mechanical ventilation, metabolic acidosis, multiple organ failure, or coma. With an overall average success rate for LIPUS >80% this is comparable to the success of surgical treatment of non-infected nonunions.

3. Low intensity ultrasound treatment for acceleration of bone fracture healing - Exogen (TM) bone growth stimulator (2001 Australian Systematic Review) [17]

Aim: To assess the safety and effectiveness of LIUS treatment for acceleration of bone fracture healing (Exogen bone growth stimulator) and under what circumstances such services should be supported with public funding.

Conclusions and results:

- *Safety:* The intervention appears safe for use in adults, however, it should not be used prior to skeletal maturation, or in patients with pacemakers.
- *Effectiveness:* The results of two high quality, randomised, placebo-controlled studies conducted on the treatment of distal radius and tibial fractures with LIUS are contradictory. It is not possible to conclude that LIUS is consistently more efficacious than current treatment of fresh fractures. Evaluation of comparative effectiveness against current Australian treatments of fracture non-union was not possible.
- *Cost-effectiveness:* The cost-effectiveness of LIUS in the treatment of fresh tibial, distal radius and scaphoid fractures does not compare favourably with a range of other common healthcare interventions.

Recommendation: Public funding under Australian Medicare benefits arrangements should not be supported for this service.

Method: MSAC conducted a systematic review of the medical literature from 1996 to October 2000. This review sought data on the use of LIUS to treat closed and/or grade 1 open fresh fractures and existing fractures exhibiting non-union. Further information was sourced from the applicant.

Randomised controlled clinical trial evidence was available for tibial, distal radius and scaphoid fresh fractures. Only non-comparative case series and registry data were available for fracture non-union. Evidence was classified and scored with respect to study design, patient characteristics, minimisation of bias, outcomes measures and statistical analyses. The primary outcome measure was time to healing defined as independent radiological confirmation of bridging of three of four cortices.

Valid comparators were determined by a review of current Australian practice. The comparator for fresh fractures of the tibia, distal radius and scaphoid was cast immobilisation (with or without closed reduction). In addition, for tibial fractures specifically, the use of an intramedullary rod was also an appropriate comparator. The comparator for fracture non-union in the publicly funded health sector was open reduction and internal fixation with bone grafting.

Economic evaluations were undertaken to determine the cost-effectiveness and cost utility ratios of LIUS treatment of fresh fractures, relative to current Australian practice. Direct and indirect costs were considered. With respect to non-unions, the cost-effectiveness of LIUS relative to current Australian practice was unable to be investigated due to the lack of comparative efficacy data.

STUDY OR CASE SERIES:

1. **Failed treatment of long bone nonunions with low intensity pulsed ultrasound [4]**

ABSTRACT

Introduction: The use of low intensity pulsed ultrasound (LIPUS) in the treatment of nonunions is still controversial. The present study is concerned with whether this procedure has a clinical use and which cofactors influence its therapeutic results.

Methods: In this prospective, single institution, observational study, data from October 2010 to October 2013 from 61 nonunions in 60 patients treated with EXOGEN® LIPUS therapy were analysed. The average age was 45.4 ± 9.81 (18–63) years. Treatment was primarily done on long bones of the lower extremity (75.4 %). All 61 nonunions were examined after treatment, and the rate of healing as well as functional and subjective results were evaluated. Based on clinical and radiological findings, patients were divided into two groups: G1—successful treatment; and G2—unsuccessful treatment. Groups were compared to one another to identify possible factors influencing treatment.

Results: Twenty (32.8 %) patients showed bone consolidation with an average time of healing of 5.3 (2–7) months. In patients without successful treatment, who underwent revision surgery instead, full weight bearing took on average 3.7 months longer, and they were able to return to work 6.8 months later. Most of the treated patients (70.5 %) reported no improvement in pain. In G2, 12 (29.3 %) patients suffered in their previous history from osteitis; in G1 there were only two patients (10 %) ($p = 0.012$). There were further significant differences in the age of the fracture, the type of osteosynthesis, the gap size, as well as the NUSS score.

Conclusion: Despite patients being chosen strictly according to EXOGEN® indications, only a small number of patients with nonunions who underwent LIPUS therapy experienced successful treatment (32.8 %). Overall, its use resulted in a clear delay in the time of treatment, so that according to our results, the use of LIPUS should be seen critically in long bone nonunions and use should be made on a case-by-case basis.

4.1.2 Cost effectiveness

- The Hospital Episode Statistic Data for the period 2010-2011 indicate that 88 patients were treated surgically for fracture non-union. Their average length of stay was 4.49 days, representing a total of 280 bed days. The average required operating time was 3 hours, representing 243 hours of theatre capacity. Taking into consideration the length of stay and theatre time and deducting the cost of EXOGEN the calculated financial benefit for the Trust is approximately £1164.00 per patient. This calculation does not take into consideration fracture clinic appointments and radiographs that

are certainly more frequent with operative management of fracture non-unions, as well as the cost of managing any complications as a result of surgery. [7]

- Despite cost savings being indicated for EXOGEN compared to surgical treatment, no costs per QALY have been found in the published literature, so the cost effectiveness of EXOGEN cannot be quantified.

4.2 Magnitude of Health Improvement Benefit

Overall, the evidence is not consistent in providing improved outcomes compared to the comparator, but that it can provide results for some patients, as can surgery.

- The case for adopting the EXOGEN ultrasound bone healing system to treat long bone fractures with non-union (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing. [1] However, the NICE MTG guidance case for adoption statement does not indicate if the intervention results in improved benefit compared to surgical treatment.
- There is some radiological evidence of improved healing when the EXOGEN ultrasound bone healing system is used for long bone fractures with delayed healing (no radiological evidence of healing after approximately 3 months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture, and about whether or not surgery would be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are costlier than current management [1].
- Out of the 24 patients that reached union 8 female and 16 males. Their average age was 52.9 years (range 22 - 78 years). 14 out of these 24 patients had already a previous operation in order to achieve union. Out of the 7 patients that have not reached union 3 female and 4 male. Their average age was 42.5 years (range 18 - 87 years). 6 out of these 7 patients had already one operation in order to achieve union. The results certainly met our expectations as 77% of the patients avoided operative management with all the associated peri and post-operative risks.[7]
- Thirteen eligible papers reporting LIPUS treatment of 1441 non-union were evaluated. The pooled estimate of effect size for heal rate was 82% (95% CI: 77–87%), for any anatomical site and fracture age of at least 3 months, with statistical heterogeneity detected across all primary studies. [3]
- 107 patients were identified. 6 were lost to follow up. n = 101 patients (109 bones) were identified, 60M: 41F with a median age of 48 (21-86).86/109 (79%) of EXOGEN applications were in long bone non-unions and were consistent with NICE criteria. The union rate in this group was 71%. The union rate for other uses was 61%. 29/109 (27%) of bones required EXOGEN treatment >3 months. No side effects of EXOGEN were reported. [8]

4.3 Safety

- Data from the TRUST trial [14] was included in a linked systematic review which provided high quality evidence showing a lack of benefit in accelerating healing for fresh fractures, it is therefore unlikely that EXOGEN would improve outcomes in patients with non-union.
- Only one study reported on adverse events. Two participants in the electromagnetic stimulation group of this trial developed an allergic reaction on the skin underlying the applied stimulator plates which resolved with topical hydrocortisone treatment. [15]

4.4 Equity issues

- Indirect links to presentation of condition in those more deprived due to direct links with smoking, diabetes, and malnutrition.

4.5 Activity and finance

In the UK there are approximately 850,000 new fractures seen each year. Rates of non-union of 5-10% of fractures have been suggested, the cost to the National Health Service of treating non-union has been reported to range between £7,000 and £79,000 per person.

A Scottish study reported that fracture non-union in the population as a whole remains low at less than 20 per 100,000 population and peaks in the fourth decade of life. [16]

NICE estimates assume that 21.4% of fractures show non-union after 9 months,
around 50% of these are not suitable for EXOGEN therapy.

5 Summary of findings

- The evidence appears mixed.
- There are multiple studies that report on the effective implementation of EXOGEN, however these should be weighed against the case studies that suggested it was not effective and surgical treatment was still required.
- The stated benefits of EXOGEN as compared to surgical treatment (that the healing time is reduced; potential complications avoided; and cost savings) as opposed to a difference for the patient in the successful outcome of either procedure.
- Although some cost savings are indicated these have not been expressed as QALY's within any of the literature found.
- Indirect links to presentation of condition in those more deprived.
- Medical Services Advisory Committee (MSAC) (Australia) recommended that on the basis of the evidence available on low intensity ultrasound treatment for acceleration of bone fracture healing, public funding should not be supported for this procedure. [17]

6 Search Strategy

The following databases are routinely searched: NICE Clinical Guidance and full website search; NHS Evidence and NICE CKS; SIGN; Cochrane; York; and the relevant Royal College and any other relevant bespoke sites. A Medline search was undertaken and a general google search for key terms undertaken.

The search identified publications with any long bone fractures and the use of Low intensity pulsed ultrasound (LIPUS) e.g. EXOGEN. The abstracts and titles were then sifted to select those that met the criteria in the PICO below. Where there was ambiguity in the PICO criteria, the reviewer also referred to the wording of the research question for this evidence review, which specified that the intervention of interest was EXOGEN ultrasound bone healing system.

6.1 PICO parameter

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). Patients are suitable for treatment if a fracture is stable, well aligned and well reduced.
Intervention: EXOGEN ultrasound bone healing system
Comparator / Control: Surgical treatment - 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 with or without bone grafting
Outcome: The outcome measures considered included:

- 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
- Saves money by avoiding further surgery, reduced out-patient care, enhanced recovery and speedier return to work and normal living.
- Improved treatment accessibility with a therapy that can be self-administered in a home environment.

7 References

[1] NICE Guidance published January 2013 and under review as of August 2018 - https://www.nice.org.uk/guidance/mtg12

[2] Low-intensity ultrasound (Exogen (TM)) for the treatment of fractures (2004 Canadian Systematic Review) - http://www.crd.york.ac.uk/CRDWeb/ShowRecord.asp?AccessionNumber=32004000158

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