



Title: Low Intensity Ultrasound (LIUS) Treatment for Acceleration of Bone Fracture Healing – Exogen™ Bone Growth Stimulation, November 2001

Agency: MSAC, Medical Services Advisory Committee
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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, randomized, 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 favorably with a range of other common healthcare interventions.

Recommendations

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.

Randomized 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, minimization of bias, outcome 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 immobilization (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 could not be investigated due to the lack of comparative efficacy data.