TITLE: Osteostimulative Bone Graft Substitutes or Demineralized Bone Matrix Preparations for use in Spinal Surgery and Long Bone Trauma Surgery: Clinical Effectiveness and Safety

DATE: 28 February 2013

RESEARCH QUESTIONS

1. What is the evidence for the clinical effectiveness and safety of osteostimulative bone graft substitutes used in spinal surgery or surgery for long bone trauma?

2. What is the evidence for the clinical effectiveness and safety of demineralized bone matrix preparations used in spinal surgery or surgery for long bone trauma?

KEY MESSAGE

One systematic review, three randomized controlled trials, and six non-randomized studies were identified regarding the clinical effectiveness and safety of osteostimulative bone graft substitutes or demineralized bone matrix preparations used in spinal surgery or surgery for long bone trauma.

METHODS

A limited literature search was conducted on key resources including Ovid Medline, PubMed, The Cochrane Library (2013, Issue 1), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI (Health Devices Gold), Canadian and major international health technology agencies, as well as a focused Internet search. No methodological filters were applied to limit retrieval by publication type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2008 and February 13, 2013. Internet links were provided, where available.

The summary of findings was prepared from the abstracts of the relevant information. Please note that data contained in abstracts may not always be an accurate reflection of the data contained within the full article.
RESULTS

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials and non-randomized studies.

One systematic review, three randomized controlled trials, and six non-randomized studies were identified regarding the clinical effectiveness and safety of osteostimulative bone graft substitutes or demineralized bone matrix preparations used in spinal surgery or surgery for long bone trauma. Additional references of potential interest are provided in the appendix.

OVERALL SUMMARY OF FINDINGS

Effective bone graft substitutes were equally or more effective and safe when comparing them to autologous bone or allografts in spinal fusions and the treatments of non-unions and fractures. Bone graft substitutes from selected references include: demineralized bone matrix (DBM) (Grafton, Grafton DBM Flex, Accell Connexus), silicate-substituted calcium phosphate (Si-CaP), Stimulan pellets (calcium sulfate), Bio-Lu bioceramics (calcium phosphate), and NovaBone (BioGlass).

Demineralized bone matrix (DBM) appears to provide an effective and safe alternative to both iliac crest bone graft (ICBG) and allograft bone in lumbar fusion and treatment of non-unions. One study showed no increases in infection or seroma formation with DBM use, while fusion rates were found to be comparable to autologous bone and allografts. No significant differences were observed in bone fusion when comparing Grafton DBM Flex and allograft bone in thoracoscopic surgery for idiopathic scoliosis. Accell Connexus (a novel DBM) was equally as effective as autologous bone (from either ICBG or a local decompression material) in one or two-level instrumented posterolateral lumbar fusion. In the treatment on non-unions, DBM produced advanced outcomes and decreases in adverse events when compared to ICBG.

Silicate-substituted calcium phosphate (Si-CaP) produced high levels of bony fusion in spinal fusion surgery. In combination with bone marrow aspirate from vertebral bodies, Si-CaP was an easy to handle, effective, and safe bone graft extender in surgery for idiopathic scoliosis. Stimulan pellets and Bio-Lu bioceramics were both convenient, safe, had few side effects with filling, and produced good fracture healing in traumatic fractures. In addition, when compared to Bio-Lu bioceramics, Stimulan was shown to provide stronger support after solidification and faster degradation. An acceleration of fracture healing that is both effective and safe was achieved with NovaBone and internal fixation (reamed interlocking nails) when examining the healing of high energy tibial shaft fractures.
REFERENCES SUMMARIZED

Health Technology Assessments
No literature identified.

Systematic Reviews and Meta-analyses


Randomized Controlled Trials


Non-Randomized Studies


APPENDIX – FURTHER INFORMATION:

Randomized and Non-Randomized Studies – Mixtures Including Bone Graft Substitutes


Randomized and Non-Randomized Studies – Hydroxyapatites


Review Articles


Additional References


