Title: Trabecular Metal™ Bone Replacement Implants for Joint Fusion in the Foot and Ankle: A Clinical and Cost-Effectiveness Review

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Context and policy issues:

In reconstruction foot and ankle surgery, structural bone grafting is used to restore more normal dimensions of the foot and ankle following previous surgery or trauma and for the management of severe arthritis or deformity. Bone grafts are also used for arthrodesis (joint fusion), angular realignment, cystic bone lesions, to fill gaps due to bone loss, and to repair nonunion after ankle fractures.

Bone graft options available to the surgeon include autograft bone harvested from another area of the patient’s body (typically from the iliac crest of the pelvis), or allograft donor bone from a bone bank. Both types of bone graft have potential benefits and associated disadvantages.

While the use of autograft bone avoids the potential for an immunogenic response, autograft bone is associated with morbidity at the donor iliac site, including fracture, hemorrhage, pain, nerve or arterial injury and cosmetic deformity. Operative time is also longer, with greater blood loss and an increased duration of hospital stay. Another disadvantage is the uncertain quality and quantity of the available bone.

Allograft bone implants are readily obtainable from a bone bank in a wide range of bone configurations in various sizes and shapes. However, allograft bone use is also associated with variable quality, as well as the potential for infectious disease transmission and immune responses that may delay the stimulation of new bone. In addition, tissue processing to prepare the allograft may result in weakening of the graft.

Regardless of the bone implant source, the bone must incorporate into the surrounding tissue for long-term clinical success. If the bone dies or does not generate new bone, there is a risk of possible graft collapse, loosening, pain, or the need for further surgery.
Implants made from biomaterials have been developed to avoid the disadvantages associated with traditional structural bone grafts. Trabecular Metal™ (manufactured by Implex Corp. and distributed by Zimmer, Inc.) is a bone replacement implant made from inert tantalum metal. The implants are composed of a carbon substrate that has elemental tantalum deposited on the surface to create a metallic strut configuration similar to cancellous bone. The porous, lattice-like configuration provides a scaffold for bone ingrowth and mechanical attachment, allowing for rapid and substantial bone and soft tissue attachment.

Tantalum has been used for more than 50 years in medical devices such as pacemaker electrodes, cranioplasty plates and foil and mesh for nerve repair. Tantalum-based implants have demonstrated an excellent biocompatibility and safety record in orthopedic, cranio-facial and dentistry applications. Porous tantalum is presently being used in several orthopedic applications, including spinal fusions, hip and knee arthroplasty and as a bone graft substitute. Further clinical applications and designs are being developed for porous tantalum, including primary femoral stems, salvage prostheses, total shoulder components and for use in joint fusions of the wrist. This report will review existing evidence for the clinical and cost-effectiveness of Trabecular Metal™ bone replacement implants when used as a substitute for bone grafts for fusion in the foot and ankle.

Research question(s):

1. What is the clinical effectiveness and safety of using Trabecular Metal™ bone replacement implants versus allograft or autograft bone grafting for joint fusion or other surgical reconstruction procedures in the foot or ankle?

2. What is the cost-effectiveness of using Trabecular Metal™ bone replacement implants versus allograft or autograft bone grafting for joint fusion or other surgical reconstruction procedures in the foot or ankle?

Methods:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 2, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 1998 and June 2008, and are limited to English language publications only. No filters were applied to limit the retrieval by study type. Internet links are provided, where available.

HTIS 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 economic evaluations, randomized controlled trials, observational studies and evidence-based guidelines.

Summary of findings:

No relevant health technology assessments, systematic reviews, meta-analyses, randomized controlled trials, or economic analyses were identified examining the clinical effectiveness or cost-effectiveness of Trabecular Metal™ blocks versus allograft or autograft bone grafting for joint fusion or other surgical reconstructive procedures in the foot or ankle.
Observational studies

One observational study was identified. In this case report, a 57-year old woman with progressive midfoot pain due to severe tarsometatarsal joint disease had metatarsophalangeal arthroplasty surgery. When this procedure failed to relieve the pain, she underwent a tarsometatarsal arthrodesis (joint fusion). Since the patient had a severe collapse of her dorsal tarsometatarsal joints, two pieces of tantalum Trabecular Metal™ were used as a structural bone substitute. A Trabecular Metal™ Cup (an implant component normally used for hip replacement) was sectioned and modified to form the tantalum pieces. One piece was inserted to maintain the correction at the first tarsometatarsal joint and the second piece was inserted at the level of the second and third tarsometatarsal joints. After the surgery, the patient wore a below-the-knee nonweight-bearing cast for six weeks, then a walking cast with progressive weightbearing as tolerated for an additional six weeks. Four months after the surgery, the patient was reportedly able to walk with full weightbearing and return to her regular activities, with no pain at the tarsometatarsal joint. Observational data obtained from a single case report is considered to be weak scientific evidence and prospective randomized studies are required to confirm these preliminary results.

Conclusions and implications for decision or policy making:

We identified only one published observational study that reported using a Trabecular Metal™ implant to fuse the tarsometatarsal joint of the foot in one patient. Investigators at the Mayo Clinic in Scottsdale, Arizona used a Trabecular Metal™ Cup intended for a hip implant to fashion two wedge-shaped implants to fit the tarsometatarsal joints in a woman with severe degenerative joint disease in one foot. Four months after the surgery, the authors reported that the patient had no pain in the tarsometatarsal area of the foot and that she was “very satisfied” with the result of the surgery. This preliminary finding suggests that Trabecular Metal™ has the potential to be developed as an alternative to autograft or allograft bone grafts in joint fusions and other reconstructive surgeries involving the foot and ankle. Prospective randomized studies are required to confirm this initial finding and to assess clinically significant outcomes, including morbidity, length of hospital stay, and long-term graft success using Trabecular Metal™ implants compared with structural bone grafts. Cost-benefit analyses are also needed.

The use of porous tantalum in orthopedic surgery is in an early stage of development. While there are ongoing trials examining the use of Trabecular Metal™ in spinal fusion surgery and knee arthroplasty, there is an absence of trials examining its use in foot and ankle joint fusion. Furthermore, no trabecular tantalum implant specific for the foot or ankle is yet commercially available. In the single case report identified, a tantalum Trabecular Metal™ hip implant was modified to create the implants to be inserted in the tarsometatarsal joint of the foot. The researchers report that Trabecular Metal™ implants for the foot or ankle can be custom ordered from Zimmer Inc. Until more conclusive evidence is available, the decision to use Trabecular Metal™ for foot and ankle joint fusion should take clinical experience and institution-specific feasibility and cost into account.

Prepared by:
Catherine Allison, B.Sc.(Pharm), MJ, Writer~Researcher – Pharmaceuticals.
Melissa Severn, MISt, Information Specialist
Health Technology Inquiry Service
Email: htis@cadth.ca
Tel: 1-866-898-8439
References:


