Influence of Electron Beam Melting Manufactured Implants on Ingrowth and Shear Strength in an Ovine Model

Nicky Bertollo, PhD, Ruy Da Assuncao, MD, FRCS,
Nicholas J. Hancock, MD, FRCS, Abe Lau, PhD, and William R. Walsh, PhD

Abstract: Arthroplasty has evolved with the application of electron beam melting (EBM) in the manufacture of porous mediums for uncemented fixation. Osseointegration of EBM and plasma-sprayed titanium (Ti PS) implant dowels in adult sheep was assessed in graduated cancellous defects and under line-to-line fit in cortical bone. Shear strength and bony ingrowth (EBM) and ongrowth (Ti PS) were assessed after 4 and 12 weeks. Shear strength of EBM exceeded that for Ti PS at 12 weeks (P = .030). Ongrowth achieved by Ti PS in graduated cancellous defects followed a distinctive pattern that correlated to progressively decreasing radial distances between defect and implant, whereas cancellous ingrowth values at 12 weeks for the EBM were not different. Osteoconductive porous structures manufactured using EBM present a viable alternative to traditional surface treatments. **Keywords:** electron beam melting, uncemented fixation, rapid prototyping, bone ingrowth, shear strength.

Uncemented fixation in joint arthroplasty is reliant upon the establishment of a biologic and mechanical interlock at the implant-bone interface through osseointegration. Roughened surfaces and porous mediums, such as sintered beads, wire meshes, and plasma-sprayed titanium (Ti PS), have been applied to metal substrates in various forms to provide for adequate anchorage via de novo cortical and cancellous bone ongrowth and ingrowth [1].

Rapid manufacturing technologies once exclusive to the aeronautics industry are now being applied in the biomedical sector for the manufacture of osteoconductive porous mediums for tissue ingrowth in uncemented fixation [2-9]. Electron beam melting (EBM) is one such method built on the fundamental tenet of additive manufacturing. Complex meshes and macro-textured mediums/shapes can be generated in a single process from powders of pure titanium and its alloys (ie, Ti-6Al-4V) that are sintered or melted together in a layer-by-layer fashion using electron beams. One of the main advantages of EBM technology is the ability to integrate the porous structure to the solid substrate instead of traditional methods in which a coating is applied separately [2,10,11]. Porosity of these structures can be tightly engineered such that the resulting constructs mimic the elastic modulus of human cancellous bone (~0.5 GPa) and potentially ameliorate the effects of stress shielding on bone resorption [2,10]. The primary mode of fixation for uncemented tibial trays, femoral components, and acetabular cups is indeed via cancellous bone ongrowth and ingrowth.

This study evaluates the osseointegration of a macro-textured ingrowth structure manufactured using the EBM process and a control Ti PS medium after 4 and 12 weeks in situ using an established ovine implantation model in the cortex of the tibia [12-15] and cancellous bone of the distal femur and proximal tibia [16]. The Ti PS coating and EBM structure represented mediums for bone ongrowth and ingrowth, respectively. Our null hypothesis was that there would be no differences between implants with respect to interfacial shear strength in cortical bone. We also evaluated the effects of surgical interface (gap, line to line, and interference) on de novo ongrowth/ingrowth in the cancellous sites of the distal femur and proximal tibia [16]. Our additional hypothesis was that implantation configuration would have no effect on osseointegration for each of the 2 test mediums.

From the Surgical and Orthopaedic Research Laboratories, University of New South Wales, Prince of Wales Clinical School, Sydney, Australia.
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Reprint requests: William R. Walsh, PhD, Director, Surgical and Orthopaedic Research Laboratories, Prince of Wales Hospital, University of New South Wales, Sydney, Australia.

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Materials and Methods

Six skeletally mature adult male sheep (crossbred Merino Wethers, 18 months, 54.8 ± 1.4 kg) were used with ethical consent from our institutional animal care and ethics body. Animals underwent a bilateral procedure in which n = 10 pre-prepared implant dowels (6-mm diameter and 25-mm long) were implanted into surgically created defects in the cancellous bone (n = 4) of the distal femur and proximal tibia [16] and cortical bone (n = 6) of the tibial diaphysis [12-16]. The implantation sites are summarized in Fig. 1. All implants were sterilized using γ irradiation.

Surfaces evaluated in this study included one manufactured using the process of EBM and another made using the process of plasma spraying (Ti PS) (Fig. 2), with the latter serving as a comparison of ultimate interfacial shear strength only. The EBM process is a layer-based additive manufacturing process in which a beam of electrons melt layers of titanium powder to form a 3-dimensional (3D) construct. The process permits a unique porous-structured construct that is integrated into the solid substrate, allowing a stronger porous-solid interface versus a porous coating that is sintered to a solid surface [2,10,11]. Pore size and porosity of the EBM construct ranged from 130 to 370 μm and 46% to 57%, respectively.

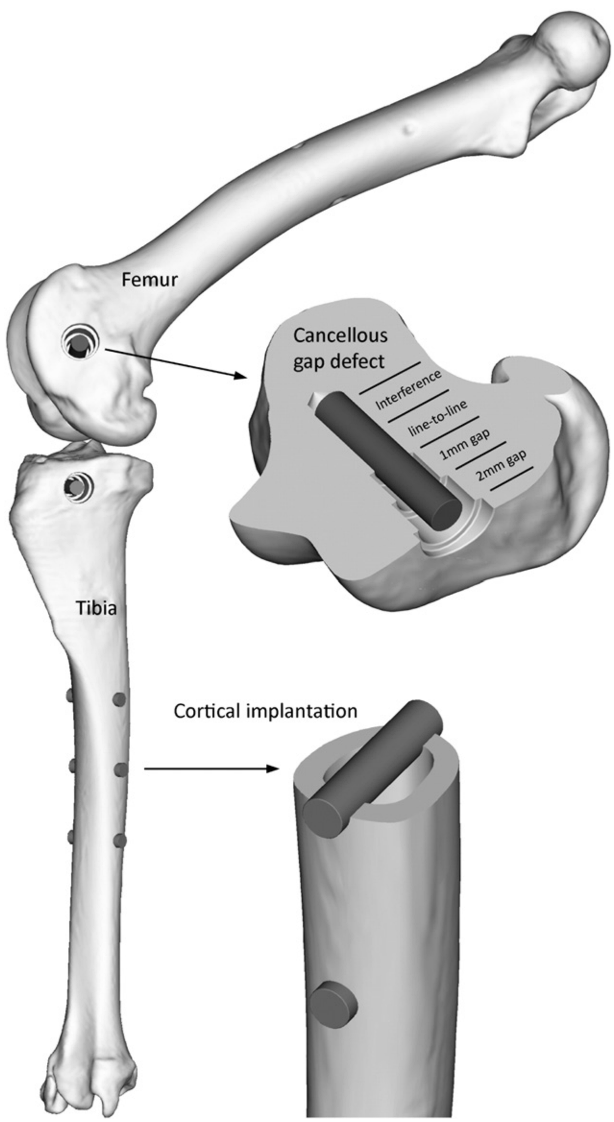

Fig. 1. Implantation schedule for the cancellous (distal femur and proximal tibia) and cortical (tibial midshaft) sites in this bilateral model. The sectioned illustrations provide an overview of the cancellous gap and cortical implantation conditions.

The surface roughness of both implants was determined using a profilometer (Surfanalyzer EMD-5400; Federal Products Co). Six implants of each type were measured along the implant length in each of 4 quadrants, and average (R_A) and root mean square (R_Q) average roughness values were computed.

The surgical models used in this study have previously been described in detail [16]. Briefly, a step drill was used to create a single defect with graduated and concentric 10-, 8-, 6-, and 4-mm diameter steps in the cancellous bone of the distal femur and proximal tibia. The length of each step was dictated by the drill step length (eg, 6 mm). This series of holes was then overdrilled with a 5.5-mm diameter bit. A custom-built impactor was used to insert implants into the cancellous defects with the 10-, 8-, 6-, and 5.5-mm stepped diameter defects, producing 2-mm circumferential gap, 1-mm circumferential gap, line-to-line, and interference fits, respectively. The impactor ensured that each of the implants was inserted to the correct depth, such that equal amounts of the implant length were exposed to each of the 4 simulated implantation scenarios. An additional step (12-mm diameter) was created in the cortex, the window through which the defect was drilled to position the contained gap defect deeper within the cancellous bone bed in an effort to further disjoin it from any immediate cortical and periosteal influence.

For cortical implantation, 3- and 6-mm diameter drills were used in sequence to create 3 bicortical cylindrical defects in the diaphysis of each tibia, as previously described [12-16]. Defects were at least 20 mm apart, and implants were inserted in a line-to-line fashion. Irrigation with sterile saline was applied during drilling of all bony defects. After implant placement the periosteum, soft tissues and dermis were closed in layers using 3-0 Vicryl (Ethicon Inc, Somerville, NJ) and 3-0 Polysorb (Covidien, Mansfield, Mass), respectively. Animals were returned to pasture after recovery and randomly assigned for euthanasia at 4 or 12 weeks after surgery (n = 3 animals per time point).

The femur and tibia from each aspect were harvested, photographed, and radiographed (anteroposterior and lateral planes). Implants and surrounding cancellous or cortical bone were isolated using a handheld saw. Axial sections along the length of the tibia were made to