White Paper: Evaluation of the Functional Osseointegration of Electron Beam Melted (EBM) Ti6Al4V Titanium Scaffolds

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Abstract

In this study the Labrynth® and Cranial Mesh scaffolds, and the As Grown surface used by Ossis to promote osseointegration of its custom implants were evaluated for mechanical fixation in cortical bone. An established clinically relevant sheep model and standard push-out test was used. For all samples the bone to implant interface strength and toughness increased with time. Scaffold implants demonstrated significantly greater bone to implant interface strength than the As Grown surface on a solid substrate. The highest mean ultimate shear stress reached at 12 weeks was 78% of that the host bone indicating that high clinical survivorship is likely. Labrynth® and Cranial Mesh were demonstrated to develop stronger implant to bone interfaces than values reported for other commercially available bone interfacing materials tested in similar models.

Introduction

Additive manufacture by electron beam melting of titanium is establishing a new standard in performance of bone interfacing materials. Previously implants were either surface modified with limited porosity and roughness, or separate coatings added to provide fixation in bone; often coatings delaminated from the substrate resulting in implant failure. EBM allows highly osteo-conductive bone tissue scaffolds to be manufactured integral with mechanical aspects of an implant providing increased osseointegration and reduced mechanisms of failure of the device.

The long-term fixation of an orthopaedic implant in bone is dependent on biological and mechanical osseointegration. Rough surfaces and porous substrates are used to promote the on-growth and in-growth of bone. Secure fixation ensures physiological loads are transferred between implant and host bone. Stress shielding occurs when an implant has a higher stiffness than the surrounding bone and flexes less when a load is applied. The result is that the implant takes a higher proportion of the applied load and shields the bone from physiologic levels of stress. Scaffold materials are designed to lower implant stiffness to that of bone. The combination of an osseointegrative implant with a physiological stiffness prevents stress shielding and can greatly reduce aseptic loosening through peri-implant atrophy.

Labrynth® and Cranial Mesh materials are new generation EBM bone tissue scaffolds based on extensive clinical experience. In this study the osseointegration of these bone-interfacing materials is benchmarked in an established large animal model and standard push-out test with a focus on early mechanical fixation. In addition to the scaffold materials tested, the surface common to these differing morphologies, As Grown, is tested.

The Electron Beam Melting Process

The electron beam melting of powdered metals is an advanced free form manufacturing technology used in medical implant production. Sequential layers of titanium alloy powder are deposited and selectively melted with an electron beam in a heated vacuum chamber in order to grow a part. Bone tissue scaffolds are grown integral to load bearing implants and provide greatly improved osseointegration over previous generations of orthopaedic implants.

Previous generations of porous metallic implants have been limited in their application. Sintered beads, vapour deposited metal scaffolds, and metal foams have been restricted to stock products with fixed geometry augments that require modification of the patient anatomy to suit the device.

The application of EBM to orthopaedic implant manufacture allows bone tissue scaffolds to be incorporated in custom devices that are tailored to match a patient's specific anatomy. In difficult reconstruction cases following revision, trauma, or tumour, the ability to fit an implant to existing bony defects enables the preservation of bone stock and the greatest chance of success.

Description of Samples

Three new highly interconnected porous scaffold structures of Ti6Al4V (Cranial Mesh [CM] and

Labrynth® [L1 & L2] and a monolithic Ti6Al4V structure sharing the common advanced surface morphology (As Grown [AG]) were additively manufactured by electron beam melting titanium alloy powder. Scaffold structures had porosities and pore sizes that enabled rapid infiltration and long-term fixation in bone [1], [2]: L1 (73%, 660 µm), L2 (71%, 580 µm) and CM (65%, 480 µm) as per Figure 1 and Figure 2 respectively. The surface of these electron beam melting manufactured implants is very rough so as to increase direct bone apposition [3], facilitate interlocking, and ultimately form a stronger bond with the surrounding bone than smoother implant surfaces.

Labrynth
Labrynth® (Fig. 3) is a unique porous titanium architecture used in Ossis' custom implants for arthroplasty revision and reconstruction surgery, and is tailored to provide optimum long-term fixation. Based on a modified dodecahedron the complex and totally interconnected structure enables substantial bone in-growth and remodelling while managing implant weight and physiological load bearing capabilities.
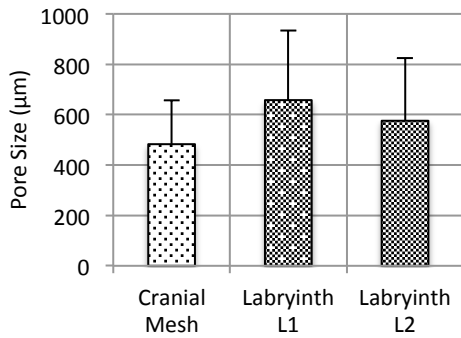
Figure 1: Pore size of scaffold samples. A pore size of 600 µm is rapidly infiltrated and able to provide long-term fixation in bone [1], [2]. There are no significant differences between scaffold pore sizes. Average pore sizes are shown with standard deviations.
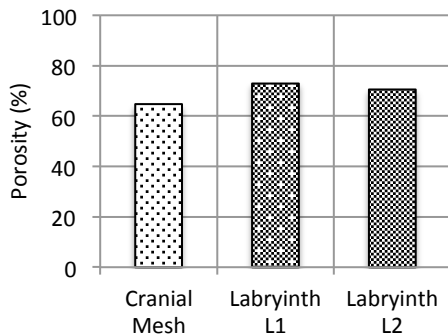
Figure 2: Porosity of scaffold samples. Highly porous interconnected structures allow for substantial bone in-growth and support osseointegration [4].

Cranial Mesh
Cranial Mesh (Fig. 4) is used in Ossis' cranioplasty and maxillofacial reconstructions where implants may need to interact with dura mater and mucosa. Cranial Mesh is an orthogonal lattice that has clear channels to enable the simple attachment of sutures.

As Grown
Common to both Labrynth® and Cranial Mesh the As Grown surface (Fig. 5) is designed to promote direct bone apposition and enhance adhesion through mechanical interlocking at a micro scale. Solid structural elements of reconstructive implants may incorporate the As Grown surface to provide additional bone or soft tissue fixation while maintaining the necessary ultimate strength.
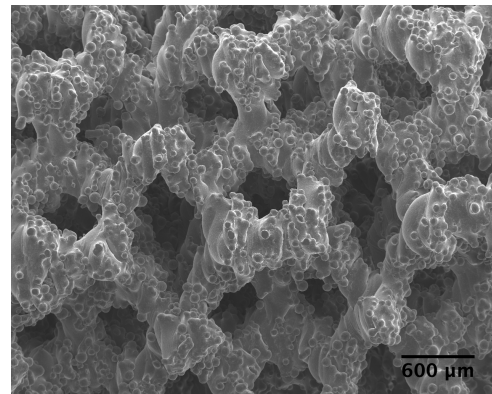

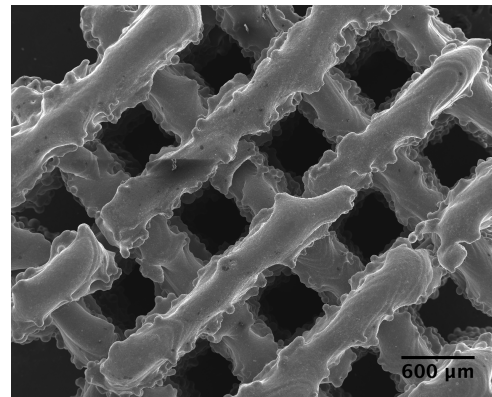Figure 3: Labrynth® SEM Image at x30 Magnification
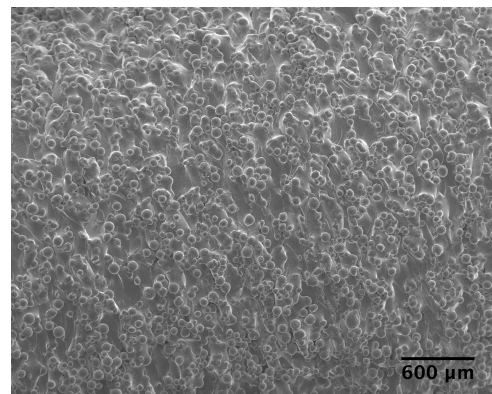

Figure 4: Cranial Mesh SEM Image at x30 Magnification

Figure 5: As Grown SEM Image at x30 Magnification

Animal Model and Surgical Technique

Skeletally mature sheep bred exclusively for research purposes were used with ethical approval. Animals underwent a bi-lateral procedure in which implant dowels were implanted under press fit conditions into surgically created defects in each tibial epiphysis and diaphysis. All implants were cylindrical EBM dowels 5 mm in diameter and 6 mm in length and were terminally sterilized by steam autoclave.

At each surgical site a longitudinal incision was made and tissue retracted to expose the bone. A cylindrical bone defect was introduced by drilling. A guide was used to ensure the axis of the defect was normal to the bone surface. Copious saline irrigation was used to prevent localised heating and bone debris was evacuated by saline lavage.

Implants were introduced axially to the defect using a custom instrument. Light impaction was used to position the implants flush with the superior surface of the bone. Incisions were closed in layers. Animals recovered with unrestricted movement in pens and monitored for 48 hours. Following recovery animals were returned to pasture to subject the implants to physiologic loading for the duration of the study. Animals were euthanized at 3, 6, and 12 weeks (n=4 animals at each time point).

Push-Out Test Procedure

The bone to implant interface strength of Labrynth®, Cranial Mesh, and As Grown materials was mechanically tested using a standard push-out test at 3, 6, and 12 weeks post-operatively. Cortical bone samples containing implants were prepared by transverse and longitudinal sectioning of the tibia followed by exposing the superficial and deep faces of the implants by grinding. Samples were rigidly fixed to a supporting jig (Figure 6) using resin and a 0.7mm circumferential clearance hole maintained for the implant to be pushed out in-to [5]. A plunger was driven axially at 0.5mm/min to dislodge the implant while force and displacement were recorded [6].

The interface stress able to be sustained by the implant and bone were evaluated at the peak loading obtained in each sample. The force needed to dislodge the implant from the bone was normalised by the interface area resulting in a measure of shear stress.

The energy absorbed by each sample prior to failure was established. The product of stress and strain was summed until peak stress was reached. The result is a measure of toughness of the interface; specifically the energy absorbed by an area of material interface for a given force over a given displacement.
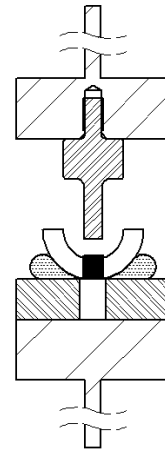

Figure 6: Push-out test rig. A 5mm diameter implant (solid black) was pushed out of the surrounding bone (solid white). The bone was supported with resin and a 0.7mm circumferential clearance was maintained.

Results

Animals recovered after surgery with no signs of infection. The mean ultimate shear strength of the implant to bone interface increased with time in cortical bone. All scaffold samples CM, L1 and L2 exhibited higher interface strength than that of the AG sample at respective time points. Generally the common mode of failure of push-out samples was shearing of de novo bone periphery to the implant; non-elastic implant subsidence was noted in one L1 sample at 12 weeks. No implant fragments or gross mechanical failures were noted at the time of testing.
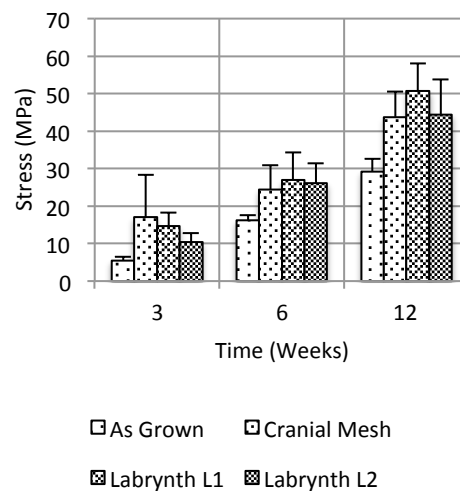

Figure 7: Bone to implant interface strength. Labrynth® reaches up to 78% of the strength of the surrounding bone [7] at 12 weeks.

Labrynth® L1 demonstrated the highest mean ultimate shear stress with 14.7 ± 3.6 MPa at 3 weeks, 26.9 ± 7.5 MPa at 6 weeks, and 50.68 ± 7.5 MPa at 12 weeks (Fig. 6). Labrynth® L1 also developed the toughest bone to implant interface with a specific energy absorption of the interface of 3.8 ± 0.7 mJ/mm^3 at 3 weeks, 6.5 ± 3 mJ/mm^3 at 6 weeks, and 13.8 ± 5 mJ/mm^3 at 12 weeks (Fig. 7). There are no significant differences between the interface properties of L1, L2, and CM samples at 12 weeks. Scaffold samples demonstrated significantly higher push-out strength than AG at all time points. Significantly higher toughness's are evident between all scaffold samples and AG.
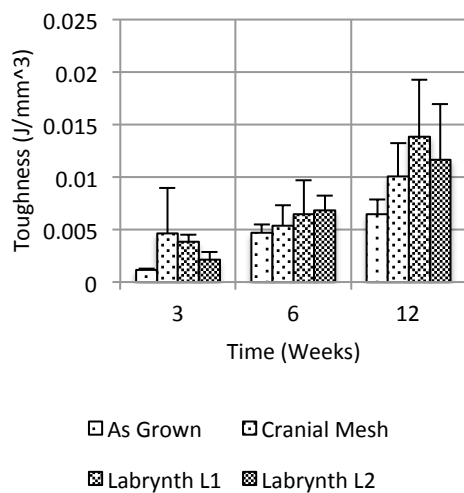

Figure 8: Bone to implant toughness. Labrynth® absorbed more energy before failing when compared with solid As Grown

Discussion

In this study electron beam melted titanium alloy implants were evaluated for mechanical fixation in cortical bone. An established clinically relevant animal and surgical model was used. A standard push-out test was applied. The bone to implant interface strength and toughness increased with time. Scaffold implants demonstrated significantly greater bone to implant interface strength than a monolithic substrate.

The animal model chosen presented well-healing bone that subjected implants to substantial in-situ loading and similar macro-physiology to that human bone. Actual results in osteopenic bone may be lower; however, this model allowed direct comparison with existing work.

The highest bone to implant interface strength achieved was 50.68 ± 7.5 MPa using the Labrynth® scaffold at 12 weeks. Both Labrynth® and Cranial Mesh demonstrated higher bone to implant strength at 12 weeks than commercially available in-growth technologies: Regenerex; Biomet, 26.1 MPa [4], BioFoam; Wright Medical Technology, 22 MPa [8], and on-growth technologies: Porocoat and DuoFix; DePuy, 35 MPa 39 MPa respectively [9], and Wright Beads; Wright Medical Technology, 13 MPa [8] (Fig. 9). A comparison of the early fixation of Labrynth®, Cranial Mesh, and As Grown, with other commercially available is shown in Fig. 9.

Generally the mechanism of failure at 12 weeks was shearing of the implant to bone interface rather than mechanical compliance of the implants. All samples were manufactured in Ti6Al4V that is of higher strength than commercially pure Ti. The mechanical integrity of the scaffold shown in this study contrasts with similar work on Trabecular Titanium; Lima, which exhibited implant subsidence in the majority of tests [10].

This study demonstrates the efficacy of Labrynth® and Cranial Mesh EBM scaffolds, and the As Grown surface, in forming a strong mechanical bond with host bone tissue in an in-vivo trial. Furthermore, the bone to implant interface strength of Labrynth® and Cranial Mesh indicate that early fixation of these scaffolds is both more rapid and ultimately stronger than other commercially available products
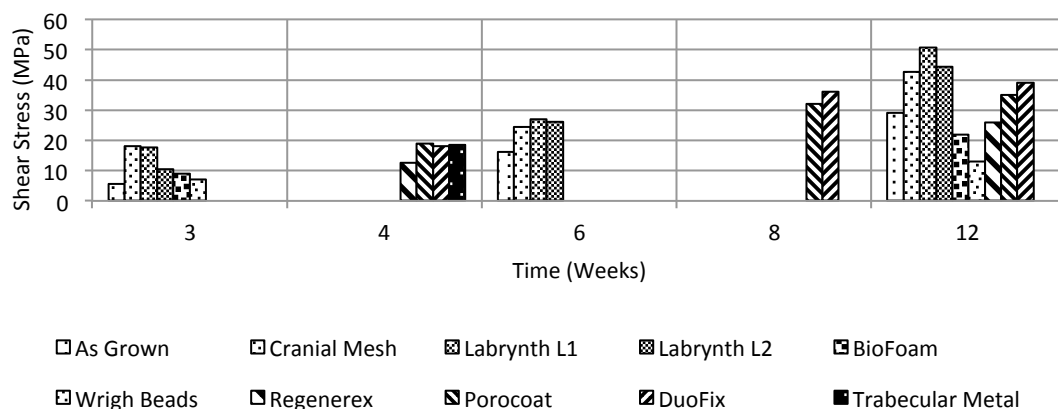

Figure 9: Bone to implant interface strength of commercially available in-growth and on-growth products. Ossis' Labrynth® and Cranial Mesh products have the highest bone to implant interface strength at 12 weeks when compared to all existing commercially available products with published data [4], [8], [9], [10], [11].

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