Next-generation biomedical implants using additive manufacturing of complex, cellular and functional mesh arrays

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In this paper, we examine prospects for the manufacture of patient-specific biomedical implants replacing hard tissues (bone), particularly knee and hip stems and large bone (femoral) intramedullary rods, using additive manufacturing (AM) by electron beam melting (EBM). Of particular interest is the fabrication of complex functional (biocompatible) mesh arrays. Mesh elements or unit cells can be divided into different regions in order to use different cell designs in different areas of the component to produce various or continually varying (functionally graded) mesh densities. Numerous design elements have been used to fabricate prototypes by AM using EBM of Ti-6Al-4V powders, where the densities have been compared with the elastic (Young) moduli determined by resonant frequency and damping analysis. Density optimization at the bone-implant interface can allow for bone ingrowth and cementless implant components. Computerized tomography (CT) scans of metal (aluminium alloy) foam have also allowed for the building of Ti-6Al-4V foams by embedding the digital-layered scans in computer-aided design or software models for EBM. Variations in mesh complexity and especially strut (or truss) dimensions alter the cooling and solidification rate, which alters the $\alpha$-phase (hexagonal close-packed) microstructure by creating mixtures of $\alpha/\alpha'$ (martensite) observed by optical and electron metallography. Microindentation hardness measurements are characteristic of these microstructures and microstructure mixtures ($\alpha/\alpha'$) and sizes.

Keywords: biomedical mesh and foam arrays; implants; electron beam melting; materials characterization; elastic modulus measurement

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For nearly four decades, porous coatings have been used to create surface roughness between orthopaedic implant devices and the surrounding bone to improve the stability of the implant by bone tissue ingrowth (Bobyn et al. 1999; Degischer & Kriszt 2002; Hacking et al. 2002; Bobyn et al. 2005). These coatings have included the addition of metal beads to a solid implant surface by a sintering or diffusion bonding process, thermal spraying of porous metal surfaces, sintering of metal cellular or mesh arrays onto the surface and the sintering of metallic foams to implant device surfaces (Bobyn et al. 1999; Wen et al. 2002). Figure 1 illustrates a commercial cellular structure composed of tantalum, developed by Zimmer Holdings, Inc. as Trabecular Metal. Like other porous surface systems, this cellular structure must be efficiently attached to the fully dense medical device. Very successful devices have been available for more than a decade (Hacking et al. 2002; Bobyn et al. 2005). However, these coating methods exhibit intrinsic deficiencies, including lack of adherence to the substrate and non-uniformity of the layer thickness as well as insufficient thickness to facilitate effective bone tissue ingrowth and desirable biomechanical compatibility. Even natural coral has been used for certain skeletal repair and replacement.

Titanium and its alloys such as Ti-6Al-4V fulfill important if somewhat limited requirements for use in medical implants: high specific strength, low stiffness, and good corrosion and fatigue resistance in biological media even in contrast to stainless steel and cobalt–chromium alloys (Co-26Cr-6Mo) (Brunette et al. 2001). However, in most orthopaedic applications, even solid (fully dense) Ti-6Al-4V exhibits notable biomechanical mismatch between the implant device and the surrounding bone tissue, leading to stress-shielding phenomena, which induce an unfavourable stress distribution at the bone–implant interface, causing retarded or irregular bone healing and remodelling in many instances (Niinomi 2008). Femoral and tibial bones in particular consist of an outer cortical region of dense bone with an elastic (Young) modulus nominally ranging from 16 to 20 GPa, whereas the inner (medullary) trabecular bone with an open cellular structure has an elastic modulus roughly an order of magnitude less than the cortical bone. Since the elastic modulus for commercial, wrought Ti-6Al-4V ranges from roughly 105 to 110 GPa, the elastic modulus variance for implant stems in the femur or tibia and the outer cortical bone can be at least a factor of 5 and up to an order of magnitude larger if the implant must match the central trabecular or intramedullary regime. In addition, since load-bearing orthopaedic implant stem devices are generally not patient-specific, this biomechanical mismatch may vary significantly from patient to patient even if thin, porous coatings as described earlier are applied.

Open cellular or foam structures can have significantly reduced stiffness or elastic moduli with reduction in density as generally described by Gibson & Ashby (1997):

\[ E = E_0 \left( \frac{\rho}{\rho_o} \right)^n, \]  

where \( E \) and \( E_0 \) are the Young moduli of the foam or cellular structure material and the fully dense material respectively, \( \rho \) and \( \rho_o \) are the corresponding porous and fully dense material densities, and \( n \) has a value shown to vary from 1.8 to 2.2
Next-generation biomedical implants

Figure 1. Commercial ‘Trabecular Metal’ cellular tantalum. Scale bar, 1 mm. (Courtesy: Zimmer Holdings, Inc.)

Figure 2. Aluminium alloy (6101) cellular foam. Pore size is designated as linear pores/inch (10, 20 and 40 ppi), as noted above each foam specimen. Foam specimens are 1.25 cm thick.

(Ashby et al. 2000). Aluminium and aluminium alloy foams, as illustrated typically in figure 2, have been fabricated for decades because of their relatively simple liquid-state processing as a consequence of their low melting point (approx. 662°C), whereas Ti or Ti-6Al-4V alloy (which melt above 1650°C) are much more difficult to process in the liquid state (Davis et al. 2001; Dunand 2004). However, even though Ti and Ti alloy foams are technically tractable, their
attachment to medical, orthopaedic devices is relatively impracticable. More recently, Heinl et al. (2008) have demonstrated that cellular Ti-6Al-4V structures with interconnected macro-porosity for bone implants could be fabricated by additive manufacturing (AM) from precursor powders using electron beam melting (EBM), and Murr et al. (2009c) have shown that Ti-6Al-4V monolithic orthopaedic device prototypes incorporating complex but regular mesh arrays with fully dense components can be fabricated by EBM.

In this research programme, we explore the fabrication of monolithic, complex mesh arrays, including functionally graded arrays and fully dense component geometries representing a variety of orthopaedic implants: tibial knee stems, hip stems and intramedullary rods. In addition, we evaluate the functionality of several mesh systems or system geometries along the lines where

\[
\text{mesh property} = \lambda \left( \frac{\rho}{\rho_0} \right)^n ,
\]

as implicit in the evaluation of foam stiffness expressed previously in equation (1.1), where \(\lambda\) can incorporate geometrical features or cell structures. These mesh systems included geometrical structures built in lattice-style, three-dimensional periodic, reticulated geometry from the so-called lattice elements or unit-cell structures embedded in computer-aided design (CAD) software driving the AM–EBM process. Variations in these unit-cell structures, including their basis size or unit-cell dimension, produced strut dimension variations and density/poreosity variations used to evaluate equation (1.2), and illustrating the potential for design specificity and biocompatibility using EBM in next-generation biomedical implant fabrication. Finally, we explore CAD development through computerized tomography (CT) scans of aluminium alloy foams and their integration into monolithic Ti-6Al-4V device structures through EBM building.

2. Materials and methods

(a) Electron beam melting processes and optimized build parameters

Figure 3 shows a schematic for the Arcam-EBM (A2) system used in this research programme, along with a scanning electron microscope (SEM) image inset showing the precursor Ti-6Al-4V-ELI (extra low interstitial) medical-grade powder having a nominal composition of 6.04% Al, 4.05% V, 0.013% C, 0.07% Fe, 0.13% O, less than 0.005% N and H, and the balance Ti (in weight per cent) (Murr et al. 2009a). In this system, the focused electron beam (1 and 2 in figure 3) is rastered over each successive layer of powder (3), which is gravity-fed from powder cassettes (4) and raked (5) into successive layers roughly 100 \(\mu\)m thick. The building component (6) is lowered on the build table (7) with the completion of each successive layer. Each newly raked powder layer is initially rastered by the beam at approximately 15 000 mm s\(^{-1}\) scan speed in 11 passes at a beam current of approximately 30 mA to preheat each layer to approximately 640 °C. This layer preheat is normally followed by a single melt scan at 400 mm s\(^{-1}\) and a beam current of 6 mA, although for some builds multiple (up to three) melt scans have been employed. The melt scan is driven by a three-dimensional CAD program, and melts only selected layer areas, which add metal to the build. The
build chamber vacuum is maintained at approximately $10^{-4}$ Torr with a He gas bleed at approximately $10^{-2}$ Torr at the build area to facilitate build cooling and thermal stability.

(b) Ti-6Al-4V foam building by EBM

One of the major advantages of the AM–EBM process is that digital CAD protocols developed by systematic scanning using, for example, CT can be integrated into complex, monolithic builds involving cellular foams functionally joined to complex mesh arrays in turn joined to fully dense component arrays. This is a distinct advantage over the traditional machining of biomedical devices from wrought or cast stock and subsequent creation of requisite surface porosities.
by sinter or spray technologies. As a demonstration of this AM innovation, we CT scanned an aluminium alloy foam similar to figure 2 and embedded the digital-layered file in a CAD model program for the Arcam-EBM system. The CT scanner was a Scanco Medical microCT 40 scanner set to scan in 36 μm slices using a microfocus (5 μm spot size) X-ray source. Bitmap files were exported and imported into Mimics 11.1 (1192 slice images measuring 1024 × 1024 pixels).

Figure 4. Software (CAD) rendering of metal (aluminium alloy) cellular foam from the microCT scan. (a) 2X base foam or starting build unit. (c) 3X base foam. (b) and (d) Three-dimensional test block CAD elements corresponding to (a) and (c), respectively. Base foam porosity, 6 ppi. Measured densities corresponding to (a) and (c) are 0.83 g cm$^{-3}$ and 0.58 g cm$^{-3}$.
These files can be altered in linear dimension, resulting in porosity increases or decreases as a consequence of pore size variations, or as noted in figure 2, variations in pores/inch (ppi in figure 2).

Figure 4 illustrates this CAD-like model file development and manipulation, which can be compared with figure 2. In this regard, it is interesting to note in figure 2 that, while there is a recognizable and systematic variance in pore size, the corresponding densities of these foams (in figure 2) are not changed. For example, for the pore size changes shown in figure 2, from left to right 10, 20 and 40 ppi, respectively, the corresponding foam densities are 0.21, 0.18 and 0.21 g cm$^{-3}$, respectively. This occurs because in the liquid-state processing of cellular foams, as the pore size increases there is a corresponding increase in the connecting bridge dimension. This is also apparent in the model scaling illustrated in figure 4 as well. While this feature has some advantages in maintaining requisite stiffness, it does not allow for systematic (functional) variances in stiffness, which may be advantageous in the development of more compatible implants, particularly in attempts to create bone-compatible stems connecting trabecular to cortical bone tissue.

Of course, these build strategies, implicit in figure 4, can also be used in scanning other cellular/mesh arrays such as those illustrated in figure 1. The advantage of such scans would be the ability to build a functional, monolithic device with a uniform composition, e.g. Ti-6Al-4V, Co-26Cr-6Mo or even Ta (in reference to figure 1), if adequate precursor powder is available for AM–EBM.

Unlike the cellular foams in figures 2 and 4, the structure in figure 1 resembles a wire-woven Kagome truss structure based on the assembly of helical wires in six directions (Lefebvre et al. 2008). However, the traditional structures are periodic, whereas those in figure 1 are irregular, foam-like.

(c) Mesh development software, design strategies and characterization

In this research programme, we used two software packages to create reticulated mesh arrays: MATERIALISE/MAGICS (http://www.materialise.com) and SELECTIVE SPACE STRUCTURES (3S), a product of Fruth Innovative Technologien GmbH (FIT), Germany (http://www.pro-fit.de). These structure generators build mesh arrays with geometries based on structure or geometry elements. The 3S software uses a so-called unit cell or lattice structure unit similar in concept to crystal lattice unit cells, but in some instances more complex. For the production of structured, three-dimensional solids or mesh arrays, a structural drawing defines the cell ranges and descriptions, and based on these instruction sets the physical building of the solid mesh structure takes place in a format similar to growing single-crystal lattices, one unit layer at a time. By changing the unit-cell or lattice structure unit dimension, the mesh geometry is correspondingly adjusted for both software programs. Similarly, as the mesh size grows, the density is reduced since open space (or porosity) increases. Changes in mesh elements or strut dimensions (diameter) or spacing can also be made, resulting in similar mesh feature changes. This is a considerable advantage over the development of cellular foams illustrated in figure 4. Depending upon the starting powder size or size distribution and corresponding beam parameter optimization in the EBM system, there are size limitations or unit-cell size limitations where proximity of mesh elements causes monolithic melting. For the 30 µm average (or mean) powder particle diameter
illustrated in figure 3, this dimension is around 0.5 mm, and for some unit-cell dimensions and complexities, there is a minimum buildable mesh structure below which irregular melt occurs and unmelted powder removal becomes difficult or impossible to achieve.

In this study, we built numerous, similar, simple mesh geometries involving a variety of unit-cell types, and simple mesh geometries using a single unit cell that was increased in size to effect a systematic variation (decrease) in density. In addition, we employed complex mesh unit cells to produce graded mesh arrays by building monolithic biomedical implant prototypes employing different unit-cell dimensions to produce mesh arrays of various density. The elastic (Young) moduli were measured in this study using a resonant frequency and damping analyser (RFDA) developed by IMCE, Belgium. This is a non-destructive testing device based on impulse excitation, where a small mechanical impulse induces a vibration in a test sample (Roebben et al. 1997). The tested material dissipates its energy into the vibration expressed as a damping sine wave. The vibration of tested samples consists of the sum of several resonant frequencies, \( f_r \), each of which will dampen according to the energy absorption of the material. For the simple rectangular test sample shapes produced in this study, there are well-defined vibration modes, and the elastic modulus is given by

\[
E = \zeta m f_r^2, \tag{2.1}
\]

where \( \zeta \) is a geometrical (specimen) shape function and \( m \) is the specimen mass (Roebben et al. 1997). Similar to ultrasonic testing, which provides more reliable elastic modulus values than compression testing (Gibson & Ashby 1997), RFDA is a reliable, non-destructive test and measurement option. It measures the dynamic Young modulus, in contrast to the static Young modulus for tension or compression testing. Generally, the static Young modulus is determined for a material and not for a structure as in dynamic testing by RFDA. Consequently, the Young modulus measurements may be more appropriately identified as a stiffness-related number rather than as the conventional Young modulus. To perform a measurement, samples are supported in two points (nodes) and gently tapped with a small hammer in the antinode to measure the resonant frequency and the wave damping, or internal friction (\( Q^{-1} \)). Consequently, no real forces are applied to the test samples. The test samples were designed to satisfy the general requirements discussed for metal foams (Ashby et al. 2000): height/width (or thickness) > 1.5; height > 7 times the cell size or largest channel size. In addition, we measured the Vickers microindentation hardness—employing 25 or 100 gf (0.245 or 0.980 N) loads in a Shimadzu HMV-2000 microindentation tester—along characteristic struts in each mesh geometry and examined the corresponding microstructures using optical metallography. To perform microindentation hardness and optical metallography (using a Reichert MEF4 A/M optical metallograph), sections of specific mesh arrays were mounted, ground, polished and etched to produce microstructural features on flat surface regions. The etching involved a solution consisting of 100 ml H₂O, 2.5 ml HF and 5 ml HNO₃ (Murr et al. 2009a). These mesh arrays were also characterized by SEM in a Hitachi S4800 field-emission SEM (FESEM) and in some cases by preparing electron-transparent specimens for observation in a Hitachi H-8000 transmission electron microscope (TEM) operated at 200 kV accelerating potential (Murr et al. 2009a).
Tensile testing for solid, fully dense cylindrical prototypes built by varying the build parameters and protocols used standard tensile specimen formats machined from these prototypes as illustrated previously (Murr et al. 2009a). Testing was performed in an Instron 500 R tensile machine using special grips at an engineering strain rate of $3 \times 10^{-3}$ s$^{-1}$ at room temperature (20°C). Following tensile testing to failure, the fracture surfaces were examined in the FESEM. Solid, fully dense monolithic hardness was also measured by Rockwell hardness C (HRC) scale using a 1 kg load.

3. Results and discussion

(a) Evaluation of some MATERIALISE software element arrays and EBM-built prototypes

One of the important issues to address with mesh arrays is their correspondence with the Gibson–Ashby formula in equation (1.1), where $n = 2$. The so-called effective elastic moduli for cellular structures are $a priori$ calculated from equation (1.1) for $n = 2$, especially for biomedical materials applications involving Ti-6Al-4V (Parthasarathy et al. 2009). Our initial approach involved building and testing a variety of build elements using the MATERIALISE software. Four basic elements were used, as illustrated in figure 5a, each with increasing complexity, beginning with the simple orthogonal, symmetric cross-1 element at the left and progressing to the dode-thin element to the right. Figure 5b illustrates the actual build models in CAD software, whereas figure 5c shows the actual Ti-6Al-4V builds corresponding to figure 5b. There are two G7 elements for builds, where G7r represents a 90° rotation about the joined pyramid axis as shown in figure 5a. While the cross-1 and G6 elements produce orthogonally symmetric meshes in both the longitudinal and transverse (face normal) axes, G7 is slightly less symmetric, while dode thin varies from twofold to threefold symmetry axes with a rotation of 45° around the longitudinal axis.

From the testing of these mesh arrays (figure 5c) along the longitudinal axes, the effective elastic moduli (or stiffness numbers) were measured as illustrated in table 1, along with the sample mass, the measured densities, porosities and array geometries. The resonant frequency is indicated along with the measured internal friction. The corresponding measured strut microindentation hardnesses are also indicated in table 1.

Using the dode-thin element (figure 5a), a series of mesh arrays were fabricated by EBM to produce a systematic variation in density. In addition, a ‘bone element’ or bone unit cell from the 3S software was also fabricated. Figure 6 shows these specific build elements looking down onto the build table in figure 1, where the build was stopped after 30 layers. These building platforms, indicated 1, 2, 3 in figure 6a, correspond to completely fabricated arrays having densities of 0.78, 0.86 and 1.22 g cm$^{-3}$ listed in table 2 and shown in figure 7. The highest-density array in table 2 ($\rho = 1.59$ g cm$^{-3}$) corresponds to the dode-thin mesh array shown in table 1. This identical array sequence was also tested by resonant frequency and damping analysis (RFDA), and the corresponding, effective moduli measured as illustrated in table 2 along with the sample mass, resonant frequency and internal friction.

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Figure 5. (a) Materialise software elements, (b) models and (c) EBM-fabricated Ti-6Al-4V prototype test blocks. G7r represents a 90° rotation of G7 design element as noted in (a) (table 1). Scale bar, 1 cm.

Figure 8 illustrates the mesh–strut structure-geometry details as observed in the FESEM. Note that Ti-6Al-4V powder particles partially melted–sintered to the layered strut sections are especially prominent in figure 8a. These sections and similar mesh array sections characteristic of the other build elements shown in figure 5a were mounted, polished and etched as described previously in §2, and microindentation measurements made as summarized in tables 1 and 2. In addition, optical metallography observations were made for these polished and etched strut sections and compared with those for polished and etched, fully dense Ti-6Al-4V EBM-built monolithic samples—usually 1 cm² × 2 cm blocks or somewhat larger cylindrical samples.

Figure 9 shows the nominal microstructures for fully dense Ti-6Al-4V components that are characterized by acicular α-phase (Widmanstätten) plates, which increase in size (particularly width) with an increase in heat-related processing depending on the number of melt passes. This increase in α-phase size is also consistent with the residual Vickers microindentation hardness
Table 1. Build elements and mesh element build properties.

<table>
<thead>
<tr>
<th>build element&lt;sup&gt;a&lt;/sup&gt;</th>
<th>strut size (mm)</th>
<th>base channel size (mm)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>mass, m (g)</th>
<th>density, $\rho$ (g cm$^{-3}$)</th>
<th>relative density $(\rho/\rho_0)$&lt;sup&gt;c&lt;/sup&gt;</th>
<th>porosity (%)</th>
<th>resonant frequency, $f_r$ (kHz)</th>
<th>internal friction&lt;sup&gt;d&lt;/sup&gt; (10$^{-4}$)</th>
<th>strut hardness, HV (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cross 1</td>
<td>0.9</td>
<td>2</td>
<td>10.6</td>
<td>0.52</td>
<td>0.12</td>
<td>88</td>
<td>10.8</td>
<td>0.58</td>
<td>4.6</td>
</tr>
<tr>
<td>G6</td>
<td>1.4</td>
<td>2</td>
<td>23.8</td>
<td>1.11</td>
<td>0.25</td>
<td>75</td>
<td>18.5</td>
<td>3.67</td>
<td>14.0</td>
</tr>
<tr>
<td>G7</td>
<td>1.1</td>
<td>2</td>
<td>34.0</td>
<td>1.83</td>
<td>0.41</td>
<td>59</td>
<td>20.8</td>
<td>6.74</td>
<td>8.6</td>
</tr>
<tr>
<td>G7&lt;sup&gt;e&lt;/sup&gt;</td>
<td>1.1</td>
<td>2</td>
<td>34.0</td>
<td>1.83</td>
<td>0.41</td>
<td>59</td>
<td>13.9</td>
<td>3.03</td>
<td>6.4</td>
</tr>
<tr>
<td>dode thin</td>
<td>0.3</td>
<td>0.3</td>
<td>21.6</td>
<td>1.59</td>
<td>0.36</td>
<td>64</td>
<td>19.8</td>
<td>6.15</td>
<td>5.7</td>
</tr>
</tbody>
</table>

<sup>a</sup>Materialise software.
<sup>b</sup>Base channels are essentially square openings in the build base.
<sup>c</sup>$\rho_0 = 4.43$ g cm$^{-3}$.
<sup>d</sup>$Q^{-1}$.
<sup>e</sup>Element axis rotated 90°.

Table 2. Dode-thin mesh build sequence properties.<sup>a</sup>

<table>
<thead>
<tr>
<th>build size (cm) (volume (cm$^3$))</th>
<th>mass (g)</th>
<th>density, $\rho$ (g cm$^{-3}$)</th>
<th>strut size (mm)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>base channel size (mm)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>porosity (%)</th>
<th>relative density $(\rho/\rho_0)$&lt;sup&gt;c&lt;/sup&gt;</th>
<th>resonant frequency, $f_r$ (kHz)</th>
<th>internal friction&lt;sup&gt;d&lt;/sup&gt; (10$^{-4}$)</th>
<th>strut hardness, HV (GPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$4.7 \times 4.7 \times 7.1$ (156.84)</td>
<td>122.5</td>
<td>0.78</td>
<td>1.2</td>
<td>2.4</td>
<td>82</td>
<td>0.18</td>
<td>0.92</td>
<td>6.9</td>
<td>3.0</td>
</tr>
<tr>
<td>$4.1 \times 4.1 \times 5.9$ (99.18)</td>
<td>85.7</td>
<td>0.86</td>
<td>1.0</td>
<td>2.0</td>
<td>81</td>
<td>0.19</td>
<td>1.53</td>
<td>7.9</td>
<td>5.0</td>
</tr>
<tr>
<td>$3.1 \times 3.1 \times 4.4$ (51.81)</td>
<td>51.8</td>
<td>1.22</td>
<td>0.8</td>
<td>0.9</td>
<td>72</td>
<td>0.28</td>
<td>2.70</td>
<td>12.9</td>
<td>2.7</td>
</tr>
<tr>
<td>$2.3 \times 2.3 \times 3.6$ (20.74)</td>
<td>21.6</td>
<td>1.59</td>
<td>0.7</td>
<td>0.7</td>
<td>64</td>
<td>0.36</td>
<td>6.15</td>
<td>19.8</td>
<td>5.7</td>
</tr>
</tbody>
</table>

<sup>a</sup>Materialise software.
<sup>b</sup>Base channels are essentially square openings in the build base (figure 6).
<sup>c</sup>$\rho_0 = 4.43$ g cm$^{-3}$.
<sup>d</sup>$Q^{-1}$.
Figure 6. Examples of early EBM-built structures for MATERIALISE dode-thin software element increases (1–3) and 3S software unit-cell ‘bone’ element (4). (a) Opaque view. (b) Transparent view showing pore-channel structure (table 2). Scale bar, 1 cm.

(HV) and the HRC. In figure 9a–c, the average α-phase widths are 2, 6 and 8 μm, respectively, corresponding to HV 3.6, 3.5 and 3.4 GPa and HRC 35, 34 and 33, respectively. It might be noted that, in an earlier work, Murr et al. (2009a) demonstrated that, even for single-melt-pass EBM building
of Ti-6Al-4V component geometries, variations in thermal histories within the builds could produce $\alpha$-phase dimensional changes with corresponding hardness changes, which ranged from HV 3.5 to 4.6 GPa, as well as corresponding HRC variations, which ranged from HRC 37 to 50, respectively.

Figure 10 compares the softest, triple-melt-pass Ti-6Al-4V longitudinal, $\alpha$-phase, acicular microstructure (figure 10a) for a solid fully dense cylinder having a width of approximately 10 $\mu$m with that typical for the dode-thin-built mesh array (1.59 g cm$^{-3}$ density) strut (figure 10b). The strut microstructure is
Figure 8. FESEM views of EBM-fabricated MATERIALISE dode-thin (figure 5) element model corresponding to a density of 0.86 g cm$^{-3}$ (table 2). (a) Strut structure. (b) Magnified view of strut structure in (a). Scale bars, (a) 0.5 mm and (b) 200 μm.

Figure 9. Optical micrographs showing acicular α-phase microstructures in a plane perpendicular to the build direction. (a) Single melt pass; scale bar, 25 μm. (b) Double melt pass. (c) Triple melt pass. Average α-phase thicknesses are 3, 4.5 and 6 μm in (a), (b) and (c), respectively.

dominated by orthogonal arrays of thin α′ (martensite) platelets with a width of approximately 3 μm intermixed with some α-phase. Comparing figure 10a and b, the corresponding microindentation hardesses were measured to be HV 3.4 and 3.7 GPa, respectively. Similarly, figure 11 shows nominal optical metallographic
images for G7 and cross-1 element (figure 5) mesh array struts (figure 11a and b, respectively), where the corresponding microindentation hardness was the same for each at HV 3.8 GPa. These harder, α′ (martensite or martensite-rich) microstructures arise as a consequence of the cooling or rapid solidification variations occurring in the thin, isolated strut sections in contrast to heat conduction features in the fully dense monoliths.

Figure 12 compares the optimized, single-pass EBM-built Ti-6Al-4V α-phase microstructure with α′ (martensite) in a fully dense Ti-6Al-4V monolith built by selective laser melting (SLM) (Murr et al. 2009b) and observed in the TEM.

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Figure 11. The $\alpha'$ (martensitic) phase dominating the microstructure of struts for mesh arrays fabricated (by EBM) from MATERIALISE software elements (figure 5a). (a) G7 element (figure 5a): $\rho = 1.83 \text{ g cm}^{-3}$ and HV = 3.8 GPa. (b) Cross-1 element (figure 5a): $\rho = 0.52 \text{ g cm}^{-3}$ and HV = 3.8 GPa. Scale bar, 50 $\mu$m.

Here, again, the significant processing feature contributing to this microstructure variation represents a two-orders-of-magnitude increase in melt scan rate for SLM in contrast to EBM (Murr et al. 2009b) and is consistent with cooling variances implicit on comparing figures 9–11.

As noted previously (figure 9), size variances in $\alpha$-phase microstructures are associated with residual hardness variations, which, in a general approximation for many metals and alloys (including Ti-6Al-4V), is related to the yield stress:

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yield stress $\approx \frac{\text{HV}}{3}$ (Murr et al. 2009a). For example, measured yield stresses for optimized, single-melt-pass EBM fabrication of fully dense Ti-6Al-4V components in this and related work (Murr et al. 2009a) have varied from 1 to 1.2 GPa, with corresponding microindentation hardness values ranging from HV 3.5 to more than 4.1 GPa. But in addition to $\alpha$-phase (acicular grain) microstructure changes, cooling rate or solidification rate variances can also cause variations in dislocation density within the acicular $\alpha$-phase grains. These features are illustrated in figures 13 and 14. Figure 13 compares a hard $\alpha$-phase microstructure component with a softer $\alpha$-phase microstructure component fabricated by EBM, whereas figure 14 shows low-density dislocation-related microstructure for a single-melt-pass, fully dense monolith.

Figure 15 illustrates the fabrication of exaggerated tibial–knee stems with various density compatibilities representing the high-end trabecular regime (approx. 0.8 g cm$^{-3}$) and the low-end cortical bone regime (approx. 1.5 g cm$^{-3}$) (Cezayirlioglu et al. 1985; Currey 2002), using the MATERIALISE dode-thin element (figures 5a and 7). Figure 15a shows a total knee replacement X-ray with femoral (F) attachment device and tibial (T) stem, which holds a highly

(b) Development of Ti-6Al-4V cellular mesh and foam biomedical device prototypes: complex cellular and functional mesh arrays
Figure 13. TEM bright-field image comparisons for single-melt-pass EBM fabrication of fully dense Ti-6Al-4V monoliths with variations in build thermal history to create dislocation density variations in the $\alpha$-phase. (a) High hardness (HV = 3.9 GPa), dislocation density approximately $10^{10}$ cm$^{-2}$. (b) Magnified view of dislocations in $\alpha$-phase in (a). (c) Low hardness (HV = 3.5 GPa), dislocation density approximately $10^{7}$ cm$^{-2}$. (d) Magnified view of region in (c). (a) and (b) After Murr et al. (2009a). Scale bars, 1 $\mu$m.

Figure 16 shows the 3S software bone element or ‘build unit cell’ that was illustrated in the build section in figure 6 along with a software model representing a 5 mm size element (figure 16a). Figure 17, correspondingly, shows
models for 5 and 7 mm bone elements along with photographs of a fabricated prototype test block (5 mm element size). The measured density for this sample and other samples fabricated from other bone element dimensions (4 and 7 mm) are tabulated in Table 3. These design and fabrication examples logically provoke prospects for complex, functional mesh or cellular foam arrays especially applicable to bone stem and rod devices and related biomedical appliances. The measured elastic moduli, sample mass, density, resonant frequency and internal friction are also listed in Table 3 for the EBM-built specimen shown in Figure 17b, d.

Figure 18 provides a compelling prospect for a compliant, patient-specific intramedullary rod or device stem. The inner 3S 7 mm bone element component measures roughly 1 cm in diameter and has a build density of 1.09 g cm\(^{-3}\) (Table 3), whereas the outer 0.5 cm cylinder component represents the 3S 4 mm bone element having a build density of 1.91 g cm\(^{-3}\) (Table 3). This rod configuration can be fabricated in any length and diameter, straight or tapered, or incorporating any other necessary design feature.

Figure 19a illustrates the software model set-up for the integrated 3S bone elements represented in Figure 18, along with initial structure models for the foams represented in Table 4. Figure 19b illustrates the actual bi-functional, two-mesh (3S bone element: 7 mm inside; 4 mm outside) cylindrical prototype, whereas
Figure 15. Knee implant (tibial stem) prototype development and EBM processing. (a) X-ray image for female right knee (total knee) replacement (femur, F; tibia, T). (Courtesy Patricia Murr.) (b) and (c) Software models of MATERIALISE dode-thin element geometries; (c) is rotated 45° relative to (b) about the stem-rod axis. The mesh array is fabricated around a fully dense Ti-6Al-4V centre rod. (d) Increasingly dense mesh array stems corresponding to (from right to left) densities of 0.86, 1.22 and 1.59 g cm$^{-3}$, respectively.
Figure 16. 3S software bone unit cell and model for a 5 mm cell dimension prototype. (a) Cubic bone (S3) unit-cell structure. (b) Corner section of three-dimensional model. (c) View of bone cell down corner axis, producing hexagonal symmetry unit. (d) Full model. (e) Corner view (diagonal plane) for bone element in (a).
Figure 17. (a,c) 3S bone element software models for 4 and 5 mm unit cell sizes, respectively, along with (b,d) views of EBM-fabricated 5 mm prototype monoliths.

Figure 19c shows a CAD cross section for figure 19b. Similarly, figure 20 shows three Ti-6Al-4V EBM-fabricated foam prototypes (from the structures shown in figure 19) whose measured properties are illustrated in table 4, for comparison with those given for reticulated mesh arrays in tables 1–3.
Table 3. Bone element cellular build sequence properties.\textsuperscript{a}

<table>
<thead>
<tr>
<th>element (cell) size (mm)</th>
<th>mass, $m$ (g)</th>
<th>density, $\rho$ (g cm\textsuperscript{-3})\textsuperscript{b}</th>
<th>relative density ($\rho/\rho_0$)\textsuperscript{c}</th>
<th>porosity (%)</th>
<th>resonant frequency, $f_r$ (kHz)</th>
<th>$E$ (GPa)</th>
<th>internal friction\textsuperscript{d} ($10^{-4}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>—</td>
<td>1.91</td>
<td>0.43</td>
<td>57</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>5</td>
<td>38.0</td>
<td>1.53</td>
<td>0.35</td>
<td>65</td>
<td>19.1</td>
<td>6.78</td>
<td>51.1</td>
</tr>
<tr>
<td>7</td>
<td>—</td>
<td>1.09</td>
<td>0.25</td>
<td>75</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

\textsuperscript{a}3S software.

\textsuperscript{b}Build volume: 2.3 \times 2.3 \times 3.6 (cm) = 20.74 cm\textsuperscript{3}.

\textsuperscript{c}$\rho_0 = 4.43$ g cm\textsuperscript{-3}.

\textsuperscript{d}$Q^{-1}$.

Examination of the implications for even more compliant and functionally complex bone inserts and orthopaedic devices implicit in figures 17–20 leads intuitively to prospects illustrated in figures 21 and 22. In figure 21, the reticulated 1.91 g cm\textsuperscript{-3} density 3S bone element mesh surrounds the 0.83 g cm\textsuperscript{-3} density cellular foam (table 4), whereas in figure 22 the 0.83 g cm\textsuperscript{-3} dense foam core is surrounded by the 1.06 g cm\textsuperscript{-3} dense foam. These arrangements can replace the stem design illustrated in figure 15 and the rod inset shown in figure 17.

Figure 23 shows a common but severe long-bone (femur) fracture repaired by a solid, fully dense, permanent, intramedullary rod fixture, whereas figure 24 illustrates a few commercial femoral hip stems, rod fixtures and orthopaedic replacement devices, including an extensively porous-coated femoral component. Figure 25, in comparison, illustrates the prospects for manufacturing patient-specific, complex, functional bone replacement devices that are not only mechanically compatible but also biologically accommodating in terms of allowing normal bone ingrowth and regrowth, vascularization and nutrient delivery, providing permanent, cementless orthopaedic replacements. Provision of an interconnected pore system with pore sizes greater than 100 \textmu m is generally required for cell penetration and vascular tissue growth (van Blitterswijk \textit{et al.} 1986; Schliephake \textit{et al.} 1991). This feature is readily achieved in the design and fabrication examples provided herein (figures 15, 17–23 and 25).

\textit{(c) Evaluation of stiffness and internal friction measurements: comparison with classic foam and open structure models}

The Gibson–Ashby model (equation (1.1)) was derived for cellular structures with relative densities typically below 0.3. On examining tables 1–4, it is apparent that, although the relative densities for all open cellular structures (including foams in table 4) vary from 0.12 to 0.43, the average relative density for all 12 different prototypes is 0.25, while the foam prototypes in table 4 average 0.16. Overall, these relative densities are well below those studied extensively in aluminium and aluminium alloys, where the exponent has varied from approximately 1.8 to 2.2. Plotting the relative stiffness (elastic modulus)
values \( (E/E_o) \), where \( E_o = 107 \) GPa from solid, fully dense Ti-6Al-4V tensile specimens, versus the relative densities for each EBM-manufactured prototype represented in tables 1–4 as illustrated in figure 26 results in values of \( n \approx 2.2–2.4 \) (equation (1.1)), slightly above the commonly accepted value of 2 (Gibson 2000). It is also interesting to note that, when the Young moduli in tables 1–4 are plotted against the prototype porosities (in per cent) (figure 27), the resulting curve

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Figure 19. CAD model showing build table set-up (a) and dual-functional, fabricated (3S bone element) cylindrical prototype of Ti-6Al-4V. (c) Software model half-section (cut-away view) for the mesh array in (b). Inner mesh density is $1.09 \ \text{g cm}^{-3}$, while outer mesh density is $1.91 \ \text{g cm}^{-3}$ (table 3). (b) Scale bar, 1 cm.

complements prior data for porous titanium (Esen & Bor 2007; Erk et al. 2008) as extended or extrapolated beyond 50 per cent porosity, but deviating from the Gibson & Ashby (1997) model and a similar model of Zhao et al. (1989).

It can be noted in figures 26 and 27 that the Ti-6Al-4V foams (table 4) deviate noticeably from the classic aluminium and aluminium alloy foams, but these foam prototypes have very high porosities in comparison (figure 2). Furthermore, from table 1, the G7 and G7r prototype mesh arrays exhibit a doubling of the stiffness for identical density, illustrating the significance of structural form.
Figure 20. Ti-6Al-4V cellular foam prototypes fabricated by EBM using the software models shown in figure 4 (table 4). (a) Three-dimensional views for increasing density from left. (b) Face views similar to model views in figure 4a and c. (a) Scale bar, 1 cm.

Table 4. Ti-6Al-4V cellular foam scan build sequence properties.

<table>
<thead>
<tr>
<th>pores/inch (ppi)</th>
<th>mass, m (g)</th>
<th>density, ρ (g cm⁻³)ᵃ</th>
<th>relative density (ρ/ρ₀)ᵇ</th>
<th>porosity (%)</th>
<th>bridge/strut thickness (mm)ᶜ</th>
<th>resonant frequency, fᵣ (kHz)</th>
<th>E (GPa)</th>
<th>internal friction (10⁻⁴)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>12.1</td>
<td>0.58</td>
<td>0.13</td>
<td>87</td>
<td>0.9</td>
<td>12.9</td>
<td>1.29</td>
<td>20.3</td>
</tr>
<tr>
<td>6</td>
<td>14.1</td>
<td>0.68</td>
<td>0.15</td>
<td>85</td>
<td>1.0</td>
<td>14.4</td>
<td>1.35</td>
<td>5.9</td>
</tr>
<tr>
<td>8</td>
<td>17.2</td>
<td>0.83</td>
<td>0.19</td>
<td>81</td>
<td>1.1</td>
<td>9.4</td>
<td>0.48</td>
<td>9.0</td>
</tr>
<tr>
<td>10</td>
<td>—</td>
<td>1.06</td>
<td>0.24</td>
<td>76</td>
<td>1.5</td>
<td>—</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

ᵃVirtual volume: 20.74 cm³.
ᵇρ₀ = 4.43 g cm⁻³.
ᶜAverage measured on build and CAD.
ᵈQ⁻¹.

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or geometry. Generally, also it is observed that the non-deformation (RFDA) measured stiffnesses tend to be significantly less than the deformation measured (by compression stress–strain testing) stiffness. For example, we measured $E \approx 1.4$ GPa in compression for the cross-1 element built prototype in Table 1 in contrast to $E = 0.58$ GPa. However, the variance of build elements and prototype geometries tend to follow a consistent slope as shown in figure 26. Figures 26

Figure 21. Software (CAD) models incorporating an inner foam element and an outer S3 bone element. (a) Three-dimensional, (b) three-dimensional half-section and (c) end views, respectively.
Figure 22. Software models incorporating different density inner and outer foam elements as in figure 21. (a) Three-dimensional, (b) three-dimensional half-section and (c) end views, respectively.

and 27 indicate significant prospects for bone mechanical compatibility as well as unique implant features for reticulated mesh arrays, or cellular foam structures, and functionally complex conditions that can allow for highly efficient tissue and vascular ingrowth.

Internal friction refers to the capacity of a solid to convert mechanical energy of vibration into internal energy, causing damping of a vibrating solid. While internal friction has been recognized for more than half a century, there is no satisfactory internal friction theory (Blanter et al. 2006). Since internal friction
measures resistance to shearing, it can be considered a solid-state viscosity. Since shearing in solids involves defects of various kinds, internal friction reflects these phenomena in complex ways. Considering the elastic energy at maximum strain ($W$) and the energy dissipated per stress cycle ($\Delta W$), $\Delta W/W$ gives a measure of the damping capacity of the solid. The internal friction is then defined by the inverse mechanical $Q$ factor,

$$Q^{-1} = \frac{\Delta W}{2\pi W}.$$  

While there is no clear correlation observed for $Q^{-1}$ in tables 1–4, the internal friction increases with increasing strut hardness (HV) as shown in table 1 for the variations in build element geometries. Since the hardness increase is associated with refined $\alpha'$-martensite and possibly dislocation density variations (figures 10–13), this may reflect deformation phenomena in these reticulated mesh arrays. Correspondingly, since yield stress values determined from 0.2 per cent offset from compression stress–strain curves for metallic foams can be predicted, using the Gibson–Ashby model (Gibson & Ashby 1997)

$$\frac{\sigma}{\sigma_o} = C \left( \frac{\rho}{\rho_o} \right)^{3/2},$$  

Figure 23. X-ray image examples of (a) right femur complete fracture (arrow) in for an 18-year-old motorcycle accident patient and (b) the corresponding bone union with intramedullary rod inserted (after 18.8 months recovery time). Adapted from Ferracini et al. (2008).
where $\sigma_o$ and $\rho_o$ denote the yield strength and density for the fully dense metal, and $C$ is a scaling factor typically near 0.3, but ranging from 0.1 to 1.0 (Ashby et al. 2000). Of course, in the absence of yield stress data, we cannot check this correspondence for the reticulated mesh arrays (tables 1–3).

4. Summary and conclusions

AM–EBM is an enabling technology described and illustrated in this work, which has enormous potential for the direct fabrication of complex, functional and fully compatible metal custom or patient-specific prostheses, including dental

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implants, craniofacial or maxillofacial implants, orthopaedic implants, etc. from computer software models and CT scan data. While we have demonstrated these issues for Ti-6Al-4V, the software design models can be fabricated by AM for any available metal or alloy powder, including Co-26Cr-6Mo, various stainless steels or Ta and Ta alloys such as Ta–Ti, which has been demonstrated to have unique microstructural features and to be biocompatible (Trillo et al. 2001; Villa et al. 2002).

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Figure 26. Relative stiffness ($E/E_0$) versus relative density ($\rho/\rho_0$) for all the open cellular and reticulated prototypes illustrated in tables 1–4. The solid line is fitted to data in table 2. The dashed line is fitted to all data in tables 1–4. Square, table 1; filled circle, table 2; triangle, table 3; and open circle, table 4.

Figure 27. Elastic modulus ($E$) versus porosity for all the open cellular and reticulated prototypes illustrated in tables 1–4. Square, table 1; filled circle, table 2; triangle, table 3; and open circle, table 4.

Systematic and various geometrical arrays of cellular, reticulated mesh and open cell foams with interconnected porosities have been manufactured in complex, functional, monolithic structures, which may allow for unique,
Next-generation biomedical implants. These complex arrays (in particular, open cellular foams of Ti-6Al-4V) have been manufactured in monolithic form for the first time and have the potential for unique bone compatibility as well as the accommodation of more natural bone tissue ingrowth, including vascular system development. Microstructural examination and mechanical testing have illustrated the harder, $\alpha'$-martensite to dominate these structures in contrast to acicular $\alpha$-phase microstructures common in fully dense monoliths. The stiffnesses (elastic moduli) of these cellular arrays vary with the density or porosity in a reasonable emulation of the classical Gibson–Ashby model (Gibson & Ashby 1997), demonstrating stress-shielding prospects and density matching of bone. While we have measured the internal friction for these cellular prototypes, there was only limited correlation with strut element hardness and strength.

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References


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