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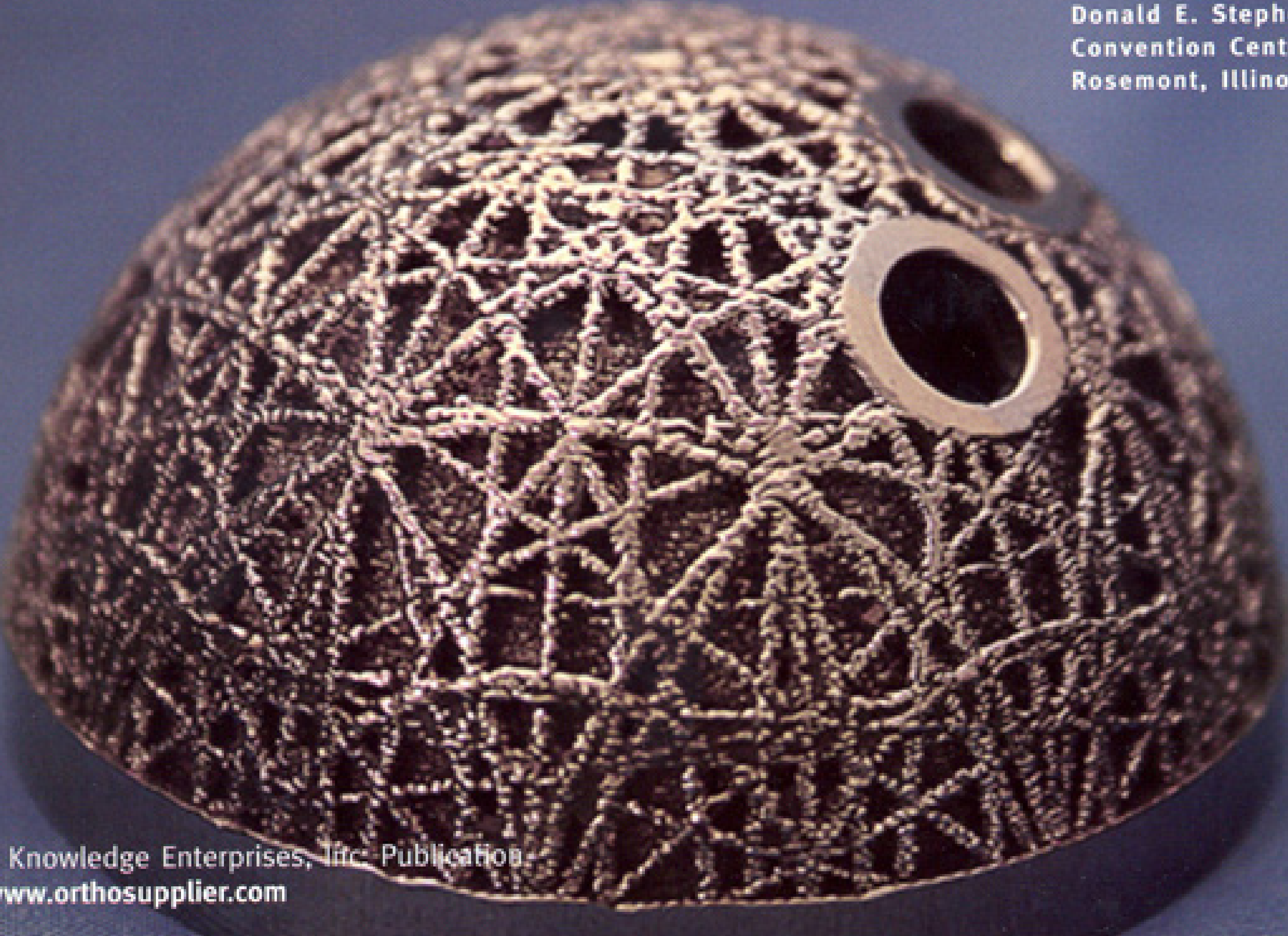

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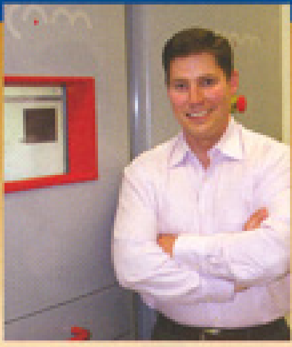


An Introduction to Electron Beam Melting with Ti6Al4V-ELI for the Orthopaedic Device Industry

Manufacturing of both off-the-shelf and custom orthopaedic devices is classically known as a material- and labor-intensive process. For safety and longevity purposes, materials utilized in orthopaedic applications are required to meet stringent performance criteria. As a result, the use of high strength materials that are typically difficult to process is necessary. Certain implant applications call for low-volumes or custom production, something that is not well adapted to today's manufacturing techniques. The deviations from standard processing techniques necessary to produce short run devices or devices designed for an individual patient can make such implants unprofitable loss-leaders for device manufacturers.

With the trend for more efficient and flexible metal manufacturing comes a new technique called Electron Beam Melting (EBM). EBM is a relatively new manufacturing method capable of producing fully-dense metal parts. Pioneered by Arcam AB, the EBM technology relies on use of a high power electron beam to provide the energy necessary to melt powdered metal in an additive, layered fashion. Taking a file directly from a CAD environment to a fully dense titanium part is now a possibility, eliminating the need for expensive processes such as tooling, machining, forging, casting and their associated long lead times. Typical parts can be taken from the designer's desk to a solid metal part in a matter of hours or days instead of weeks to months. The agility of this manufacturing method allows freedom and cost-effectiveness for low-run parts that has not been seen before.

The EBM Process starts by distributing a 100 µm layer of fine metal powder on a steel platform. An electron beam scans areas as defined by the computer model, fully melting the powder in the areas scanned, after which the steel platform is lowered by 100 µm and a new layer of powder is distributed on top of the previously melted layer. This process continues, layer by layer, until a complete part is produced. Figure 1 shows the machine used in the EBM process.

Figure 1: The Electron Beam Melting manufacturing method is carried out using a high power electron beam and a strong vacuum, ensuring fast throughput and reliable chemical specifications for Ti6Al4V-ELI parts. (Courtesy Arcam AB)

The powder used has been produced by a gas atomization process and contains particles ranging from 45 µm to 100 µm in diameter. The EBM process has been shown to produce quality parts using powders produced by other processes, such as plasma rotating electrode processing. Although this article focuses on the production of Ti6Al4V-ELI parts, the EBM technology has been applied to the production of cobalt-chrome alloy as well.

The melting and forming of titanium parts mandates that this be done in a vacuum chamber, which also minimizes chemical reactions between the melting metal powder and the surrounding atmosphere. This feature is extremely beneficial in producing objects out of Ti6Al4V-ELI material, because the low levels of interstitial elements such as O, N and H can be controlled during production.

In a recent study, several material properties were examined in order to confirm that EBM-produced material meets the per-

Figure 2: A hip stem produced by the EBM manufacturing process. (Courtesy Medical Modeling LLC)

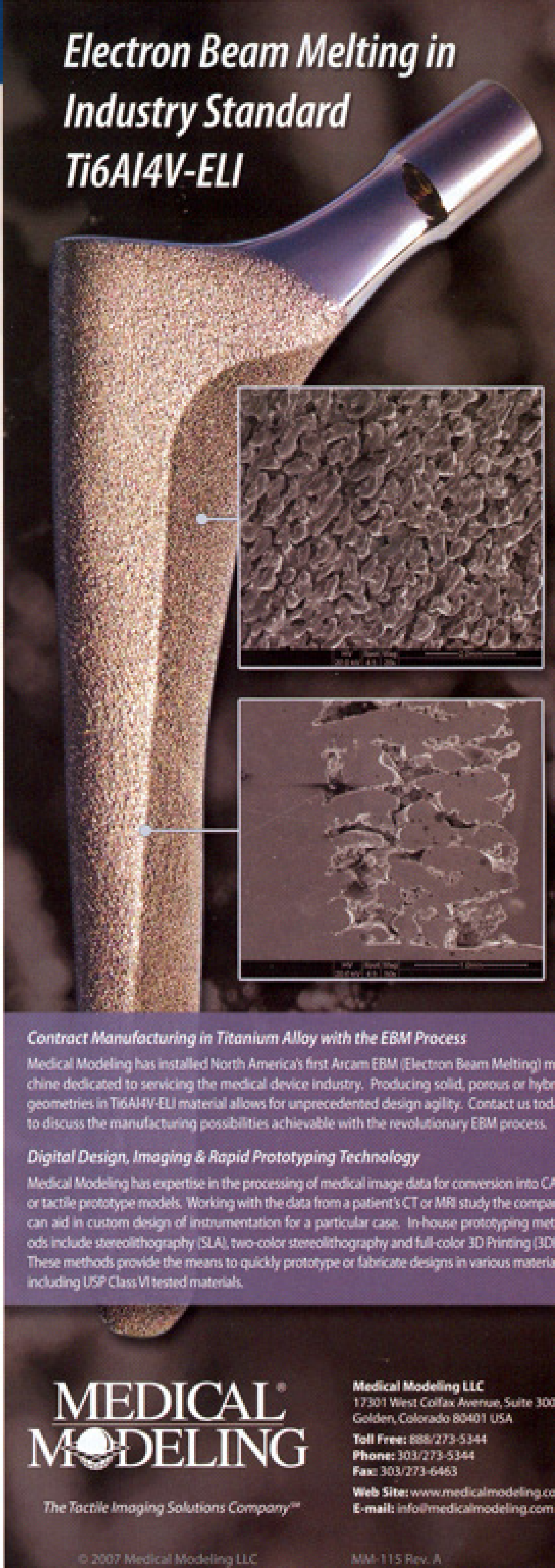
formance criteria currently used for orthopaedic implants. Chemical composition, microstructure and tensile strength were chosen because they are specified in the ASTM standards used to regulate orthopaedic implant materials. Fatigue behavior was also examined because it is one of the key performance requirements for orthopaedic implant applications. Table I lists properties for EBM produced parts as manufactured by Medical Modeling LLC as well as the property requirements for the two principal ASTM specifications applied to Ti6Al4V materials for orthopaedic implants. Mechanical properties shown for parts produced at Medical Modeling are on test specimens that have been through a hot isostatic pressing (HIP) cycle following production and prior to testing.

Table I: Metallurgical Property Comparison

	EBM Produced Ti6Al4V-ELI	**ASTM 1108 Investment Cast Ti6Al4V**	**ASTM 136 Wrought Ti6Al4V-ELI**
Chemical Composition			
Al (wt %)	5.74	5.5-6.75	5.5-6.5
C (wt %)	0.014	0.10 max	0.08 max
Fe (wt %)	0.073	0.30 max	0.25 max
H (wt %)	0.0011	0.015 max	0.012 max
N (wt %)	0.035	0.05 max	0.05 max
O (wt %)	0.12	0.20 max	0.13 max
Ti (wt %)	Balance	Balance	Balance
V (wt %)	3.9	3.5-4.5	3.5-4.5
Mechanical Properties			
Yield Strength (MPa)	820	758	795
Tensile Strength (MPa)	913	860	860
Elongation (%)	17	8	10
Fatigue Limit (10^7 cycles)	550-600 MPa	N/A	N/A

There are many manufacturing methods and processes capable of producing implant devices from Ti6Al4V-ELI material. The most prevalently used manufacturing methods for producing these devices include:

continued on page 16



Electron Beam Melting, continued from page 14

1) Investment cast shapes from raw material ingot
2) Forged shapes from wrought bar, and
3) Machined shapes from wrought bar or plate product

The EBM method of manufacturing represents a 4th method of a near net shape configuration for production of an orthopaedic implant device. Table II shows a comparison between these four near net shape processes in the manufacture of an implant device. The flexibility and speed of the EBM process open up application possibilities in the orthopaedic implant industry that would have previously been unachievable. These span applications for off-the-shelf as well as custom implants and associated instrumentation and include:

Short Run Implants of Low or High Complexity

TABLE II: Comparison of 'Near Net Shape' Manufacturing Processes for Orthopaedic Devices

	Investment Casting	Forging	Machining	EBM
Microstructure	Course acicular • , thick prior beta grain boundaries	Dependent on processing parameters. No beta grain boundaries.	Dependent on processing parameters. No beta grain boundaries.	Fine acicular • , thin prior beta grain boundaries. Slightly elongated prior beta grains.
Strength	Adequate strength	Typically highest strength	High strength	Moderate-high strength
Tooling Requirements	Initial High Cost – Long Lead Times	Initial High Cost – Long Lead Times	Initial Moderate Cost – Moderate Lead Times	No Cost –No Lead Time – Minimal Programming
Process Intensity & Lead Time	Multiple Operations – Very Labor Intensive	Moderate Operations – Fast Production	Moderate Process Time – Minimal Labor	Moderate Process Time – Minimal Labor
Product Surface Finish – for further processing	Fine 'orange peel' finish – gate removal grind	Fine smooth finish – flash parting-line removal grind	Moderate machine finish – deburr grind removal	Course ripple finish – fixture support removal
Porous Coating Application	Added Processing Time – retain adequate strength	Added Processing Time – lose high strength w/ some coatings	Added Processing Time – lose high strength w/ some coatings	No Added Processing Time – retain strength

With the ability to quickly "print" any combination of parts within the same processing batch, the EBM process is capable of producing any number of implants with varying shapes and sizes with a short lead time. Since no part-specific production tooling is needed in the EBM process, there is no additional cost or change-over time associated with switching between part models or sizes. This feature of the process makes it ideal for producing short run, low volume implant parts. It allows the manufacturer to produce these low volume parts on an as needed basis with more favorable costs and lead times.

Off-the-Shelf Implants of Highly Complex Form

Several applications for highly complex implants produced in titanium alloy are actually cast as opposed to machined because of their difficult to manufacture shapes. As tested, EBM parts have better mechanical properties when compared to the standards for investment cast titanium parts. This benefit combined with the ability to make very complex shapes makes EBM an

Figure 3: Acetabular cup produced in Ti6Al4V-ELI showing a complex backing design. (Courtesy Medical Modeling LLC)

interesting manufacturing process for complex, freeform implant geometries, such as seen in Figure 3.

Off-the-Shelf Implants with Integrated Porous Coating

EBM manufacturing offers a unique approach to porous coating by allowing for singularly formed components with an integrated ingrowth surface area. Traditional application of porous coatings can be detrimental to the material properties of the implant and may lead to problems at the interface such as shedding of the porous surface. By having the porous structure completely integrated at the time of implant manufacturing, this issue is avoided. The elimination of complex secondary coating processes decreases lead-times and overall production costs. The process also allows the manufacturer to produce devices with porous structures in areas that are typically difficult or impossible to coat using traditional techniques.

Off-the-Shelf Porous Lattice Structures

When a design calls for reduction in the volume of titanium to be used or for purposes of tissue ingrowth, a roughened or porous surface structure can be produced with EBM. Applications for this technology stretch beyond standard components such as spinal cages and may be an ideal, low weight, high strength scaffold structure for graft materials, such as that seen in Figure 4.

Custom Implants, Trials and Osteotomy Guides

Patients requiring revision arthroplasty or oncologic resection of large areas of bone often benefit from custom-fit prostheses. The EBM manufacturing technique offers a "direct from CAD" method of production with industry standard Ti6Al4V-ELI. Literally within the same machine process batch, the implant, trials and other associated instrumentation can be manufactured simultaneously. Time and cost are also affected in a positive way due to fast part processing and less scrap material as compared to traditional titanium implant manufacturing techniques.

The Electron Beam Melting process has been proven to produce fully-dense titanium alloy parts that meet ASTM specifications

Figure 4: Model of the spine showing a lattice cage implant produced using the EBM manufacturing technique. (Courtesy Medical Modeling LLC)

for the orthopaedic implant industry. Interesting applications for hybrid porous coatings or fully-porous structures may allow for construction of parts too difficult to manufacture in the past. The technology has distinct advantages for short run and custom projects and should be considered a fourth method for production of near-net-shape implants. Design iterations can also be quickly accommodated for short run or custom instrumentation, allowing for greater manufacturing agility. By allowing direct production from the CAD environment a number of advantages are seen, including reduction in tooling, time and ultimately cost.

Medical Modeling LLC is a medical rapid manufacturing service bureau. Mr. Christensen has worked in the medical device industry since 1992 and participated globally in thousands of patient cases where "tactile imaging" models have been used for surgical planning, implant design and surgical navigation. Mr. Christensen has written extensively about the use of this technology within the medical field. He is a contributor to the Rapid Prototyping and Tooling State of the Industry Report, published annually by Wohlers Associates, and his interests lie in medical applications of RP&M, biomaterials research, conjoined twins and strategies for surgical separation, image processing and prosthetic design. Andy can be reached at andy@medicalmodeling.com.

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