Additive manufacturing of metallic alloys and its medical applications

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Introduction

The term ‘3D printing’ received worldwide attention following an article published by The Economist in April 2012.

In this article a third industrial revolution was predicted, made possible by the virtue of layer-by-layer additive manufacturing technology.

According to this article, in the near future, moulds and casting or costly machining of parts and products will not be longer required. Using 3D printing on demand and on location production could be done in the vicinity of the end user.

The software that drives the machines allows for designs to precisely meet the demands of the user.

Unused material is saved and used for the next production run, resulting on less waste and less pollution. Also, in large scale factories of the (near) future, digitisation will have a disruptive effect.
“...it will allow for things to be made economically in much smaller numbers, more flexibly and with much lower input of labour” (The Economist, 2012).

New materials, new processes such as 3D printing, automation and machine-to-machine talk and new collaborative manufacturing services will bring to a more efficient the production process online.
Additive Manufacturing (AM) technologies have been increasingly adopted to produce near-net-shape metal parts in small batches, i.e. in the biomedical field to produce tailored surfaces with osseo-integration capabilities.

Semi-finishing and/or finishing machining operations are still required to obtain adequate geometrical tolerances and surface characteristics on functional surfaces.
Introduction

3D service, products and materials market

Expected growth rate of 30%


3D Printer installed

CAGR: 95%

# of unit installed in k

2012

2017E
Currently metal AM is not a process for the basic mass production of millions of identical parts.

However, some applications, for example dental restorations, really tap the full potential of AM.

In this highly individualised production process it is economically viable to use AM technologies, speeding up the production time without in inflating the costs per part. AM advantages come from its extremely high flexibility due to the product being produced directly from a CAD model without the need for tooling.
Direct process **powder-bed systems** are known as **laser melting processes** and are commercially available under different trade names such as **Selective Laser Melting** (SLM), **Laser Cusing** and **Direct Metal Laser Sintering** (DMLS). The only exception to this process principle is the Electron Beam melting (EBM) process, which uses an electron beam under full vacuum.

The melting process is repeated slice by slice, layer by layer, until the last layer is melted and the parts are complete. Then it is removed from the powder bed and post processed according to requirements.
Today AM systems

- Direc Metal Laser
  - Sintered DMLS
- Direct Metal Laser
  - Sintering + Heat Treatment
- Electron Beam
  - Melted EBM
- Acicular α'
  - (martensite)
- Lamellar α + β
- Wrought
- Acicular α + β
- Recrystallized equiaxed α + β
Today AM systems

Although **powder-fed** systems use the same feedstock, the way the material is added layer by layer differs notably. The powder flows through a nozzle being melted from a beam right on the surface of the treated part.

Powder-fed systems are also known as *Laser Cladding, Directed Energy Deposition* and *Laser Metal Deposition*. The process is highly precise and based on an automated deposition of a layer of material with a thickness varying between 0.1 mm to several centimetres. The metallurgical bonding of the cladding material with the base material and the absence of undercutting are some features of this process. The process is dissimilar to other welding techniques in that a low heat input penetrates the substrate.
Metrology needs for Additive Manufacturing Powders

Powders for AM are typically tens of micrometers in size, and have morphologies that are generally spherical, although a given batch of powder may include many instances of non-spherical or quasi-spherical morphologies.

A given batch of powder, particularly for AM powder-bed systems, needs to have a distribution of sizes so as to allow for better packing (e.g., higher packing densities) if it is to be used in a powder-bed AM system.

These distributions are not always rigorously optimized for a given powder, and the interaction between this size distribution and a given AM process has not been quantified and could have significant effects.
Metal powders for AM

<table>
<thead>
<tr>
<th>Material</th>
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<tbody>
<tr>
<td>Aluminium Alloys</td>
<td></td>
</tr>
<tr>
<td>AlSi10Mg</td>
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<tr>
<td>AlSi7Mg</td>
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<tr>
<td>AlSi12</td>
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<tr>
<td>Cobalt Based Alloys</td>
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<tr>
<td>ASTM F75</td>
<td>2.4723</td>
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<tr>
<td>CoCrWC</td>
<td></td>
</tr>
<tr>
<td>Tool Steels</td>
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</tr>
<tr>
<td>AISI 420</td>
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<td>1.2709</td>
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<tr>
<td>H13</td>
<td>1.2344</td>
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<tr>
<td>AISI D2</td>
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<tr>
<td>AISI A2</td>
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<tr>
<td>AISI S7</td>
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<tr>
<td>Inconel 713</td>
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<td>Stainless Steels</td>
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<td>SS 410</td>
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<td>17-4 PH</td>
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<td>Ti6Al4V</td>
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<td>Ti6Al4V ELI</td>
<td>3.7165 ELI</td>
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<td>TiAl6Nb7</td>
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<td>Precious Metal Alloys</td>
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<td>CC 480 K</td>
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</table>

**Metallic materials which can be manufactured for AM**

- stainless steels
- aluminium
- nickel
- cobalt-chrome
- titanium alloys

Currently, the main powder suppliers for AM are the system manufacturers, but this is expected to be a fast rising market for newcomers and well established powder manufacturers.
Metal powders for AM

Material properties such as tensile strength, hardness and elongation, are important and often used as reference points for the decision about the right material.

Different alloys in an extensive range of yield strengths. This diagram can help the user to pick the appropriate material depending on two mechanical characteristics. The values for the yield strength have been taken from the manufacturer’s data sheets and represent the minimum measured values.
Typical AM products for implants

- Acetabular cups
- Femoral stems
- Tibial plates
- Femoral knee parts
- Components for spinal surgery
- Dental screws
- Cranial plates
- …
Qualified materials for implants

• Ti6Al4V, CoCrMo, 17-4PH and Titanium grade 4
• In agreement with applicable standards for medical market
• Oxygen content of the melted Ti6Al4V acceptable

<table>
<thead>
<tr>
<th></th>
<th>Ti6Al4V EBM</th>
<th>Ti6Al4V laser</th>
<th>ASTM F3001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yield (MPa)</td>
<td>830±7</td>
<td>935±12</td>
<td>&gt;795</td>
</tr>
<tr>
<td>UTS (MPa)</td>
<td>914±10</td>
<td>1073±4</td>
<td>&gt;860</td>
</tr>
<tr>
<td>ΔL (%)</td>
<td>13.12±0.41</td>
<td>12.00±0.18</td>
<td>&gt;10</td>
</tr>
<tr>
<td>Bending fatigue limit @2*10^6 cycles (MPa)</td>
<td>441±42</td>
<td>440±53</td>
<td>445±7*</td>
</tr>
</tbody>
</table>

*ASTM F3001 does not indicate a fatigue limit, this value was found using specimens machined from a bar wrought and annealed
To evaluate a net structure several tests can be used:

- Optical and SEM observation: for the topography characterization (as ex. pores dimension and fraction.)
- Mechanical tests as ex. compression, tensile, bending, fatigue etc.
In general:

- Adhesion - more than 40 MPa (in general > 75 MPa)
- Pores size - ≥ 200 μm
- Compression - more than 80 MPa
• The smallest pores and struts can be about 200 μm and even less
• Porous structure cleaning represents a limit to take care during structure design
• Surface grip can be also modeled and tailored
A first step of cleaning (blasting) is essential to significantly reduce the potential risk of particles loosening.
Surface cleaning: cleaning and modification of the porous layer surface

Further cleaning steps may be applied for removing more beads and modifying the struts surface.
Surface cleaning: cleaning and modification of the porous layer surface

Results may however be dramatically different for some other topographies:

If lattice structures are not well designed, it is almost impossible to clean them properly.

BAD DESIGN

GOOD DESIGN
Medium/long term implications of additive manufacturing?

In many regards, it is a technology that is still in its infancy and it represents a very small segment of manufacturing overall.

That small segment is growing quickly....
Custom medical devices fabricated with additive manufacturing

Additive manufacturing is also being used for the direct creation of custom medical devices.

An often referred to example is the additive manufacturing of custom fitted in the ear hearing aids.

These devices would have been manually created by a skilled technician, but now waxy impressions are made of the patient’s outer ear and three dimensional scanning is used to digitize the impression and the resulting CAD models is modified to accommodate internal circuitry. The models are then sent to an additive manufacturing machine for printing and delivery to the individual customers after the electronic components are installed.
Additive manufacturing of orthopedic implants

With the recent improvements in direct metal additive processes like electron beam melting and selective laser sintering as well as the availability of some biocompatible plastics for additive manufacturing, there has been a great deal of interest in the direct fabrication of patient specific medical and implant devices.

Ti alloys are available for many direct metal additive processes and is often used in medical applications because of their biocompatibility.

One of the primary barriers to the practical implementation of direct metal additive manufacturing technologies has been attributed to the various regulatory agencies, particularly in the United States, but recently the US Food and Drug administration has approved the production of certain products fabricated using Arcam’s EBM process1. Several companies, including Adler Ortho S.r.l (Italy), have been manufacturing standard, commercial sizes of acetabular cups for hip replacement surgeries using the Arcam electron beam melting process.
Additive manufacturing of orthopedic implants

One of the primary this is that engineered lattice structures which can be optimized for the be incorporated and built into the parts.

Figure 5 Photographs showing several orthopedic implants fabricated using EB. (a) Acetabular hip cup with integrated bone ingrowth surface (photographs courtesy of Adler Ortho S.r.l, Italy). (b) Low stiffness hip stem implant optimized to promote bone ingrowth and reduce stress shielding. (c) Patient specific transcutaneous osseointegrated implant for the direct attachment of a prosthetic limb to the skeletal anatomy. The implants in B and C were fabricated at NC State University.
Additive manufacturing of orthopedic implants

Examples of commercially developed femoral hip, rod and stem devices. The middle stem is a fully porous-coated device.

*From www.disanto.com/images/hip%20parts.jpg; courtesy DiSanto, Inc.*
Additive manufacturing in tissue engineering

The flexibility in geometries and materials that AM accommodates coupled with precision computer control of the placement of those materials has given rise to a very interesting application: tissue engineering.

The layered nature of additive manufacturing facilitates the generation of complex tissue scaffolds. The scaffolds are often in the form of porous implants designed to provide structural support for seeded/deposited living cells.

The bounding geometry of the scaffolds themselves can be derived from patient specific wound or defect.
Conclusions

Additive manufacturing has enormous potential for the direct fabrication of complex, functional and fully compatible metal custom or patient-specific prostheses, including dental implants, craniofacial or maxillofacial implants, orthopaedic implants, etc. from computer software models and CT scan data.