New Considerations Regarding the Use of Selective Laser Sintering Technology for Biomedical Metallic Implants

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ABSTRACT

The functional and design capabilities of a metallic implant are important with respect to the metal's ability to be formed, machined, and polished. An implant metal must be capable of being utilized with state-of-the-art metallurgical techniques. In addition, the implant device must remain functional during its expected performance life; it must not be degraded with time in the body through fatigue, fretting, corrosion, or impact loading. Titanium and its alloys meet all of these requirements. The principles of design, selection of biomaterials and manufacturing criteria for orthopedics implants are, basically, the same as for any other product that must be dynamically stressed. However, even the replacement of human tissues with materials similar in shape and density seems tempting, in fact this is much difficult task to undertake. That is because the living tissue has some extraordinary characteristics including the capacity of remodeling both micro structural and macrostructural under the different directions loads.

Keywords: mechatronics, biomechanics, rapid prototyping, new materials and alloys, 3D modeling

INTRODUCTION

In this paper will be presented a new technology, using new materials especially designed for complex geometries, extensively used in research-development and innovation area. For this purpose, the paper will be focused on 3 major area of interest:
1. Presentation of the basic principles for the rapid prototyping technology, materials and capabilities.
2. A short display of the parts, industry sectors that can use this technology, future prospections.
3. The implementation of this technology on Biomechatronics field in National Institute of Research and Development for Mechatronics and Measurement Technique, Bucharest, Romania.
Metal parts directly from CAD data

EOSINT M 270 is a system for Direct Metal Laser-Sintering (DMLS). It builds metal parts directly on the basis of three-dimensional CAD data, fully automatically, without requiring any tools and in just a few hours. The parts are built up layer by layer by melting a fine metal powder using a laser beam, thereby allowing even extremely complex geometries to be created.

The ability to produce such parts very quickly enables flexible and economic manufacture of individual parts or batches, which in turn enables design or manufacturing problems to be identified at an early stage of product development and time to market to be shortened.

Figure 1. EOSINT M – Operating Sequence

EOSINT M 270 contains many features to ensure high productivity and part quality, for example:

- powerful Yb fibre laser (200W)
- variety of metal materials optimized for various applications
- building volume up to 250 mm x 250 mm x 215 mm (including building platform)
- high speed, high precision scanner with active cooling and home-in sensor
- F-Theta objective lens for precise laser beam focussing
- dual focus system for optimal combination of detail resolution and productivity
- optimised exposure strategies
- removable building platform for immediate reload

Figure 2. Examples of a wide range of biomedical prosthesis with a great variety of geometric shapes
EOSINT M – Advantages
- Net-shape metal parts created directly in one step; no binder removal, generally no post-machining;
- Very high geometric flexibility (e.g. free-forms, deep slots and curved cooling channels);
- Fully automatic operation, high productivity and low personnel costs; low level of training and experience necessary;
- Low material consumption; optimal usage of material, unsintered powder can be reused;
- Compatibility with other processes; parts can be milled, drilled, welded, etc.

Figure 3. EOSINT M – Operating Sequence

Categories of metal powders that can be used

This is only a short list, because constantly are developed new powders with increased mechanical, physical and thermal properties.

<table>
<thead>
<tr>
<th>Material name</th>
<th>Material type</th>
</tr>
</thead>
<tbody>
<tr>
<td>DirectMetal 20</td>
<td>Bronze-based mixture</td>
</tr>
<tr>
<td>DirectSteel H2O</td>
<td>Steel-based mixture</td>
</tr>
<tr>
<td>EOS MaragingSteel MS1</td>
<td>18 Mar 300 / 1.2709</td>
</tr>
<tr>
<td>EOS StainlessSteel 17-4</td>
<td>Stainless steel 17-4 / 1.4542</td>
</tr>
<tr>
<td>EOS CobaltChrome MP1</td>
<td>CoCrMo superalloy</td>
</tr>
<tr>
<td>EOS Titanium Ti64*</td>
<td>Ti6Al4V light alloy</td>
</tr>
<tr>
<td>EOS Titanium TiCP*</td>
<td>Pure titanium</td>
</tr>
</tbody>
</table>
Titanium alloys offer a unique combination of properties for many biomedical applications.

Summary of important biomedical properties:
- Excellent corrosion resistance, biocompatibility and bioadhesion;
- Titanium and its alloys are used for many biomedical and dental applications (implants, screws, crowns...).

<table>
<thead>
<tr>
<th>Property</th>
<th>Stainless steel</th>
<th>Titanium alloys</th>
<th>CrCo alloys</th>
<th>Nb/Ta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corrosion resistance</td>
<td>O</td>
<td>++</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>O</td>
<td>++</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Bioadhesion</td>
<td>O</td>
<td>++</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Price</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

Titanium alloys offer a unique combination of properties for many engineering applications.

Summary of important engineering properties:
- Light weight material with high specific strength (strength per weight)
- Ti6Al4V with high strength also at elevated temperatures
- The combination of mechanical properties and the corrosion resistance is the basis for applications in Formula 1 and aerospace.

Various grades of Titanium (alloys) are commonly used in industrial applications.
Table 2: Summary of the most important Ti materials

<table>
<thead>
<tr>
<th>Material name</th>
<th>Composition</th>
<th>Typical applications</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP Ti grade 1</td>
<td>Ti; O &lt;0.18%; N &lt;0.03%</td>
<td>Medical and dental</td>
</tr>
<tr>
<td>CP Ti grade 2</td>
<td>Ti; O &lt;0.25%, N &lt;0.03%</td>
<td>Medical and dental, chemical industry</td>
</tr>
<tr>
<td>CP Ti grade 3</td>
<td>Ti; O &lt;0.35%, N &lt; 0.05%</td>
<td>Medical and dental</td>
</tr>
<tr>
<td>CP Ti grade 4</td>
<td>Ti; O &lt; 0.40%, N &lt; 0.05%</td>
<td>Medical and dental</td>
</tr>
<tr>
<td>Ti6Al4V (grade 5)</td>
<td>Ti; Al 6%; V 4%; O &lt;0.20%, N &lt; 0.05%</td>
<td>Aerospace, motor sport, sports goods, medical and dental</td>
</tr>
<tr>
<td>Ti6Al4V ELI</td>
<td>Ti; Al 6%; V 4%; O &lt;0.15%, N &lt; 0.05%</td>
<td>Medical and dental</td>
</tr>
</tbody>
</table>

CP = commercially pure, ELI = extra-low interstitials

Examples of other possible future materials

EOS is developing micro-laser-sintering of metals in cooperation with 3D Micromac.

Figure 6. Example of micro-laser-sintering
Technology development:
— Micro-laser-sintering uses powder grain size typ. 1 - 20μm, layer thickness 1 - 5μm to achieve detail resolution <30μm
— Originally developed by Laserinstitut Mittelsachsen and licensed exclusively to 3D Micromac
— development cooperation between EOS and 3D Micromac
— EOS has exclusive sales rights
— Commercialization status
— currently R&D status with limited part-building possibilities
— further development towards commercialization is ongoing.

EOS has successfully produced parts in Inconel alloys on EOSINT M 270.

Description
— Material type
  - nickel-based superalloy, commonly used for high-temperature engineering applications such as aerospace turbine parts
— Alternatives
  - can in many cases be substituted by EOS CobaltChrome MP1
— Commercialization status
  - so far only in R&D
Figure 8. Example of new materials used

EOS has successfully produced parts in gold on EOSINT M 270.

**Description**

- **Material type**
  precious metal, used in various purities / alloys for jewellery, electronics and dental restorations
- **Alternatives**
  currently no comparable commercial material available for EOSINT M
- **Commercialization status**
  so far only in R&D

Figure 9. Example of new materials used (gold)
Various grades of Titanium (alloys) commonly used in industrial applications

Table 3. Mechanical properties of conventional barstock

<table>
<thead>
<tr>
<th>Material name</th>
<th>Tensile strength (*) [ MPa ]</th>
<th>Elongation at break (*) [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>CP Ti grade 1</td>
<td>240</td>
<td>24</td>
</tr>
<tr>
<td>CP Ti grade 2</td>
<td>345</td>
<td>20</td>
</tr>
<tr>
<td>CP Ti grade 3</td>
<td>450</td>
<td>18</td>
</tr>
<tr>
<td>CP Ti grade 4</td>
<td>550</td>
<td>15</td>
</tr>
<tr>
<td>Ti6Al4V (grade 5)</td>
<td>895</td>
<td>10</td>
</tr>
</tbody>
</table>

CP = commercially pure, ELI = extra-low interstitials
(*) Source: Euro-Titan Handels AG, Solingen, Germany

EOS Titanium - light alloy materials for prototyping and series production

Characteristics and applications
— Several versions will be available
  EOS Titanium Ti64 (Ti6Al4V)
  EOS Titanium Ti64 ELI (higher purity)
  EOS Titanium TiCP (commercially pure)
— Key characteristics
  lightweight
  high strength
  biocompatibility
— Typical applications
  aerospace and engineering applications
  biomedical implants

Figure 10. Comparative examples of parts developed that can be used on maxillofacial surgery
EOS Titanium Ti64 parts fulfil relevant industrial standards and relevant requirements.

Physical and chemical properties:

— Physical properties
  - Laser-sintered density: approx. 100 %
  - Only single pores
— Chemical properties
  - Laser-sintered parts fulfil requirements of ASTM F1472 (for Ti6Al4V) and ASTM F136 (for Ti6Al4V ELI) regarding maximum concentration of impurities
    - Oxygen < 2000 ppm or 1500 ppm
    - Nitrogen < 700 ppm
— Bioadhesion
  - Cell growth tested with good results

EOS Titanium Ti64 produces parts with excellent mechanical properties.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultimate tensile strength</td>
<td>approx. 1100 MPa</td>
</tr>
<tr>
<td></td>
<td>approx. 159 ksi</td>
</tr>
<tr>
<td>Yield strength (Rp 0.2 %)</td>
<td>approx. 1000 MPa</td>
</tr>
<tr>
<td></td>
<td>approx. 145 ksi</td>
</tr>
<tr>
<td>Young’s Modulus</td>
<td>approx. 120 GPa</td>
</tr>
<tr>
<td></td>
<td>approx. 17 msi</td>
</tr>
<tr>
<td>Elongation at break</td>
<td>approx. 8%</td>
</tr>
<tr>
<td>Hardness</td>
<td>approx. 450 HV = 45 HRC = 425 HB</td>
</tr>
</tbody>
</table>

Figure 11. Mechanical properties

Figure 12. Different types of spinal implants from EOS
EOS Titanium Ti64 produces fully dense parts with dendritic, martensitic grain structure.

**Metallurgy:**
Typically martensitic structure with grains growing from layer to layer
preferential Z orientation
grain size >> layer thickness

![Figure 13. Dendritic, martensitic grain structure](image)

EOS Titanium TiCP produces fully dense parts with very fine, uniform grain structure.

![Figure 14. Optical micrographs of laser-sintered EOS Titanium TiCP (commercially pure)](image)

EOS Titanium TiCP produces parts with excellent mechanical properties.

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ultimate tensile strength</td>
<td>approx. 557 MPa</td>
</tr>
<tr>
<td>Yield strength (Rp 0.2 %)</td>
<td>approx. 477 MPa</td>
</tr>
<tr>
<td>Young's Modulus</td>
<td>approx. 114 GPa</td>
</tr>
<tr>
<td>Elongation at break</td>
<td>approx. 32 ± 5 %</td>
</tr>
</tbody>
</table>

![Figure 15. Mechanical properties](image)
Main site installation

Due to its high reactivity, EOS Titanium is processed on a special version of EOSINT M 270.

System requirements:
Hardware and software requirements
- argon atmosphere from external bottles
- cylindrical radial-flow nozzle in process chamber
- additional safety features
- special version of PSW to control additional features
- titanium building platforms
(Source: EOS).

EOSINT M 270 Titanium Version

![Figure 16. EOSINT M 270 Titanium Version](image)

1 Machine
2 Anti-static mat
3 Indicator
4 Fire extinguisher

A Waste gas filter system connection
(640 mm above floor)
B Wet separator connection
(320 mm above floor)
C Power connection
(740 mm above floor)
D Compressed air connection
(250 mm above floor)
E Network connection
Main advantages of rapid prototyping technology

Finally, to name just a few of the key advantages of this technology:
- no tooling or part-specific tools required
- no tool path generation or design of EDM electrodes necessary
- metal parts created directly in one step
- simple, fully automatic operation
- complex geometries such as freeforms, deep slots and conformal cooling channels can be produced without additional effort
- unsintered powder can be reused, giving minimal waste.

CONCLUSIONS

The functional and design capabilities of a metallic implant material are important with respect to the metal's ability to be formed, machined, and polished. An implant metal must be capable of being utilized with state-of-the-art metallurgical techniques. In addition, the implant device must remain functional during its expected performance life; it must not be degraded with time in the body through fatigue, fretting, corrosion, or impact loading. Titanium and its alloys meet all of these requirements.

Many different kinds of parts have been built in EOS Titanium Ti64.
The principles of design, selection of biomaterials and manufacturing criteria for orthopedics implants are, basically, the same as for any other product that must be dynamically stressed. However, even the replacement of human tissues with materials similar in shape and density seems tempting, in fact this is much difficult task to undertake. That is because the living tissue has some extraordinary characteristics including the capacity of remodeling both microstructural and macrostructural under the different directions loads.

Orthopedics will emerge as the single most promising source of future investor returns in healthcare, given the confluence of demographics, technology and global expansion. While other healthcare sectors such as cardiovascular devices, cancer or biotech may have been more lucrative in the past, what the American Association of Orthopedic Surgeons (AAOS) calls the "Decade of Orthopedics" provides the best opportunity for future investor profits in healthcare.
A number of elements will create this opportunity for the next ten years:
- Increased life expectancies, which is a powerful demand driver that uniquely favors orthopedic devices.
- Technological innovation, which will change the entire complexion of the industry.
- Attractive industry economics and profitability.
- Combined, these elements will cause the industry to grow more than twofold, from $30 billion per year to $65 billion in the coming decade, resulting in as much as $40 billion of potential investor profits.

This combination of factors supports sustained, attractive industry valuations. We must understand that science and innovations are keys to SUCCESS.

REFERENCES


[7] Euro-Titan Handels AG, Solingen, Germany