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Bio-Materials that can be used for 3D printed Medical Implants

Part 1: Metallics

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WHITE PAPER

CONTENTS

Introduction
The use of biomaterials for implants

Currently, around 70-80% of the clinically used implants are made from metallic materials (Ni et al., 2019), such as:

- Stainless steel
- Cobalt chromium alloys
- Titanium alloys
- Nitinol
- Tantalum
- Niobium

The research and development of biodegradable metals such as; magnesium, iron, zinc and calcium for orthopaedic and cardiovascular biomedical applications has emerged over the last decades, mainly due to their superior mechanical properties compared to biodegradable polymers (Eli Aghion, 2018).

However, in vivo results of such metals indicated major complications, such as corrosion performance and degradation rate, limiting their structural capabilities for biodegradable implant applications (E. Aghion & Levy, 2010; Cheng et al., 2013).

Another reason for new material and manufacturing developments is the mismatch between a metallic implant and bone, which results in stress shielding and consequently bone resorption and failure of the implant (España et al., 2010).

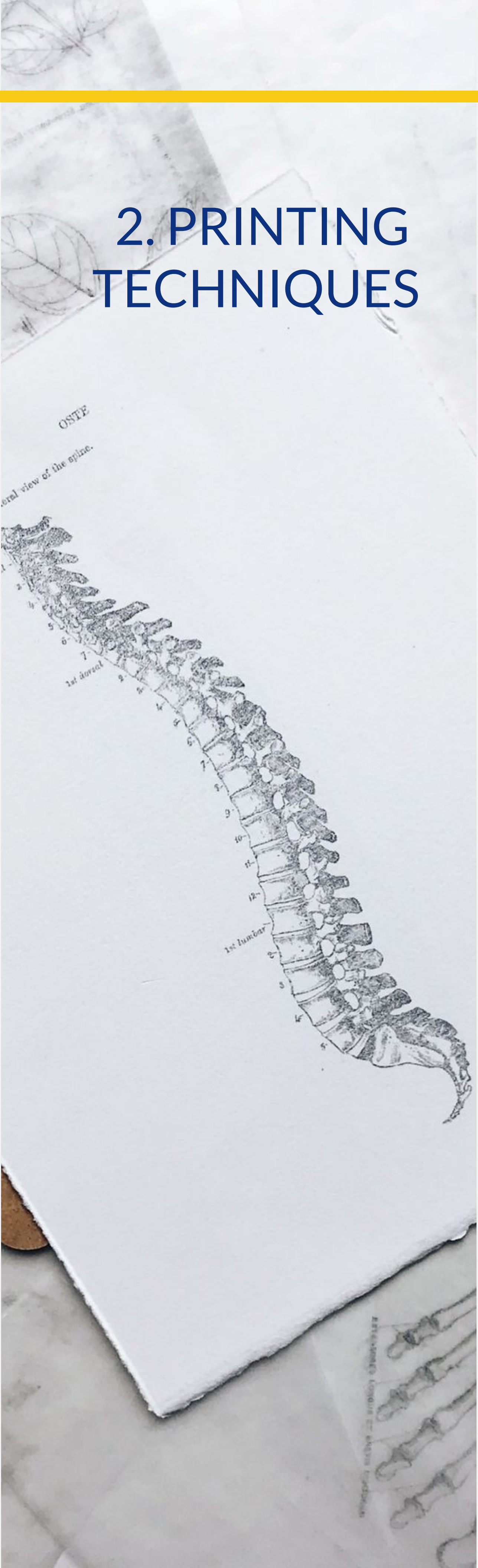
With 3D printing it is possible to design and manufacture complex internal and external structures, which are otherwise not possible with conventional manufacturing methods. Therefore, it is possible to control the implant's porosity and mechanical properties and ultimately reduce the effect of stress shielding between bone and implant.

Abstract

In the design process of medical implants, the choice of the manufacturing material is essential to meet safety requirements, biocompatibility and sterilization requirements. This document contains an overview of suitable 3D printed bio-metals in the orthopedic field.

This report includes the mechanical properties like Young's modulus, elongation and tensile and yield strength.

The created bio-metals database can potentially be used as a guideline for the design and manufacturing of a variety of 3D printed orthopedic implants and is an important step in the design process of Permanent 3D-Printed implants, the design of spinal implants, but also as an input for optimised design of implants.



2. PRINTING TECHNIQUES

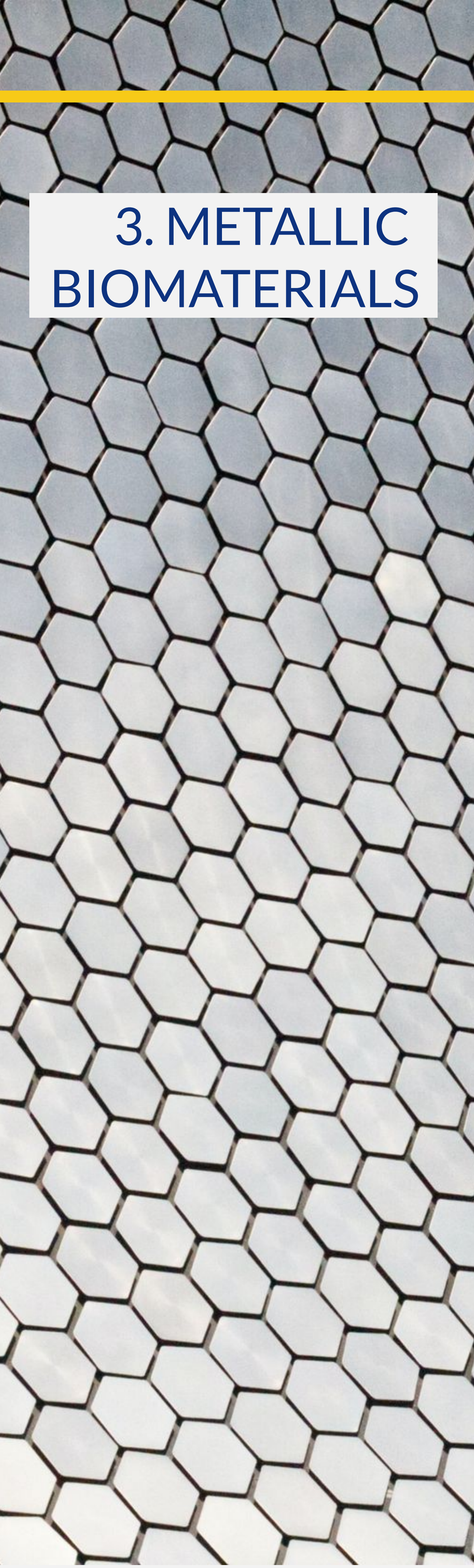
3D Printing is a very promising technique for the mass production of patient-specific medical implants. There are several Additive Manufacturing (AM) processes available for printing bio-metals for biomedical applications, including liquid state processing, solid processing, electro depositioning and vapour depositioning. AM processes are affected by a large group of process parameters such as; power, scan speed, scan strategy, hatch spacing and layer height. Furthermore, the powder choice is also essential in the interaction between the laser or electron beam and the powder bed concerning absorptivity, physical properties, particle size and shape. Also, the heat dissipation during the printing process is likely to affect the properties of the finished product.

Currently, the spot size for laser and electron beams is 50-100 μm and 200 - 400 μm with a suitable powder size of 20 – 50 μm and 50 – 100 μm, respectively (Qin et al., 2019). Layer thickness will vary between 20 – 80 μm and 100 μm for Laser Print Bed Fusion (L-PBF) and Electron Beam Print Bed Fusion (EB-PBF) applications resulting in a higher accuracy for L-PBF while vacuum used in EB-PBF avoids impurities during the process (Qin et al., 2019).

A summary of the current available AM techniques including their advantages and limitations can be found in Table 1 (Ni et al., 2019).

Table 1 | Overview of 3D printing techniques for biometals (Ni et al.2019)

Name	Applicable Metals	Processing parameters	Advantages	Limitations
Selective Laser Sintering (SLS)	Titanium alloys, cobalt, chromium, stainless steel, nitinol	• Laser sintering • Powder • Inert environment • CO2 laser • Uni,- and bidirectional fills	• Great amount of materials • High utilization • No support requirements	• Postprocessing required • Precision limited by particle size
Selective Laser Melting (SLM)	Metal alloys	• Laser melting • Powder (10-45 μm) • Inert environment • Nd-YAG / Fiber laser • Uni,- and bidirectional fills	• Ability to tune process properties during printing • Relatively low direct costs • Comprehensive functionality • Good mechanical properties and surface roughness	• Expensive • Relatively slow printing speed • Acute size restrictions
Laser Direct Metal Deposition (LDMD)	Metal alloys	• Laser melting • Powder (20-200 μm) • Inert environment • Nd-YAG / Fiber laser • Uni,- and bidirectional fills	• Local heat input • Low distortion • Fabrication of near net-shaped parts • Fabrication of functional gradient materials and parts	• High capital costs
Selective Electron Beam Melting (SEBM)	Metal alloys	• Electron beam melting • Powder 45 - 106 μm) • Vacuum chamber with small amount of helium • Uni, and bidirectional fills	• High density • High product strength • Less impurity • Fabrication of brittle materials	• Requires vacuum environment • Requires postprocessing • Expensive equipment
Laser Induced Forward Transfer (LIFT)	Chromium, Tungsten, Gold, Nickel, Aluminium	• Pulse laser/layer	• Very small-scale part processing • Operation without vacuum environment or cleanroom • Wide range of materials • High accuracy	• Small-batch production • Small size • Thin layers • Weak constructional support
Atomic Diffusion Additive Manufacturing (ADAM)	Sinterable metal powder, such as stainless steel, ti alloys	• Metal powder wrapped in plastic binder	• Part density can reach 95-99% • Low cost • High quality surface • Precise complex structure • Excellent isotropic performance • Batch production	• Longer lead time for solid/stronger parts
Nanoparticle Jetting (NPJ)	Ti alloys	• Inkjet nozzle • Metal nonaparticles wrapped in liquid ink	• High speed • Low cost • Simple and safe operation • High resolution (1 μm) • High precision and surface finish	• Low temperature tolerance compared to other printing techniques
Inkjet 3D Printing/ Binder Jetting (3DP)	Ti alloys	• Fine water het/metal powder	• Low cost • Simple and safe operation	• Low precision



3. METALLIC BIOMATERIALS

This section provides an overview of the bio-metals in the orthopedic field that are either currently used in a clinical setting or under development. In section 4, biodegradable metals are discussed.

3.1 Tantalum

Due to the high manufacturing costs, biomedical applications using tantalum (Ta) were once limited, but currently there are several applications for porous tantalum implants (Balla, Banerjee, et al., 2010). New manufacturing techniques such as Laser Engineered Net Shaping (LENS), Spark Plasma Sintering and Selective Laser Melting (SLM) are capable of creating porous tantalum structures with a Young's modulus between 1.5 and 20 GPa depending on the porosity (Balla, Bodhak, et al., 2010). A major drawback is the melting point of tantalum exceeding 3000 degrees Celsius and therefore most of the current 3D printing techniques cannot work with tantalum (Ni et al., 2019).

Compatibility

Tantalum has excellent biocompatibility and good chemical stability (Levine et al., 2006) and is therefore used in the dental and orthopaedic field since the 1940s. Compared to identical porous Ti-6Al-4V samples, the porous pure tantalum showed excellent bone osteoconductive properties, higher normalized fatigue strength and ductility (Wauthle et al., 2015).

Figure 1 | Example of Tantalum implant: TMS-Cervical Fusion Device, Zimmer Biomet, Warsaw, Indiana, USA.

Spherical tantalum mechanical properties (SLM) (Sungail & Abid, 2020)	
Yield strength (MPa)	285
Ultimate strength (MPa)	660
Elongation (%)	4
Vickers hardness (Hv)	237

Spherical Tantalum powders chemical properties (Sungail & Abid, 2020)													
Lot	**(ppm)**												
	O	N	H	C	S	Cr	Fe	Mg	K	Ni	Na	Ti	W
Ta-1	829	11	20	11	<10	11	12	<1	<1	33	1	8	<1

3.2 Titanium alloy

Titanium (Ti) and titanium alloys are widely used as implant material for biomedical applications including dental, orthopaedic implants, bone screws and many more (Ni et al., 2019).

Mechanical properties

Titanium alloys have a lower Young's moduli, 55 GPa for commercially pure titanium (CP-Ti) to 110 GPa for Ti-6AL-4V, compared to 316L Stainless Steel (210 GPa) and Cobalt Chromium alloys (240 GPa) (Zhang & Attar, 2016). The mismatch between Young's modulus of titanium and cortical bone, around 10-30 GPa, causes stress shielding effects which may lead to complications such as bone resorption, implant loosening and failure of the implant (Ni et al., 2019). To obtain a lower stiffness, many non-toxic β-type titanium implant materials have been developed or porous structures have been introduced to reduce both the modulus as well as the material weight (Zhang & Attar, 2016). The Young's modulus of porous Ti-6AL-4V can be as low as 2.5 GPa which is close to the human cancellous bone (Li et al., 2009).

Compatibility

Titanium is known for its excellent biocompatibility, corrosion resistance and hight strength (Elias et al., 2008). Furthermore, porous titanium implants are capable of bone ingrowth by supporting the natural growth of human bone cells, has an attractive surface morphology for cell attachment and proliferation providing a strong connection between the implant and bone (Tan et al., 2017).

Figure 2 | Example of Titanium alloy implant: Modulus XLIF, Nuvavisve, San Diego, California USA

For commercially pure titanium (CP-Ti) fabricated by SLM (Zhang & Attar, 2016)	
Yield strength (MPa)	555
Ultimate strength (MPa)	757
Elongation (%)	19.5
Vickers hardness (Hv)	261±13

For Ti-6AL-4V fabricated by SLM (Zhang & Attar, 2016)	
Yield strength (MPa)	1110
Ultimate strength (MPa)	1267
Elongation (%)	7.28
Vickers hardness (Hv)	409

3.3 Cobalt-Chromium alloy

Cobalt-chromium (CoCr) alloys have excellent corrosion, wear and high temperature resistance combined with excellent mechanical properties and outstanding biocompatibility, suitable for almost any load bearing or dental application (M et al., 2015; Ni et al., 2019).

Mechanical properties

The Young's modulus of Cobalt- chromium, around 220-230 GPa, alloys is around twice than that of Titanium alloys. With LENS CoCrMo alloy samples can be manufactured with a total porosity between 10-18% with a corresponding Young's modulus of 30-43 GPa (España et al., 2010).

Compatibility

Excellent results on the microstructure, mechanical properties, corrosion behaviour and biocompatibility were also found for samples prepared by SLM (Ni et al., 2019). In vitro experiments showed that CoCrMo alloy are non-toxic and retain their biocompatibility after AM (España et al., 2010).

Figure 3 | Example of Cobalt chromium implant: Dental Implants, 3D Systems, Rock Hill, South Carolina, USA.

Cobalt-chromium alloy SLM (Song et al., 2018)	
Yield strength (MPa)	800-850
Ultimate strength (MPa)	1070
Elongation (%)	7.2
Vickers hardness (Hv)	37.5-40

3.4 Nitinol

Figure 4 | Example of Nitinol implant: Continuous compression implants for trauma applications, Johnson & Johnson Medical, New Brunswick, New Jersey, USA.

SLM processed NiTi/Ni50.2Ti (Elahinia et al., 2016)	
Plateau start (Mpa)	148-168
Yield strength (MPa)	1400-1420
Ultimate strength (MPa)	3209-3469
Elongation (%)	37-42
Vickers hardness (Hv)	540-735

Nitinol or nickel-titanium (NiTi) is commonly used as a shape memory alloy due to its good super elasticity, shape memory effect, low stiffness, biocompatibility, superb wear resistance, high strength, excellent ductility and good corrosion resistance (Chekotu et al., 2019).

Mechanical properties

In the martensitic condition, the Young's modulus of NiTi alloys (28-41 GPa) closely match of human cortical bone which is around 20 GPa. (Bernard et al., 2012). At a porosity of 58%, the Young's modulus was reduced to 9 GPa (Sabahi et al., 2020). The 0.2 proof stress (MPa) decreases with the relative density from 971 MPa for 98% relative density to 368 MPa for 80% relative density (Bernard et al., 2012).

Compatibility

Excellent corrosion resistance has been demonstrated for NiTi alloys, comparable with titanium and Ti-6AL-4V materials, which can be explained by the addition of a Ti-oxide film on the surface (Dadbakhsh et al., 2016). Furthermore, SLM made NiTi porous structures confirm osteogenic cell activity of stem cells even in a salty environment or controlled compression loading (Dadbakhsh et al., 2016). Besides an improved permeability, porous NiTi alloys exhibits superior mechanical compatibility with bone compared to other biocompatibility metals (Dadbakhsh et al., 2016). Therefore, AM-produced NiTi biomedical applications can be designed and manufactured with maximal biomechanical and physiological compatibility for each patient (Dadbakhsh et al., 2016). However, an excessive amount of Nickel (Ni) may result in toxicity affecting the biocompatibility of the material (Khoo et al., 2018).

3.5 Stainless steel 316L

Due to its low costs compared to titanium and cobalt chrome, Stainless steel 316L is often used as a material to manufacture dental implants, orthopaedic implants for hip and knee replacements, or bone tissue engineering scaffolds (Cosma et al., 2020). This type of stainless steel has an extra low carbon content and an increased concentration of chrome and nickel making it more durable against corrosion.

Compatibility

One of the main limitations of austenitic stainless steels when clinically used is the tendency to corrode when implanted. The corrosion products of stainless steel and their deleterious effects in several organs and tissues have been demonstrated in the past (Martinesi et al., 2007). The corrosion resistance of these alloys is based on the formation of a protective film and the quantity of released metal ions, which can be improved by means of surface treatment (Martinesi et al., 2007)

SLM-processed 316L samples (Cosma et al., 2020)	
Yield strength (MPa)	590-780
Ultimate strength (MPa)	640-840
Elongation (%)	10-13

4. BIO-DEGRADABLE METALLIC BIOMATERIALS

Treatment of bone defects with permanent implants is yet one of the challenges in orthopedic surgery, as the current clinical solutions can be associated with long term complications such as infection, wear or failure. These complications potentially can be minimized by implanting bio-materials which degrade over a certain period of time.

This section provides an overview of applicable 3D-printed **biodegradable** metals in the orthopedic field.

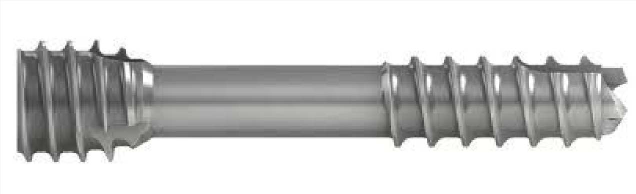


Figure 5 | Example of Magnesium implant: Magnezix CS - Syntellix, Hannover, Germany

Magnesium aluminium alloys (AZ91)	
Yield strength (MPa)	290
Ultimate strength (MPa)	417
Elongation (%)	9.45

Magnesium zinc alloys (ZK60)	
Yield strength (MPa)	235
Ultimate strength (MPa)	315
Elongation (%)	8

Magnesium silicon alloys (Mg-Si alloys)	
Yield strength (MPa)	52
Ultimate strength (MPa)	152
Elongation (%)	9.5

Magnesium zirconium alloys (Mg-Zr alloys)	
Yield strength (MPa)	60-125
Ultimate strength (MPa)	200-290
Elongation (%)	14-38

4.1 Magnesium

Magnesium (Mg) alloys has similar biomechanical properties as the human bone and therefore minimizes the amount of discomfort compared to the use of stainless steel or titanium. Furthermore, magnesium is absorbed by the human body, releasing magnesium ions to enhance the proliferation and differentiation of osteoblast, stimulating bone growth and healing (Witte et al., 2007). However, compared to other bio-metals, magnesium alloys are very difficult to process using AM techniques due to their flammability.

Mechanical properties

The density of Magnesium is only 1.74 g / cm^3. The ultimate tensile strength of pure Magnesium is around 90 MPa which can be increased to 200-300 MPa while using Magnesium alloys (Friedrich & Mordike, 2006). The Youngs modulus of pure Magnesium alloys is around 36 GPa but can be increased for magnesium alloys up to 63 GPa (Friedrich & Mordike, 2006).

Compatibility

Due to their similar density, magnesium alloys have the best biomechanical compatibility with bone and consequently also a minimum associated discomfort compared to stainless steel or titanium alloys (Ni et al., 2019). However, despite the excellent mechanical properties of Mg-Al based alloys, aluminium is known to be harmful to neurons and osteoblast, especially at higher concentrations such as in AZ91 (Chen et al., 2014).

4.2 Zinc

Zinc (Zn) has gradually replaced iron and magnesium alloys to be used to fabricate biodegradable medical implants due to its almost ideal degradation rate. Because zinc is one of the indispensable trace elements in the human body, it is involved in several processes in the human body such as tissue regeneration.

Mechanical properties

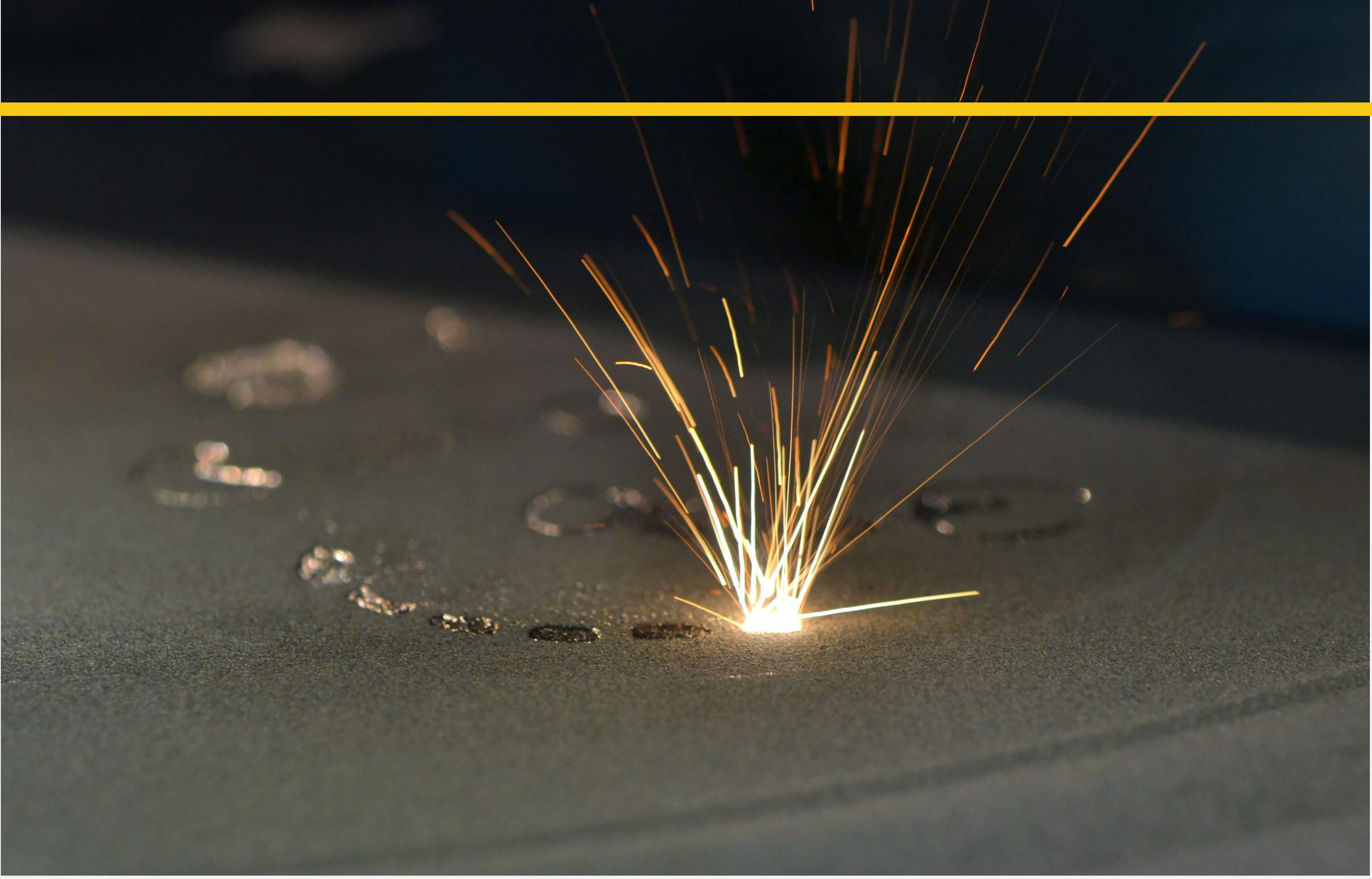
The Young's modulus of solid zinc parts with a density of 99,5% produced by SLM are around 23 GPa (Wen et al., 2018). Furthermore, the yield strength, ultimate strength and elongation were also superior to samples produced by conventional manufacturing methods (Ni et al., 2019).

Compatibility

Although recent studies have shown that Zinc has a proven antibacterial effect and that the toxicity of zinc is neglectable, there are still concerns about the use of Zn metal as an implant material (Ni et al., 2019). Zinc plays an essential role in the formation of bone by stimulating osteoblasts and inhibiting osteoclasts from differentiation (Yang et al., 2020).

Figure 6 | Example of metal stent made of Zinc
https://www.mddionline.com/stent-designers-think-zinc

SLM processed Zinc samples (Wen et al., 2018)	
Yield strength (MPa)	114
Ultimate strength (MPa)	134
Elongation (%)	10.1
Vickers hardness (Hv)	42



Future Challenges

At this moment only a few well-established materials are available for 3D printing such as titanium alloys, stainless steel and Cobalt Chromium, indicating a clear need for more high-quality materials that can be used for printing. However, there are more specific quality requirements for raw materials compared to solid materials. Examples of such requirements are particle size, size distribution, uniformity, oxygen content and fluidity of the raw material which need to be controlled.

New materials also need to meet biological requirements before they can be used in a clinical setting. For each material it is necessary to consider the safety, biocompatibility, degradation performance, and biological activity before and after printing to meet the requirements for industrialization and clinical use. However, there is a lack of standardization of the biosafety of bio-metals used for 3D printed medical applications, which makes it difficult to release new materials.

There are unlimited possibilities of new technologies to be made using 3D printing. One of the key challenges is to discover these possibilities and find out where 3D printing can be used and improve current treatments and develop new products or solutions.

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