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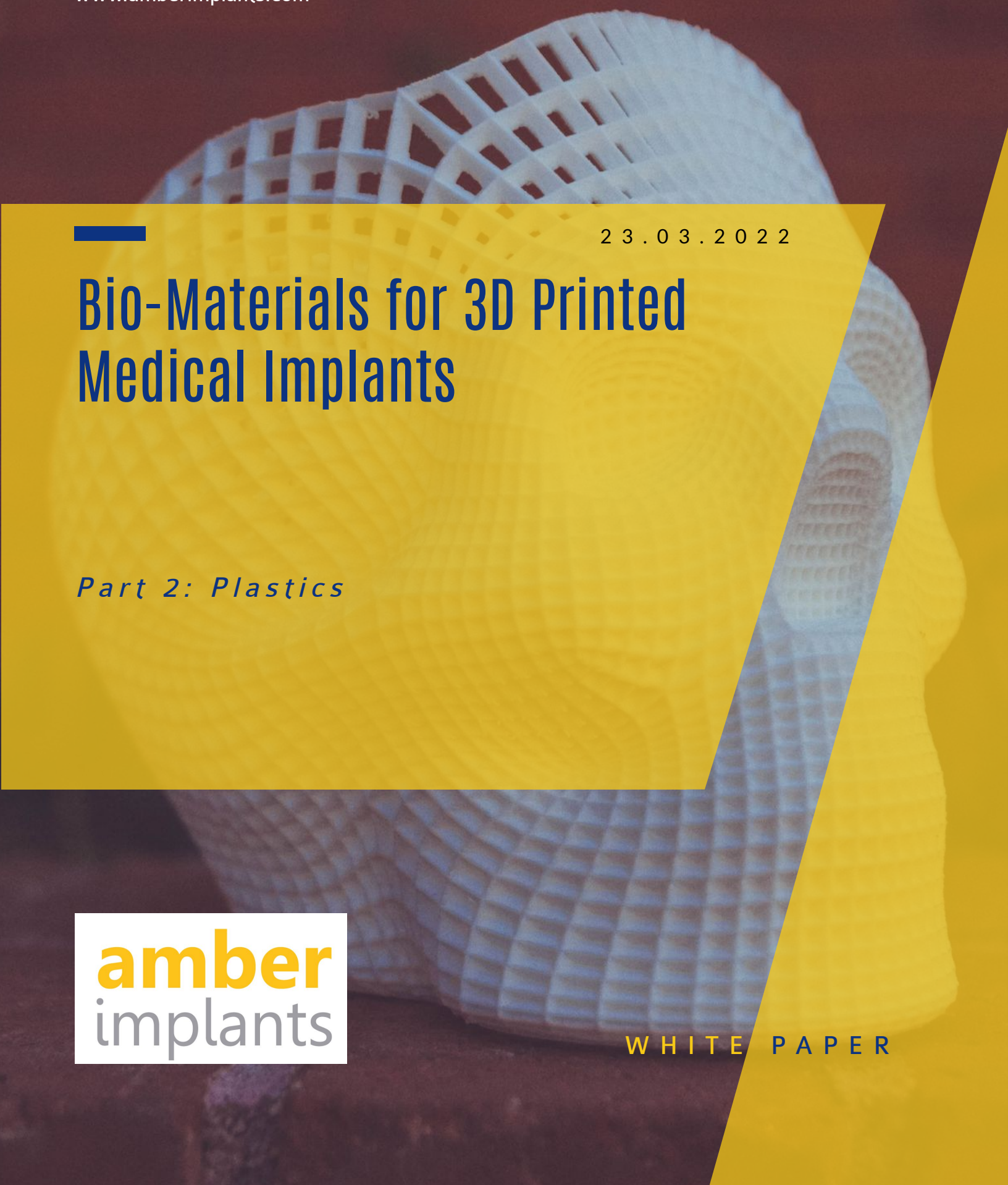

23.03.2022

# Bio-Materials for 3D Printed Medical Implants

*Part 2: Plastics*

amber implants

WHITE PAPER

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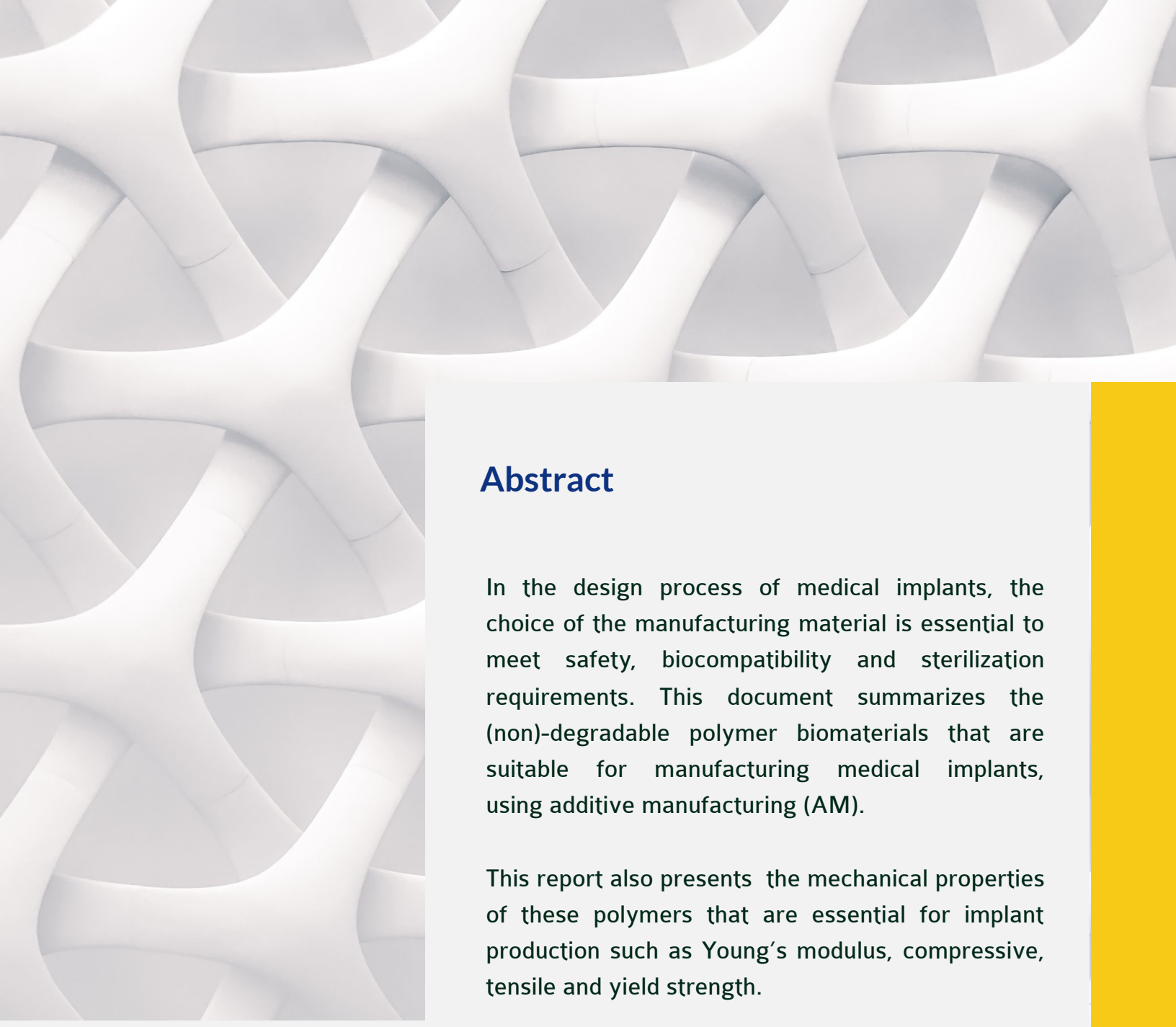


## Abstract

In the design process of medical implants, the choice of the manufacturing material is essential to meet safety, biocompatibility and sterilization requirements. This document summarizes the (non)-degradable polymer biomaterials that are suitable for manufacturing medical implants, using additive manufacturing (AM).

This report also presents the mechanical properties of these polymers that are essential for implant production such as Young's modulus, compressive, tensile and yield strength.

The created bio-plastics database can be used for the design and additive manufacturing (AM) of a variety of medical 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 implant design.

# Introduction
## The use of polymer biomaterials for implants

Polymers are particularly attractive in the medical device field due to their biocompatibility, mechanical properties comparable to those of the host tissues, and customizable manufacturing processes. Continuous innovations in material design and fabrication processes are giving rise to polymeric implants with improved performance.

Many synthetic polymers have been in clinical use for decades. These polymers may be non-degradable, such as polypropylene (PP), polytetrafluoroethylene (PTFE), polymethylmethacrylate (PMMA), and polyetheretherketone (PEEK), or degradable, such as polycaprolactone (PCL), polyglycolic acid (PGA), polylactic acid (PLA).

The 3D printing technology plays an increasingly important role in implantable medical devices due to its ability to print structures with complex geometries, thereby mimicking intricate designs found in nature and offering the possibility to create personalized geometries.

Polymer 3D printing enables low-cost fabrication of functional parts with tuneable characteristics. By altering the printing parameters and using design strategies, complex materials with e.g., hierarchical design can be obtained, which allow for an optimal balance between mechanical and biological properties.

Additionally, the use of polymers has advantages over metal printing approaches, which often result in metal implants that do not degrade in the body and may lead to mechanical issues such as stress shielding.

# 2. PRINTING TECHNIQUES

Polymer 3D printing can be achieved by different processes such as powder sintering (direct 3D printing and Selective Laser Sintering, SLS), curing of a photosensitive polymer resin (Stereolitography, SLA), or extrusion of filaments (Fused Deposition Modeling, FDM). Low-temperature Deposition Manufacturing (LDM) is a more recent technique that uses non-heating liquefying processing to dissolve polymers which are then kept at temperatures below 0 °C and extruded through a nozzle at higher temperature (Liu et al. 2016). The wide choice of printing techniques provides versatility for material selection and supports designs with diverse structures and features.

Design strategies provide the possibility to manufacture 3D-printed parts with specific desired characteristics beyond simple printing. These strategies include architected materials engineered with a regular patterning; responsive polymers that go undergo a state change under external stimuli; multi-material combinations; functionally graded materials that provide a smooth transition of properties; and customization, particularly useful for patient-specific manufacturing (Arefin et al. 2021).

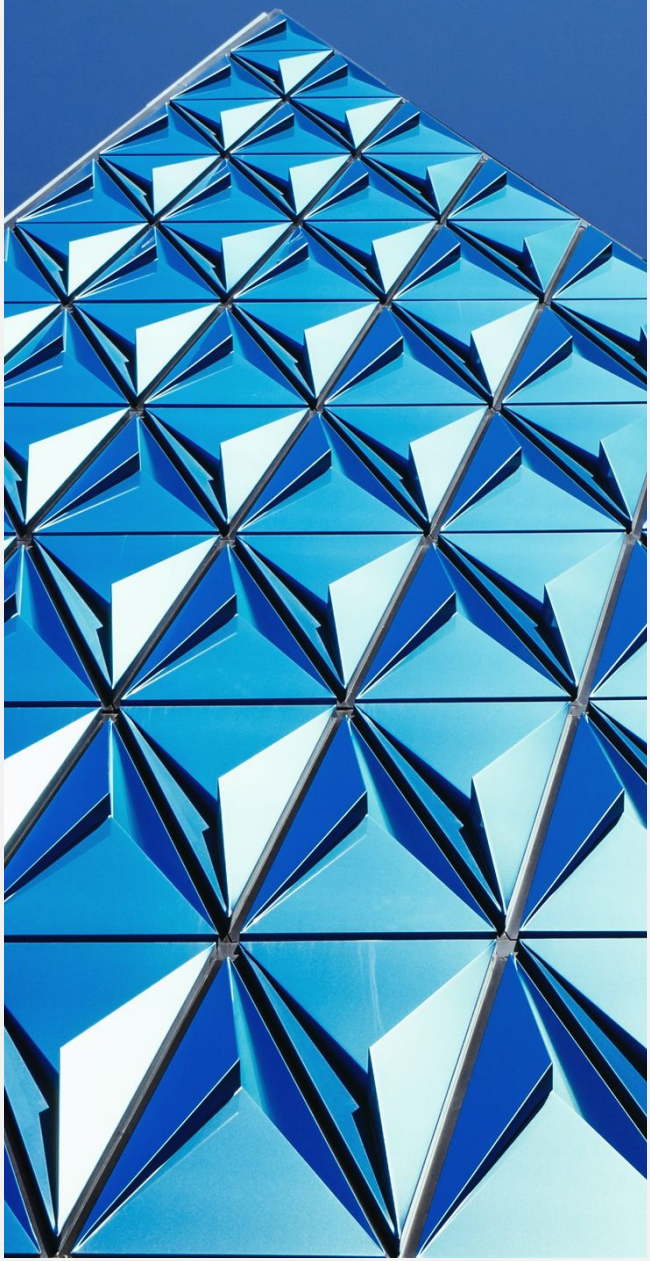
A summary of the currently available AM techniques for polymers including their advantages and limitations can be found in Table 1 (Arefin et al. 2021; Wang et al. 2021; Okolie et al. 2020; Ni et al., 2019; Liu et al. 2017).

Table 1 | Overview of 3D printing polymers for implants.

| Name | Applicable plastics | Processing parameters | Advantages | Limitations |
|---|---|---|---|---|
| **Direct 3D printing/Inkjet** | PCL, PLLA, PLGA | • Powder and liquid binder solution<br>• Inkjet nozzle | • Useful for soft tissues<br>• Print of functional cells | • Support is required for intricate structure printing<br>• Limitations on nozzle size |
| **Selective Laser Sintering (SLS)** | PCL, PA, PLA, PEK, PVA, PC | • Laser sintering<br>• Powder<br>• Inert environment<br>• CO2 laser<br>• Uni- and bidirectional fills | • High resolution<br>• Variety of materials<br>• High utilization<br>• No support requirement; powder gives support to complicated structures | • Postprocessing required<br>• Precision limited by particle size<br>• High temperatures needed<br>• The material must be shrinkable and heat resistant<br>• Low strength and poor surface quality of parts |
| **Stereolithography (SLA)** | PPF, PEG, PEGDA, PCL | • Photocurable, photosensitive polymer<br>• UV laser beam (300-400 μm) | • High resolution<br>• High fabrication speed<br>• Smooth surface finish | • Support is required for intricate objects<br>• Cost extensive<br>• Biomaterial must be photopolymeric |
| **Low-temperature Deposition Manufacturing (LDM)** | PLGA, PU, PDLLA, PLLA | • Freezing forming chamber temperature (-30 °C)<br>• Multi-nozzle extrusion system<br>• Dissolved polymer particles (micro/nanometer scale) | • Green manufacturing due to non-heating material liquefying processing<br>• Allows design of complex organs | • Limitations on nozzle size<br>• Limited choice of solvents to dissolve polymers<br>• Difficult degradation control of obtained product |
| **Fused Deposition Modeling (FDM)** | PLA, PLC, PLGA, PU, PCL, PEEK, ABS,PCU/UHMWPE, PC, PETG, PMMA | • Thermoplastic filament<br>• Heated nozzle | • Relatively low costs for the material and printer<br>• Reduced toxicity compared to direct 3D printing | • Low resolution<br>• Support required for complex structure printing<br>• Postprocessing required<br>• Only non-biodegradable materials<br>• Material limitations that rely on thermoplastics |

ABS, Acrylonitrile butadiene styrene; PA, Polyamide; PC, Polycarbonate; PCL, Polycaprolactone; PDDLA, Poly(D,L-lactide); PEK, Polyetherketone; PEEK, Polyether ether ketone; PEG, Polyethylene glycol; PEGDA, Polyethylene glycol diacrylate; PETG, Polyethylene terephthalate; PLA, Polylactic acid; PLC, poly(l-lactide-co-ε-caprolactone); PLGA, Poly(lactic-co-glycolic acid); PLLA, Poly-L-lactic acid; PPF, Poly(propylene fumarate); PU, Polyurethane; PVA, Polyvinyl alcohol; UHMWPE, Ultra-high-molecular-weight polyethylene.

# 3. NON-DEGRADABLE POLYMER BIOMATERIALS



This section will provide more detailed information on three of the most commonly used non-degradable polymer biomaterials in a clinical setting: PTFE, PMMA, and PEEK.

## 3.1 Polytetrafluoroethylene (PTFE)

Over the past years, fluoropolymers such as PTFE are progressively replacing other plastics in a variety of medical applications due to their physical and biocompatibility properties. These materials entail a wide variety of favourable performance criteria, including biocompatibility, chemical inertness, sterilization requirements, dielectric properties, lubricity, and a wide temperature use range (Shukla, 2015). A common application of PTFE in maxillofacial practices is its usage as a biomaterial to guide tissue regeneration in the defect area (Figure 2.1). Nowadays, microporous non-resorbable PTFE membranes are often part of the reconstruction procedure to facilitate guided bone regeneration at the ridges of the atrophic jaw (Rakhmatia et al. 2013). However, manufacturing PFTE implants using additive manufacturing is challenging due to the fact that it disintegrates before the melting point. Currently, the material is more suitable for injection molding than for additive manufacturing techniques, but the first printer that is capable of printing PFTE was released by 3M in 2019.

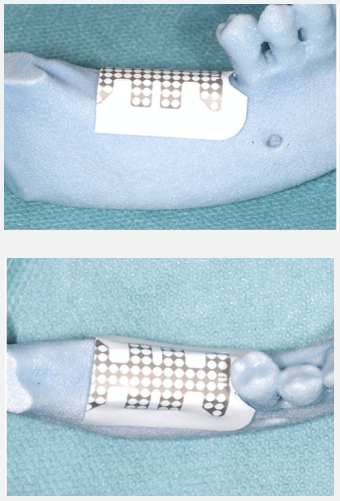


Figure 1 | Example of a Ti/reinforced PTFE membrane contoured over a syntethic mandible model. (Poli et al. 2020)

**Mechanical properties of sintered PTFE membranes for two different sintering temperatures (Zubir & Ismail, 2002)**

| Sintering temperature (°C) | 350 | 385 |
|---|---|---|
| Tensile strength (MPa) | 11.59 ± 1.50 | 19.02 ± 1.46 |
| Tensile strain (%) | 172.55 ± 25.42 | 351.04 ± 23.12 |
| Young's Modulus (GPa) | 20.478 ± 51.10 | 14.177 ± 35.15 |
| Energy to Break (J) | 0.42 ± 1.01 | 1.29 ± 0.59 |

***Compatibility***

Similar to titanium, the biocompatibility of PTFE as a non-degradable material is very high and the material is approved as an implantable material by the FDA for granular molding powders (ASTM F754). The risk of long-term complications is low, and its mechanical performance is predictable and clinically easy to manage. Besides, the porosity of such membrane structures can be adapted relatively easily, and many designs are commercially available (Rakhmatia et al. 2013). However, full closure of soft tissue around the defect is required, as membrane exposure may cause minor to severe problems resulting from wound dehiscence (Maridati et al. 2016). Due to the limited amount of printers that are capable of manufacturing PFTE implants using additive manufacturing techniques, the long term biocompatibility effects of these implants are not yet known.

## 3.2 Polymethylmethacrylate (PMMA)

PMMA cement is a well-established material that has been used for decades in the field of orthopedics. Before curing, the cement can be molded and easily trimmed, making it very suitable for the reconstruction of defects with complex geometries, for example as a bone substitute in skull reconstruction. Although its application in facial bones is still limited, PMMA bone cement proved successfu in providing temporary space maintenance of mandibular continuity defects following a resection (Goodger et al. 2005) Besides, PMMA can be used to fix an artificial device, such as an endoprosthesis, in the remaining bone to restore mandibular discontinuity defects (Lye et al. 2013). Besides giving structural support, the cement can be embedded with bioactive substances so that it can serve as a drug carrier to promote bone healing (Zhang et al., 2019).

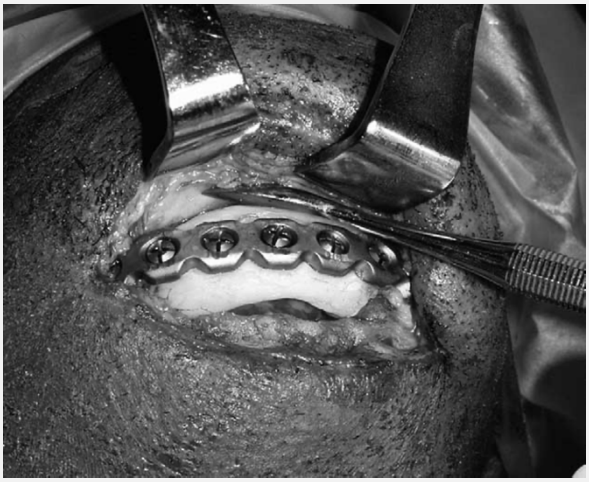


Figure 2 | Example of a methylmethacrylate space maintainer (white) fixed to the mandible prior to adding bone graft material (Goodger et al., 2005)

| **Mechanical properties of PMMA bone cement used in medical applications (Lee, 2005)** | |
|---|---|
| Young's modulus (GPa) | 3-4 |
| Tensile strength (MPa) | 35.3 |
| Shear strength (MPa) | 42.2 |
| Compressive strength (MPa) | 93.0 |
| Bending strength (MPa) | 64.2 |
| Bending modulus (GPa) | 2.552 |

***Compatibility***

PMMA is highly biocompatible with human tissue. Even though the application of plain PMMA is usually successful, the material is also reported to be associated with long-term device failure and infection as a result of aseptic loosening. These issues have led to the development of modified PMMA cements with improved bioactivity and tissue response. Osteoconductive compounds embedded in the cement establish direct bone-cement bonding and, following progressive resorption of these substances, create a rough and porous surface that allows for bony ingrowth (Lye et al. 2013). Zhang et al. (2019) point out that manufacturing processes still need to be improved to reduce toxicity and purify the materials in the material synthesis step in order to prevent exposure to toxic substances, such as unreacted methylmethacrylate monomers. However, (meth)acrylate monomers with pH-sensitive linkages for tissue regeneration are currently being investigated (Ligon et al. 2017).

## 3.3 Polyetheretherketone (PEEK)

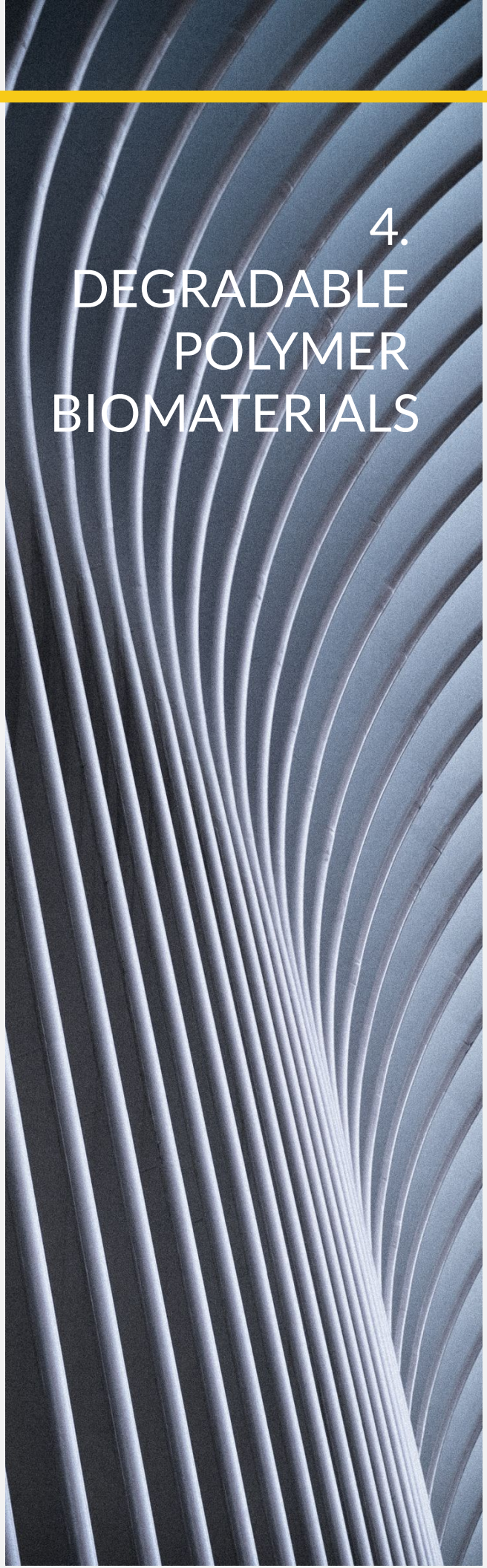
Clinical studies have shown that the use of commercial titanium plates for mandible reconstructions has repeatedly led to mechanical failure of the plate in the form of plate fracture or screw loosening. Besides, the high elastic modulus of titanium may cause stress shielding with loosening of the implant or device as a result. As a response to these issues, multiple efforts have been made to use 3D printable materials derived from the Polyaryletherketone (PAEK) family, such as thermoplastic polymers like Polyetheretherketone (PEEK) and Polyetherketoneketone (PEKK), as an alternative to metallic implants (Mehle et al. 2016, Cheng et al. 2020) (Figure 3). Nowadays, PEEK is routinely used for orthopedic surgeries and reconstruction of craniofacial defects (Järvinen et al. 2019). Even though the applications of PEEK and PEKK in mandibular reconstruction is are still under research, their bone-like Young's modulus and favorable biocompatible properties make PEEK and PEKK promising candidates to be used as a permanent implant.


Figure 3 | Example of a PEKK bone analog manufactured using FDM (Chang et al., 2020)

| Mechanical properties of PEEK implants (Haleem & Javaid, 2019; Wu et al., 2015) | |
|---|---|
| Young's modulus (GPa) | 3-4 |
| Tensile strength (MPa) | 90-100 |
| Melting temperature (°C) | 343 |
| Compressive strength (MPa) | 118.0 |
| Compressive modulus (GPa) | 3.8 |
| Bending strength (MPa) | 163.0 |
| Bending modulus (GPa) | 4.0 |

***Compatibility***

Both optically amorphous and crystalline PEEK polymers are well known for being highly biocompatible, radiolucent and nonallergenic, as well as having superior chemical resistance and an elasticity similar to that of bone (Cheng et al. 2020). Histological evaluations showed mild tissue reactions and stable long-term mechanical characteristics, making PEEK plates suitable for fixation of osteotomies and fractures (Nieminen et al. 2008).



# 4. DEGRADABLE POLYMER BIOMATERIALS

Degradable polymers are temporary structures that break down over time and are subsequently removed from the physiological environment. This section will provide more detailed information on two degradable polymer biomaterials that are currently most commonly used in a clinical setting: PLA and PCL.

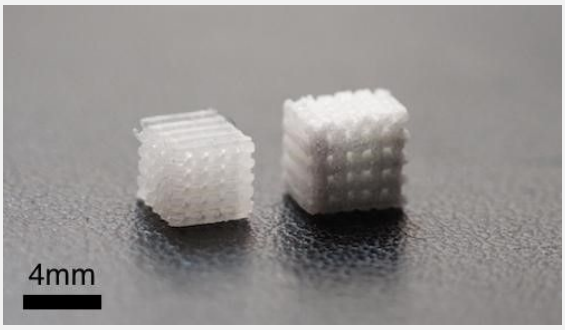



Figure 4 | Example of 3D printed PLA scaffolds for bone tissue engineering purposes (Marascio et al., 2016)

| Mechanical properties of PLA (Farah, Anderson & Langer, 2016) | |
|---|---|
| Polymer density (g/cm3) | 1.21-1.25 |
| Tensile strength (MPa) | 21-60 |
| Tensile modulus (GPa) | 0.35-3.5 |
| Ultimate strain (%) | 2.5-6 |
| Specific tensile strength (Nm/g) | 16.8-48 |
| Specific tensile modulus (KNm/g) | 0.28-2.8 |
| Glass transition temperature (°C) | 45-60 |
| Melting temperature (°C) | 150-162 |

## 4.1 Polyactic acid (PLA)

The 3D printed aliphatic polyester polylactic acid (PLA) is an inexpensive and easily manufactured material that is widely used in different fields, including the medical field. Due to its biodegradability and easy production, this material is often preferred over other traditional medical polymers. Application of PLA in mandibular reconstruction procedures is mostly under research, but some efforts have been made to use this material for the printing of customized grafts, scaffolds or tubes to mimic mandibular bone with a certain internal porosity (Helal et al. 2019; Hu et al. 2019; Schliephake, Jamil & Knebel, 1998).

***Compatibility***

The biodegradable property of PLA avoids problems encountered with reactions initiated by the body to reject the material. PLA turns into lactic acid following hydrolyzation, which in turn is metabolized by cells into non-toxic biocompatible compounds (water and carbon dioxide) upon contact with biological media or excreted via respiration and urine (da Silva et al. 2018). Depending on the type of PLA composition, the material degradation time varies between several weeks to more than a year.

## 4.2 Polycaprolactone (PCL)

Clinically available biopolymers such as PCL are a common material used with AM techniques for the fabrication of biodegradable scaffolds for bone or cartilage repair (Meng et al., 2020) due to their robust mechanical properties. Over the past years, extensive research have been done to tailor the mechanical properties of biodegradable tissue-engineered scaffolds for soft tissue engineering by adapting the micro- and macro-structure of the scaffolds. PCL has certain advantages relative to other polymers such as PLA. PCL is more stable in ambient conditions, less expensive and available in large quantities (Williams et al., 2005).

PCL is a member of the biodegradable polyester family and consists of aliphatic semi-crystalline polymers with a melting temperature between 59 and 64 °C and a glass transition temperature of -60 °C. At body temperature, PCL attains a rubbery state resulting in a high toughness and good mechanical properties. PCL has a degradation time of more than 2-3 years and is degraded by microorganisms or by hydrolysis of its aliphatic ester linkage under physiological conditions (Dwivedi et al., 2020). Furthermore, to enhance cellular response and bone generation, composite scaffolds made of a combination of PCL and Hydroxyapatite (HA) with varying content of mineralization have been introduced.

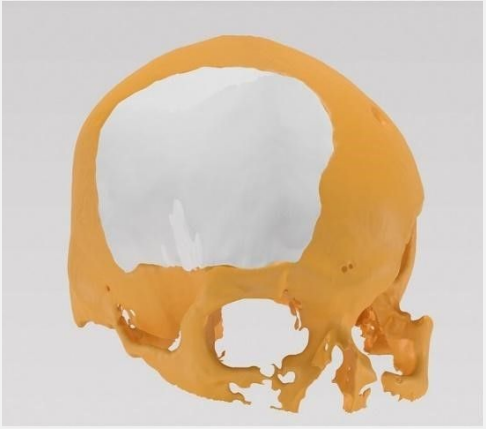


Figure 5 | 3D printed bioresorbable PCL regenerative bone implant for cranioplasty by Osteopore

| Mechanical properties PCL (Williams et al., 2005) | | |
|---|---|---|
| | Scaffold | Solid material |
| Pore Size (x/y (mm) * z (mm)) | 1.75 * 1.75 2 * 2.5 | - |
| Actual Porosity (%) | 37.5-55 | 17.8 |
| Young's modulus (MPa) | 52-67 | 122 |
| Yield strength (MPa) | 2.0-3.2 | 11.7 |

***Compatibility***

Several studies have demonstrated good biocompatibility of PCL filaments made by AM both *in vitro* and *in vivo* (Meng et al., 2020). However, previous generations of PCL scaffolds were unable to provide optimal mechanical strength and biocompatibility (Dwivedi et al., 2020). Nevertheless, blending PCL with natural or synthetic polymers or ceramics resulted in improved mechanical properties, controllable degradation rates and enhanced bioactivity (Dwivedi et al., 2020). The biocompatibility of PCL can be further improved by adding Aluminium Oxide and Hydroxyapatite to PCL nanocomposite scaffolds.

## Conclusion

The use of additive manufacturing technology in the medical field is continuously expanding due to its revolutionary possibility to produce customized implants and prostheses cost-efficiently.

Currently, there is a limited number of biodegradable polymers available for 3D printing. Therefore, there is a major need for research to fabricate novel biopolymers with tunable properties that can restore functionality at the site of application. Current research is particularly focused on synthesizing new composites of existing inexpensive polymers with excellent mechanical and biodegradable properties such as PLA and PCL and traditional biomaterials like HA and tricalcium phosphate (TCP), thereby providing higher printability, mechanical stability, and better tissue integration.

Ideally, in the future, implants will be produced that recapitulate not only the original tissue anatomy, but also its structure, function, and even mechanical response. With the recent developments in the field of mechanoresponsive materials, an implant material could become a living tissue with strong similarity to the original organ.

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