4D Printed Surgical Devices: Current Capabilities and Challenges

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Abstract: The concept of 4D printing refers to the ability of a 3D printed material or device to change shape in a predefined manner controlled from the design stage. Currently, 4D printing research is performed by employing various additive technologies and materials, whose special design features or functional properties allow for these shape transformations or metamorphoses after printing. This smart shape-morphing behaviour is already providing innovative concepts for biomedical engineering and healthcare technologies, although important advances are still needed towards impactful transfer to society. This study presents different polymeric additive manufacturing technologies: stereolithography, digital light processing and selective laser sintering, that can be employed towards shape-morphing or 4D printed medical devices, in some cases at prototyping level, in others for final production. Through the prototyping of different joints and kinematic chains, configured as potential surgical actuators, the potentials and limitations of these resources are studied and good design practices and future applications for 4D printed biodevices are provided. The applicability of polymeric 4D printing to emulate and predict 4D printability with high-performance alloys is discussed.

1 INTRODUCTION

Industry and consumers already benefit from a wide set of additive manufacturing or 3D printing technologies, capable of processing polymers, metals, ceramics, composites, biomaterials and even living materials, such as stereolithography (SLA), selective laser sintering (SLS), fused deposition modeling (FDM), selective laser melting (SLM), electron beam melting (EBM), bioprinting, lithography-based ceramic manufacturing, to cite a few. Due to their usual ability to produce products directly from the raw materials, without involving costly production tools, 3D printing technologies have sparked a lot of interest among academic institutions and major corporations.

The nature of 3D printing is highly interdisciplinary, especially in the healthcare arena, and involves the collaboration of materials scientists, mechanical engineers, software developers, data scientists, product designers, biomedical engineers, healthcare professionals among many others.

Besides, as regards the biomedical industry, the remarkable geometrical complexity achievable by 3D printing technologies through layered manufacturing processes is of special relevance for achieving medical devices capable of interacting with the complex morphologies of nature, human organs and tissues. This enables biomimetic design approaches towards medical devices with enhanced performance, and the toolless production routes achieved through additive manufacturing can importantly promote personalized healthcare strategies.

Indeed, the developments in 3D printing in recent years have enabled researchers to create complex shapes that were impossible to produce using the old traditional techniques. For instance, researchers have been successful in creating remotely actuated robots,

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designs using algorithms and machine learning, multi-material bioinspired designs, micro-environments cell culture processes, special biointerfaces for interacting with human tissues, and drug delivery systems using the 3D printing technologies.

However, because of the lack of regulations or the slow production cycle, additive manufacturing technologies are not yet transforming several sectors as expected. Along with the limited printing volume and certain typical defects, like warping or high porosity ratio, that may occur if the printing process is not perfectly performed, the limited number of high-performance materials processable through 3D printing is also a current barrier. In many cases though, the advantages of additively manufactured components outweigh the disadvantages.

Recently, contributions from materials scientists have led to a remarkable increase of the range of printing materials, including the use of some smart or stimuli-responsive options like shape memory polymers and alloys, piezoelectric ceramics, electroactive polymers, to cite a few families, through which several smart devices, even for the medical field, can be straightforwardly designed and created.

Thanks to the possibility of printing with smart materials and to the capability of creating functional geometrical gradients, it is possible to obtain structures with controlled geometrical modifications after printing, which led to the concept of “4D printing”, as recently reviewed (Aamir Ahmed, 2021).

In short, the term “4D printing” describes the single-material or multi-material printing of a device or an item that can change from a 1D strand into another pre-programmed 1D, 2D or 3D shape, from a 2D surface into another pre-programmed 1D, 2D or 3D shape, and to morph between 3D and other dimensions. Such transformations are facilitated by, e.g., heating, light, or swelling in a liquid, electrochemical reactions and by programming differential behaviors across the printed geometry through functional gradients of materials or structures. These 4D printing methods open new possibilities for non-electronic based materials to incorporate programmability and clear decision-making. They also provide flexibility and dynamic responses for structures and systems of varied sizes and herald important healthcare transformations.

The shape-morphing behavior of these smart products, including shape-shifting and evolutive medical devices, relies mostly on five fundamental factors that must be kept in view while performing design for 4D printing. These are: 1) the AM process, 2) the material used for printing, 3) the triggering stimuli, 4) the mechanism of interaction, and 5) the shape-morphing modeling (Farhang Momeni, 2017).

The first aspect is the AM process used for printing. Numerous AM techniques exist, as already mentioned. Almost all of them can print a 4D material or device as long as the printing method and material are suitable for the printer. The second factor is the printing material which needs to respond to stimuli, in some exceptional cases during printing or, in most cases, after printing. These materials are frequently referred to as smart materials (SMs) or programmable materials. The kind smart material employed defines the triggering stimulus, and the material’s reaction to the triggering stimulus determines the self-transformation ability. The third aspect, the actual triggering stimuli, can be physical, chemical, and biological. Physical stimuli include light, moisture, magnetic and electric energy, temperature, UV light, etc. Chemical stimuli include the use of chemical reagents, the pH level, the employment of oxidizing or reducing conditions, among many others. Among biological stimuli it important to highlight the use of enzymes and glucose or even the employment of living cells and tissues during printing. In 4D printing, when a stimulus is introduced, the structure undergoes physical or chemical changes, such as relaxation of stresses, molecular motions, and phase changes, which cause the structural deformation. The mechanisms of interaction and modeling are the fourth and fifth factors. Not all materials can perform the necessary transformation when a stimulus is applied to smart material. We should offer an interaction method that will plan the sequence of form change, such as mechanical loading or physical movement. The modeling is necessary to determine how long the stimulus will affect the smart material after providing the interaction mechanism.

Our team, within the **iMPLANTS-CM** project, is focused on the development of biomedical devices with shape-morphing properties. These are achieved through 4D printing using a wide range of additive technologies and materials and special design features for empowering the shape changes. In this study and introduction to 4D printing with polymers is presented and illustrated through a set of rapid prototypes designed as concepts for innovative surgical actuators. Through their design and 4D printing different good practices are reported.

2 MATERIALS AND METHODS

This section details the materials and technologies used in the **iMPLANTS-CM** project with the objective of validating the design and polymeric 4D printing of shape-morphing concepts of medical devices. Both conventional and shape-memory polymers are employed, and the design of printable kinematic chains or mechanisms is utilised for enhancing the metamorphic properties. The materials used to this end correspond to each of the additive manufacturing processes employed: photosensitive resins and photosensitive resins with shape memory for additive photopolymerization processes like laser stereolithography (SLA) and digital light processing (DLP) and nylon (PA12) and thermoplastic polyurethane (TPU) for selective laser sintering (SLS). Details are provided below.

2.1 Materials

2.1.1 Photosensitive Resins

Photosensitive materials are those that upon receiving an amount of energy, typically from an ultraviolet light source or laser beam, photopolymerize and lead to solid components through additive or layered photopolymerization procedures. They usually consist of three components: the core composed of different monomers; the photoinitiators, molecules that react to ultraviolet light and initiate the polymerization process; and, finally, the additive additives that add color and some special properties to the resin (Min Hong, 2015). In this study, Somos epoxy resin is employed for laser stereolithography and Anycubic resin compatible with the used digital light processing is selected for printing purposes.

2.1.2 Nylon (PA12)

Polyamide 12 is one of the many materials belongings to the group of aliphatic polyamides, also known commercially as nylons. Although PA12 has slightly inferior mechanical properties than those of PA6 or PA6-6, it has become the most common material in polymeric SLS 3D printing mainly for two reasons: its lower melting point that facilitates processing and its quite low hygroscopicity. The one used here, provided by Sinterit, has an ultimate tensile strength of 41 MPa with an elongation at break of 13%, as well as an impact strength of 15 KJ/m2, making it a highly versatile material for a wide set of applications (Benjamin Shaw, 2016) and for rapid prototyping.

2.1.3 TPU

Urethane-based thermoplastic linear elastomers, also known as TPE-U or TPU, are a group of block copolymers of polyols and diisocyanates. The ratio between the two polymers determines the final properties of the material, ranging from semi-rigid materials to materials with high elasticity. In general, urethane-based elastomers stand out for their high resistance to wear and abrasion, high tensile strength, good cushioning capacity, good toughness and resistance to grease and oils. In addition, it is compatible with skin and has a high resistance to fungi, which makes it suitable even for medical or orthopedic applications. The one used here, provided by Sinterit, has a tensile yield strength of 1.8 MPa and a compressive yield strength of 3.5 MPa and an ultimate tensile strength of 3.7 MPa with a strain at break of 137 % (Tao Xu, 2020). It is selectively melted using a laser and constitutes a good complement or alternative to PA12 for soft devices.

2.2 Methods

2.2.1 DLP

Digital light processing (DLP) is a 3D printing technology used to rapidly produce photopolymer parts. The light is reflected on a Digital Micromirror Device (DMD), a dynamic mask consisting of microscopic-size mirrors laid out in a matrix on a semiconductor chip. Rapidly toggling these tiny mirrors between lens(es) that direct the light towards the bottom of the tank or a heat sink defines the coordinates where the liquid resin cures within the given layer. Because the projector is a digital screen, the image of each layer is composed of square pixels, resulting in a three-dimensional layer formed from small rectangular cubes called voxels (Jiumeng Zhang, 2019). In this study Anycubic M3 and M3 Plus DLP printers are employed. (Formlabs, s.f.)

2.2.2 SLA

Laser stereolithography (SLA) is the foundational 3D printing technology. It works by using a high-powered laser to harden liquid resin that is contained in a reservoir to create the desired 3D shape. In a nutshell, this process converts photosensitive liquid into 3D solid plastics in a layer-by-layer fashion using a low-power laser and photopolymerization. In this study a 3D Systems “legacy” SLA-3500 SLA printer is employed.

2.2.3 SLS

SLS operation principle is powder sintering with the help of infrared laser, working within an elevated temperature chamber, which helps the grains of the powder to consolidate before being bound with the laser beam. In the conventional SLS printer there is a so called “bed” on which the roller spreads a thin layer of powder followed by sintering according to the layers sliced from a 3D model file. Afterwards the platform moves down by a small increment and the process repeats until the last layer is formed. After the process comes the post-processing part, which requires removing the model from the un-sintered powder suspension and sandblasting it.

Probably the most interesting advantage of SLS, as compared with polymeric SLA and DLP or with metallic selective laser sintering or melting (SLS / SLM) is the fact that 3D printing is performed without any supporting structures, as the complex-shaped models are supported by the powder during the printing process. This constitutes a very remarkable aspect in 4D printing, as moveable objects, interwoven elements and mechanisms can be printed with great accuracy (Abishek Kafle, 2021). In this study a Sinterit Lisa Pro SLS printer is employed.

Table 1 below provides a comparative study of the features of the different printing technologies and materials used, which provide a varied selection of resources usable for polymeric 4D printing. (Piszko, s.f.)

Table 1: Summary of polymeric 4D printing tools used in this study.

Technology	DLP	SLA	SLS
Machine	Anycubic Photon M3 Plus	3D Systems SLA3500	Sinterit Lisa Pro
Build volume	245x197x122 mm	350x350x400 mm	110x160x245 mm
Layer height	0.02-0.200 mm	0.05-0.150 mm	0.075-0.175 mm
Resolution	6K screen (44 μm/pixel)	0.250-0.300 mm beam diameter	0.350-0.400 mm beam diameter
Materials	Photo sensible resin	Photo sensible resin	PA, TPU, PP

3 RESULTS AND DISCUSSION

3.1 Differences Found in Technologies

The central objective pursued by the aforementioned **iMPLANTS-CM** project is the fabrication of biomedical devices using shape memory materials, specifically NiTi, to obtain final products. As this technology has a high cost and is currently under development, other 4D printing technologies with polymers are employed for rapid prototyping purposes.

These more accessible technologies and materials, already presented in section 2, support designers during the conceptual, design and prototyping phases, before resorting to the printing in high-performance materials such as NiTi. For instance, in the example shown in figure 1 below, laser stereolithography with shape-memory epoxy is employed to obtain an articulated mechanism. 4D printing is illustrated by heating the mechanism after its printing and performing the training of the shape memory effect (opening of the actuator). Once cooled down, a subsequent heating leads to shape recovery.

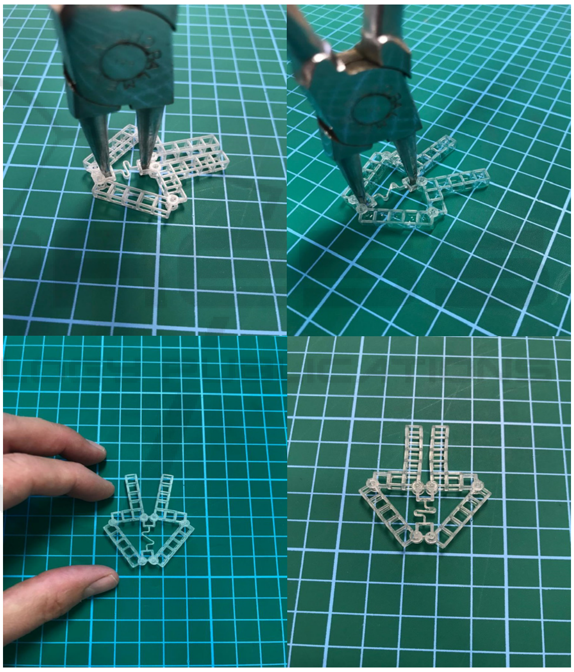

Figure 1: Example of 4D printing in a photosensitive shape memory resin. The previously heated and deformed device returns to its original position when heated. The shape-memory is empowered by the printing of an articulated mechanism. Upper images: training process. Lower images: trained and recovered geometry after activation of shape-memory effect.

Prior to redesigning for SLM and to analysing the applicability of these rapid prototyping tools (polymeric 4D printing processes) to emulate the final SLM with special alloys, it is crucial to consider the variations and similarities between each of the methods used.

First, some of the analogies between photopolymerization -as possible rapid prototyping technology- and SLM -as final production method- are discussed. According to the screen resolution, the size of the pixels utilized in DLP technology is comparable to the laser hatch used in SLM technology. Some similarities are also detected, as regards the utilization of supports throughout the part construction process. The analogies with SLA are the same as with DLP, but DLP is in general a quicker and less expensive process than SLA, although printing volume is compromised. In consequence, depending on the design and part size under evaluation, the more adequate is chosen.

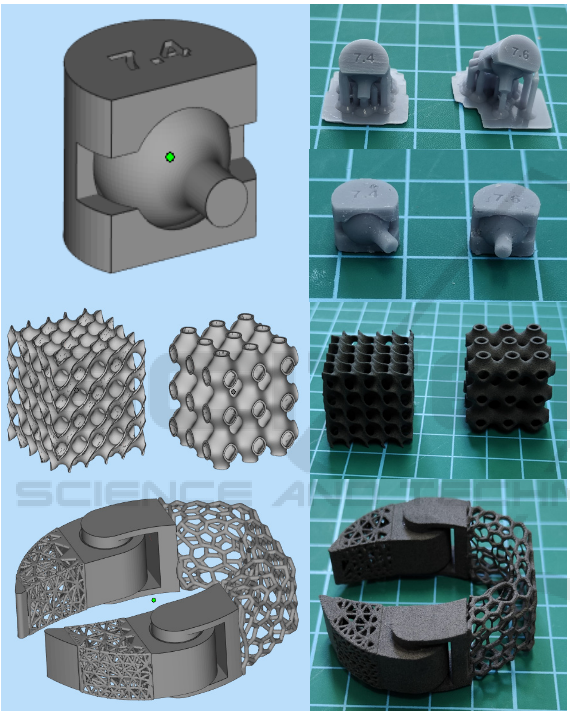

Figure 2: Collage of different prototypes of joints and lattices for 4D printed surgical actuators; from up to down: a spheric joint printed in DLP, examples of superelastic unit cells printed in TPU, gripper 3D with hyperbolic joints printed in nylon (PA12).

Second, the common features of polymeric SLS and metallic SLM are analysed. Although the SLS printer's laser precision is less precise than the SLM printers, using both powders enable us to study how the concentration of heat affects the powder during the printing process, enabling us to determine which printing direction can produce the best results but taking into account that SLS technology is self-supporting and SLM technology is not, so we cannot establish more similarities between these printing processes.

In summary, each of the technologies employed provides relevant information when planning an SLM print using NiTi, as a shape memory material, to enable 4D applications.

To better illustrate the interest of polymeric 4D printing for the rapid prototyping of shape-morphing devices, some additional joints, lattices and kinematic joints or mechanisms are designed and manufactured employing the different thermoset photopolymers, thermoplastics and elastomers and the polymeric processing technologies described in section 2.

By means of example figure 2 presents a set of selected prototypes are obtained employing digital light processing and selective laser melting. Among them, different links, joints and structures for conceptual surgical actuators or manipulators are shown.

3.2 Difficulties During the Polymeric 4D Printing Processes

First, the need to use supports in SLM technology, like in DLP and SLA, restricts the usable printing direction and leaves aesthetic defects at the contact points between supports and model that need to be post-processed for enhanced interactions with the skin, tissues and organs of interest. In this regard, the employment of DLP and SLA as rapid prototyping tools can help to emulate the expected surface finish and to plan the required supporting structures, when printing using other more high-performance materials and processes, such as SLM of NiTi.

Second, although polymeric SLS was initially expected to be much more adequate for emulating metallic SLS and SLM, the lack of supports in polymeric SLS makes it quite different from a design perspective.

3.3 Validated Concepts

In any case, it is important to point out that the experience gained with all the technologies mentioned above has allowed us to additive manufacture actuators and conceptual devices that validate the shape memory or superelastic properties of polymers employed for additive manufacturing using laser stereolithography, digital light processing and selective laser sintering.

In this regard, according to prototypes shown in figure 1 and 2, the employment of designs involving kinematic chains and joints forming mechanisms has been found to enhance the shape-morphing or metamorphic ability of these devices. Lightweight design is promoted by means of topology optimizations as shown in the actuator's structure.

Current research trends include the exploration of the possibility of printing these kinds of designs in NiTi using SLM technology, for which the various polymeric 4D printing technologies and materials used here provide interesting insights.

Furthermore, for supporting researchers working in the field, table 2 provides a summary of tolerances, results and proposed good practices for different printed joints and polymeric additive manufacturing technologies applicable to the 4D printing of conceptual medical devices. Among them, the various applicable tolerances for reaching adequately movable links in 4D printed mechanisms, for the different geometries, materials and technologies used, are highlighted, and constitute relevant design guidelines.

4 FUTURE LINES

There is room for improvement in the world of 4D printing, and some challenges should be overcome before these procedures make a real impact in the medical arena:

Further progress must be made in the knowledge of the mechanisms that stimulate the extra dimension added by this type of technology, as well as the control of the displacements generated with the intention of obtaining a better programmability of the materials.

Additionally, the usage and development of new processes that enhance the current manufacturing and surface finish restrictions, so that the finished products can be used in sectors with strict regulatory requirements, like the medical industry.

In this study some preliminary designs of joints, mechanisms and structures for medical actuators, for example for surgical practice, but with potentials for biomedical robotics and artificial limbs, have been presented. Polymeric 4D printing has verified their manufacturability and serves as a set of technologies for planning the creation of similar geometries with higher-performance materials and technologies, as has been discussed.

Towards the future, other designs linked to shape-morphing or evolutive prostheses, fostering minimally-invasive surgical procedures and capable of evolving with patients, according to their healing and growth processes, should be explored. Some applications in the emergent area of 4D bioprinting, within the fields of tissue engineering, regenerative medicine and biofabrication, are also foreseen.

5 CONCLUSIONS

The increase in demand for customized devices has led to an impressive growth in 3D printing over the last few years. The ability of certain materials to add a new dimension, 4D printing, also allows the possibility of extending the functionality of devices, as well as their useful life. It is crucial to consider aspects like printing direction, design tolerances, and

Table 2: Summary of tolerances, results and proposed good practices for different printed joints and polymeric additive manufacturing technologies applicable to the 4D printing of conceptual medical devices.

Technology	Joint type	Tested Tolerances	Results	3D printing advice
DLP	Cylindrical	0.2-0.4 mm	Good results starting at 0.4 mm	It is important to keep in mind that the first layers of adhesion are overexposed, so we need to compensate our design in dimensions to avoid the elephant foot effect, or otherwise bend the parts in such a way that the parts that are overexposed are the first layers of the support material of our part. That is why with this technology it is not recommended to place the flat parts fixed on the printing surface.
	Spherical	0.2-0.6 mm	Good results starting at 0.5 mm	
	Hyperbolic	0.2-0.4 mm	Good results starting at 0.4 mm	
SLA	Cylindrical	0.2-0.4 mm	Good results starting at 0.3 mm	The orientation of the parts is important in this technology, in the case of the joints both parts must maintain the same angle of inclination during printing to avoid that the pickling defects may include unwanted roughness between the joint faces. In addition, it is important to have a good configuration of supports, since being more difficult to remove than in DLP technology, the contact points between part and support should be well optimized to avoid defects.
	Spherical	0.2-0.6 mm	Good results starting at 0.3 mm	
	Hyperbolic	0.2-0.4 mm	Good results starting at 0.3 mm	
SLS	Cylindrical	0.2-0.4 mm	Good results starting at 0.5 mm	In this technology it is recommendable to use small layer heights (0.125 or less) for small parts to improve the adhesion of the material from layer to layer. It is important to choose the printing direction that uses the least surface of the part to avoid as much as possible the heat concentration points that can lead to dimensional deformations.
	Spherical	0.2-0.6 mm	Good results starting at 0.6 mm	
	Hyperbolic	0.2-0.4 mm	Good results starting at 0.5 mm	

surface finish in order for our 4D printed product to be effective because these elements collectively determine whether a product is valid or not.

The printing direction influences the device to show better mechanical properties if the chosen direction is the right one. In addition, this direction influences the surface finish, another of the factors mentioned, since, depending on the printing direction, the layer-by-layer effect will be different, having relevance in final parts as well as in parts that need post-processing to obtain the desired finish.

Finally, tolerance control is vital in the design phase, being a relevant factor in the performance of actuators, mechanisms and joints that may be integrated into a final product.

This article tries to show that 4D printing is useful and a reality today, but it also demonstrates that a proper design phase, if possible, is more relevant than in conventional manufacturing methods, since a number of factors that affect the quality and performance of the final product are brought to light, but once they are successfully controlled, they allow us to squeeze the most out of additive manufacturing using new innovative materials, taking advantage of the benefits from the point of view of customization of the final product, making this technology being used in leading sectors such as medicine, automotive or aerospace industry.

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