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Design Rules for Producing Cardiovascular Stents by Selective Laser Melting: Geometrical Constraints and Opportunities

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Abstract

Additive Manufacturing (AM) has risen great interest in biomedical applications, for its flexibility and the possibility of producing patient-customized devices. Customization has high importance to limit inflammation and rejection. Moreover, some occlusions may take place in bifurcation sites, which require the insertion of multiple stents, increasing the risk and complexity of the procedure. Selective Laser Melting (SLM) can be exploited to realize metallic stents with geometries not depending on tubular precursor, allowing the study of devices with new shapes, such as for occlusions in high-tortuosity vessels and in bifurcated arteries. The geometrical flexibility of SLM is largely exploited for large components, while for small implants such as cardiovascular stents it has not been studied in depth. Accordingly, this work analyses the geometrical requirements of cardiovascular stents starting from traditional meshes and identifies design rules for AM.

Initially, traditional stent meshes are analysed to assess their feasibility in layer-by-layer production by SLM. An accurate investigation of the limitations imposed by the powder-bed process nature, the powder size and the laser spot diameter is performed, considering the relationship with stent dimensions, cell shape and strut inclinations. Finally, a set of design rules for SLM of stents are defined. These rules are used to design novel meshes producible with an industrial SLM system using cobalt-chromium powder. In particular, tubular stents are produced in expanded and semi-crimped configurations. Additionally, multi-branch stents were designed and produced to prove the capability of the process for bifurcation applications.

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In conclusion the validity of the defined design rules is assessed by the successful production of cardiovascular stents by SLM and their expansion.

Keywords: Additive manufacturing; Selective laser melting; Design for additive manufacturing; Cobalt-chromium alloy; Bifurcation

1. Introduction

Additive manufacturing (AM) shows great potential for the realization of patient-specific medical devices and its use has been widely investigated for dental applications and other biomedical implants (Ngo et al. (2018)). Polymeric stents have been previously reported by employing AM techniques (van Lith et al. (2016), Misra et al. (2017), Guerra and Ciurana (2018)). The production of metallic stents through selective laser melting (SLM) process is a recent concept. SLM is an additive manufacturing technique, where a laser beam selectively fuses metallic powders in a layer-by-layer fashion. Starting from a 3D model, the component is sliced into equal layers, where the layer pattern is selectively melted on the powder bed by a focused laser beam. Currently, the conventional manufacturing technique to realize metallic stents from metallic precursors is laser cutting of tubular precursor (Demir and Previtali (2014)). With the use of SLM, the limitations deriving from the tube precursor might be eliminated together with the drawbacks of the classical technology. In fact, the use of tubular precursors implicates that the stent dimensions are linked to the available tubes, whose manufacturing cost is high when small diameters are required. Moreover, the use of standard tube diameters results in the use of oversized stents, even 20% more than necessary, due to the fact that a 10% excess is used to ensure the stent apposition, and the excessive oversizing can induce an inflammatory response (Duraiswamy et al. (2008)).

Wessarges et al. (2014) produced stent-like structures with helical design using AISI 316L metallic powder and a SLM laboratory setup. They were able to produce such structures and expand them, but scanning electron microscope (SEM) images showed cracks when expanded. Demir and Previtali (2017a) used instead a CoCr alloy powder and an industrial SLM system, highlighting the presence of critical features in a commercial stent and producing then a simplified stent, but they did not study in detail the expansion behaviour or the mechanical properties. Wen et al. (2018) produced cardiovascular stents from zinc powder, using the design from Demir and Previtali (2017a), showing promising results for the realisation of SLM biodegradable implants. However, the full potential of producing stents through SLM has yet to be discovered. Key issues as the stent design, mechanical characteristics and consequently the expansion behaviour are still on the way.

Accordingly, in this work the design of stents for SLM process is studied. In particular, design rules are determined for processability of the geometry both in single tube and bifurcated configurations, as well as the achievement of desired expansion behaviour by means of an angioplasty balloon.

2. Analysis of existing manufacturing cycle and stent designs

Figure 1 shows a conventional manufacturing scheme of metallic stents compared to the possible use of an AM technique in the production cycle. Conventionally, metallic stents are cut from tubular precursors, which are produced through a tube extrusion and drawing cycle. Therefore, the tubular feedstock size determines the size of the stent, where a discrete number of diameters are available. To obtain a final stent with the required properties, chemical etching, heat treatment, surface cleaning and coating procedures are then performed. On the other hand, the feedstock material in SLM is the metallic powder. The process gives a near-net shape to the stent by scanning the powder bed in a layer-by-layer fashion. Potentially, stents sizes and forms can be varied in a more flexible way. However, manufacturing process constrains play an important role in the design phase.

Intrinsically, most of the conventional stent designs are adapted to a conventional production route. An analysis of commercial stent designs from a manufacturing point of view shows that the meshes can be classified in main two families: i) closed-cell and ii) open-cell. As described by Stoeckel et al. (2002) with closed-cell design, the stent is made of sequential rings which are connected at any peak and valley point and they provide an optimal scaffolding and plaque compression. On the other hand, open-cell stents have just periodic connections between the rings, and this gives higher flexibility during the implant procedure.

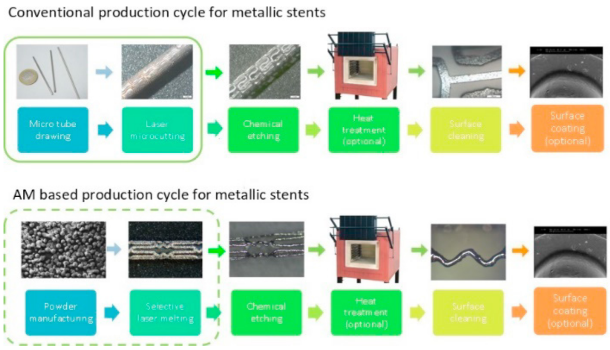

Fig. 1. Conventional stent manufacturing compared to a novel production cycle making use of AM.

A stent mesh is commonly described in an unwrapped configuration, which is later on projected to a tubular surface. Conventionally, a laser beam executes the mesh trajectory on a rotating and translating tube. The main issue remains as the evacuation of the scrap parts, which are commonly facilitated by the addition of destruction cuts (Catalano et al. (2018)). Indeed, a layer-by-layer additive manufacturing process of a stent mesh requires a distinct way of design pathway. Hence, the different designs need to be carefully analysed and modified to guarantee that the stents can be produced by SLM. Essentially, the design should guarantee that no features are built on the powder bed without connections to previously melted material. From this point of view, open-cell meshes appear problematic.

For similar reasons, the inclinations of the struts should be chosen to guarantee limited overhang regions, otherwise the growing feature will collapse. In addition, some limits are also posed to the geometry of the links between stent rings.

The current stent designs also evolve towards the use of the so-called ultra-thin struts, in which the thickness is below 70 µm (Bangalore et al. (2018)). For achieving such dimensions with SLM systems, an accurate selection of the process parameters is mandatory. In conventional SLM systems, the size of the powder feedstock, laser beam spot, and layer size are comparable to the strut size. The common powder size range for SLM systems is between 15 and 45 µm, the beam sizes vary between approximately 50 and 100 µm, whereas the layer thicknesses range between 25 and 100 µm. While for large components, these dimensions are negligibly small, for thin stents struts they determine the process resolution. As a rough example, the size of a 90 µm-thick struts is measurable by approximately 3 powder particles along the thickness. Due to melt pool effects and sintered particles, the size of the struts produced by SLM tend to be larger than the nominal one, meaning that ultra-thin struts cannot be easily achieved right after SLM. However, careful management of the process parameters, especially the use of pulsed wave laser emission, can provide features smaller than the laser beam size (Caprio et al. (2019)). The SLM produced surfaces are characterized by high surface roughness (Ra>10 µm) due to sintered particles, which results in significant dimensional error in small components (Demir and Previtali (2017b)). Net-shape production of parts via SLM is still a challenge for large components. For small stent struts, post-processing for surface finishing remains a crucial step, where dimensional accuracy should also be maintained throughout the process.

3. Definition of design rules for producing expandable stent meshes

Production of cardiovascular stents by SLM requires new designs which meet the requirements and the constraints given by the technology. The layer-by-layer melting of the powder set some constraints which must be considered in the design phase of the components. These constraints regard mainly orientation of the component, features inclination, connection with previously melted powder and spacing between adjacent features. Design for SLM rules have been set and conventionally used by designers for large components and lattice structures ((Redwood et al. (2017) and Renishaw (2017)). They constitute a starting point for smaller stents, while some additional constraints should be added. The basic design rules for producing expandable stent meshes are as follows.

- Support structures: Support structures are commonly used in SLM for providing mechanical link with the base plate as well as maintaining heat dissipation (Calignano (2014)). Concerning micro components such as stents, the size of these support structures becomes comparable to the one of the stent struts. Hence their removal has high probability of damaging and deforming the stent itself. For this reason, the use of supports should be avoided in the design of stents for SLM.
- Part orientation: Part orientation determines the slicing and build direction of the component, as well as the regions to support. The vertical orientation of the stent is arguably the best one for the build. In fact, other orientations would lead to the presence of overhang regions which would require supports.
- Cell configuration: Once the vertical orientation is chosen, the next problem arises from the cell configuration. In an open cell design, there is a high number of cell extremities which would require to be melted on loose powder of the previous layer, without any solid mechanical connection to the rest of the workpiece or the baseplate. Consequently, the new solidified material is not anchored and can be potentially removed by the movement of the powder recoater.
- Strut inclinations: In addition to the vertical orientation of the stent itself, strut inclinations, taking as reference the powder bed plane, should be carefully set to have self-supporting features and achieve good surface quality. The inclination must be higher than a certain value related to material, layer thickness and laser parameters. This value is approximately 45° for CoCr alloys, based on indications from SLM system producers.
- Strut overhangs: Overhang regions can be designed up to 1 mm otherwise supports are needed above this threshold to guarantee that the part is successfully built. Bridged gaps, which are features connected on both ends to the built component, can be designed with length up to 4 mm without the need of additional supports. This means that all strut lengths should be lower than such value.
- Strut spacing: When designing the cell of the mesh, another constraint to be followed regards the minimum horizontal spacing of the struts, that is the cell width itself. The minimum strut spacing must be higher than 0.3 mm to guarantee that the struts do not merge.
- Layer thickness: For the strut thickness instead, the minimum achievable dimension is limited by the melt pool size, which relies on beam diameter, powder size, and process parameters. Concerning the dimensions of the stent, the so-called staircase effect due to the layered process can become more pronounced. The choice of a small layer thickness is opportune to avoid the staircase effect formation. In order to maintain geometrical accuracy, it is preferable to set all vertical distances between vertices and extremities as a multiple of the powder layer thickness.

4. Design of tubular and bifurcated stents

4.1. Tubular stent design for SLM

Employing the SLM process, stents can be designed and produced in theory with any diameter. In addition, the unmelted powder can be recycled and reused with a very small fraction of loss (to authors' experience < 10%), in contrast with scrap from tubular laser cutting. In terms of the material usage, crimped, semi-crimped, or deployed stent configurations are feasible for the production through SLM. It should be however noticed, that on the same baseplate a high number of crimped or semi-crimped stents can be placed in comparison with target vessel diameter stents, allowing to have a higher production rate. In addition, the use of stents produced with the target diameter increases the radial deformation during crimping on the catheter and this mechanical aspect should be studied to understand the consequences on stent expansion and performance. For comparison purposes, both semi-crimped and target diameter stents were designed and studied for this work.

The starting point in the design of SLM optimized stents was the cell shape thought by Demir and Previtali (2017a) for semi-crimped configuration, which could be successfully produced through SLM. The 3D model of their design is reported in Figure 2.a. Such stent does not exhibit any non-supported features or excessively low inclinations and can be successfully built. However, the geometry of the cell was not optimized for flexibility and expansion behaviour.

Moreover, SLM produced alloys are known to have higher hardness and rigidity due to the fine microstructure generated through the fast cooling cycles induced by the process (Song et al. (2015)).

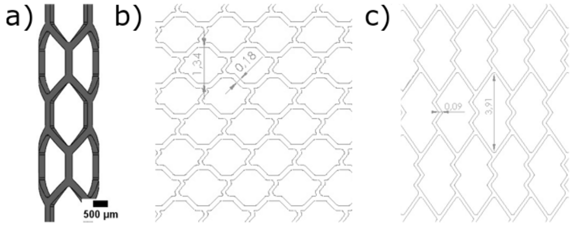

Fig. 2. a) 3D model based on the design by Demir and Previtali (2017a). Examples of b) a hexagonal cell mesh with corrugated links and c) an elongated cell mesh. Build direction is vertical to the image plane and parallel to the axial direction of the stents. Dimensions are in millimetres.

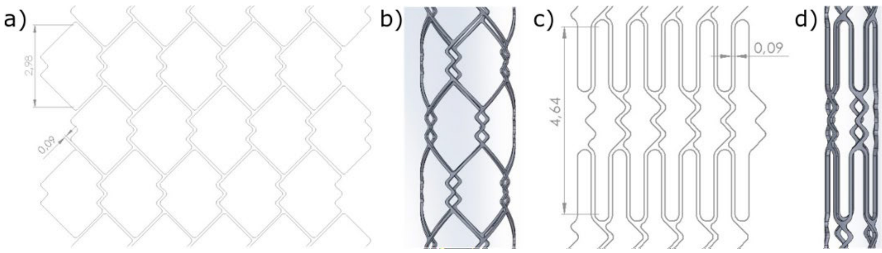

Fig. 3. a) 2D mesh and b) 3D model of a stent to be produced by SLM in the target vessel diameter. c) 2D mesh and d) 3D model of a semi-crimped stent optimized for SLM production. Build direction is vertical to the image plane and parallel to the axial direction of the stents. Dimensions are in millimetres.

To overcome these limitations, new cell shapes with corrugated connection geometries were designed. For what concerns stents to be produced with the target vessel diameter, Figure 2.b shows a mesh in which non-linear connectors were introduced between the struts. To increase furthermore the stent flexibility, a more elongated cell shape and with more corrugated links was designed as reported in Figure 2.c. Corrugated links were used to increase the flexibility of the closed cell design, both to facilitate the expansion and to ensure more adaptation to the vessel tortuosity. Inclinations of links and struts were chosen equal to 45 degrees, that is the minimum inclination with reference to the powder bed plane which ensures good quality with the used material and SLM system. As a final iteration, another mesh with wider cells and more rounded corners was drawn as reported in Figure 3.a.

For stents in the semi-crimped configuration instead, a cell shape with the same features of the one in Figure 3.a was used. Vertical struts were elongated and narrowed to obtain flexibility during expansion from the rotation of the struts around the connection points and the consequently enlargement of the cells along the stent circumference. In Figure 3.c, a 2D mesh designed with the final cell-shape is reported, following the previously stated rules and requirements for SLM production. A 90 µm nominal strut thickness, equal to three times the powder layer thickness, was chosen. The internal cell width is the result of the combination of three different inputs: the strut width, the internal stent diameter, set to 1.2 mm to easily crimp the stent on a catheter, and a target of 5 cells along the circumference. This combination gave as outcome a cell width equal to 344 µm, enough to ensure no merging of the struts. The 3D model obtained using such mesh is reported in Figure 3.d.

4.2. Bifurcated stent design for SLM

Multi-branched stents were designed to explore the realization of complex devices to be used for lesions in bifurcation sites. The best strategy for the treatment of bifurcation lesions has still not been defined and one of the used procedures requires more than one tubular stent to cover the main and the side branch (Hildick-Smith et al. (2016)), which implicates longer procedure time and inability to uniformly cover the vessel walls. The use of a single device could improve these aspects and SLM process can be exploited to produce non-tubular stents. Two different concepts were tested concerning the process feasibility.

The first concept was based on a multi-branch stent consisting of three tubular ones connected together. Such connections were obtained realizing loft features between one extremity of the main branch stent and the proximal extremities of the side branches. The chosen building direction was the one with the main branch stent with vertical orientation and the side branches placed below, otherwise the central connection would not be supported. The two side branch stents had axis inclined of 10° and the cells were designed with a maximum inclination of 35°, to not overcome the chosen 45° limit. In the design of the loft connections, inclinations were controlled to guarantee a proper support of the upper branch and their dimensions were set to create hexagonal closed-cells in the connection region. The same device was designed in two very similar configurations, with and without connection between the side branches, to understand the flexibility of the design and the capability of the SLM process.

The second concept consisted of the three vertical and parallel branches. The design requires fewer layers for production and allows to respect the design rules in terms of strut inclinations and size in avoiding the inclined branches. Loft features were used to connect the side branches to two opposite sides of the main one. The idea is to obtain the desired relative position of the branches deforming the connections and “opening” the stent. Connections were again designed to obtain hexagonal cells in the bifurcation region.

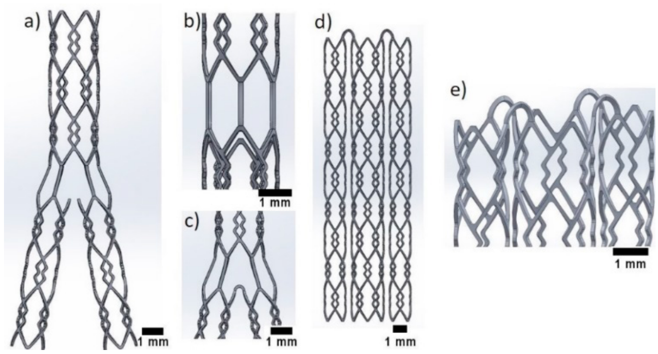

Fig.4. a) Stent for bifurcation with inclined non-connected side branches. b) Lateral view of the central connections. c) Focus on stent for bifurcation with connected side branches. d) Stent for bifurcation with parallel branches design. e) Focus on connections between branches.

5. Production of the designed stents

A Renishaw AM250 (Stone, UK) SLM system fitted with a reduced build volume (RBV) platform was used. The system was equipped with a 200 W fibre laser operating with pulsed wave emission by power modulation and an optical chain providing a 75 µm spot diameter. Process parameters were selected based on the results of a previous work by Demir and Previtali (2017a). Prototype stents were produced based on the mesh specifically designed for SLM production, using a constant powder layer thickness set to 30 µm. The material was a CoCr alloy (LPW Technology, Cheshire, UK), characterized by a particle size between 15 µm and 45 µm. The chemical composition of the alloy (Cr 27-30 wt%, Mo 5-7 wt%, Co bal.) is similar to ASTM F75 standard, very close to alloys normally used for commercial stents, such as L605, MP35N and Phynox/Elgiloy as reported by Poncin et al. (2004). Stents were analyzed for their geometrical integrity after the process. Tubular semi-crimped design was functionally tested by expanding with a balloon catheter. The bifurcated designs were functionally tested by deforming between the branches.

6. Integrity analysis of the prototype stents

6.1. Tubular stents

Two designs for tubular stents were used to validate the mesh and prove their successful production with SLM technology. A stent in semi-crimped configuration based on mesh in Figure 3.c and one with a vessel-like diameter, based on Figure 3.a, were produced. Optical and SEM images of the stent in semi-crimped configuration in as-built condition are reported in Figure 5.a and Figure 5.c, respectively, while Figure 5.b and Figure 5.d show images of the target-vessel diameter stent. It is possible to notice that both the stents were produced with good morphological accuracy, confirming that the designs meet the requirements of the SLM process. As visible in Figure 5 and Figure 6, supports were extruded from the lower extremity of the stents to attach them to the substrate. The optimization of such structures was not carried out in this work, but it will be done in future to obtain supports which can be easily removed with mechanical methods without damaging the stents.

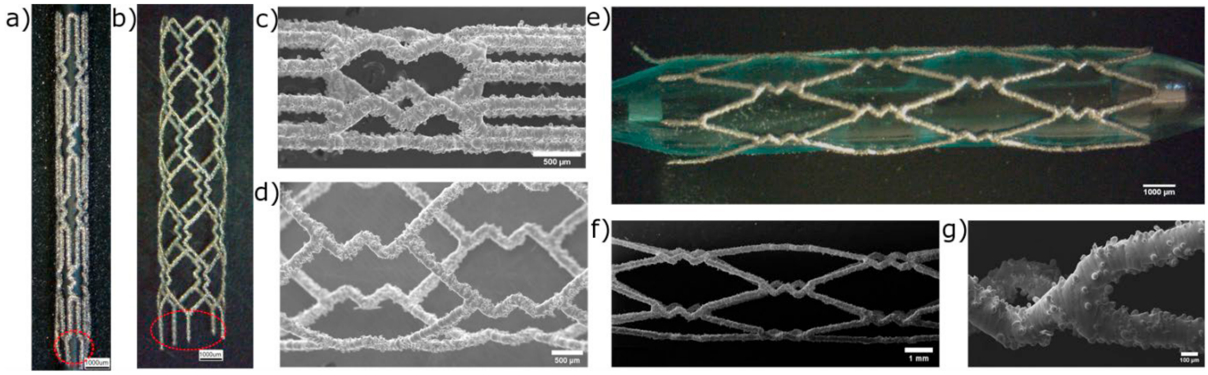

Fig.5. a) Semi-crimped stent in as-built condition with highlighted supports and c) SEM image of a detail. b) Target-vessel diameter stent in as-built condition with highlighted supports and d) SEM image of a detail. e) Expanded stent mounted on a balloon catheter. f) SEM image of the expanded stent. g) SEM image of a joint at a cell extremity.

To verify the applicability of the designed stent in terms of expansion, the semi-crimped stent was mounted on a medical balloon which was inflated with a screw pump. A final inflation pressure of 8 bar was reached and the result is shown in Figure 5.e. The external stent diameter increased from the measured value of 1.64 mm to 4.50 mm. A SEM image of the expanded stent is shown in Figure 5.f and a focus of the joints between cells is reported in Figure 5.g, in which cracks are absent.

6.2. Bifurcated stents

Figure 6.a and Figure 6.b shows the bifurcated stent concepts produced by SLM. Both concepts were successfully built without breakage and cracking. Same outcome was achieved for the vertical design, shown in Figure 6.c, which was then deformed to assess the validity of the loft connections, as visible from the SEM image in Figure 6.d.

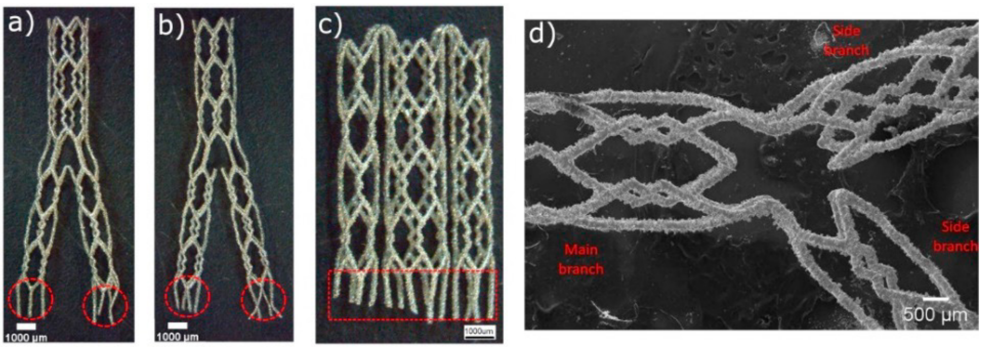

Fig. 6. a) b) and c) Stents for bifurcated lesion in the as-built condition with highlighted supports. d) SEM image of the central connections after deformation.

7. Conclusions

In this work, design rules for SLM were identified and implemented for producing CoCr cardiovascular stents. Cell shapes were investigated to provide flexibility and good expansion behaviour. Tubular stents with semi-crimped and target-diameter configurations were investigated, as well as novel geometries to treat complex lesions which can occur in bifurcation sites. The designed stents were successfully produced using an industrial SLM system with commercial powders. Tubular semi-crimped stents could be successfully expanded without cracks or breakage. The bifurcated designs showed sufficient flexibility in the connection sites for deformation to the desired final shape. The results also show that the surface should be further studied. The material allowance should be determined to compensate the material loss through the chemical and electrochemical polishing techniques suited for the process. The material properties and mechanical behaviour are part of future studies. Concerning the novel shape possibilities and bifurcation designs the simulation tools are expected to be of great importance to predict the deformation behaviour prior to the implantation stage.

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