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Patient-specific cardiovascular superelastic NiTi stents produced by laser powder bed fusion

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Abstract

To date, there is a general lack of customizability within the selection of endovascular devices for catheter-based vascular interventions. Laser powder bed fusion (LPBF) has been flexibly exploited to produce customized implants using conventional biomedical alloys for orthopedic and dental applications. Applying LPBF for cardiovascular applications, patient-specific stents can be produced with small struts (approximately 100-300 µm), variable geometries, and clinically used metals capable of superelastic behaviour at body temperature (eg. equiatomic nickel-titanium alloys, NiTi). Additionally, the growing availability and use of patient-specific 3D models provides a unique opportunity to outline the necessary manufacturing process that would be required for customizable NiTi devices based on patient geometry. In order to fulfil the potential of the patient-specific superelastic stents, process and design know-how should be expanded to the novel material and fine details at the limits of conventional LPBF machines. In this work, a framework for developing a patient-specific superelastic NiTi stent produced by LPBF is demonstrated. At a proof-of-concept stage, the design procedures are shown in a geometry similar to the artery. The stents with 100 µm nominal strut diameter are later produced with a $Ni_{50.8}Ti_{49.2}$ powder and heat treated. The results confirm the possibility of producing stents with a design suitable for highly complex patient-specific anatomies and having superelastic behavior at body temperature.

Keywords: Nitinol; additive manufacturing; customized implants

1. Introduction

Laser powder bed fusion (LPBF) is an established method for producing customized implants in the dental and orthopedic fields. Stainless steel, CoCr, and Ti6Al4V are most widely used for producing patient-specific implants starting from digitally acquired computed tomography data [1][2][3]. The metallic powders are melted in a layer-by-layer fashion to produce the implant geometry conformal to the patient's anatomy. Other advantages of using LPBF include the possibility to produce lattice structures and thin struts that can be exploited to minimize stress-shielding effects and improve tissue integration to the body [4]. Typically, the micro struts used in these geometries have diameters in the range of 0.5 mm or larger. A stent is geometrically very similar to the lattice structures, while the material type and the strut dimensions of a stent can be very different.

The use of LPBF for producing cardiovascular stents has been first discussed a few years ago [5][6]. Essentially, the LPBF technology can be exploited to produce patient-specific

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stents with potentially much shorter lead times [6][7]. The design flexibility has also been demonstrated with the production of bifurcated geometries [8] as well as open-celled meshes [9]. The mechanical integrity of LPBF produced stents are adequate for balloon expansion [10]. The use of superelastic NiTi for producing open-celled stent designs with variable diameters and lengths displays the additional possibility of using this technology for patient-specific superelastic devices.

LPBF of patient-specific superelastic implants poses several challenges in terms of dimensional accuracy and material properties. The thin strut sizes (100-300 µm) are comparable to the size of the powder particles (10-60 µm) and the laser beam (50-100 µm). This requires careful control of the energy release but also the scan vector accuracy. NiTi alloys are notoriously difficult for processing via LPBF due to their intrinsic sensitivity to heat [11–13]. A key issue regards the chemical composition variations during the LPBF process and the formation of intermetallic precipitates, which change the mechanical behavior. Hence, often the process is accompanied by a heat treatment to recover the superelastic behaviour.

To date, there is a general lack of customizability within the selection of endovascular devices for catheter-based interventions. On market, stent devices are available in a variety of sizes that clinicians must choose from on a case-by-case basis. Vessel sizing is done beforehand using clinical imaging modalities, and a stent is selected using manufacturers' recommendations based on length and diameter. For situations where the lesion length is longer than the available stent sizes, multiple stents can be used to account for the difference[14]. While this is an appropriate treatment strategy, the clinic could benefit from the use of stents with custom lengths and diameters that mimics the patient vessel size closely. In some femoropopliteal stenting cases, up to five overlapping 10 cm stents can be used in lesions that extend up to 30 cm in length[15].

The use of superelastic variable geometry stents is also a potential solution for treating complex cardiovascular pathologies. Furthermore, an understanding of patient vascular geometry before cardiovascular procedures via 3D modelling has already been realized clinically [15]. Three-dimensional patient-specific models derived from CT scans have been utilized in the planning of complicated procedures such as transverse aortic arch hypoplasia[16], and transcatheter valve implantation[17]. Clinicians have used these models to practice the complex delivery of endovascular devices, as well as identify the appropriate sizing parameters for some selected endovascular devices. The growing availability and use of patient-specific 3D models and the need for customizable load-bearing superelastic devices provide a unique opportunity to outline the necessary manufacturing process that would be required for customizable NiTi devices based on patient geometry. Despite the available tools, such biomedical devices have not been yet developed especially due to the lack of knowledge in the design and manufacturing phases. To authors' knowledge, no previous work in literature has demonstrated additive manufacturing of stents following the shape of an artery.

Accordingly, this work described the phases for producing patient-specific superelastic NiTi stents directed towards variable patient geometries. The work describes the design methods starting from mimicked patient data. Furthermore, our work reports the manufacturing conditions allowing to produce the desired form with superelastic behaviour at body temperature.

2. Patient-specific stent modeling

The computed tomography (CT) data can be prepared while the patient is receiving pre-operation care such as surgical planning and anatomical evaluation/ modelling (Fig.1). The digital data can be processed to outline the stenting zone. The use of a parametric model, which allows us to generate patient-specific geometries within a very short time, becomes a key element for the application of complex patient-specific procedures. Using CT data of the patient, measurements can be performed on images and the dimensions can be added in the stent model. A unitary geometry can be applied to a base surface defined by the patient anatomy and the stent is generated from its repetition and thickening.

Combined with finite element modelling (FEM) the 3D stent model can be validated before additive manufacturing. The patient-specific stent can be produced within a single day employing smaller sized LPBF machines in the hospital or the local additive manufacturing hub. If required, several types of variations can also be produced contemporarily allowing the surgeon to have greater flexibility with the operation. The metal additive manufacturing device can be matched with a polymeric model producing a real-sized replica of the artery for the surgeon to physically see the intervention zone. All of such possibilities require a better understanding of the manufacturing processes involved.

Fig. 1. Timeline of the development of a clinically relevant patient-specific model. The dashed grey box shows imaging that can take place before the procedure. The full-lined boxes show operations after imaging and modelling. All of the production and validation must take place before the endovascular intervention, which should happen within a < 1-2-week time frame for non-emergency cases[18].

3. Design of a patient-specific stent

In this work, a patient-specific design was mimicked on a similar geometry without the use of patient data as a means to demonstrate the feasibility of the approach. To exploit the full potentiality of LPBF process for stent production, the design of stents based on patient data is needed. In particular, Fig. 2 shows a design methodology to create 3D models of patient-specific stents. The methodology consists in adapting a stent mesh to a surface that mimics the patient's vessel wall.

Once a 3D wireframe is created on the vessel base surface, the stent can be modeled through the use of the sweep function. The wireframe is based on a conventionally employed diamond cell shape, which allows having processability with LPBF avoiding large overhangs. This kind of design strategy allows assigning various kinds of shapes and dimensions to the strut section.

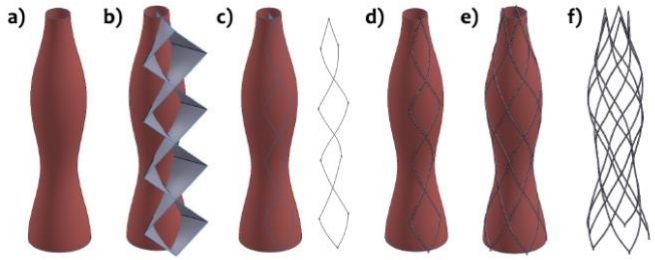

Fig. 2. (a) Base surface from mimicked patient data, b) reference surfaces for the mesh, c) baseline obtained from the intersection between the base surface and reference d) 3D wireframe with circular profile following the base surface, e) complete stent on the base surface, f) final stent.

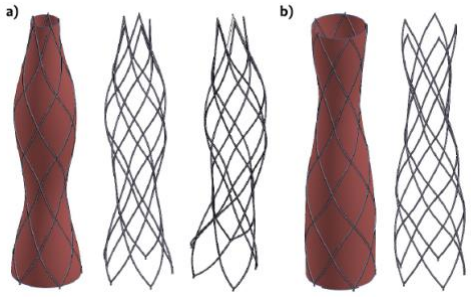

Fig. 3. Design adaptation for differently mimicked patients: a) stent bending for non-rectilinear applications and b) adaptation of the same mesh to a different base surface.

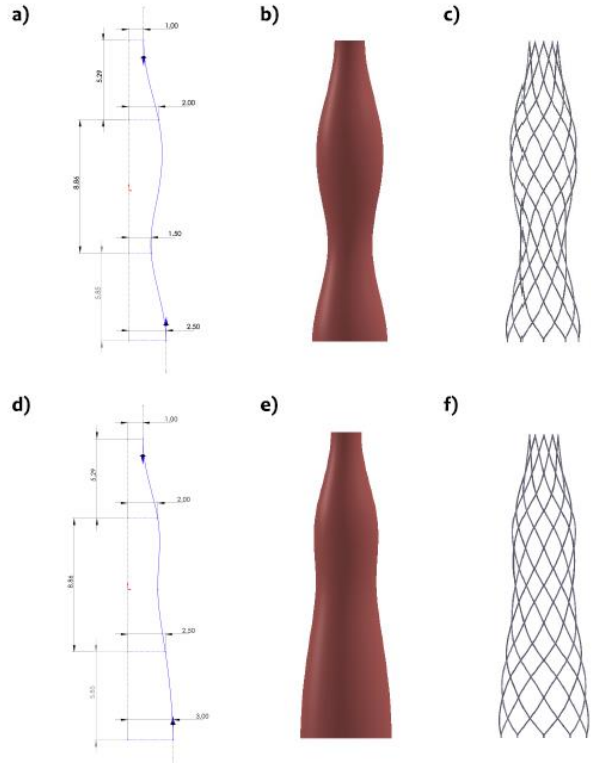

Fig. 4. Patient-specific stent adapted to different vessel dimensions. a,d) control points for surface generation; b,e) base surfaces and c,f) stent models for LPBF production.

As shown in Fig. 3 the design can be personalized based on the specific patient even in terms of a non-rectilinear axis. In Fig. 4 two stent geometries are presented with their base surfaces. Since the base surface is defined through splines, it is fully parametric and it is sufficient to change the values of the vessel dimension to regenerate the 3D model. The produced stent is based on these designs to assess the feasibility of the additive manufacturing process chain.

4. Additive manufacturing of the designed stent

$Ni_{50.8}Ti_{49.2}$ powders were used throughout the work (SAES Getters, Lainate, Italy). Fig. 5.a shows an SEM image of the powder. The nominal chemical composition of the powder was suitable for superelastic behaviour and an austenitic microstructure at the body temperature. Indeed, the austenitization finishing temperature of the powder was measured at 16°C.

Renishaw AM250 (Stone, UK) was the employed LPBF system. The machine was fitted with a reduced build volume (RBV) system, reducing the build volume to 78x78x50 mm^3 (see Fig. 5.b). A single-mode fiber laser (R4 from SPI, Southampton, UK) with a maximum power of 200 W provided the processing beam. The minimum laser beam was 75 µm at the focal point. The LPBF process was carried out in pulsed mode (PW), with µs-long pulses. Before the LPBF process the build chamber was kept filled with Ar, and the process was carried out operating at <1000 ppm of O_2.

The process parameters were chosen to have sufficient part density (>99.5%) and were a result of extensive experimental analysis not reported here for the sake of brevity. The volumetric energy density was 185 J/mm^3 with a meander scan strategy on 100 µm nominal strut size. The stents were consecutively heat-treated at 500°C for 15 min under Ar. Table 1 summarizes the processing conditions used in the production.

Table 1. Summary of process parameters used in the stent production.

Parameter	Value
Energy density	185 J/mm^3
Scan strategy	Meander
Heat treatment	500°C; 15 min under Ar

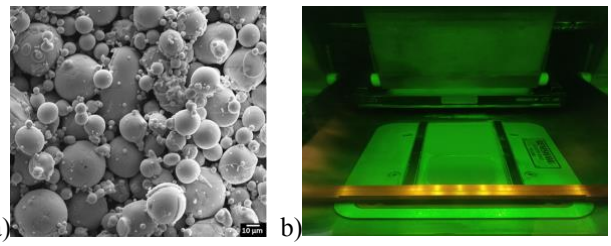

Fig. 5. a) NiTi powder used in the study. b) Reduced build volume platform inside the build chamber.

Fig. 6 shows the produced stent. It can be seen that the geometries could be produced with high fidelity and detail. The diameter variations could be achieved and the junctions were successfully produced without strut breakages.

Fig. 7 shows the differential scanning calorimetry (DSC) analyses after the heat treatment. Different curves depict different measurement repetitions. The curves indicate that the austenite finish temperature was 28.0± 2.7°C. The values are

below the body temperature, which confirm the suitability of the material for producing superelastic properties.

The present results confirm the suitability of the proposed approach for the production of patient specific superelastic stents in terms of geometrical capabilities and transformation temperatures. Indeed, the mechanical properties require further attention. The NiTi alloys employed in cardiovascular devices should have adequate static and fatigue resistance. Compared to the conventionally produced stents via laser microcutting or wire braiding the LPBF produced stents may show different behaviour due to the different microstructure produced by the rapid solidification process, layered material structure and internal porosity. Such differences may be confronted through topological optimization in the FEM stage.

Fig. 6. Patient-specific NiTi stent produced with LPBF.

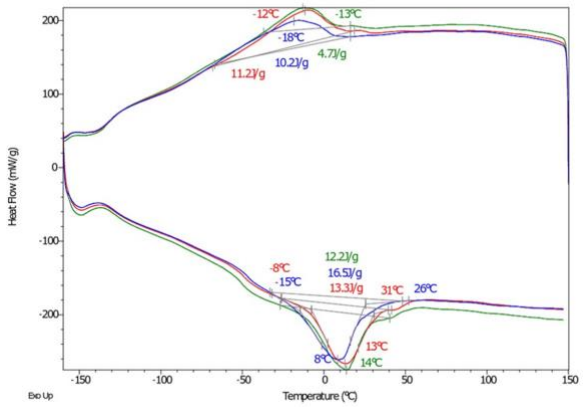

Fig. 7 DSC pattern of the NiTi stent after the heat treatment.

5. Conclusions

The present work shows the feasibility and workflow for the additive manufacturing of superelastic and geometrically variable patient-specific NiTi stents. The results confirm that by careful adaptation of the additive manufacturing process chain and the correct use of the design for additive manufacturing rules, functional devices can be made with a rapid turnaround. The work shows results up to the proof of concept at a geometrical degree. Indeed, mechanical testing of the superelastic behavior is further required to assess the material properties but also to acquire the data for the finite element modelling. Future works will look into mechanical behaviour and biological performance of additive manufactured NiTi in terms of in vitro, in-vivo testing as well as fluid dynamic measurements.

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References

[1] Yadroitsev I, Krakhmalev P, Yadroitsava I. Selective laser melting of Ti6Al4V alloy for biomedical applications: Temperature monitoring and microstructural evolution. J Alloys Compd 2014;583:404–9. doi:10.1016/j.jallcom.2013.08.183.

[2] Hooreweder B Van, Lietaert K, Neirinck B, Lippiatt N, Wevers M. CoCr F75 scaffolds produced by additive manufacturing: Influence of chemical etching on powder removal and mechanical performance. J Mech Behav Biomed Mater 2017;70:60–7. doi:10.1016/J.JMBBM.2017.03.017.

[3] Kong D, Ni X, Dong C, Lei X, Zhang L, Man C, et al. Bio-functional and anti-corrosive 3D printing 316L stainless steel fabricated by selective laser melting. Mater Des 2018;152:88–101. doi:10.1016/j.matdes.2018.04.058.

[4] Carluccio D, Demir AG, Bermingham MJ, Dargusch MS. Challenges and Opportunities in the Selective Laser Melting of Biodegradable Metals for Load-Bearing Bone Scaffold Applications. Metall Mater Trans A Phys Metall Mater Sci 2020. doi:10.1007/s11661-020-05796-z.

[5] Wessarges Y, Hagemann R, Gieseke M, Nölke C, Kaierle S, Schmidt W, et al. Additive manufacturing of vascular implants by selective laser melting. Biomed Tech 2014;59:S401–4. doi:10.1515/bmt-2014-5005.

[6] Demir AG, Previtali B. Additive manufacturing of cardiovascular CoCr stents by selective laser melting. Mater Des 2017;119:338–50. doi:10.1016/j.matdes.2017.01.091.

[7] Moore SS, O’Sullivan KJ, Verdecchia F. Shrinking the Supply Chain for Implantable Coronary Stent Devices. Ann Biomed Eng 2016;44:497–507. doi:10.1007/s10439-015-1471-8.

[8] Finazzi V, Demir AG, Biffi CA, Chiastra C, Migliavacca F, Petrini L, et al. Design Rules for Producing Cardiovascular Stents by Selective Laser Melting: Geometrical Constraints and Opportunities. Procedia Struct Integr 2019;15:16–23. doi:10.1016/j.prostr.2019.07.004.

[9] Maffia S, Finazzi V, Berti F, Migliavacca F, Petrini L, Previtali B, et al. Selective laser melting of NiTi stents with open-cell and variable diameter. Smart Mater Struct 2021;30:105010. doi:10.1088/1361-665X/ac1908.

[10] Finazzi V, Demir AG, Biffi CA, Migliavacca F, Petrini L, Previtali B. Design and functional testing of a novel balloon-expandable cardiovascular stent in CoCr alloy produced by selective laser melting. J Manuf Process 2020;55:161–73. doi:10.1016/j.jmapro.2020.03.060.

[11] Dadbakhsh S, Speirs M, Kruth JP, Schrooten J, Luyten J, Van Humbeeck J. Effect of SLM parameters on transformation temperatures of shape memory nickel titanium parts. Adv Eng Mater 2014;16:1140–6. doi:10.1002/adem.201300558.

[12] Biffi CA, Bassani P, Fiocchi J, Tuissi A. Microstructural and mechanical response of Niti lattice 3D structure produced by selective laser melting. Metals (Basel) 2020;10:1–9. doi:10.3390/met10060814.

[13] Biffi CA, Fiocchi J, Valenza F, Bassani P, Tuissi A. Selective Laser Melting of NiTi Shape Memory Alloy: Processability, Microstructure, and Superelasticity. Shape Mem Superelasticity 2020. doi:10.1007/s40830-020-00298-8.

[14] Laird JR, Katzen BT, Scheinert D, Lammer J, Carpenter J, Buchbinder M, et al. Nitinol stent implantation versus balloon angioplasty for lesions in the superficial femoral artery and proximal popliteal artery: Twelve-month results from the RESILIENT randomized trial. Circ Cardiovasc

Interv 2010;3:267–76. doi:10.1161/CIRCINTERVENTIONS.109.903468.
[15] Giannopoulos AA, Mitsouras D, Yoo SJ, Liu PP, Chatzizisis YS, Rybicki FJ. Applications of 3D printing in cardiovascular diseases. Nat Rev Cardiol 2016;13:701–18. doi:10.1038/nrcardio.2016.170.
[16] Valverde I, Gomez G, Coserria JF, Suarez-Mejias C, Uribe S, Sotelo J, et al. 3D printed models for planning endovascular stenting in transverse aortic arch hypoplasia. Catheter Cardiovasc Interv 2015;85:1006–12. doi:10.1002/ccd.25810.
[17] O'Neill B, Wang DD, Pantelic M, Song T, Guerrero M, Greenbaum A, et al. Transcatheter caval valve implantation using multimodality imaging: Roles of TEE, CT, and 3D printing. JACC Cardiovasc Imaging 2015;8:221–5. doi:10.1016/j.jcmg.2014.12.006.
[18] Enzmann FK, Nierlich P, Aspalter M, Hitzl W, Dabernig W, Hölzenbein T, et al. Nitinol Stent Versus Bypass in Long Femoropopliteal Lesions: 2-Year Results of a Randomized Controlled Trial. JACC Cardiovasc Interv 2019;12:2541–9. doi:10.1016/j.jcin.2019.09.006.