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Assessment of heart valve frame manufactured by laser powder bed fusion

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Abstract: Typically, the frames of replacement heart valves are manufactured by laser cutting. Whilst this method limits the scope for novel concepts are made possible by additive manufacturing. With this in mind, the feasibility of manufacturing heart valve frames by laser powder bed fusion (LPBF) has been investigated based the SAPIEN 3 frame. Using stainless steel powder, this study has demonstrated the feasibility of successfully manufacturing frames with 0.4 mm cross-sectional dimensions. Although geometric accuracy and surface quality need to be improved, a low porosity of 0.5% was achieved and the frames could be successfully crimped and expanded without any breakages.

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I. Introduction

Aortic stenosis (AS) is the most common form of heart valve disease affecting tens of millions of people across the world. In AS, the valve leaflets fail to open and close due to thickening and calcium deposition. The current state of art for the treatment of AS is rapidly moving towards transcatheter aortic valve implantation, TAVI [1]. There are two major kinds of TAVI devices, namely balloon expandable devices and self-expandable devices [2]. The stent frames in these valves are generally produced by laser cutting from metallic tubes. However, maturing metal AM technologies have introduced the capability to develop new valve concepts which can't be produced by laser cutting, such as frames changing shape along the radius direction.
LPBF is one of the most popular metal AM technologies, and it can produce high quality parts from a wide range of materials, including stainless steel, titanium, and Ti-based alloy, aluminium, and Al-based alloys, metal matrix composites, and nitinol [3-5]. In this study, the feasibility of manufacturing SS heart valve frames using LPBF was investigated, based on a representative model of the market leading balloon expandable SAPIEN S3 (Edwards Lifesciences).

II. Material and methods

Several frames were fabricated by SISMA S.p.A (Italy) with strut thicknesses of 0.3 mm and 0.4 mm. A MySint 100 system (depicted in Fig.1a) was used, which has a 200 W fiber laser with a 55 μm laser beam. The process parameters were set as follows: laser power of 113 W, scan speed of 700 mm/s, layer thickness of 20 μm. Since the cross-section area of struts was very small, the laser scanned along the border without a filling scan. One frame was treated with sandblasting to compare with the as built frames.

316L SS (EN 1.4404) powder was used in the fabrication with a spherical morphology and a size distribution between 10 and 45 μm. Strut geometric accuracy of the as-built frames was assessed (i) by measuring the vertical struts and inclined struts six times each with a digital caliper and (ii) by high resolution X-ray CT scanning and analysis using Thermo Scientific Avizo Software. Further, the frames were examined with the Alicona 3D optical microscope system.

Then, the frames were physically crimped and expanded with an Edwards Commander Delivery System (26 mm balloon). The diameter and height of the opened frames were measured and recorded.

Figure 1: (a) SISMA MySint 100 printer, (b) S3 type frames on the metal plate.

III. Results and discussion

III.I. Dimensional accuracy and surface quality

The printed frames – three of each size – are illustrated in Fig.1b. Unfortunately, all the frames with 0.3 mm strut thickness were damaged during removal from the build plate, and the 0.4 mm frames suffered some minor distortion in the bottom cells. With reference to Table 1, the 0.4 mm frames had vertical and inclined strut widths of 0.4±0.01 mm and 0.6±0.05 mm, respectively.

Table 1: The strut width of the S3 frames (0.4 mm).

Frame treatment	Strut width (mm)	
As built	Vertical strut	0.4±0.01
	Inclined strut	0.6±0.05
Sandblasted	Vertical strut	0.37±0.008
	Inclined strut	0.59±0.03

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Due to the relatively large dimensional error of 50% in the inclined struts, the frames were sand-blasted. This reduced the respective widths by 0.03 mm and 0.01 mm.

The surface roughness is summarized in Table 2. For the as built frame, the side surface had the lowest surface roughness of Ra = 11.05±2.64 µm and the top surface had a surface roughness of Ra = 23.39±11.29 µm. The bottom surface had the largest surface roughness of Ra = 50.09 ±6.67 µm. After sandblasting, the side surface and top surface were slightly improved by between up to Ra = 5 µm. However, the roughness of the bottom surface was significantly reduced by 32.3%.

Table 2. The surface roughness of S3 type frames.

Frame treatment	Surface roughness (Ra/ µm)		
	Side surface	Top surface	Bottom surface
As built	11.05±2.64	23.39±11.29	50.09±6.67
Sandblasted	8.43±3.91	19.08±6.13	33.85±10.69

III.II. High resolution CT scanning

One of the as built frames was scanned by high resolution X-Ray CT scanner. The segmentation of CT data was processed in Avizo. The porosity was 0.5% based on the volume fraction of the metal and pore voxels. As shown in Fig.2, the pores were distrusted in the centre of the inclined struts and the leaflet assembly slot. The pores in the inclined struts are very small, while the pores in the leaflet assembly slot have much larger size. The pores are open and connected thin layer pores, with equivalent diameters as high as 0.42 mm. This is most likely due to only the borders being scanned with insufficient overlap between the tracks, such that the centre volume may not be fully densified.

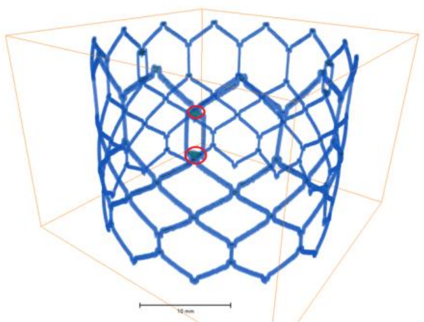

Figure 2. The reconstructed S3 type frame with pores.

III.III. Crimping and expanding

Fig.3 illustrates the deployment procedure of the sandblasted S3 type frame. Considering the rough surface of the frame, a thin fabric was placed between the frame and the balloon to avoid bursting of the balloon.

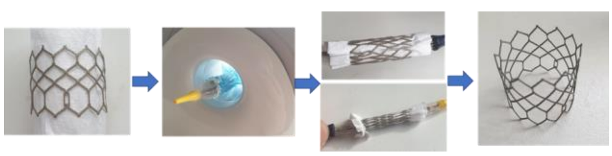

Figure 3. The deployment procedure of the S3 type frame.

The frame could be fully opened with the 26 mm balloon. The diameter and height of the frame was measured and summarised in Table 3. The diameters of the 1st, 2nd and 3rd, and 4th layer cells are 24.89 mm, 24.2 mm, and 24.32 mm, respectively. This indicates larger deformation at the top and bottom of the frame compared with the middle cells. This can be explained by the dog-boning effect common in the balloon expansion of stents and stent-like frames. Compared with the designed height of 20 mm, the height of the opened frame ranges from 21.4 mm to 24.16 mm. It's obvious the frame was not uniformly expanded along the circle possibly due to non-uniform crimping.

Table 3. The dimensional data of the expanded frame.

Dimension	Diameter (mm)			Average (mm)	
4th layer cell	24.3	24.25	24.41	24.32	
2nd and 3rd layer cells	24.13	24.17	24.3	24.2	
1st layer cells	24.93	24.95	24.79	24.89	
Height	21.4	22.42	23.64	24.16	21.9

IV. Conclusions

Through LPBF manufacture and analysis of a representative SAPIEN S3 type replacement heart valve frame, the potential of LPBF technology has been demonstrated for these thin strut structures. The results can be concluded as follows:

1) Strut cross-sectional dimensions of 0.4 mm can be successfully fabricated by LPBF.
2) The LPBF frames had a low porosity of 0.5% as determined by high resolution X-Ray scanning.
3) The surface roughness of the struts was relatively high (Ra 8-50 µm) but could be improved following sand-blasting.
4) Good geometric accuracy was achieved for vertical struts but, for the inclined struts, it was low with a 50% discrepancy.
5) The LPBF frames were successfully crimped and fully opened without breakages but better control of the final shape was required than that achieved in this study.

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AUTHOR'S STATEMENT

Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

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