Rapid Fabrication of Annuloplasty Rings by Electron Beam Melting

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1 Background

Electron Beam Melting (EBM) is an Additive Manufacturing (AM) technology capable of producing intricate parts by melting powder metal with the aid of an electron beam gun. EBM has facilitated the production of standard and customisable implants. Customizable implants such as orthopaedic implants, cranial implants and dental implants have already been developed and implanted successfully after being fabricated by AM technology. [1] Other medical devices can also benefit from the possibilities offered by AM. An example of such a medical device would be the annuloplasty ring. Standard annuloplasty rings are implanted whenever a patient is diagnosed with mitral valve regurgitation (see Figure 1). This problem arises when the mitral valve does not close properly, causing back leakage through the closed valve resulting in blood flowing to the atrium instead of the aorta during systole. The latest designs of annuloplasty rings allow restoration of the mitral annulus configuration to a saddle-shaped shape.

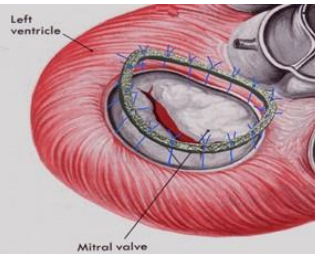

Figure 1: Annuloplasty ring superimposed on mitral valve – adapted from [2]

2 Methodology

Standard annuloplasty rings with a saddle shaped structure have been modelled using Computer Aided Design (CAD). Two distinctive designs, differing in their size were chosen as the basis of this research. In, addition, one pre- and one process parameter were altered, namely the standard tessellation language (STL) file and the focus beam offset. The STL file translates the CAD model into a number of triangulation facets. The number of triangular meshes determines the resolution of the tessellated CAD geometric model. For this experimental procedure, two levels were chosen - low and high resolution. Switching between low and high resolutions causes surface deviation, normal deviation and the maximum edge length to change whilst the aspect ratio remains unchanged. Another parameter that was chosen was the focus beam offset which is a critical melt parameter for EBM. This is defined as the additional current flowing in the respective electromagnetic coil and can be rendered into an offset from its starting position, zero of the focal plane. Thus, it defines the size and depth of the melt zone. Opting for a small focus beam offset results in a concentrated beam spot having a deeper melting zone. Inversely, when altering to a high focus offset, a larger beam is obtained which can become blurry such that it may result in partially melting the titanium powder.

A multi-factorial design of experiment procedure was adopted. Table 1 is the factorial table with the defined factors when altered between two levels.

Table 1: Design of Experiments Structure

Experiment	STL file		Focus Offset	
1	-	Low	-	3mA
2	+	High	-	3mA
3	-	Low	+	8mA
4	+	High	+	8mA

The EBM S12 machine from *Arcam* was used in this research and the material chosen was Ti-6Al-4V ELI powder m. After the initial batch was successfully built, the experimental procedure was repeated, however this time support structures were incorporated with the modelled annuloplasty rings. This research was particularly interested in how parts can maintain dimensional accuracy, since EBM has been fairly criticized for parts that tend to lose their geometrical accuracies. An engineers' microscope was used to record measurements in the x and y-axis. In addition a digital dial gauge was used to record measurements in the z-axis.

3 Results

From the measurements recorded, dimensional accuracy (DA) value for each ring was calculated. Table 2 arrays dimensional accuracy yielded for the smallest saddle shaped ring with and without support structures. A smaller value for dimensional accuracy suggesting that a higher dimensional accuracy was attained Figure 2 compares the saddle shaped rings obtained which appertain to experiment three.

Similarly, Table 3 shows dimensional accuracy obtained for the larger saddle shaped rings with and without support structures. Figure 3 shows the large saddle shaped rings fabricated by EBM with and without support structures. Again the rings represented appertain to experiment three.

Table 2: Dimensional accuracy for smallest ring with(out) support structures

Expt. No.	Without Supports, DA %	With Supports, DA %
1	9.18	3.12
2	8.20	2.87
3	3.56	3.32
4	5.26	4.12

(a) (b)

Figure 2: Small saddle shaped ring per experiment 3, a) without support structures b) with support structures

Table 3: Dimensional accuracy for largest ring with(out) support structures

Expt. No.	Without Supports, DA %	With Supports, DA %
1	10.39	6.57
2	9.65	2.95
3	11.33	3.78
4	11.01	3.29

(a) (b)

Figure 3: Largest saddle shaped rings a) without b) with support structures

A main effect plot was adopted to single out each factor and signify its consequence on the dimensional accuracy. Figure 4 shows a main effect for the larger saddle shaped ring without support structures. Similar results were achieved, in the sense that a higher gradient was achieved for the focus beam offset parameter in attaining dimensional accuracy.

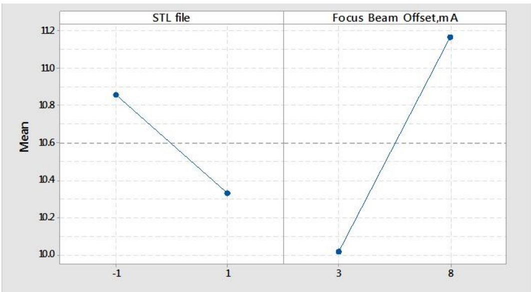

Figure 4: Main effect plot for saddle shaped ring without support structures

4 Interpretation

For the small saddle shaped rings, without support structures, increasing the focus beam offset, resulted in an increase in the dimensional accuracy. In contrast, for the largest rings increasing the focus beam offset resulted in a decrease in dimensional accuracy. The larger saddle shaped rings are characterized by an overhanging feature on the side of the rings which is much more prominent than the smaller saddle shaped rings. Gong *et al*. [3] reasoned out that on increasing the focus offset value, the morphology of the melt pool is changed, causing it to widen and reduce its depth. Increasing the focus offset parameter has been a subject of discussion in many investigations, as it is believed that by increasing this value, the part would be prone to a number of defects. Gong *et al.* [4] also noticed that as the beam diameter increases, stemming from the increase of the focus offset, the energy density is significantly reduced, resulting in an increase in porosity within parts. In fact, warping was anticipated in the larger rings and it occurred on the anterior side of the ring, which has a more prominent overhanging feature in contrast to the posterior side, as can be seen in Figure 3(a). Moreover, warping occurred in both experiments where the focus beam parameter was set high, which arguably resulted in a decrease in the dimensional accuracy of these rings.

Although the build chamber within EBM is maintained between 500 to 700^{o}C, thus relieving stresses during the build cycle, warping is still a potential issue. Meriam *et al.* [5] made a similar observation and related warping to thermal stresses involved during the build cycle. As the molten powder solidifies, thermal stresses are relieved at the stage where the parts are detained at high temperatures, causing warping. Warping is also the result of the non-uniform heat distribution located at the start plate's surface, resulting in uneven thermal stresses in the parts.

Although the main effect plot depicted in Figure 4 suggests that the STL file factor was not of a great influence to the dimensional accuracy as compared with the focus beam offset, in all experiments were the STL file resolution was increased, dimensional accuracy of the parts always improved from the preceding experiment. It was also noted that when parts where incorporated with wafer type support structures a major improvement in accuracy was achieved. A similar repetition of the previous investigation results was noted, where the focus beam offset parameter was more critical in attaining dimensional accuracy. The low beam focus offset and high STL file resolution appertaining to experiment two, yielded the highest dimensional accuracy for both saddle shaped rings. Irrespective of the process parameters, no distortions were noted as was observed in the preceding experiments. The adoption of support structures was critical for the mitigation of distortions within the overhanging features and thus improving accuracy. The purpose of the support structures is to prevent distortion by securing the build to a substrate. Such structures provide heat transfer by conducting energy from the melt pool to the start plate, resulting in heat dissipation from the part being scanned, thus eliminating residual thermal stress.

This paper sheds light on EBM capability in producing annuloplasty rings. When overhanging features are required, support structures should be mandatory to attain dimensional accuracy required and reduce the chance for defects. It was also noted, that irrespective of the process parameters and support structures, the machine is limited to a certain degree of accuracy. In fact an error of ±0.5mm was always noted suggesting that there is a place for compensation strategies to be taken. As future work, other strategies for manufacturing annuloplasty rings, such as CNC milling used by Mazittelli *et al.* [6], should be compared with EBM.

References

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