CHAPTER 3

MODELING AND FABRICATION OF CUSTOMISED BONE SCAFFOLD

This chapter presents the methodology used to model a customised bone scaffold, directly from the patient’s CT scan data and the methodology to fabricate customised bone scaffolds using Additive Manufacturing technique.

3.1 COMPUTERISED TOMOGRAPHY (CT) SCAN

The Computerised Tomography (CT) scan is a medical imaging procedure that uses computer-processed X-rays, to produce tomographic images or slices of specific areas of the body. It uses a highly sensitive X-ray beam focused on specific parts of the body, and a detector picks up the beam as it passes through the body and obtains the 2D image data. Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing and transmitting information in medical imaging.

The input data used for the current study, pertaining to a 23 year old adult male with a Body Weight (BW) of 800 N. The CT scan data in DICOM format containing 1173 tomography slices has been used. Sample data of the 2D slice image is shown in Figure 3.1
3.2 MATERIALISE INTERACTIVE MEDICAL IMAGE CONTROL SYSTEM (MIMICS)

MIMICS is a 3D medical image processing and editing software. It translates the scanned data into full 3D CAD models, FE meshes or RP data, and allows the simulation of surgical procedures. This software is used to convert the CT data into a series of contours, to simulate the outer cortical and intramedullary cancellous surfaces, by segmentation and 3D rendered objects.

3.2.1 Import Modules

MIMICS imports 2D stacked images such as CT, MRI or Microscopy data in a wide variety of formats, far beyond DICOM. The import software provides direct access to images written on proprietary optical disks and tapes, converts them into the Materialise image format, and preserves all the necessary information for further processing. The DICOM format is a standard in the Medical Imaging world and most recent scanners are DICOM compliant. MIMICS can import DICOM images that are compressed with the JPEG algorithm.
3.2.2 Visualisation

MIMICS displays the image data in several ways, each providing unique information. MIMICS includes several visualization functions such as contrast enhancement, panning, zooming and rotating of a 3D view. MIMICS divides the screen into four views as shown in Figure 3.2.

a) The original axial view
b) The coronal view (made up by the resliced data)
c) The sagittal view (made up by the resliced data) and
d) The 3D view

Figure 3.2 Four views of CT images loaded and registered in MIMICS

3.2.3 Segmentation

In MIMICS, segmentation masks are used to highlight Region Of Interest (ROI). To create and modify the masks, the following functions are used:
3.2.3.1 Thresholding

Thresholding is the first action performed to create a segmentation mask. For extracting the cortical and trabecular tibia bone features accurately, the threshold value is adjusted from 226 to 1956 Hounsfield Units (HU) in MIMICS, which corresponds to the bone density interval. The accuracy of the model can be ensured by smoothing the model, till the desired level is reached.

3.2.3.2 Region Growing

Region growing eliminates noise and separates structures that have failed to connect. Then, region growing is used to separate the ROI from the selected object. In this work, the 3D model of the left side tibia bone was selected as a ROI to generate the customised bone scaffold. To check the results, the 3D model had to be evaluated.

3.2.3.3 Editing

Manual editing functions make it possible to draw, erase or restore parts of images with a local threshold value. With the multiple slice edit tool, the changes made on one slice can be continued through to several other slices. This tool greatly reduces the amount of manual work needed to eliminate artifacts and separate structures.

3.2.4 MedCAD Interface

The MedCAD interface, normally a standard module of medical image processing software, is intended to bridge the gap between medical imaging and CAD design software. The MedCAD interface can export data from the imaging system to the CAD platform and vice versa, through either
IGES (Initial Graphic Exchange Specification), STEP (Standard for Exchange of Product model data) or stl (stereolithography) format. The interface provides for fitting of primitives such as cylinders, planes, spheres etc, with the (imaging) 2D segmentation slices.

In the present study, the MedCAD module in MIMICS was used to export the 3D model data of the region of interest, namely, tibia bone, from the imaging system to the CAD system, as an IGES file format, as shown in Figure 3.3. For each section polylines were generated, and 1677 polylines were obtained from the tomography slices. This was then utilized for further CAD analysis. The IGES format was chosen for exporting the model, as it is commonly used for most engineering applications.

![Figure 3.3 IGES data from MIMICS](image)

### 3.3 MODELING OF CUSTOMISED BONE SCAFFOLD

For bone tissues, an ideal scaffold micro-architecture should be highly porous with interconnected pores of defined pore sizes of 200–900 µm in diameter in the case of bone (Liu 1997, Chu et al 2001) and exhibit a high
surface area-to-volume ratio (Shieh 2000) to allow high rates of mass transfer (Shieh 2000), cell in-growth and vascularization (Borden et al 2002).

In regenerating bone tissues in vitro, some researchers (Robinson et al (1995), Boyan et al (1996)) indicated the need for pore sizes ranging from 200 to 400 µm, while Yoshikawa et al (1996) successfully employed scaffolds with 500 µm nominal pore size. Scaffolds with pore sizes between 20 and 125 µm have been used for regenerating adult mammalian skin (Yannas et al 1989) and 45-150 µm for regenerating liver tissues (Kim et al 1998). When the pores employed are too small, pore occlusion (Rout et al 1998) by cells will prevent cellular penetration and matrix elaboration within the scaffolds.

Custom implants are necessary for those situations when off-the-shelf standard size is not suitable. These are usually complex cases involving trauma or disease resulting in bone deformity or loss (Cruz & Coole 2009).

In the present work, the 3D data of the tibia bone was exported into solid works software to generate the solid model. The total length of the tibia bone was 376 mm. Figure 3.4 shows the region selected for study. This region has been taken at a distance of 164 mm from the knee. The height of this region was taken as 5 mm and modeled as 4 layers each of 1.25 mm thickness. Figure 3.5 shows the outer curves and inner curves for the selected bone region, to generate the customised bone scaffold.

The fifteen customised bone scaffolds with three different pore sizes of 0.6 mm, 0.7 mm and 0.8 mm diameter (Liu 1997, Chu et al 2001) and inter pore distances ranging from 0.6 mm to 1 mm in steps of 0.1 mm were created, using the modeling software (SOLIDWORKS 2011).

Figure 3.6 shows the enlarged view of the 3D customised scaffold model. Figure 3.7 shows how the customised scaffold will fit in place in the
patient’s tibia bone. This selective diseased bone area will be removed and in its place the scaffold is to be placed. Table 3.1 presents the 3D CAD model, developed for the fifteen customised bone scaffolds.

**Figure 3.4 Region selected for study**

**Figure 3.5 Outer and inner curves for the selective bone region**
Figure 3.6 Computer Aided 3D scaffold model

Figure 3.7 Replacement of defective part by 3D Scaffold
Table 3.1 3D CAD model of fifteen customised bone scaffolds

<table>
<thead>
<tr>
<th>Pore size (mm)</th>
<th>0.6</th>
<th>0.7</th>
<th>0.8</th>
<th>0.9</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.6</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
<td><img src="image5.png" alt="Image" /></td>
</tr>
<tr>
<td>0.7</td>
<td><img src="image6.png" alt="Image" /></td>
<td><img src="image7.png" alt="Image" /></td>
<td><img src="image8.png" alt="Image" /></td>
<td><img src="image9.png" alt="Image" /></td>
<td><img src="image10.png" alt="Image" /></td>
</tr>
<tr>
<td>0.8</td>
<td><img src="image11.png" alt="Image" /></td>
<td><img src="image12.png" alt="Image" /></td>
<td><img src="image13.png" alt="Image" /></td>
<td><img src="image14.png" alt="Image" /></td>
<td><img src="image15.png" alt="Image" /></td>
</tr>
</tbody>
</table>
3.4 FABRICATION OF CUSTOMISED BONE SCAFFOLD

Magics RP software is used to convert the 3D CAD model imported in IGES format into the required data for the AM process. The imported files are converted to a digital CAD structure, according to user defined accuracy. The resulting *stl* file is ready to produce scaffolds without the need for further conversion. The data preparation and job preparation are the two main steps involved in the Magics software.

1. Data preparation
   i. Positioning of the components
   ii. Orientation of the components
   iii. Error removal of the *stl* file

2. Job preparation
   i. Loading the job
   ii. Automatic sorting of parts
   iii. Setting the exposure type and job parameters

3.4.1 Data Preparation

Good data preparation is a prerequisite for the correct function of the building process. Poor data or data errors can cause a job to crash or result in poor parts quality. Figure 3.8 shows schematically, the basic sequence for data preparation.
3.4.1.1 Positioning

The parts should be positioned in the middle of the building area. It is possible to utilize the complete building area of 200 × 250 mm and a building height of 330 mm. As a rule, the temperature profile starting from the middle has a circular shape with the highest temperature in the middle and the lowest temperature in the corners.

The closer the parts are positioned to the edge of the building area, the greater the risk that parts could be torn out or that parts could be deformed.

The distance between the parts should be at least 5 mm. The parts must be positioned at a Z position of at least 6 mm. At least 6 mm must be applied to the parts in layers before they start; otherwise the parts can start to
curl or deform. After aligning, positioning and scaling the parts, they should be saved with a new name. Figure 3.9 shows the positioning of the components in the software.

Figure 3.9 Positioning of the scaffolds

3.4.1.2 Orientation

First an overview of the part to be built has to be considered and the best building position has to be determined. During this process the following points have to be considered:

1. To ensure high process stability, sudden changes in the surface area should be avoided; i.e., parts start with small surface areas and grow slowly in the x-direction. Angles of less than 15° should not be used, as otherwise steps will be formed on the surface of the part.
2. For optimal part quality and a short building time, parts should be positioned as flat as possible. The axes of cylindrical bodies, e.g., very precise bores, should be aligned vertically if possible.

With complex parts it is seldom possible to achieve an ideal orientation, as there may be bores on several axes and the surfaces of the part may have different angles, such that it is not possible to avoid angles less than the limit angle at some points. Certain amount of operator experience is necessary to find the best building position for a specific part taking into account the intended application. Figure 3.10 shows an example of the optimal arrangement of components.

![Figure 3.10 Arrangement of the scaffolds](image)

3.4.1.3 Error removal of the stl file

Accuracy of a model is influenced by the errors caused during tessellation and slicing at data preparation stage. In tessellation surfaces of a CAD model are approximated piecewise by using triangles. The deviation
between the actual surfaces and approximated triangles can be reduced by reducing the size of the triangles. The resolution of the STL file is controlled by a parameter namely chordal error or facet deviation.

3.4.2 Job Preparation

3.4.2.1 Loading a job with default parameters

It is possible to load a job which was created, using default parameters. In doing so, all the parameters saved in the job will be ignored, and the current valid parameters will be allocated to it. The steps involved in the process are listed below

1. Creating a job
2. Loading parts
3. Deleting parts
4. Creating, ungrouping and deleting part groups

3.4.2.2 Automatic sorting of parts

The parts loaded are exposed in the order in which they are listed in the Job parameters window. Optimal sorting of the parts prevents unnecessary jumps between the parts during exposure, and therefore reduces the building time. Some of the commands available for sorting are listed below.

1. Moving parts
2. Rotating parts
3. Mirroring parts
4. Duplicating parts
3.4.2.3 Setting exposure parameters

It is possible to adapt the beam offset to the individual parts, so that they are allocated specific undersize or oversize.

Exposure types have a decisive effect on the quality of parts, and should be carefully selected for this reason. Figure 3.11 shows the exposure parameters utilised for fabrication of scaffolds for the present work.

![Exposure parameters](image)

**Figure 3.11 Exposure parameters**

3.4.2.4 Setting the job parameters

The setting of the powder layer which is placed on top of the job after exposure of the last layer is known as top layers. In the SLS process polyamide powders are spread and exposed to laser heating, to selectively sinter the region of interest. Next, the model is lowered and another layer of powder spread over it. The sintering process is continued till the entire build up process is completed in a similar way. After the completion of the job another layer of powder is applied. This is referred to as the top layer, which
prevents ageing of the last job layer and minimizes distortion and shrinkage. Figure 3.12 shows the job parameters.

Figure 3.12 Job parameters

FORMIGA P 100 is a plastic laser-sintering e-Manufacturing system for the direct manufacture of series, spare parts and functional prototypes. FORMIGA P 100 is mainly used for laser-sintering in the compact class with a build envelope of 200 mm × 250 mm × 330 mm. FORMIGA P 100 produces plastic products from polyamide or polystyrene, within a few hours directly from CAD data. Figure 3.13 shows a FORMIGA P 100 AM machine. The fifteen customised bone scaffolds were fabricated using 3Dfast Srl on a FORMIGA P 100 system (EOS GmbH) in polyamide EOSINT P/PA2200. The details of machine specification are given in the Table 3.2.
Table 3.2  FORMIGA P 100 - MACHINE DETAILS

<table>
<thead>
<tr>
<th>Feature</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effective building volume</td>
<td>200 mm × 250 mm × 330 mm</td>
</tr>
<tr>
<td>Building speed (material-dependent)</td>
<td>Up to 24 mm height/h (0.94 in/h)</td>
</tr>
<tr>
<td>Layer thickness (material-dependent)</td>
<td>Typically 0.1 mm (0.004 in)</td>
</tr>
<tr>
<td>Support structure</td>
<td>Not necessary</td>
</tr>
<tr>
<td>Laser type</td>
<td>CO(_2), 30 W</td>
</tr>
<tr>
<td>Precision optics</td>
<td>f-theta lens</td>
</tr>
<tr>
<td>Scan speed during build process</td>
<td>Up to 5 m/s (16.4 ft/sec)</td>
</tr>
<tr>
<td>Wall thickness</td>
<td>Not less than 1 mm</td>
</tr>
<tr>
<td>Laser beam diameter</td>
<td>Approximately 0.6-0.7 mm</td>
</tr>
<tr>
<td>Accuracy-Dimensions&lt;100mm</td>
<td>+/-0.1 mm</td>
</tr>
<tr>
<td>Accuracy-Dimensions&gt;100mm</td>
<td>+/-0.3 mm</td>
</tr>
</tbody>
</table>
3.4.3 Sequence of operation in customised scaffold fabrication using the SLS Technique

Figure 3.14 Sequence of operations in scaffold fabrication using the SLS technique

The sequence of operations used in the scaffold fabrication is shown in Figure 3.14.

1. First, a CAD model of customised tibia bone scaffold was modeled in SOLIDWORKS 2011.

2. The second step involves the conversion of the CAD file into the *stl* format. This format represents a three-dimensional surface as an assembly of planar triangles. Since the *stl* format is universal, this process is identical for all the AM build techniques.

3. In the third step, a pre-processing program was used to prepare the *stl* file for construction. For this purpose, several programs are available and the size, location and orientation of the model can also be adjusted by the user. (Hur et al (2001)).
The *stl* model of the customised bone scaffold was sliced into 10 layers, each of 0.5 mm thickness, to obtain a build height of 5 mm using the preprocessing software Magics.

4. In the fourth step, the actual construction of the part was done. Polyamide powder material was used to fabricate the object. After slicing the model of the customised bone scaffold, the machine takes the layers of the bone scaffold as the input, and constructs the final 3D object (Venuvinod & Ma 2004, Pandey et al 2003). The AM machine then builds the customised bone scaffold, one layer at a time till the entire model is achieved.

5. The final step is post-processing. In this step, the customised bone scaffold is taken out of the machine, and the supports detached by hand brushing. The hard powder in the porous structure is removed by glass blasting.

One of the major limitations of the SLS process lies in fabricating a scaffold with a pore size lesser than its laser spot diameter (Yang et al 2002). The laser beam diameter of the machine used for scaffold fabrication was 0.6 mm to 0.7mm. Hence, using the steps enumerated in section 3.4.3, fifteen customised bone scaffolds with pore sizes of 0.6 mm, 0.7 mm and 0.8 mm diameter and inter pore distances ranging from 0.6 mm to 1 mm in steps of 0.1 mm were fabricated. Even if a scaffold is fabricated with a smaller pore size, removing the unsintered powder particles from small pores could be difficult. It is due to the ‘partial sintering’ effect, a common phenomenon occurring in the laser sintering process, where the laser energy penetrates beyond the designed scanning path (Zhou et al 2008).
Figure 3.15 Polyamide Scaffolds with pore size of 0.8 mm and inter pore distance of 0.6, 0.7, 0.8, 0.9 and 1 mm respectively
Figure 3.16 Polyamide Scaffold with pore size of 0.8 mm and inter pore distance of 1 mm (Fabricated Model)

Figure 3.17 Scaffold with pore size of 0.8 mm and inter pore distance of 1 mm (CAD Model)

Among these fifteen scaffolds it was found that for the small pore sizes of 0.6 mm and 0.7 mm diameter, the laser sintering process caused clogging of the pores, which is due to pores filled with unsintered polyamide powders. Hence, five scaffolds as shown in Figure 3.15 with a pore size of 0.8 mm diameter and inter pore distances ranging from 0.6 mm to 1 mm in steps of 0.1 mm, were used for testing and analysis.
The fabricated Polyamide scaffolds possessed well defined pores, as shown in Figure 3.16, and their structural configurations were also observed to be consistent with the CAD data, as shown in Figure 3.17.

3.5 SUMMARY

In this chapter, the methodology to model the customised bone scaffold directly from patient’s CT scan data has been presented. Then, the procedure to fabricate customised polyamide bone scaffold using SLS technique was discussed.