Design, Test and FEM Analysis of Customized Titanium Alloy Implant with Scaffold Based on Additive Manufacturing

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Abstract. In order to design the prosthesis which can mimic the surroundings for bone cell proliferation and cell attachment and avoid stress shielding effect by matching the Young’s modulus with different parts of human bone, we come up with the porous structure with scaffold design. This paper is presenting the scaffold of design, the mechanical property of the biomimetic scaffold and the relative error rate between the Finite element analysis (FEA) and compressive test. However, most of the models of the porous structure are designed in the STL format especially the high topological model which will make the FEM preprocessing procedure difficult. According to the reason above, we used the concept of the CT-based voxel mesh method for high complex STL model, which skips the time-consuming mesh and repairing reconstruction process. Lastly, we successfully designed the porous prosthesis according to the data from FEA and compressive test.

1. Introduction
In recent years, due to the rapid-aging society, the need of the prosthesis has increased, and the mature of the additive manufacture (AM) technology, the design of the prosthesis gets more flexible. The three factors affecting the mechanical property of the implant are the types of unit cells of the scaffold, the layout of the scaffold, and the size of the pore, respectively. Through the algorithm aided design (AAD) platform, we can control three factors precisely, which makes the Young’s Modulus of the implant match to the patient’s bone defect area, lower the risk of the stress shielding effect [1]. As the mature of the AM technology, most of the model choose to be designed and saved in the STL format. However, this kind of format is required a complex preprocessing process for Finite Element Analysis (FEA) to repair the mesh and geometry reconstruction. The process is time-consuming and costs a lot of system resources, so most of the company decided to use trial and error to probe the Young’s modulus of the scaffold. In order to increase the efficacy, in research we proposed a rapid method to help the complex STL model to skip mesh repair and geometry reconstruction process. Using the concept of voxelize mesh allows the complex STL model to execute directly the preprocess. After comparing the Young’s modulus from FEA and compressive test, a stable error rate of 19% can be obtained. We can use the error rate as a reference for the design of the implant in the future.

2. The design of the scaffold
2.1. The Morphology of the Scaffold
Through the internal logic component of the AAD software “Grasshopper”, we come out with three different types of unit cells. The first one also the basic one is the line structure-based scaffold, pore size, and the diameter of the struts are easy to control, but lack of topological trait. The second is the Gyroid
scaffold, it has good topological trait and unanimous pore size, but the control flexibility of the pore size is very poor [2]. The last one is the biomimetic scaffold, this design was based on the Voronoi algorithm [3], using the randomly cell expanding concept, by mimicking the nature trabecular bone we can offer the similar surroundings for the bone cell to grow [4][5]. Three types of scaffolds are shown in the Figure.1(a),1(b), 1(c) pore size of these three types of scaffold are all above 300μm according to [5]’s research.

2.2. The layout of the scaffold
In this study, we propose the method for the layout of the scaffold.
To start, we use the iso-curve to subdivide the iso-surface according to the UV value (Figure.2), and then the length and the width of the unit cell can be obtained after the subdivide. Next, we create two surfaces and then subdividing them with an equal amount of UV value in the three-dimensional region. Additionally, we extract the nodes from each surface partitions and connect these eight nodes to become a closed geometry. In the end, we can split the unit cells along the Z-axis to define the desired height of the unit cell when the height of the unit cell has been obtained, as shown in Figure.3
Not like the other method we can’t just define the centroid of the unit cell as a moving coordinate. The strut will not be contained inside the unit cell. In order to avoid this problem, we need to add the eight nodes of the unit cell into the moving coordinate, so that the strut of the scaffold will fit inside the unit cell. As shown in Figure.4.
3. FEM analysis of the scaffold

3.1. Voxel Mesh & Boundary condition
The difference between the CT and the Stl-Based voxel mesh is that the CT-Based voxel mesh is generated directly from pixel to voxel, on the other hand, the Stl-Based voxel mesh consists of unsmooth hexahedron mesh (Figure.5), while the unsmooth hexahedron mesh doesn’t make the significant effect on the result of stress and strain in FEA [6-8].

![Figure 5. The unsmooth hexagonal mesh.](image)

The purpose of this study is to explore the equivalent Young's modulus rather than the behavior beyond the elastic limit. As a result, we fix the bottom of the specimen, and make the displacement along the Z-axis in liner analysis, then calculate the Young’s Modulus from the elastic gradient.

3.2. Mesh Convergence
In order to find out the most stable and efficient element size before proceeding with the FEM analysis, we will have a mesh convergence. The sizes of the elements are range from 0.15 to 0.06, as the size of the element become smaller, the cost of system resource will increase. As a consequence, we can clearly see that the deviation of the force became smaller, as shown in Figure.6. According to the cost of system resource and efficiency in research, we choose a 0.08mm element size to run the analysis.

![Figure 6. Mesh convergence.](image)
4. Method and result of mechanical testing
In recent years most of the research still working on the geometry of the biomimetic scaffold, its mechanical property is rarely discussed. According to the reason, in this study, we follow the ISO13314 specification to conduct the compressive test. We use HUNG TA (HT-2402) computer servo-controlled material testing machine with $10^{-2}$ s$^{-1}$ strain rate to test the eight different types of specimen of porosity from 80% to 54% (Figure 7), while there are five specimens for each porosity. The material property of the specimen can be obtained from the tensile test report offer by the specimen which is made by Renishaw metal 3D printing machine which uses selective laser melting (SLM) technique (Figure 8), due to the thickness of the metal powder and the power of the laser beam, the Young’s Modulus of the SLM Ti6Al4V is 33.7Gpa [9]. According to the stress and strain data, we can obtain the Young’s Modulus of each porosity, as shown in Figure 9. According to the Figure 9, we can discover the trend that the Young’s Modulus will increase as the porosity decrease. However, there is one exception, the struts of the porosity 62%(B) were specifically design into a thin blade shape. As the result turns out, the blade shape affects the rigidity of the scaffold. According to the comparison between 62%(A) and(B) are shown in Figure 10, the mechanical property comparison is shown in table.1 [10][11].

![Figure 7: Porosity 80%, 70%, 60.8%, 54%](image1)

![Figure 8: Tensile test](image2)

![Figure 9: Young’s Modulus of each porosity](image3)

![Figure 10: Structure of 62% (A) and (B)](image4)
Table 1. Mechanical property comparison.

| Source                    | Type of bone          | E(Gpa) | Porosity of the Scaffold |
|---------------------------|-----------------------|--------|--------------------------|
| Runkle and Pugh (1975)    | Human, Distal Femur   | 8.69   | 54%                      |
| Ku et al. (1987)          | Human, tibia          | 3.17   | 70%                      |
| Mente and Lewis (1987)    | Human, tibia          | 5.3    | 62%(B)                   |
| Choi et al. (1989)        | Human, tibia          | 4.59   | 62%(B)                   |
| Kuhn et al. (1989)        | Human, iliac crests   | 3.81   | 70%                      |
| Jensen et al. (1990)      | Human, vertebra       | 3.8    | 70%                      |
| Amirouche et al. (2014)   | Acetabular            | 5.78-4.13 | 62%(B)                   |

5. Discussion
In order to facilitate the compare process, we choose four different porosity of the specimen for the FEM analysis. Comparing both of its Young’s Modulus which obtain from compressive test and FEM analysis can realize that the exception of the error rate of the specimen P80 is 40% and others are under 19%, as shown in Figure.11 and Figure.12.

Turning now to the experimental result on the error rate, we can summarize the dimension inspection table (as shown in table.2). On the basis of table.2, we sort and make the error rate of the volume and length into the charts as shown in Figure.13 and Figure.14.

From the previous charts, it can be presumed that most of the error came from inside of the scaffold, which means there might be few powders that fail to exhaust still inside the scaffold. There are few powders inside the scaffold, which may cause the pore fail to take shape and become a closed pore indirectly increase the rigidity of the scaffold.

It is also worth noting that the specimen P80 has the highest volume error rate, the presumption explains the reason that the analysis error rate of P80 can reach 40%.

Figure 11. Comparison of the Yong’s modulus.

Figure 12. Error rate.

Figure 13. Volume error rate

Figure 14. Length error rate
Table 2. Dimension inspection

|         | 54% |         | 60.8% |         | 70% |         | 80% |
|---------|-----|---------|-------|---------|-----|---------|-----|
|         | Length (mm) | Weight (g) | Length (mm) | Weight (g) | Length (mm) | Weight (g) | Length (mm) | Weight (g) |
| Standard | 19  | 3.361   | 19    | 3.0174  | 19  | 2.425   | 19  | 1.864   |
|         | 19.16 | 3.5    | 19.11 | 3.1    | 19.11 | 2.7    | 18.97 | 2.1    |
|         | 19.02 | 3.4    | 19.11 | 3.1    | 18.99 | 2.6    | 19.16 | 2.1    |
|         | 19.09 | 3.5    | 19.16 | 3.1    | 19.15 | 2.7    | 19.12 | 2.3    |
|         | 19.12 | 3.5    | 19.16 | 3.2    | 19.11 | 2.7    | 19.13 | 2.3    |
|         | 19.20 | 3.5    | 19.16 | 3.2    | 19.06 | 2.6    | 19.10 | 2.2    |

P.S.: The density is 4.417 (g/cm³)

In addition, we use the data of the result form FEA and compressive test to manufacture the porous prosthesis with similar mechanical properties to human bone, as shown in Figure 15 and Figure 16.

Figure 15. Fusion cage.  
Figure 16. Customized implant for hip.

6. Conclusion

In this study we successfully design the porous specimen with a scaffold, which can mimic the Young’s modulus of trabecular bone, improve the chance of cell proliferation and cell attachment, etc. In the FEM analysis, we offer a more efficient method to replace trial and error, and we can obtain the most results of error rate under 19%.

However, there is the problem of precision for the AM machine. If the AM machine can achieve 40–90 μm, we can design and fabricate the structure of the compact bone and combine the trabecular bone, allow future design to be more flexible.

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