Design, Analysis and Fabrication of Human External Ear by Using Fused Film Fabrication

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Abstract. The conductive hearing loss due to ossicular abnormalities occurs from many causes, including trauma, cholesteatoma, infection, surgery and congenital anomalies. Recent developments in the area of tissue engineering as well as in the area of fused film fabrication promise to profoundly affect the practice of reconstructive surgery. Therefore, a human external ear prototype is built by using the 3D printing technology from the CT scan by conversion using 3D slicer software. Firstly, the human head computer tomography (CT) scanned file of DICOM data format is collected. Then the DICOM data file is converted into NRRD file format by using 3D slicer software and saved in a folder. Then the NRRD file is converted into 3D printable STL file format by using Embodi3D.com website. Here the STL file is imported into 3D slicer for separation of external ear from total head model by using Mesh mixer. Then the STL file of the ear is imported into the 3d printing machine which builds the prototype of ear. The prototype was made with PLA plastic using an FDM 3D printer. During the prototype building, various parameters of printing machine are recorded. The analytical tests were carried on ANSYS by applying various Bio compatible stresses on the ear surface and the results are recoded.

Key words - Infection, Tissue engineering, Dicom, Reconstructive surgery, CT scan, parameters.

1. Introduction
Fused film fabrication is the process of new age manufacturing 3D Printing is a part of fused film fabrication in this process the physical object is printed layer wise with the three-dimensional CAD model, in this process the fabrication is completed in successive layers. With this process the digital object will be converted to physical printed object in the number steps in the form of layers. This process also be called as rapid prototyping. The 3D printing is useful for all special purpose applications like to print intricate shapes and imagination related components, these components have lighter weight and stronger. 3D printing is efficiently utilized in various fields such as aerospace, automobile, medical, construction and in manufacturing of many household products. Before rapid prototyping the preparation of medical models for demonstration of individual patients or to medical student classes was very rare due to the difficulty and cost of generating (usually by CNC machining) complex geometric shape associated with anatomy. The CAD methods gave a good level of accuracy in
the view of shape, size and position of the prosthesis, and significantly shorter lead time compared to conventional technique. [1][2].

Recently, fused film fabrication technique precisely 3D printing technology has been introduced in the biomedical field for preparation of models to ease surgical planning and simulation in the area of implantology, neurosurgery and orthopaedics, etc [3]. The printing of ear prosthesis using computer aided Drawing/Drafting was advantageous because a highly qualified technician is not necessary to sculpt an ear in wax. This process to be carried out in a computer and patient can visualize the result at the screen before fabrication. The method of fabricating the auricular prosthesis using CAD/CAM and rapid prototyping technologies is a simple process compared to traditional methods [4][5]. Therefore, it is possible to implant or replace the human tissues into the body after the fabrication by 3D printing which is also called as Tissue Engineering. The study investigates about the fabrication and Analysis of human external ear by using 3d printing technology and applications of technology in different areas.

1.1. Fused Deposition Modeling (FDM)

The Fused Deposition Modeling is one of additive manufacturing techniques which is a solid based rapid prototyping technique. With the assistance of FDM, you can print not just operational prototypes, but also ready for use products such as plastic gears etc. All components printed with FDM can go in high performance and engineering-grade thermoplastic, which is quite beneficial. 3D printers which use FDM Technology construct objects layer by layer from the very bottom up by heating and extruding thermoplastic filament. In addition to thermoplastic, a printer may extrude support materials (Nylon is typically used as a support material). The printer heats thermoplastic until its melting point and extrudes it throughout nozzle on a printing bed, which you may know as a build platform or a desk, on a predetermined pattern determined by the 3D model and Slicer software.

![Figure 1. Fused Deposition Modeling](image)

1.2. Poly Lactic Acid

PLA (Poly lactic Acid) is one of the two most commonly used desktop 3D printing materials (with the other being ABS). It is the ‘default’ recommended material for many desktop 3D printers, and with good reason. PLA is useful in a broad range of printing applications, has the virtue of both odorless and low warp and it will not require a heated bed. PLA plastic is also one of the eco-friendlier 3D printer materials available. Its printing temperature is 180-220°C. Its bed temperature is 20-55°C.

2. Literature survey

Elisa mussi et.al [6] plan to portray and investigate the various materials and techniques embraced during the historical backdrop of autologous ear remaking (AER) reproduction to prepare specialists
by training on mathematically and precisely exact physical copies. Ongoing advances in 3D displaying programming and assembling advances to build the viability of AER test systems are especially portrayed to give later results. Daniel Blair Thomas and et.al[7] they have studied about the Bigger scope highlights of the dogfish chondrocranium and frog skeleton were all around settled and unmistakable in the 3D computerized models, and numerous better scale highlights were likewise very much settled, yet some more unpretentious highlights were missing from the advanced models (for example endolymphatic foramina in chondrocranium). Their technique portrayal and contextual investigations show that negligible hardware and preparing is expected to create sturdy skeletal examples. These innovations uphold the custom-made creation of models for explicit classes or exploration points.

Jung seob lee and et.al [8] they have created the composite structure for practicality testing, fulfilling desires for both the calculation and life systems of the local ear. They likewise completed in vitro examines for assessing the chondrogenesis and adipogenesis of the cell-printed structure. Thus, the chance of ear recovery utilizing 3D printing innovation which permitted tissue arrangement from the independently printed chondrocytes and adipocytes was illustrated. Manu Sebastian Mannoor and et.al [9] they presented a novel technique for conquering troubles utilizing added substance assembling of organic cells with auxiliary and nano molecule inferred electronic components. As a proof of idea, they produced a bionic ear by means of 3D printing of a cell-cultivated hydrogel grid in the anatomic math of a human ear, alongside an interlaced leading polymer comprising of injected silver nano particles. This took into consideration in vitro refined of ligament tissue around an inductive curl radio wire in the ear, which hence empowers readout of inductively-coupled signs from cochlea-molded terminals. Yong Ho Cha and et.al [10] they have designed and also manufactured the Ankle Foot Orthosis with additive manufacturing methods and using the automatic Computer Aided Design and drafting software’s. These 3D printed AFO displayed comparative usefulness as the ordinary AFO and significantly fulfilled the patient as far as the measurement, weight, alteration, usability, and solace. There was no break or harm after 300,000 redundancies in the toughness test. They set 300,000 redundancies (4-month span) in spite of the fact that these are insufficient to test the sturdiness of the orthosis in view of the test time, cost, and accessibility of the test machine [11].

3. Methodology

3.1. Creating of Human head from CT SCAN
The first software program we had downloaded is 3D Slicer. 3D Slicer is a free medical imaging program available on Windows. After installing software load dicom data into slicer for medical image formation.

Figure 2. Dicom data in to slicer for fig3 image formation
After loading dicom data select volume rendering option and it clearly shows the images of CT scan.
Save the dicom file as NRRD format from the slicer. Then the put NRRD file in EMBODI3D website for the STL file formation. Then complete all the processing parameters for the file completion process. The it takes around 60 minutes for STL file formation of human head. Then download STL file.

3.2. Separation of Human EAR from head STL file
The ear is separated from the head STL file by using the software Mesh Mixer. The first step is to download the mesh mixer software from online website. Then by using setup install the app and open it on the desktop. Then load head STL file into meshmixer.
Then apply plane cut for the HEAD STL file for separating of human ear. Save as STL file of ear for 3D print.

**Figure 6.** Applying Plane cuts for head STL file

After applying plane cuts in various direction then ear is formed. Then is is saved as STL file.

**Figure 7.** EAR STL FILE

3.3. *Preparing STL file for 3D printing*

Firstly, download and install the idea maker software for slicing of STL file. Then load or import the STL file into the app and open it. Select scale and give width, depth, height dimensions to STL file placed in correct position by leaving some gap at end of the bed. Then Selection of quality of the prototype by selecting template and slicing for STL file which is to be manufactured.
path of the nozzle in order to manufacture the product layer by layer on the heated bed. After scaling and slicing of the STL file then it is exported to 3D Printable file. Before exporting the STL file the estimated print result and price is shown.

### 3.4. Fabrication of Ear using FDM

This is the final step in the 3D printing Technology which builds prototype by importing STL file into the machine. The FDM machine and PLA material is used for 3D Printing Process. The STL file, is imported into 3D Printing machine with the help of pen drive. Then select the file to be printed. The STL file shows the details of file name, date, print time etc. then select print option for further process. After importing STL file into 3D Printing machine then select print and enter the temperature values of Nozzle and Bed.

After entering all the values of 3d printer then select print for the fabrication. Then when the printing is started the metal is rolled through rollers slowly and melted. The metal comes from right nozzle and slowly product forms layer by layer.

| Table 1. 3D printer Information |
|---------------------------------|
| 1. Name                         | RAISE 3D N1                   |
| 2. Nozzles                      | 2                             |
| 3. nozzle diameter              | 0.41mm                        |
| 4. Right nozzle temperature     | 215°C                         |
| 5. Heat bed temperature         | 40°C                          |
| 6. Filament Diameter            | 1.75mm                        |
| 7. Filament type                | PLA                           |
| 8. Layers                       | 162                           |
| 9. Filament length/ weight      | 5 grams/1.68m                 |
| 10. Printing time               | 1 Hour 11 mins                |
Figure 9. Fabrication of Human ear by layer formation

The prototype forms layer by layer within the estimated time. The process after completing 100% the finished product is formed. After the total fabrication is completed then slowly turn off the temperature. The prototype is removed from the heated bed. Before starting of printing, fevicol is used for smooth removal of product. The final product formed after fabrication is shown below.

Figure 10. Ear prototype formation

3.5. Analysis in ANSYS
Static structural analysis is carried out in the ANSYS software by importing the ear geometry into it for Titanium prosthesis. First select the static structural analysis after opening the Ansys. Then select
Engineering data followed by geometry to import ear part from the storage. Here the material applied for analysis of ear is Titanium because of its durable metal for engineering applications. It is corrosion resistant and also very strong and very light. Then the geometry is shown in the below figure.

![Geometry of the component](image1)

**Figure 11.** Geometry of the component

Next step is to insert constraints for the geometry part. Select the static structural analysis, then insert fixed support by applying 1 face fixed. Then insert standard earth gravity by giving negative Y direction. Then click solution and insert some bio-compatible stress like total deformation, equivalent stress and equivalent elastic strain for analyzing of ear by deformation when it is applied by some bio-compatible stresses. Then select solve option after inserting the bio-compatible stresses then meshing starts and status is shown on the screen.

![Mesh generation of the model](image2)

**Figure 12.** Mesh generation of the model

After inserting all required constraints select solve for status of meshing by selecting the option mesh[12]. The mesh is generated after some seconds and by clicking every constraint we get each results of bio-compatible stresses. After generation of mesh completely then click solution information for each results of applied stresses. Note down the results of total deformation, equivalent stress and equivalent elastic strain.

### 4. Results

The testing was carried out analytically on ANSYS. The compression test is carried out by applying bio-compatible stresses on geometry part and results are noted and analyzed. The results obtained from total deformation, equivalent stress, equivalent elastic strain on the ear is obtained in terms of deformation and stress. The ear part was given titanium alloy properties and the reference temperature was given as 23°C by body and the stiffness behavior was flexible.
4.1. Total Deformation
Total deformation is chosen and evaluated for the results where the maximum deformation was recorded at stress levels of 3.348MPa and the minimum deformation was recorded as 0 MPa which are shown in the figure below.

![Figure 13. Showing the Minimum Deformation 0 MPa](image)

4.2. Equivalent Stress
Equivalent stress is chosen and evaluated for the results where the maximum stress was recorded as 9.363MPa and the minimum stress was recorded as 3.764MPa which are shown in the below figure.

![Figure 14. Figure showing the minimum, stress of 3.764MPa](image)

4.3. Equivalent Elastic Strain
Equivalent elastic strain is chosen and evaluated for the results where the maximum stress was recorded at stress levels of 815MPa and the minimum stress was recorded as 1.959MPa which are shown in the figure below.
5. Conclusion
The Ear which is manufactured with Additive manufacturing process has a lot of benefits for the human beings, because ear cannot be donated or received for implantation that all peoples ear doesn’t have same size and shape. The ear as observed shown that the part was safe which is converted with the help of CT Scanning of head file for rapid prototyping. By rapid prototyping of ear has advantages which costs less price and less time compared to traditional method. After manufacturing of ear various analytical tests is conducted by applying bio-compatible stresses. Total deformation is obtained the results of max stress levels of 3.348MPa and min as 0 MPa. Equivalent stress is obtained the results of max as 9.363MPa and min as 3.764MPa. Equivalent elastic strain is obtained the results of max as 4.185MPa and min as 1.959MPa. These results thus show that the design is safe for given CT scan file. Thus, manufacture of ear by additive manufacturing is best and suitable manufacture for implantation of ear for human body which is converted from CT scanning.

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