International Journal of Science and Research (IJSR)
ISSN (Online): 2319-7064
Impact Factor (2012): 3.358

An Experimental Method for Customized Mandible Fabrication and Image Preparation: A Rapid Prototyping Approach

Rahul M. Sherekar[1], Dr. Anand N. Pawar[2]

[1]Assistant Professor, Department of Mechanical Engineering, Jawaharlal Darda Institute of Engineering and Technology, Yavatmal,(M.S.) Pin- 44500. India

[2]Professor, Department of Mechanical Engineering, Government Polytechnic, Amravati (M. S). India.

Abstract: ***Reproduction of anatomical structures by rapid prototyping has proven to be a valid adjunct for craniofacial surgery, providing alternative methods to produce prostheses and development of surgical guides. The aim of this study is to introduce a methodology to fabricate asymmetric human mandibles by rapid prototyping technique. This paper presents a methodology for the design and fabrication of mandible. Computer-aided design (CAD) and rapid prototyping (RP) selective laser sentering (SLS) are used in this paper for designing & manufacturing the implant. Design methods for medical RP of custom-fabricated are presented, Computed tomography (CT)/ MRI data in the form of DICOM were used to create a three-dimensional model of the 47 year old male patient's prosthesis. After a stepwise data conversion and reconstruction, the customized shape of the implant was designed in CAD environment and fabricate by using SLS RP process. Results shows that the custom made implant fit well the defect. Overall, excellent mandible evenness and stability were achieved with the custom made implants. The high degree of fitting is achieved also patient performs all the regular activities due to increase in accuracy. The operating time is reduced. The methods describes above suffer from the expensive cost of RP technique & gives better results for designing of implant.***

Keywords: CT/MRI, CAD, Rapid prototyping

1. Introduction

During the past few years, the combination of medical imaging and rapid manufacturing technique has proven to be a very important improvement. On the other hand, the conventional method has some drawbacks. For example, it takes longer time for an operation[6]. The defects of the mandible may result bone infections and. The loss of a mandibler bone leads to severe deformation and difficulty in chewing & like other important activies. Rebuilding of the mandible after resection is often necessary to maintain the anatomical equivalence and to provide reliable reestablishment of the jaw's shape and restoration of appearance and oral cavity function that permit patients to maintain good enough quality of regular life.

Approach for reconstructing mandible defects involve intraoperative modeling of harvested bone[4] . Various types of reconstruction have been described to improve the aesthetic outcomes after mandibler segmental defect.Until now, in mandible reconstructive surgery, the reconstruction plate still by hand contoured from the surgical site during operation. However intraoperative fabrication by hand carving of bone grafts or contouring alloplastic implants may be difficult because the surgeon has difficulty to achieve an adequate mandibler shape during intraoperative alteration of the implant due to lack in idea of the actual mandible anatomy[1]. In consequence the intra-operative molding process of implant usually leads to more persistent surgery, increase operation time. It is worth pointing out that shaping these materials to form a desired shape, which can fit the missing part, depends largely on the sculpting skills of the surgeon. In a number of situations, it is not possible to contour the renewal plate on the mandible, for example, when shape of the mandible caused by bone tumor and secondary reconstructions in which a irregularity. In these cases, different plate shaping techniques have to be used and the degree of accuracy they achieve is not possible all time[5]. Thus, this technique increases the risk of a second interference and, therefore, puts extra anxiety on the patient.

Recently, as the result of the growth in computerized three-dimensional data processing, an implant that match the skeletal structure can be accurately designed from computer aided design (CAD) technique and the physical model of implant or skull replica can be produced through rapid prototyping(RP). In addition, the accuracy of fit and permanence of this implant mainly depends on the expertise of the surgeon[2].

Manufacturing of customized implants includes RP and casting techniques. The casting techniques usually involve the RP pattern, a wax model derived from the negative silicone mold is used in a lost wax or investment casting process for the production of the final implant. Since, this technique involves a number of steps, would lead to raise manufacturing cost and time. Despite this process eliminates costly tooling, but the overall mold design process and production is time consuming and may lead to increase the cost.

A rapid prototyping approach for designing & reconstruction of implant for a mandibler bone defect providing long-term stable, correctly fitting alternate, a new type of prefabricated implant design method based on SLS RP technique is described in this paper. The implant CAD model is designed based on mirroring technique and other mandible data. Fabrication of the implant is carry out by Selective Laser

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sintering (SLS) process, then SLS pattern is directly used in investment casting process to create the mold[7]. Then the custom implant was made using the plaster mold. After investigating the actual model surgeons have given satisfactory remarks for fitting for use[8].

2. Methods

The flow chart shows the details of the method used for custom made implant (Figure. 1). It includes: Patient anatomical data by CT scanning processes 3mm layer spacing, three-dimensional reconstruction of the patient anatomical data through medical imaging processes, implant geometry modeling, solid freeform fabrication, and casting the part & finally surgery.

Medical image processing

The medical CAD software allows interface of the CT information with CAD along with all 3D data. This data is then converted in to .stl format for the input for RP system. Skull detection is necessary to remove the Mandible from skull. From CT images 3D reconstruction of the patient skull for the implant design in mandible part replacement requires the segmentation of anatomical bone structures[10].

The CT images can be processed through Invesalius an open source software & MIMICS software to obtain the 3D volumetric image of the patient skull . After the creation of individual computer-based 3D model of the bony structure, these data were then transferred for the designing steps.

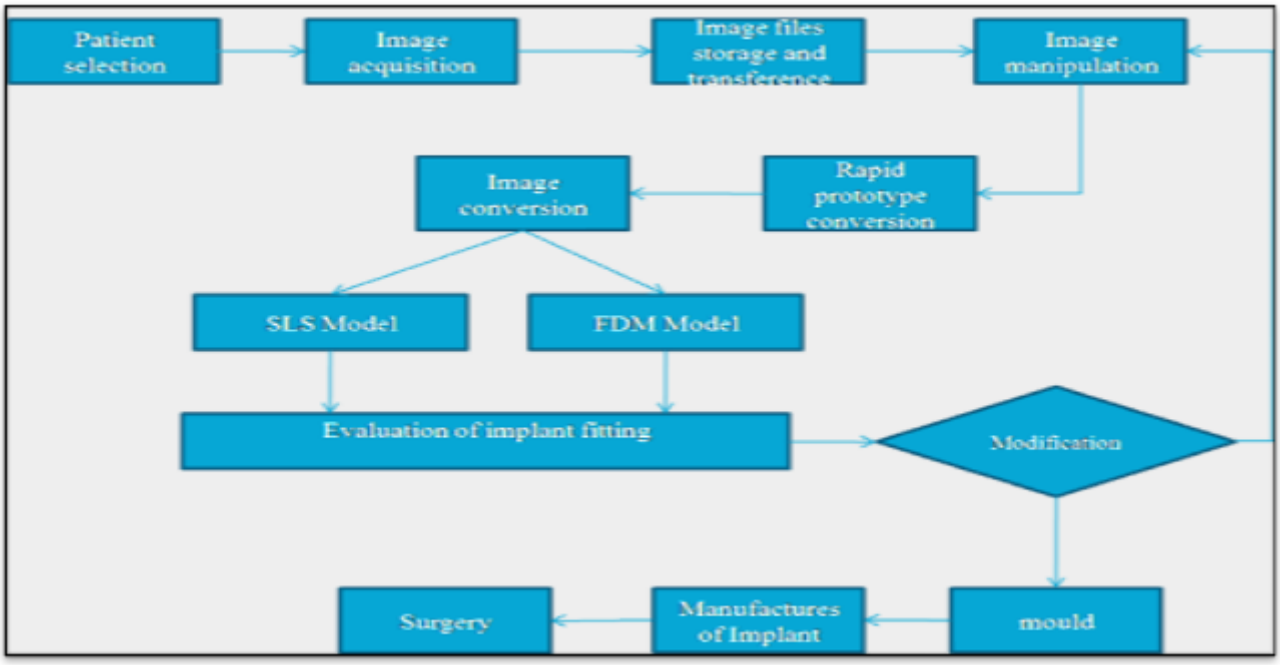

Figure 1: Flow chart of geometric modeling for the production of custom implants

3. Design of Implant Geometry & Modeling

In the CAD system the implant geometry design include:

1. Origin of the mandible missing part contour either from the unchanged contra-lateral side and another mandible curve geometry.
2. Defective borders designing of the implant ;
3. Entity constructions of micro plates for fixation from the data of the patient Mandible curve; and

Modeling the absent part depends largely on the extend of the fault:

- Then the mirror-image technique can be used to design the implant geometry.
- The Very long defect of mandible particularly which cross the midline of the mandible, is based on both mirror-imaging technique and another individual mandible data.Then the frontal defect (midline part), which the mirror-imaging technique cannot be used, the implant geometry of this portion of the defect can be obtained from skull data by scaling it in the 3 directions for getting the best fit with the patient's mandible Figure 2.

The shapes of the curves were modified by picking points on a curve and moved them to preferred positions until the curve geometry satisfies the desire requirement. In order to provide a better smooth surface construction, the curve-fitting technique was used. Also series of curves using B-spline surfaces. Finally, the smooth surface was then used to generate the solid model of the implant[11].

After the design phase, the STL files were then transferred in a SLS machine to produce patients skull model and customized implant. Before casting a part, the degree of the fit the implant can be measured. The skull mock-up is used to check the precision of fitting, shape, symmetry of the implant of SLS model. Revision will be made until if the result is not satisfactory. Then the SLS implant is used in casting like Quick Cast.

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Selective Laser Sintering (SLS):

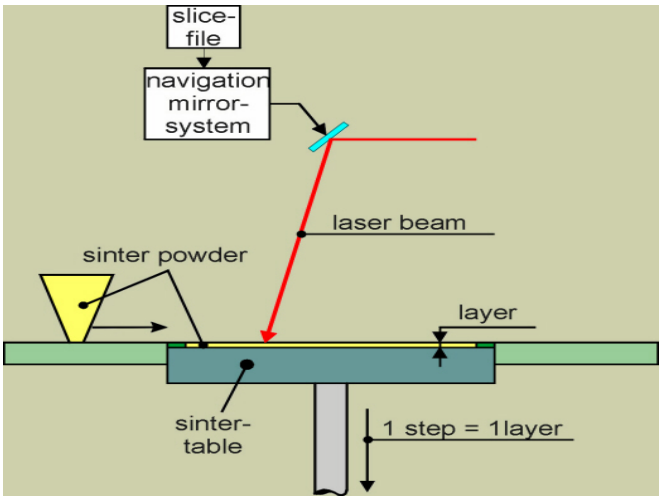

Figure 1a: Construction & working of SLS Machine

4. Process Description

The process of selective laser sintering is similar to the process of stereolithography. Figure 1a. shows the details of construction & working of SLS machine. In this selective laser sintering, the laser beam contacts a surface of compacted powder. The powder covering the surface of the build cylinder is spread by a roller and consists of a thermoplastic material. The amount of powder moved by the roller on to the building cylinder is controlled by the powder delivery piston. As the powder delivery piston position increases, the fabrication piston is lowered to compensate for the movement of powder. During the fabrication process, the system temperature is kept slightly lower than the melting point of the thermoplastic powder by sealing the system. When the compacted thermoplastic powder is traced by the laser it melts due to the heat generated by the laser. The heat generated from the laser raises the temperature slightly to induce sintering and increase the speed of the process. The laser is controlled by the scanner system, and produces a concentrated infrared heating beam. Explosion is a possibility if a nitrogen atmosphere is not maintained when large quantities of powder are being handled.

Once the part is produced, the fabrication piston is fully raised to lift the part out from the surrounding powder. The excess powder is then brushed away from the final part and additional cooling time is permitted before the part is moved from the build cylinder. Here this RP technique is used for manufacturing of anatomical part.

Advantages of SLS

- Good part stability.
- Wide range of processing materials.
- No part supports required
- Little post-processing required.
- No post-curing required.

Disadvantages of SLS:

- Large physical size of the unit.
- High power consumption.
- Poor surface finish.

5. Medical application- A Case Study

A 47-year-old male patient with a severe mandible defect. The left side of mandible was infected by tumor & has to replace with prosthesis about 40% part was under reconstruction. Also there were complexity in movement of the jaw and the patient was not able to open and close the jaws. Due to this the patient had been fed through a gastrostomy tube[13]. A operation of the mandible consists of a customized design of the implant & decision to restore bony connections, facial form and the mandible function.

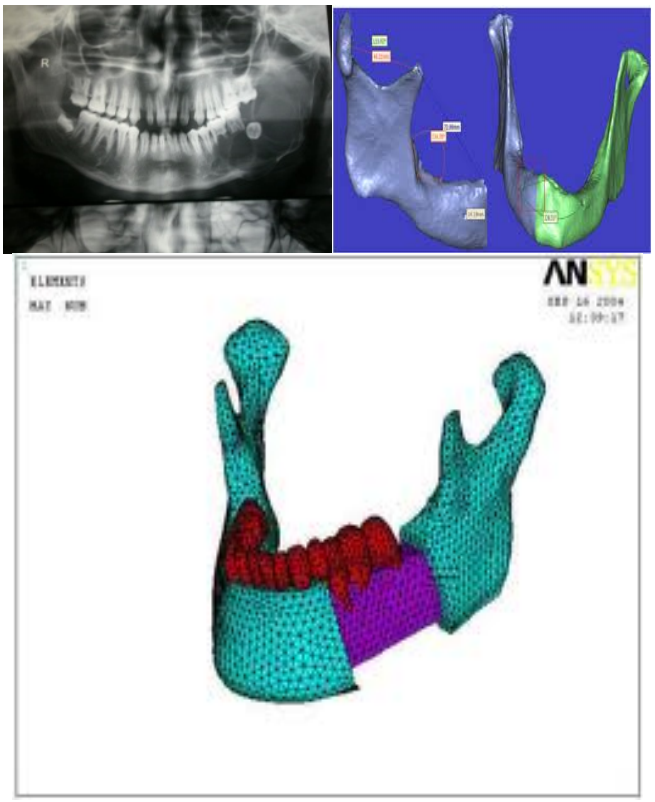

Figure 2: Mandible reconstruction

After CT data acquisition, the CT data were reconstructed (Figure 2) and transferred to CAD environment for implant design. The implant CAD design was based on combination of the mirror imaging technique and another mandible use as template as the one shows in figure 2. First, the remaining undefected mandible was mirrored to the defect side. The other mandible image was scaled and used as template to

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complete the implant contour design[15]. The implant SLS model were fabricated by RP machine was used to preoperative case study & also used for casting the implant (Figure 3).

Figure 3: Fabricated Mandible model by SLS & Preoperative Study

The mandible defect reconstruction after resection, a custom made implant is fabricated using CT data, CAD and RP technique. The combination of both three dimensional mirror imaged model of the uninjured mandible (lateral defect), and the superposing template from other mandible data to construct the implant overall contour was an invaluable tool for the design of precise fit implant for large mandible segmental defect reconstruction after resection. The virtual production of implants by computer-aided design system was proved to have better functional and cosmetic result than manually fitting the implant on the biomodel[16,17] . The implant was then sent to maxillofacial department for surgical operation as shown in Figure 4.In surgery near anout 40% portion is about to remove also muscles related to this is also removed. For this purpose the muscles from tibialis anterior & gastrocnemius muscles are used.Fig 4 is showing the surgery for fitting the implant.

Figure 4: Surgery for fitting the implant

6. Result & Discussions

The customized fabricated implants fit the skull defects well in the patient, and no adjustments were needed during the surgery. Therefore, the operation time was reduced. The fixation of the implants was achieved using screws to skull & was excellent. The mandible reconstructed geometry and the facial regularity were judged to be good in the patient, as shows in Figure 4. Complications, exposure were not served during 6 months follow-up. The patients do eat & perform regular activities normally after surgery.

The study has revealed that the most advanced manufacturing technique i.e rapid prototyping in mechanical engineering has great potential in the Manufacturing of complex intricate parts. Hence this feature can be used for manufacturing of customized anatomical implants. Now a days, SLS, which is used in the manufacturing industry have gained increasing recognition in medical area due to the accuracy of these models Surgical applications using arising technologies in SLS have recently been explored in many area of expertise such as orthopedic surgery & reconstruction of cranial defect and for reconstruction of maxillo-facial defects after tumor resection.

The case presented demonstrate the efficiency of using combined technologies of CT three-dimensional data and SLS for custom-made implant modeling. The patient selected with large mandible defect.

Figure 5: Photograph of Patient before & After mandible reconstruction

& the size of the implant should fit well with the size of the injury cavity and the RP SLS technique is an adequate production tool to achieve requirements for developing permanence(fig 5), precision of fit implant in reconstructive surgery.

The results showed that this method could be used as substitute to oromandibler construction, less invasive, time saving, and accurate. The custom made implant found to be strong enough to withstands functional forces, no implant extrusion and exposure were found during 6 months follow up. In comparison to the conventional method, custom-made implant shows several advantages: production of precise fit implants, shorter delivery and operation time. Furthermore, the accuracy of virtually designed implant models and the individual fit of the implants can be evaluated using the physical RP model. This evaluation allows correcting all error in implant shape before surgery. Thus, this reduces the risk of a second intervention, and the mental stress of the patient will be eliminated. However, the disadvantage of using three dimensional imaging to design the individual implant include artifacts in the reconstructed images, increased radiation exposure, and increased cost.

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A mold can be directly designed in CAD system for preoperative implant fabrication With regards to production time and cost, the design of reconstruction implant is more effective than the design of a mold. The mold includes an outer and inner part, so the biggest the mold volume is would lead to increase fabrication time in RP process then producing an implant. We directly use SLS parts like Quick Cast pattern in investment casting instead of wax patterns, because the thickness of the implant positive discrimination. SLS material to be burned out at high temperature[18,19]. This process eliminates expensive tooling and rapidly delivers metal parts with growing exactness and complexity.

7. Conclusion

This method allows perfect fabrication of the implant. The advantages of using this technique are that the physical model of the implant can be fitted on the skull model so that the surgeon can plan and prepare the surgery in advance and a less insidious surgical procedure and 40% time reduction in operation. In this we conclude that CT imaging, RP and computer modeling have improved the surgery planning and the manufacturing of customized implants and have also achieved competent instant rebuilding. In this case, a computer-generated model allows the fabrication of a custom implant that very accurately represents the anatomical defect. The use of these techniques leads to reduced operating time and eliminates operation errors, precise fit, and high permanence. The advantages include overview of the surgical procedure. Therefore, actual surgery consists only of defining the defect and position and fixation of the prosthesis.

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Author Profile

Rahul M. Sherekar is working as Assistant Professor in Mechanical Engineering Department at Jawaharlal Darda Institute of Engineering and Technology, Yavatmal,(M.S) India. He owes around 11 years of experience of teaching.He has completed his Bachelors degree in Mechanical Engineering from Amravati University, India. He then persuaded M.E in CAD/CAM Mechanical Engineering, From Amravati University, India. Now he is pursuing Ph.D in Mechanical Engineering from Amravati

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University,India. He has published 13 papers in National and International Journals. Also he has presented 05 papers in international conferences. His area of interest in Rapid prototyping, image processing, CAD/CAM.

Dr. Anand N. Pawar is working as Professor of Mechanical Engineering Department at Govt. Polytechnic Amravati India. He owes around 22 years of experience in teaching. He has completed his Bachelor's degree in Mechanical engineering. He then persuaded M.E in Thermal Power Engineering. From Govt. college of Engineering., Amravati, India. He has persuaded Ph.D in Mechanical Engineering from Amravati University, India. He has published number papers in National and International Journals. Also he has presented number papers in international conferences. His few publications have appeared in prestigious Springer, Emerald, and Inder science journals. State Government has honored him by giving Best Technical Teacher Award for his contribution in academics.

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