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DESIGN AND MANUFACTURING OF CUSTOMIZED ANATOMICAL IMPLANTS BY USING RAPID PROTOTYPING TECHNIQUE

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Abstract- The development of Rapid Prototyping technology for customized implants that minimize bone removal while maximizing the fit and the "usability" of the implant. The process involves integrating technologies of Computed Tomography (CT), image processing, Fused deposition modeling (FDM), finite element analysis (FEA), and lost wax casting in the design and fabrication of a near optimal fit between the patient's bone and the implant component.The analysis verified that the optimized interface surface produced a more even load distribution compared to the "standard" design. A conservative calculative estimate of 50% decrease in bone removal may result by adopting the following procedure.

Key words- MRI, Computer Tomography (CT), CAD/CAM, FEA, FDM, Rapid Prototyping, Medical Modeling.

1 Introduction

Recent advancements in the areas of Rapid Prototyping (RP), Reverse Engineering (RE) and Image Processing (IP), lead to the emergence of the field of Medical Applications of Rapid Prototyping. It is completely multidisciplinary approach. Soon after the introduction of Rapid Prototyping to industry, the advantages of this new technique were realized and researchers started to look at the medical community to implement new applications. With improvements in the medical imaging, it is now feasible more than ever to produce a physical model "directly" from Computed Tomography (CT) scan or Magnetic Resonance Image (MRI) with great accuracy [1]. RP requires that CAD files be provided in layers. Since medical data resulting from CT/MRI is usually provided in a slice format, it seemed natural to be able to produce physical models directly by the new layer manufacturing technique. By combining RP, RE and Image processing, the medical applications took off and have been under constant development ever since.

While the technology is still in its developing stage, compared to other improvements in the medical environment, the technical challenges and the pace by which such technology is advancing proves very promising. In this paper we provide an overview of a procedure of implant design & Manufacturing.

2. Methodology

The proposed procedure involves the integration of several technologies. As it is a multidisciplinary approach it requires a good coordination among engineers, radiologists & orthopedicians.

Fig. (1).shows an overview of the procedure for required custom implant.

2.1. Acquisition of CT-scan

The most commonly used techniques for capturing internal medical data are the Computed Tomography (CT) and the Magnetic Resonance Imaging (MRI). Either of the technique s provides cross sectional images of a scanned part of the human body. The main difference is that the CT scanner uses radiation in the process while MRI does not. The quality of the finished model totally depends on the accuracy of the scanning machine and the resolution of the data. Decreasing the scan distance, which produces more slices along the scanned region, can increase resolution results good implant. The longer scanning period required for a high-resolution scan, however, must be weighed against increasing the patient's exposure to radiation, scan time and cost, and patient discomfort. The new spiral CT-scan technology allows faster acquisition of smaller scan distances compared to traditional scanners that must translate the patient for each transverse section. [2]. In either of the techniques, the output of the scanning process is a set of cross-sectional data images. CT-data is most suitable for modeling bone structures and MRI-data is best suited for modeling of soft tissues. Fig.**(2)**. is a typical CT scan process while Fig.**(3)**. shows the outcome of the process.

2.2. Conversion of CT-data into CAD & solid model generation

The following steps summarize the conversion process:

1) **3D digital image**- The scanned data from the appropriate medium i.e. typically from the CT/MRI equipment can supply scanned data on magnetic tape or optical disk [11].
2) **Data transfer, processing and segmentation-**Converting the data into a manipulative format i.e. DICOM Used in the CT/MRI is translated into an image format specific for the conversion software [4].
3) **Creation of 3D-model** -To generate a 3D-model from the 2 dimensional scaned images, contours have to be identified for the targeted element using statistical analysis and the gray scale of the target region. Once selected the different layers has to be tied together to enable the generation of the CAD model in a solid object. The outcome model is shown in Fig.(4)

2.3 Design of the implants

With the availability of solid model customization of implant can be achieved using different design tools and patient data. However, the data used is dependent on the implant being designed, Typical data may include patient age, weight, activity, and others. Coupled with the natural bone design and the patient bone density and certain designs are selected to achieve near optimal fit while minimizing bone removal. Traditional and non-traditional design formulas are used in shaping up the final design. Customized implants are far superior than “standard” implants. In addition to the robustness in the design, there are usually less natural bone removal that may result. Fig.**(5)**. is atypical “standard” Knee implant, while Fig.**(6)**. is customized implant [3]. An estimated 50%less bone removal may result from such customization.

2.4. Producing the Pattern and casting the implant

Rapid prototyping technology is used to produce the pattern for lost wax /investment casting. The accuracy of the produced patterns is compatible with the accuracy of used in medical field especially for orthopedic surgery. Rapid Prototyping is also used to test the pattern against a replica of the patients’ model.The Doctor can view & handle the model before surgery which is of great benefit in evaluation of operation procedure & implant fit in complicated cases.

In the example shown in Fig (7). The pattern a knee implant design is tested against a replica of the patient femur also produced from the CT scan. The pattern is then used for investment casting and finishing of the final product. When the RP medical model is manufactured it should be validated by surgeons. If there are no errors the model is ready for application [3]. Fig (8). shows the typical outcome of the design & Manufacturing.

3. Accuracy of Rapid Prototyping Models

The development of computers and CAD-systems has pushed the manufacturing technology forward, which increases the accuracy of the end product / models from millimeters to thousands of a millimeter.

RP is an unconventional way of minimizing the time of producing prototypes, thus this technique is called as freeform fabrication. Fused deposition modeling is one of the best & accurate techniques for manufacturing purpose. So we are mainly focusing on this technique to fabricate most accurate medical models to avoid further complications by using standard anatomical implants.

Fused Deposition Modeling (FDM) creates the model by extruding thermoplastics, most common ABS, or resin and it is extruded through a nozel where the material is wormed up just above its melting point. The material is applied after a given profile and it cures directly. If the model has weak areas a support structure can be designed to stabilize the model during building. [7,8] The RP process fulfills the general demand in manufacturing medical models allowing inaccuracies of $\pm$1mm [9] with a resulting mean deviation of 0.3805mm by taking scan parameters of 0.1mm for slice increment and 0.6mm for slice thickness.

The quasi-generative RP process itself has a mean deviation of 0.063 mm. The main deviation occurs along the 3D-reconstruction process. In having a best case with a slice thickness of 0.6mm and a slice increment of 0.1mm there is a reconstruction failure of 0.3175mm which cannot be eliminated by a better manufacturing method [10].

4. Conclusion

RP technologies are definitely widely spread in different fields of medicine and show a great potential in medical applications. The applications of CAD/CAM, RE and Rapid prototyping techniques in the medical field are an invaluable contribution of engineering technology to the medical field. The ability to produce physical models directly from the scanned data, promises to be the way of the future in medical surgery. Due to RP technologies doctors and especially surgeons are privileged to do some things which previous generations could only have imagined. It is the ability of such engineering techniques to produce complex “designs” coupled with the advances in surgical procedures that will enable replacement of human parts, reconstruction of others, and the performance of operations with great precision.

The process of custom designing implants for each patient based on CT/ MRI-data has been proven feasible and promising. However, further research is necessary to lower the cost of such a process. If the process of custom designing and manufacturing implants based on patient specific data can be further streamlined and the cost reduced to an acceptable level, this could become the common process for the future. With the ability to design and fabricate all type of implant at very low cost. Also proposed procedure will decrease the bone loss by 50% and prevent related problems like muscle and joint stiffness.

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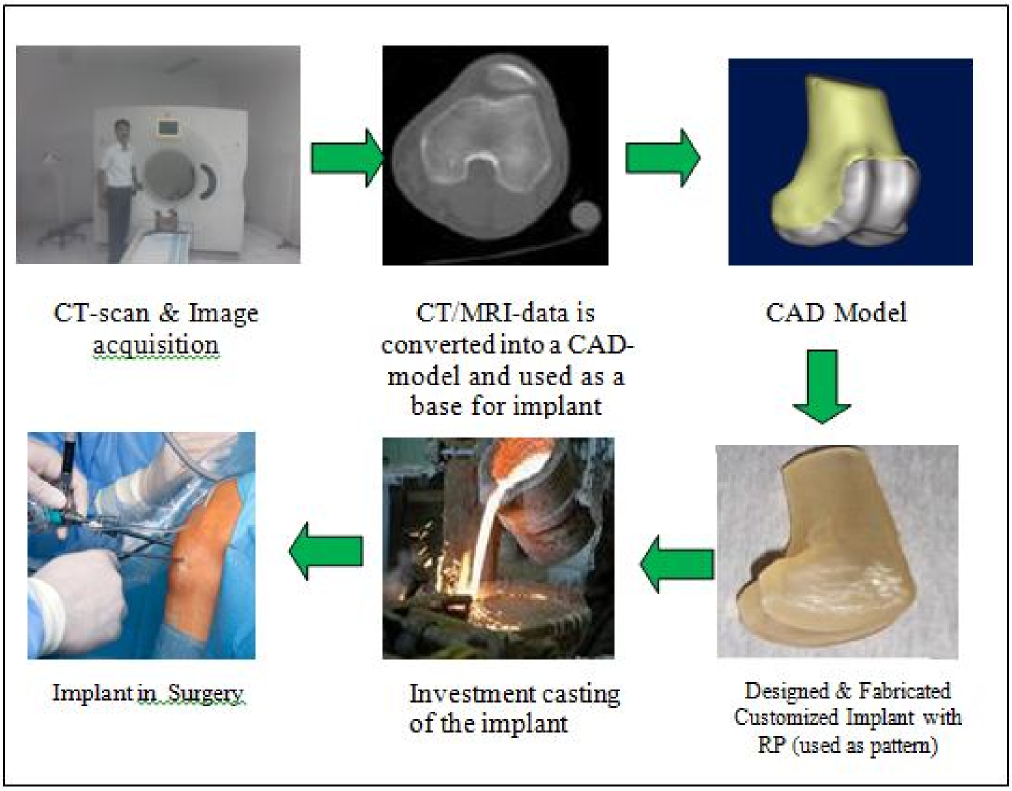

Fig.1- An overview of the detail procedure used for implant customization

Fig.2- CT/ MRI Scanning

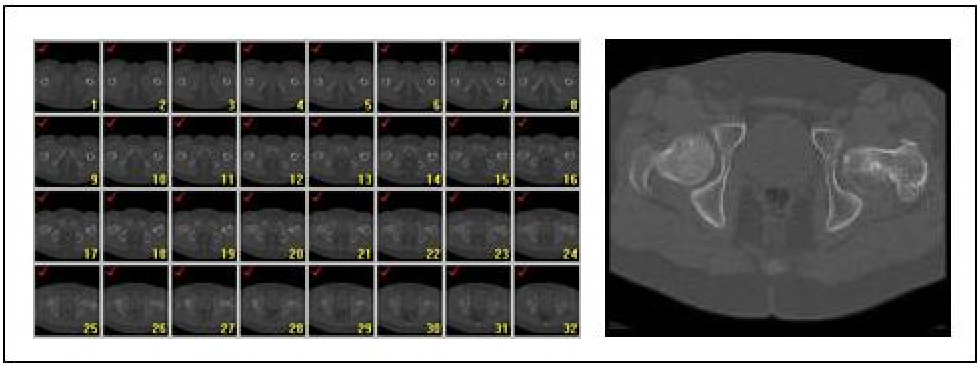

Fig.3- Typical outcome of the scan process.

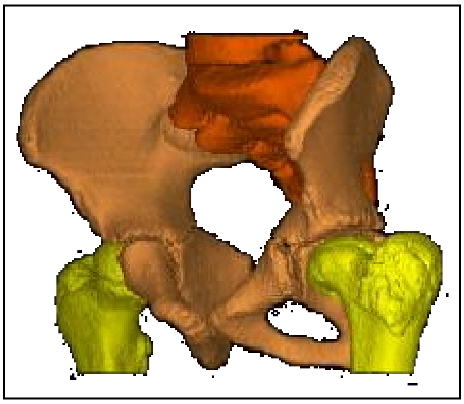

Fig. 4-The solid CAD model of a hip joint.

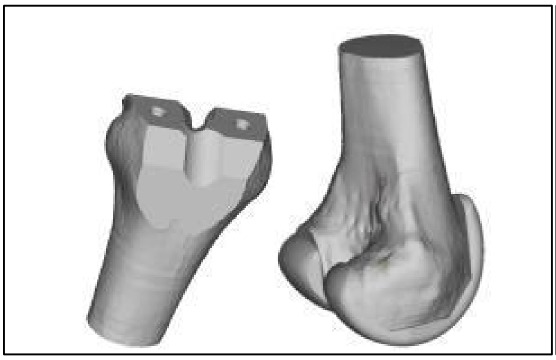

Fig.5- Standard implant

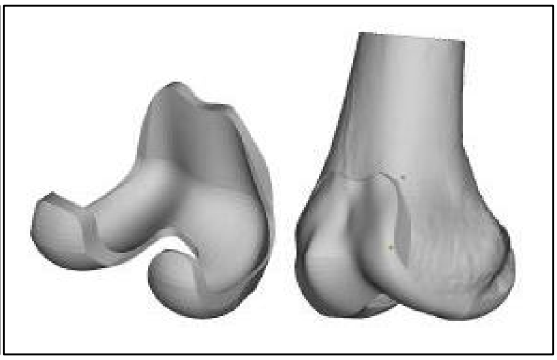

Fig. 6-Customized Implant

Fig.7-The designed & fabricated pattern can be tested against a patients organ replica

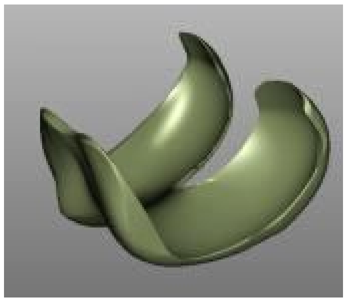

Fig.8-Customized implant

The following flow chart shows the details of process chain for design & manufacturing of customized anatomical implant.