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Review Article

A REVIEW ON RAPID PROTOTYPING TECHNOLOGIES IN BIOMEDICAL APPLICATIONS

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ABSTRACT

Rapid Prototyping (RP) is an novel technology and emerging rapidly in medical & engineering applications. RP technology works on the principle of layer by layer manufacturing. Recent studies proves that Bio-RP plays a key role in tissue engineering, preplanning of complex medical surgeries, manufacturing of prosthesis, forensic pathology, surgical simulation, diagnosis, design & manufacturing of implants and as well as medical tools. This Bio-RP gives a new dimension to the medical field. Now a day's medical models are also fabricated with biocompatible materials which can be implant directly in to the patient. Bio-RP models are fabricated as per patient specific requirement. These models are not only having biocompatibility but also having high accuracy, low cost, time saving and biodegradable in specific scenarios. This article provides overall understanding of Bio-RP models, Bio-printing process, fabrication of RP methods and its applications.

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INTRODUCTION

Rapid Prototyping (RP) is a process in which physical model can directly fabricated with help of Computer Aided Design (CAD) design, Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) data or any reverse engineering techniques [1]. Initially mechanization technique took birth in 1770 and after long research for more than 200 years first commercial RP system came out in 1988 [2]. After evolution of commercial RP systems, RP machines are used to generate complex physical models with in less time and cost, compare to traditional prototyping technique [3]. After continuous advancements for more than 20 years these systems are stepped in to each corner of the globe with various names such as Additive Manufacturing (AM), 3D Printing, Additive Fabrication, Additive Processes, Additive Techniques, Additive Layer Manufacturing, Layer Manufacturing, Freeform Fabrication and many more [4]. These systems also provide lot of flexibility in case of material choice from plastic to metal and paper to ceramic. These systems also provide high dimensional accuracy and good surface finish for the use of visualization or functional testing of the model [5, 6]. Now a day's RP machines are used in wide range of applications such as manufacturing industries, medical surgeries, clothing industries, aerospace applications and automobile industries [2].

In most of the cases medical models are fabricated for patient specific [7]. CT and MRI images are common input source to fabricate medical models with high accuracy in less time. These

medical models are used in various applications such as preplanning of complex medical surgeries, manufacturing of prosthesis, forensic pathology, surgical simulation, diagnosis, design & manufacturing of implants and as well as medical tools [8, 9]. The technology in medical models has reached to an extent that the models are fabricated with biocompatible material which can be implanted directly in to patient body [10]. High accuracy and appropriate material selection is required in case of fabricating medical models. Wide range of materials are available to choose for fabrication of medical models like peek, titanium alloys, cobalt chromium alloys and stainless steel etc. [11]. In some cases these materials should be biodegradable depends on the natural growth of replaced body part [12]. Recent studies in bio fabrication area is growing very fast and throwing lot of challenges to the medical industry. Lot of lives have been already saved with help of bio fabrication and made many impossible things to possible. In near future, bio fabrication is expected to grow to a situation where machines can print human organs with life and those can be implanted directly in to a patient to replace damaged part [13]. The research is also growing to an extent where someone can save their tissue at teen age and replace to themselves when they grow old. Currently Bio fabrication is largely used in the various medical fields like oral and maxillofacial surgery, dental surgery, reconstructive surgery and orthopedics, heart surgery etc. [14-18]. Steps involved in conversion of CT or MRI to physical model are explained in detail in this study.

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Construction of CT/MRI data to Medical Model

Medical models are constructed on the basis of CAD data acquired from CT/MRI. For construction of 3D CAD model from CT/MRI involves several steps. Flow chart for medical model construction is shown in Fig. 1 [19]. Data for the CT/MRI stores in the DICOM format. To convert DICOM to CAD design medical software's are required. MIMICS is one among them, which is also capable of editing and manipulating of the CAD data in to the required region of interest in case of designing custom prosthesis.

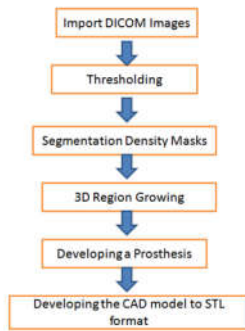


Fig 1. Flow chart for medical model construction

Import DICOM Images

Initially the acquired CT data (Digital Imaging and Communications in Medicine (DICOM) Images) were processed in to medical modeling software like MIMICS, 3D Slicer and 3D Doctor etc. Till this stage the data will be in the form of $2\frac{1}{2}$ D (two dimensional data with equal thickness),

these medical software's converts the $2\frac{1}{2}$ D data to 3D data.

These 3D CAD data helps for better visualized or modification of data easily.

Thresholding

Threshold value is the one, which segregates the human anatomy such as bony part or soft tissue from the DICOM images. In most of medical software's threshold value for the DICOM ranges -1024 to +3071 Hounsfield Unit (HU), these values may vary from software to software. Depending on the value of Thresholding number software segregates the soft tissue or hard bone separately. Thresholding value for hard bone is 226 (for MIMICS software) and value less than this is for soft tissue.

Segmentation density masks

The quality of the 3D model created is dependent on the quality of segmentation process. Different algorithms have been proposed for segmentation of medical images. In segmentation, pixels of common specifications like colour, intensity or texture in each image are separated. In segmentation the voxels are united to form the entire layer of the 3D image. Complete 3D image is constructed by using the all the layers.

3D Region Growing

In 3D region growing the selective part of the model is selected from entire 3D CAD model for example: mandible is selected from the complete 3D model of skull. In this stage the

unwanted data is removed from the 3D model. Region growing will eliminate noise and separate structures that are not connected.

Developing a prosthesis

The development of the prosthesis starts after completion region growing operation. In this stage the prosthesis is designed in the medical software from the acquired data of DICOM image. These prosthesis are made as per the patient requirement.

Developing CAD model to STL format

Since STL file format is globally accepted by all the RP machines. 3D CAD model is converted in to the .stl format to process through any RP machine. In this stage all the CAD data will be transformed into triangular facets. Finally these STL model is used to fabricated RP model with appropriate RP machine, these are disused in the following section.

RP Technologies

All RP processes have basic principle in common. Specifically, input to the system consists of STL data, and fabrication occurs by joining materials in successive layers. However, a wide range of discretely different processes is available under the RP umbrella. As per the ASTM F 42 committee the classification of RP process are as follows.

- Material extrusion
- Material jetting
- Binder jetting
- Sheet lamination
- Vat photo polymerization
- Powder bed fusion
- Directed energy deposition

While coming to the medical modeling generally the material extrusion is used in case of preplanning of complex surgeries and this is the cheapest available technology in RP. Material jetting and binder jetting technology are used to fabricate medical model with multiple colors or materials to visually represent each feature separately. These were mostly used in teaching of medical case studies. The sheet lamination process is also capable of fabricating the model in multiple colors, but entire layer should be in single color. Vat photo polymerization process is used to fabricate the Bio models with high accuracy. Vat photo polymerization process has the highest level of accuracy among all the RP process. Powder bed fusion technology is used to fabricate final implants or prosthesis for the patient specific. Directed energy deposition process is a very costly technology among all the RP processes and this technology is rarely used in case of medical models or implants. Different RP machines support different materials, the application of RP materials in medical industry is disused in below section.

Biomaterials

Biomaterials are used to fabricate Bio models for replacement of partially or fully of the human anatomy in physiologically, reliable, economic and safely manner. This can be hard bone or soft tissue. Generally hard bone replacement is done in case of knee joints, total or partial hip replacement, supports for fracture bones and dental implants [20]. Soft tissue replacement

is done in case of damage in muscular or circulatory system with help of muscle stimulators and artificial heart valves respectively. Identification of the appropriate biomaterials is a challenging task due to mechanical, physical and surface properties. These biomaterials properties may need to serve differently for bone and soft tissue. In case of bone replacement mechanical properties are given priority even though it should satisfy other requirements [21]. But in case of soft tissue replacement mechanical properties may not be dominating. Some of the defects in anatomy and its applications are listed below in Table 1. The bio materials used in bio fabrication are shown in below Table 2.

Table 1 Use of biomaterial and its applications.

Defects in anatomy	Applications
Rectification of minute defects	Chin expansion, mammosurgery
Rectification of functional abnormality	Cardiac pacemaker
Enhance functionality	Contact lens
Partial or full replacement of part	Hip joint, knee joint, plates and screws

Table 2 Material types and material used in biofabrication.

Types	Materials
Metals	Titanium alloys, cobalt chromium alloys and stainless steel etc.
Ceramics	Alumina, zirconia, and bioceramics with porous structure.
Liquid	Photosensitive resins
Plastics	PCL-hydroxyapatite (HA), polypropylene-tricalcium phosphate (PP-TCP), starch-based polymer for 3DP, polyetheretherketone-hydroxyapatite (PEEK-HA).
Powder	Calcium phosphate powder binders.

Biomedical Applications of RP

In biomedical applications implants are fabricated for custom use, the entire design and fabrication of these implants are done for patient specific requirement. These models help surgeons from preplanning to direct implant in patient body. In some scenarios patient specific guides or tools are made, these make surgery easy and safe. The uses of these are widely spread and some of them are listed below. These implants or prosthesis helps patient to recover in short time. The surgeons will have complete information of the surgery before starting the surgery. This Bio model reduces surgery time and improves the success rate of surgery.

Tissue engineering

Langer and Vacanti are the one who made road for tissue engineering in 1993. The role of RP tissue fabrication is to inclusion of computer controlled cells in generation of living cell/material instead of cell-free scaffolds. The basic theory in tissue engineering is to unite scaffold or matrix of living cells to regenerate a tissue which repair or heal the existing tissue [22]. The scaffold or matrix need take care of support cell colonization, differentiation and growth. In case of patient specific implant the external size and shape of scaffold also plays a major role. Apart from these the strength and degradation properties are also taken into consideration. Here the biocompatibility and mechanical or corrosion properties play a major role. Apart from this weight, stiffness, strength and porosity are also taken in to consideration [23]. From the past few years the replacing of scaffolds or use of tissue engineering is growing rapidly. The most common use of this scaffolds are to replace partially or fully of the breast.

According the surveys almost 1 out of 3 women's are suffering from this problem. Breast cancer is one of the common diseases which can attack to women. Generally these are sponge like structures and these should allow the blood and other cells to pass through it and that should not harm the scaffold or vice versa. The major thing to achieve optimum porosity, strength and weight ratio. Not only in case of structure of scaffolds but also in case of material choice is the research going on. These materials should allow the living tissue to stay or pass through it. Some of applications in tissue engineering are shown in below Fig. 2.

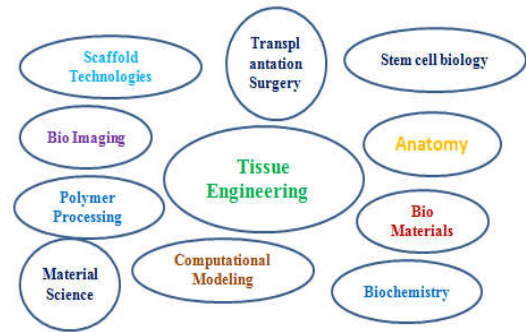


Fig 2 Research areas in Tissue engineering

Preplanning of complex medical surgeries

In case of complex surgeries RP provides surgeons to do a mock surgery on the Bio models. Currently preplanning of surgery is most commonly done in case of dental implants or oral maxillofacial surgeries [24, 25]. Before to RP models surgeons are having only CT/MRI data but after this evolution of RP technology now surgeons can have the physical model of the case in advance to the surgery. These models are identical to patient data in majority of the cases. These models are created as per the bone anatomy of the patient. When a patient having abnormal bone structure due to any accident or natural disorder and which can be reconstructed, in these cases RP models plays a vital role. One of the recent studies in NITW are a child (Name: Deekishta Gender: F) 8 years old girl, born with problem in Temporary Mandible Joint (join of maxilla and mandible) as shown in Fig. 3. Due to this natural disorder the baby cannot open her mouth from birth. To solve this case initially RP model has been constructed from patient CT data. RP model has been fabricated from mojo 3D (Stratasys, USA) printer. Surgeons had done a mock surgery on this RP model, which saved a lot of time in actual surgery to surgeon and it also helped to perform safe surgery. Now patient is able to open her mouth for first time after her birth. This is one of the medical wonder for the patient's family and brought lot of smiles to everyone. This is only one of the examples like this there are many surgeries where RP models played a key role. Some of these images are listed below.

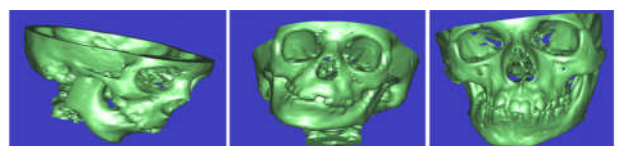


Fig. 3 Different views of TMJ joint (join of maxilla and mandible)

Manufacturing of prosthesis

RP Prosthesis are made unique to fit patient's specific part. This prosthesis can be of prosthetic arms, knee joints, hip sockets and many others. Only E-NABLING THE FUTURE network

with passionate volunteers in 3D printing had provide more than 700 prosthetic hands for those who need around globe in the year 2014 [26]. These RP hands give almost full functionality of the natural hand. Among these one of the case study is done at University of Central Florida (UCF) team developed a 3D printed functional prosthetic arm for 6-year-old Alex, who born without right hand Fingers [27]. First thing done by this child after fixing the arm is real hug to his mother. With help of these prosthetic arms they can play, do bicycling and any other thing that could done by original hand to an extent. Some of these images are given below in Fig. 4. This technology not only created wonders in replacements of hands but also in case of hip joints and knee joints. Generally the old people over age of 50 will be suffering from osteoarthritis in this case patient specific knee replacement will relieve pain for patient. These replacements also help for the patients who suffer physical disabilities due to some accident [28, 29].

stage. After attaining required results in simulation planning for actual surgery takes place.



Fig 5 skull alone& skull with soft tissue from CT data [9]



Fig 4 Kids with artificial prosthetic arms provided by E-NABLING [27]

Forensic pathology

RP also stepped in to forensic pathology, where the reconstruction of face can be made from skull data [9]. This reconstruction can be done on the basis of soft tissue, individual's sex, age, height and weight as shown in below Fig. 5. As another milestone in RP even from the buried skull also by adding soft tissue in medical software individuals face can be identified. In some cases by adding or removing some amount of soft tissue the change in face can be viewed, which helps in plastic surgery for aesthetic purpose. Even though forensic pathology is a new thing in the court trails, but in the near future this technology also helps to solve crime cases effectively.

Surgical simulation and diagnosis

Surgical simulation refers to a virtual simulation of surgery, which can be done in the simulation software before actual surgery [30, 31]. In this stage the implant will be in design stage and simulation is done on these designs, on the basis of this simulation results actual surgery is planned. The weight, design and material properties are keenly considered at this

Some of the applications in surgical simulation are treating patient for cancer effected zones in cist and tumor [32].

In this simulation the STL file is taken and sent to finite element analysis for meshing and then after passing in simulation the design will be sent to RP machine for final fabrication. This step not only minimizes the risk of the complex surgeries also analyzes the mechanical behavior of the material. This technology already saved many lives. The beauty of this is the results can be expected in advance to the actual surgery.

Design & manufacturing of implants

Broadly design of implants can be classified in to two categories they are custom based or patient specific and standard design. Till the evolution of RP in medical industry standard design was monopoly. RP changed the game from standard to custom based. Generally these designs are made for dental implants, rods, plating, screws, and hearing aid machine. When standard design implants for tooth replacement or hearing aids, lot of patients use to undergo pain due to

incompatible implants. But previously they don't have the option of compatible ones, out of the standard sizes patient use to get the appropriate ones instead of exact ones [33, 34]. Patient's life became easy after RP start producing these custom based implants. Most commonly used implants are tooth replacement and hearing aids, because almost everyone has to use at least one of them in their entire life at certain point of time. In RP after collection of medical, data design of implant was done in design software and in this stage modification and finalization of design takes place.

Medical tools

In the current situations RP models are not only used for implants but also as medical guides or tools. Recently doctors started using patient compatible tools to operate surgeries, which reduces a lot of pain for patient at the time of surgery, for example: stunts and guides in case of bypass surgery. These tools are very easy to fabricate with help of RP technologies. One interesting case where medical guides saved life of 6 months baby is as follows. A 6 months old baby was suffering from severe breathing problem. The respiratory system is not functioning properly due to a block at one place and doctor lost hope. As a last try they made a RP model which is biocompatible valve kind of thing, which has placed at the blocked place to open it. The surgery was successes and little baby survived because of RP [35]. These medical tools or guides are fabricated on basis of patient specific requirements. These tools help to provide safe surgery.

Bio-Printing

Bio-printing has been introduced very recently in the year 1999, which follows the basic principle of 3D printing technique (one layer of cell deposition at a time) [7]. Instead of plastic, ceramic, metals here the input materials is considered as bio-ink, tissues and stem cells etc... As per current advancements Bio-printing of human organ with life is also possible today. Even though this is a great breakthrough in Bio-printing, it has its own boundaries. Currently there are many organizations and research institutions at infant stage in these directions, most of these are now printing organs for pre-clinical trials and some of them are ready to implant in to human body directly. The major challenges in this area are to print organs with living cells and biocompatible to human body.

Bio-Printing technique follows layer by layer deposition of cells and it continuous till it reach top layer of the organ. Once the layers start contact with each other the cells start diffusing as a result this forms in to single organ with life[36]. To form this all cells as a single organ chemical and biological reaction took places in this process. Each cell initially behaves as an individual unit until they merge in to an Organ. This process majorly consists of three stages as shown in Fig 6. The initial stage is pre-processing here the individual cells are collected or generated to the required amount with which an organ can be printed sufficiently and also finalizes the shape and structure of the organ (3D CAD data) . Next stage is processing, in which these cells are systematically arranged or printed with help of the organ printing machine to the required shape. The final stage is of post processing stage this consists of various processes such as sterilization, Autoclave and testing (Viability of cell life). This post processing stage starts from printed

organ from the machine till the implantation of organ to actual or preclinical surgery.

The Applications of bio printing is growing rapidly, some of organs artificially 3D printed with life are human liver, kidney, heart, skin and cartilage layer etc.. The artificial livers can be made out of various techniques like bioplotting, cell assembly, 3D bio assembly, cell patterning, 3D photo fabrication, 3D micro patterning and etc... Out of these techniques each has their own pros and cons [37, 38].

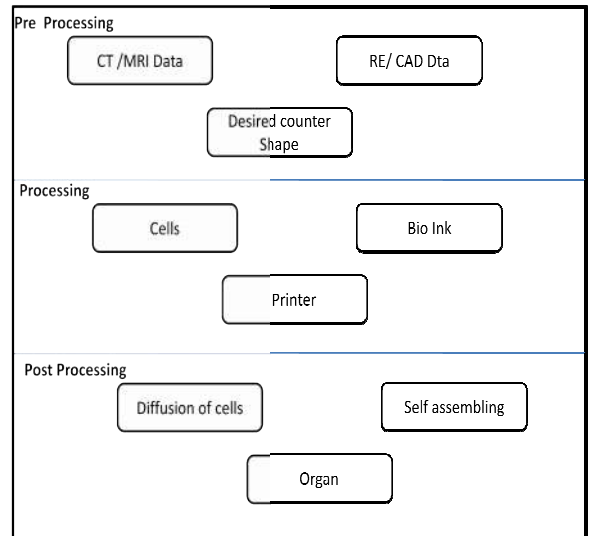


Fig.6 Various stages in Bioprinting

In some other cases where heart cannot function for longer time and those cases requires the replacement of entire heart from a donor or an artificial bio printed heart should replace the original heart. In this direction a team at the University of Louisville has started 3D printing of artificial human heart from fat cells [39]. As per the research studies lead by Wake Forrest School of Medicine under Anthony Alata have developed a printer which can be capable of printing human skin, these 3D printer can print the cells inside the lab from the own patients cells [40]. As the humans growing older or due to lack of minerals in the body cartilage layer got disappears or dissolves. Due to this the outer portion of the bone becomes smooth and may lead to from minor crack to breakage of the bone, these injuries are called Osteochondral. To control these injuries researchers developed a technique in 3D printing, where they can inject the stem cells and those cells start growing in four weeks. These seeded stem cells form cap like structure on the top like a scaffold structure. These can be used in case of repairing of the cartilage layer also. This technique is applicable in the joints like elbow, knee and ankle etc... this research was conducted at University of Melbourne [41].

CONCLUSION

From the above literatures it can be concluded that RP has strong hold medical applications. Medical models for RP can be made out of various RP techniques, with help of these medical models the surgery time reduces and the success rate also improves a lot. In some cases medical guides or tools are fabricated to operate surgery, which reduces pain to the patient such as medical guides in case of bypass surgery. In current world RP has flexibility in case of material choice and fabrication technique. RP technologies made surgeons to create

new era in medical history. In the current days bio printing is successful in case of pre clinical trials. In the near future these Bio printed organs will be ready for implantation to the patient body. Still some of unsolved problems in medical models are speed and cost mainly in biomaterials. To improve this contribution from engineers, radiologists, RP vendors and surgeons are desired. This will make RP to reach one more step in medical industry.

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