Medical Applications of Additive Manufacturing

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Abstract: Additive Manufacturing (AM) has found one of its most innovative and versatile applications in the field of medicines and healthcare. AM technologies are presently not only being used to fabricate prototypes for training, simulation and pre-surgical planning of complex surgical procedures but also for producing end-use metallic customized implants, prosthetic limbs and medical tools. This paper discusses the key AM technologies, biomaterials, various medical applications of AM and the methodology to obtain medical prototypes and implants from Computer Tomography (CT) and Magnetic Resonance Imaging (MRI) scan data. Three case studies have also been included at the end.

Keywords: Additive Manufacturing, Computer Tomography, Magnetic Resonance Imaging, Digital Imaging and Communication in Medicine (DICOM), Surface Tessellation File (STL), Implant, Prosthesis.

I. INTRODUCTION

Additive Manufacturing (AM) is an umbrella term used for a number of processes involved in fabrication of 3D prototypes, tools and fully functional products. AM processes fabricate the final part by depositing material layer by layer in additive fashion. AM processes do not recognise geometric complexity and intricacy. Physical models of any shape, form and dimensions can be fabricated using AM technologies. Functionally graded parts can be made with ease, accuracy and precision with minimum human attention during the fabrication stage. Earliest AM process and machine was developed in 1984 by Charles W. Hull, known as Stereolithography (SLA). It was a liquid based process using UV laser to sure a liquid acrylic polymer resin, layer by layer, to produce the 3D part. Afterwards several other AM technologies emerged such as Selective Laser sintering, Laser Engineered Net Shaping, Fused Deposition Modelling, etc. Materials for AM also increased in variety ranging from nylon , acrylic polymers composites, metals, alloys, etc. Some of the most popular AM processes used for medical applications are being discussed in brief in the following paragraphs.

FUSED DEPOSITION MODELLING

In FDM the model is produced by extruding beads of semisolid material through a heated nozzle which gets hardened immediately upon extrusion. The part is then produced layer by layer by successive deposition of the extruded material. The material is in the form of thermoplastic filament, wound on a coil, which is unreeled to supply material to an extrusion nozzle head. The nozzle head has a resistive heating filament which heats the material to flow ability limit. The material comes out in flow able state and is solidified. Stepper or servo motors are used to move the extrusion head and control the flow. The extrusion head movement can be obtained in both horizontal and vertical directions.

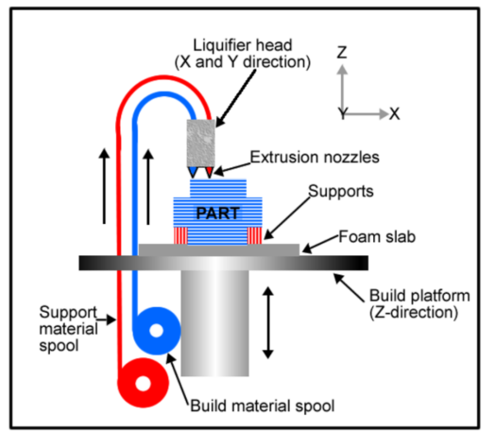

Fig.1 Fused deposition modelling [27]

STEREOLITHOGRAPHY

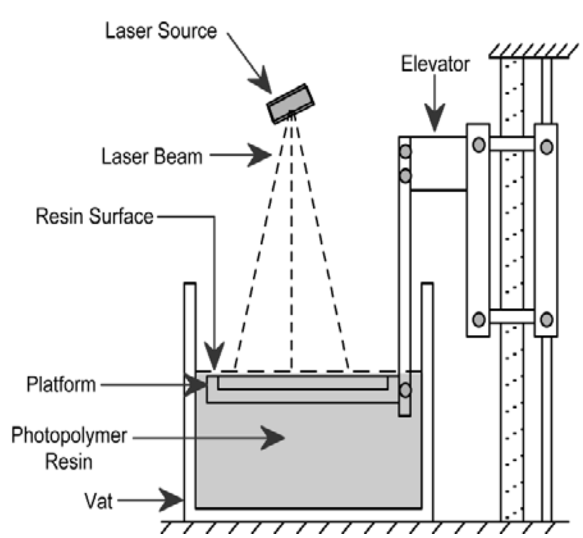

Fig.2 Stereolithography apparatus [26]

The principle of photo polymerization is used in this process, in which a vat of photo curable acrylic liquid polymer is exposed to UV light. The exposed liquid polymer gets solidified and the build platform moves down in small increments by one layer thickness and the liquid polymer is again exposed to UV light. The process repeats until the 3D part is built. Finally, the liquid polymer resin is drained from the vat and the solid model is left behind [14].

SELECTIVE LASER SINTERING (SLS)

SLS is a relatively new technology that so far has mainly been used for rapid prototyping and for low-volume production of components. It uses a laser beam to sinter metal or polymer powdered material. SLS is similar to Direct Metal Laser Sintering (DMLS). Selective Laser Melting (SLM) is slightly different from the SLS.

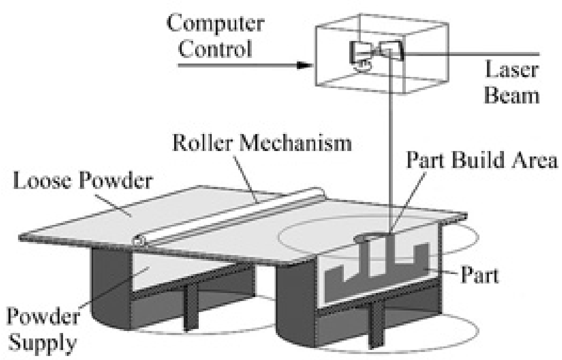

Fig.3 Selective laser sintering process [27]

In SLM the material is fully melted rather than sintered i.e. heated to 70-90% of it’s melting point [18]. It can produce parts in wide variety ranging from powder materials (polymer acrylics such as nylon, polyphenol sulphone, polystyrene etc.) to alloys and metals, such as aluminium, steel, titanium, alloys, composites etc. Depending on the material, up to 100% density can be achieved with material properties comparable to those produced from conventional manufacturing methods and sometimes better than that. Large numbers of parts can be packed together within the powder build volume, allowing very high production rates [27].

II. APPLICATION AREAS OF AM

AM technologies have got applications in almost every part of the society. Some of the major application areas of AM are mentioned below:

- Conceptual Design: AM is used widely in product development cycle by allowing manufacturers to make an easy to interpret prototype which can be viewed, held, compared and tested.
- Rapid Manufacturing: It is the use of an AM process to directly produce end use parts with higher production volumes, shorter lead times and increased cost effectiveness.
- Rapid Tooling: AM can be used for moulds and dies along with other tools for high volume production.
- Aerospace industry, Marine and Automotive industries.
- Medical Science
- Architecture and Construction
- Mass Customization
- Terrain Modelling: For survey, catchment design, topographical study.
- Electronics, Fashion, Footwear industries

III. ADDITIVE MANUFACTURING IN MEDICAL FIELD

AM is influencing medical science in several important ways, most significantly in designing and developing medical devices and instruments. Any domain where it's imperative to decrease product development time and simultaneously provide users with functional performance is an excellent prospect for AM [17].Therefore, it follows that since human lives depend on the quality and ease of the use of several medical products there is added advantage to use AM technologies in their development and production. For example, medical instruments designed using the AM technology include scalpels retractors, surgical fasteners, display systems etc.

Following are the salient reasons behind increasing use of AM processes in medical area:

- Complex, Free Form and intricate geometries such as vertebral implants, bone models, prototypes can be easily fabricated which is not possible by conventional methods.
- Design iterations which be held viewed and studied.
- Fewer Constraints in part Design, sculpture shapes such as bone head, scaffolds, can be easily fabricated.
- Perfectly accurate models and implants, no approximations are required.

- No tooling cost, no fixtures are required.
- Fully Customized implants and prosthesis can be fabricated.
- Wide spectrum of materials can be used ranging from Titanium alloys, stainless steel mesh to bio degradable polymer resins to suit different medical requirements.

The major medical applications of AM are as follows:

- Fully Customized Implants
- Patient Specific Prosthesis
- Scaffold for bone repair and Tissue Engineering
- Dental restoration and Prosthesis, Orthodontics, etc.
- Pharmaceuticals and chemicals, timed drug discharge instruments and devices.
- Electronics and Photonics industry
- Biocompatible composite material testing and development

Surgeons are increasingly using AM models for planning, diagnosis and explaining complex operations such as maxillofacial and craniofacial surgeries. A transparent or colour model fabricated by stereolithography or 3D printing proves very useful in distinct visualization of tumours or other anomalies within the surrounding tissues or bones to a surgeon and his team prior to the actual surgery. Scientists such as palaeontologists, anthropologists and forensic experts also use AM models to identify skeletons and fossils, develop precise replicas of rare finds and build museum exhibition models.

There are items that must be customized for each patient are now being recognized being manufactured additively for example, nearly all hearing-aids today are made using either SLA or SLS. Recent improvements in AM technology are leading to the increased use of RP to make replacement teeth, dentures etc. [13]. AM is also being used to fabricate drug dosage forms which would be difficult if not impossible to make using conventional manufacturing. It is possible to fabricate tablets with precise and complex time release characteristics or those which dissolve and almost instantly deliver the dosage. Medicines can be made more effective and safer in this way and drug companies may be able to realize stronger revenue streams from older compounds with expired patents by supplying them in novel and beneficial dosage forms as required by the patient. Direct manufacture of biologically active implants is also being explored. It is possible to print hard parts like bones as well as complex soft tissue structures such as kidney liver, heart, etc. using AM technologies [25].

IV. MATERIALS FOR MEDICAL APPLICATIONS OF AM

There are varieties of materials which can be used for medical applications of AM. Material selection depends on the purpose of AM model such as planning procedures, customized implants, prosthetic limbs, surgical tools, tissue scaffolds, etc. Apart from this, materials must show biological compatibility [19]. Several materials have been explored and found suitable for the above mentioned medical applications such as:

- Photo-curable acrylic resins
- Metals (stainless steel, titanium alloys, cobalt, chromium alloys, magnesium alloys)
- Advanced bio-ceramic materials (alumina, zirconia, calcium phosphate-based bio ceramics, porous ceramics, etc.
- Polymer-ceramic composite scaffold made of polypropylene-tricalcium phosphate (PP-TCP). PCL and PCL-hydroxyapatite (HA)for FDM, PLGA, starch-based polymers, polycaprolactone (PCL) based scaffold structures and polyetheretherketone-hydroxyapatite (PEEK-HA), etc. in tissue engineering applications
- A new calcium phosphate powder binder known as bone cement which is a mixture of tetracalcium phosphate (TTCP) and beta tricalcium phosphate (TCP) and similar materials, Polimethylmethacrylate (PMMA), polymer calcium phosphate cement composites for bone and cartilage substitutes, implants and prosthesis.

V. METHODOLOGY

The process of making 3D medical models using AM involves the following four major steps:

1) 2D Digital Image Generation
2) Data Transfer With its Processing and Segmentation
3) Evaluation of Design
4) AM Medical Model Fabrication

However, the detailed methodology for converting DICOM data into implant or prosthesis has been shown in Fig. 4.

1) 2D Digital Image Generation: A 2D digital image can be obtained by using CT or MRI scanner. These imaging technologies are used for modelling internal structures of human body i.e. bones, soft tissues, etc. Models for medical use made from this data need to be very accurate and requires a spiral scanning technique, which allows a full volume scan of the body part. This generates a high number of slices of thickness 1-2 mm. The pixel dimension in each slice could be reduced depending on each case and requirement. Mostly the CT and MRI units have the ability of exporting data in DICOM format [22].

2) Digital Data transfer, Data conversion, Processing and Segmentation: The DICOM file is a 2D image. A number of these 2D images are superimposed to obtain a 3D model of the scanned body part or the organ. To achieve this, a suitable software package such as Mimics, DeVide, etc. is used [3]. These software packages allow segmentation by implementing the threshold technique by considering the tissue density. Thus, at the end of image segmentation process, we have only pixels with a value equal or higher than the threshold value. The virtual model of internal structures of human's body, which is required for final generation of 3D physical model requires very good segmentation with a good resolution and high pixel density. It requires a very good knowledge and experience so that the design engineers can exclude all objects which are not the subject of interest in the scanned image and select the required region of interest i.e. separating bones from tissues, inclusion of a certain bone part, exclusion of redundant and anomalous objects, noise and other problems. This step usually demands collaboration of reverse engineering principles with radiologists and surgeons resulting in the generation of a 3D CAD model of the required accuracy, segmentation and surface finish [2].

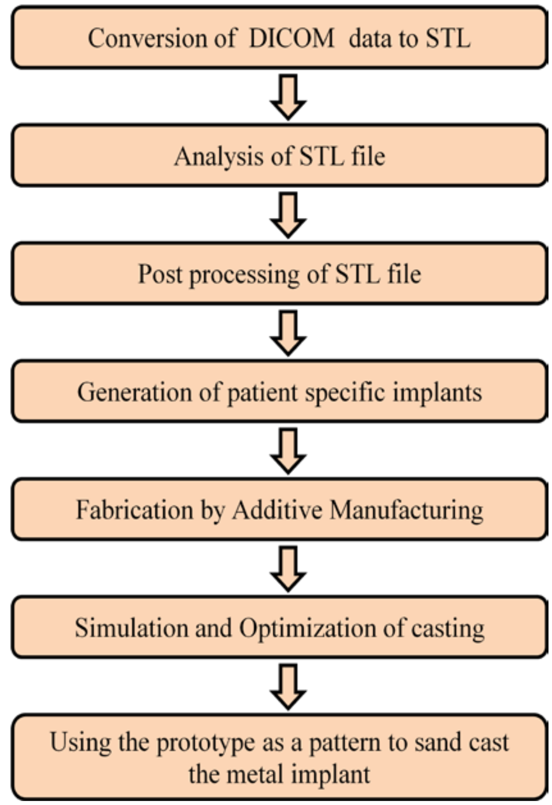

Fig.4 Conversion of 2D DICOM images into physical AM model

3) Evaluation of Design: In this step the generated 3D model is imported in a suitable 3D modelling software package for the purpose of viewing it and assessing the various parameters associated with the model. The design engineers along with the surgeon/doctors decide that how the model should be modified so as to fulfil the requirements of the patient. The 3D model may be exported directly as an STL file and fed to an AM machine for part fabrication or it may be modified to obtain the desired shape, form and characteristics if the part needs to be fully customized, for example prosthesis, implant, hearing aid, denture, etc. In case only a particular section of the 3D model needs to be modified or is required to be separated from the main part, as in the case of bone replacements and implants, then it may also be carried out in this step. Finally, the 3D model is exported as an STL file and post processing of the STL file is carried out to remove various errors which may have crept in during the tessellation process to make it ready for the AM machine to accept.

4) AM Medical Model Fabrication*:* In this step we choose the suitable AM process according to end use of model itself as well as surface accuracy, finish,

strength, appearance, desired mechanical properties. Thus, the generated 3D CAD model is inputted to the AM machine for fabrication of physical model of the object. The quality of fabricated physical model is influenced by quality of the STL file used as input, orientation of the model in AM machine and process parameters for building the model in the same machine [10].

VI. CASE STUDIES

1) AM Fabricated Skull Successfully Implanted in a Woman

In this case the woman suffered from severe headaches due to a thickening of her skull and slowly lost her vision along with her motor coordination abilities. Doctors at University Medical Centre Utrecht in the Netherlands replaced the top part of a 22 year old woman's skull with a AM (Stereolithography) fabricated plastic one [1]. An AM fabricated plastic skull was implanted by the doctors (as shown in Fig. 8) that was manufactured by an Australian company known as Anatomics [9], which specializes in AM [8]. Within three months of the surgery, the woman’s pain was gone and she could see and work again without any traces of the surgery.

Fig.5 Implanting SLA produced skull in the patient [7]

Because cranial implants must fit the exact specifications of an individual’s skull in order for long-term success and comfort and no post surgical complications, CEIT, a Slovakian company in the field of biomedical engineering has sought the use of AM to create implants as described above. CIET obtained the approval for using AM to fabricate fully customized cranium implants and thus paved the way for a whole new approach to patient care process. CIET has also developed the medical standard titanium alloy Ti-6Al-4V. The resulting part was 1.5 mm thick weighed 63 grams and made with a hollow lattice structure to promote the growth of bone tissue and the incorporation of small sensors for collecting medical data from the patient post the surgical procedure.

Though, the above case study cites the use of acrylic polymer based cranial implant fabricated using SLA, recent advancement in AM processes have enabled us to fabricate implant using super alloys of titanium as shown in the Fig 6 below.

Fig.6 TI-6Al-4V cranium Implant [7]

2) AM Produced Heel Bone Saves Man From Amputation:
A person was diagnosed with cancer in heel bone of his right foot. Doctors said that the foot needed to be amputated otherwise the tumour would spread to other parts of the body. However, this would have cost the man his livelihood as he was a construction worker.

Fig.7 Titanium mesh implant of the heel bone [7]

Fortunately, this case came to the notice of CSIRO, a company which specializes in medical AM technologies. The engineers at CSIRO collaborated and decided to restore the worker’s heel bone by replacing it with an AM produced titanium alloy heel bone implant.
Firstly, the medical team scanned the patient’s in-tact heel bone form his left foot. A mirror image for his right foot was created and the resulting 3D model was sent to CSIRO, where an exact replica in titanium using Arcam‘s LENS Apparatus was produced [7]. After the tumour was removed the doctors were able to successfully implant the new heel bone in the foot. This procedure was a world’s first, because most AM implants are not load-bearing to the extent as this heel bone. Also, the implant required both a

smooth surface in order to work with his other foot bones and porous structure so that tissue could grow inside of it and allow the body to accept it after the surgery.

3) Exoskeleton Produced by FDM Enables a Paralyzed Woman to Walk Again:

Fig.8 Prosthetic exoskeleton [8]

This is the case of Amanda Boxtel, an avid skier before she suffered a serious fall on the slopes of Aspen, Colorado in 1992. This accident left her paralyzed below the waist and she was told she would never be able to walk again **[6]**. However, things changed when Ekso Bionics and 3D Systems 3D Printed her a bionic exoskeleton, enabling her to walk again along with other leg movements.

VII. CONCLUSIONS

AM technologies are widely spread in different fields of medicine and show a great potential in medical applications. Various uses of AM within surgical planning, production of models of simulation, hard tissue, training, prosthetics and implants, tissue engineering, biomechanics, and many other applications open up a new domain in medical science. Due to AM technologies, doctors and especially surgeons are privileged to do some things which previous generations could only have imagined.

However, this is just a small step forward. There are many unsolved medical problems and many expectations from AM in this field. AM developments in terms of speed, versatility, cost and other parameters are making good progress, however there is still a huge scope of further improvement and advancement of AM, so that this technology becomes economically viable and within a common patient's financial reach. Nevertheless, AM has opened new avenues to make impossible surgical procedures an easy task and will help in saving countless lives of critically ill patients.

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