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PRODUCTION OF ANATOMICAL MODELS BY RAPID PROTOTYPING TECHNOLOGY

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ABSTRACT
This project investigates the suitability of using RP technology and associated medical software solutions to transfer 2D Digital Imaging and Communications in Medicine (DICOM) data into 3d Standard Triangle Language (STL) data. This data is then utilized using medical software solutions to manufacture preoperative planning models and customized medical implants for the benefit of patients and surgical planning teams alike. The project also gives an overview of relevant subject matter such as medical scanning, preoperative planning models, customized implants, jigs and biocompatible materials. Case studies are included as a method of illustrating how the different technologies integrate and function to produce tangible successful outcomes that make a significant difference in medical interventions.

KEYWORDS: *stereo lithography apparatus (SLA), CAD/CAM, rapid prototyping (RP), femoral component.*

INTRODUCTION
Prior to RP the production of medical models of individual patients was very rare due to the difficulty and cost of generating (usually by CNC machining) complex geometry associated with anatomy. Medical implants were manufactured using pressing, forging, machining and casting processes. Unfortunately, due to the limitations of the manufacturing processes this often resulted in bulky, poorly fitting and costly implants. With the introduction of RP technology, these types of problems were solved using the additive manufacturing (AM) or "layer by layer" process. Building intricate geometrical parts suddenly became less problematic and cheaper this helped RP technology gain acceptance by the medical profession.

RAPID MANUFACTURING
The term rapid prototyping (RP) refers to a class of technologies that can automatically construct physical models from Computer-Aided Design (CAD) data.

History of Rapid Prototyping

Additive manufacturing (AM) of which rapid prototyping (RP) is a subset augments traditional material forming, removal and assembly methods of manufacturing. This overcomes traditional restrictions in manufacturing technology, with significant commercial and technological implications. The huge potential of this technology led to the rapid development of RP, firstly by Magnus in 1965 and then by Swanson in 1971.Thereafter the first stereolithography apparatus (SLA) by 3D Systems appeared in 1987 followed by selective laser sintering (SLS) by EOS in 1990. In 1991 three new technologies were released; Fused Deposition Modeling (FDM) by Strathy's, Solid Ground Curing (SGC) by Cubital and Laminated Object Manufacturing (LOM) by Helisys. In 1996 the first 3D Print technology was released Stratasys. This technology breakthrough set the stage for the commercial integration of AM within manufacturing industry.

Principles of RP

A prototype is a fundamental part of the product development process. Getting the focus right at an early stage establishes the design intent and will help reduce the time and effort spent preparing the prototype for market. A prototype can be defined as "The first or the original example of something that has been or will be copied or developed". A prototype enables a design development team to analyze, plan, experiment and learn the process while designing the product. Material properties may limit the RP process capability. The four key points in any RP process are:

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Input

The term Input refers to the computer generated data (solid model or a surface model) required to describe the physical object.

Method

Presently there are more than 20 manufacturers of RP systems. The method applied by each manufacturer can be classified into the following categories:

- Photo-Curing
- Cutting and Gluing
- Melting and Fusing
- Joining and Binding

Applications

Generically speaking applications can be grouped into the following areas:

- Design
- Engineering Analysis and Planning
- Tooling and Manufacture

Materials

Material used can come in either solid, liquid or powder form. In the solid state it can exist as pellets, wire or laminates. The material type can come in the form of nylon, wax, resins, metals, and ceramics. One of the more convenient ways of classifying these processes is with reference to the initial form of the material, these are;

- Liquid Based
- Solid Based
- Powder Based

Process Overview

The build platform reciprocates vertically and is located in a vat of liquid resin. Before the build commences the build platform is placed slightly below the surface of the resin surface. The recoating blade passes over the build area to help discard any excess resin and generates a homogenous layer of resin. A laser beam passes over the layer and cures the resin. The laser will scan the part being built in addition to the support material. The support material maintains the position of the structure in its build orientation, including any overhanging features. When the first cross section has been completed the platform will be lowered one layer thickness into the vat. The recoating blade recoats the build area. This process repeats itself until the component is complete.

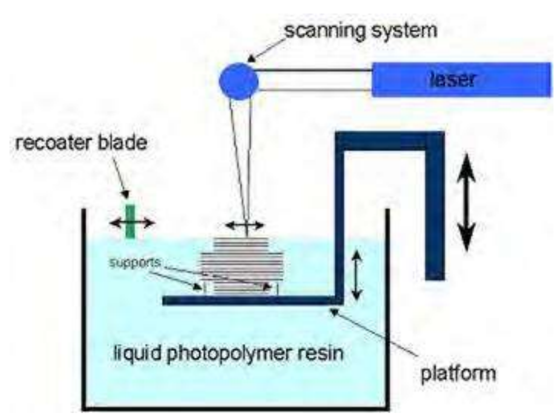

Figure 1 The SLA process.

Figure 2 Component made by the SLA process suspended on support material which is attached to the build area.

speed, accuracy and surface finish. The main drawback is the limited selection of materials for use as functional models but new materials are now being used to create color highlighted models.

SLS

The SLS process uses a CO2 laser to fuse or sinter a powder material. The laser traces the parts cross sectional profile layer by layer. SLS creates accurate and durable parts but surface finish is relatively poor. Factors such as z axis height, enclosed pockets or build orientation can greatly affect the surface finish and geometry, especially with circular parts.

Process Overview

The SLS method uses fine powders that are exposed to a laser beam that fuses the powder granules together. Slice file data is fed to the CO2 laser and the laser scans the image onto a preheated hyphenate bed.

The feed piston is used to measure and feed powder that is spread over the build platform by a spreading apparatus, usually a roller. Once a layer is spread onto the build chamber, a laser, controlled by a scanning device usually a galvanometer sinters the material together. After the first cross sectional area is complete the feed elevator raises one layer thickness and the build chamber lowers one thickness. The roller spreads the next layer of powder over the first layer. The next cross section is sintered which bonds the current layer to the previous layer. This process is continued until the part is completed. When the build is completed the part is left for post curing to take place. When this time has expired any excess powder is carefully removed and the part is extracted from the build chamber. The part is then coated with special epoxies that protects the surface and prevent overhanging features and delicate parts from breaking off. The advantages of this process are that the unfused powder acts as a support material to help stabilize the part during the build process. Unused material can be partially recycled which helps to reduce material costs. Material densities ranging from 75% to 98% are achievable.

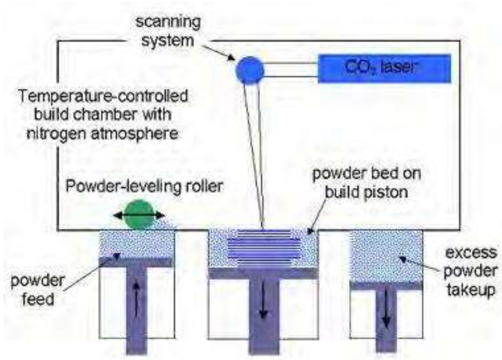

Figure 3 The SLS process identifying the main components.

One disadvantage of SLS is that the parts have a rather porous surface finish due to sintering. This can be a drawback for some applications and may require infiltrating with other materials to fill any voids present.

Materials available include:

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- Polyamide
- Glass filled polyamide
- Elastomers
- Polystyrene
- Foundry Sand
- Stainless Steel

Figure 4 A Stryker knee implant made from cobalt chrome using an EOS SLS process.

FDM

The FDM process involves heating a filament of thermoplastic polymer that is forced through a circular nozzle to form the RP layers. The materials include polyester, acrylonytrile butadiene styrene (ABS), elastomers, and investment casting wax.

Process Overview

The modelling material is contained on spools and is fed into an extrusion head and heated to a semi liquid state. The semi liquid material is extruded through the head, and is deposited in very fine layers from the extrusion head one layer at a time. Since the ambient air temperature is maintained at a point below the melting point of the materials, the material quickly solidifies. As the X-Y plane moves, the head follows the tool path generated by the software, and the next layer is dispensed. The width of the bead can vary between 0.250mm to 0.965mm depending on the model of FDM machine. Thermoplastics, such as ABS, can be used to produce structurally functional models. Two build materials can be used, and latticework interiors are an option.

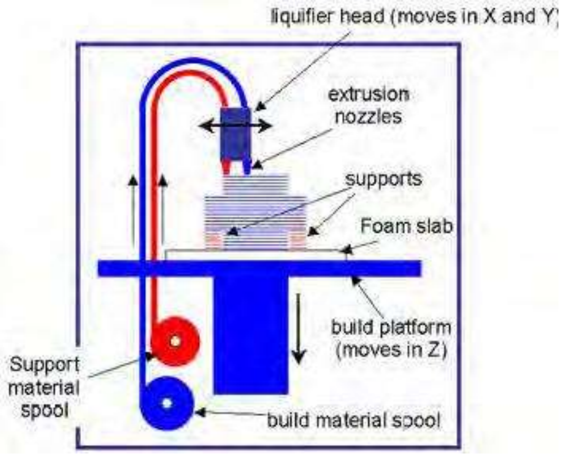

Figure 5 and 6 components manufactured by the FDM process

3D Printing

The Z-Corp three dimensional printing inkjet based process prints the part's cross sectional geometry on layers of powder spread over each other. This process enables models to be built quickly and affordably. Models may also be printed in colour. Z-Corp 3D printing is similar to the SLS method except instead of using a laser to sinter material a print head dispenses a solution to bind the powder together.

Process Overview

The feed piston measures and dispenses powder that is spread across the build area by means of a spreading apparatus. Once the initial layer is spread, the lowest cross section of the part is printed by spraying a binder solution on the powder substrate by means of an inkjet print head located on the print head gantry. After the initial layer is printed, the feed piston raises one layer thickness and the build piston lowers one thickness and the spreader disperses a layer of powder over the first cross section. The print heads then print the next layer. This process continues until the part is completed. Once complete and the binder has dried, the part can be removed and excess powder blown off. No support structures are needed because the excess powder on the build platform acts as a support during the build. Once the part is de-powdered, the part can be finished using infiltrates.

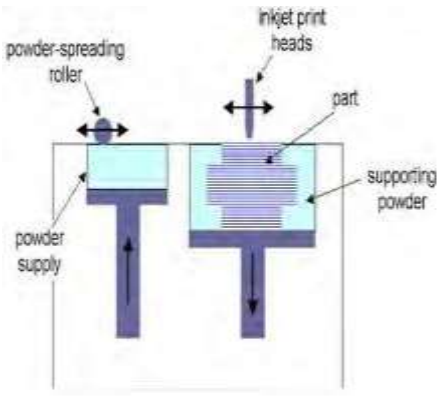

Figure 7 3D Printing process.

The 3D Printing technology allows parts to be built very quickly and inexpensively. This makes these types of models excellent for visual aids and concept models. Some limitations of this technology is the surface finish, accuracy and strength are poor compared to other methods. The material selection is limited to plaster or starch. It is recommended that the plaster based system be used where possible as it is more durable and gives better resolution. The starch hold be used only if one is making investment moulds.

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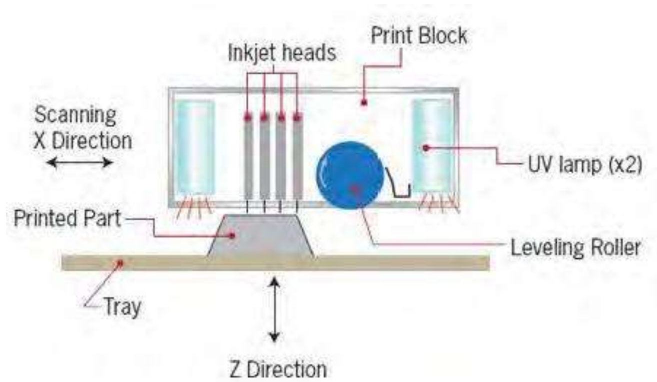

Figure 8 Objects polyjet process uses UV lamps to cure the layers as they are been printed.

SLM

It is a relatively new RP process. This process has been specifically targeted at the medical sector and is currently been used to produce customized implants and jigs.

Process Overview

The workings of the process are very similar to the SLS or SLA process. In this process a high powered laser is used to melt powder metal particles and fuse them together. When the laser has fused one complete layer another fresh layer of powder is dispersed across the build chamber. The thickness of this layer can vary from a minimum of 20 to a maximum of 100 microns. The parts produced are dense metal parts and are available in materials such as tool steel, stainless steel, cobalt chrome and titanium. When reactive materials such as titanium or aluminum are being used the oxygen content within the sealed chamber must be reduced to prevent oxides forming with consequent material defects. This is achieved by charging it with a high purity argon gas.

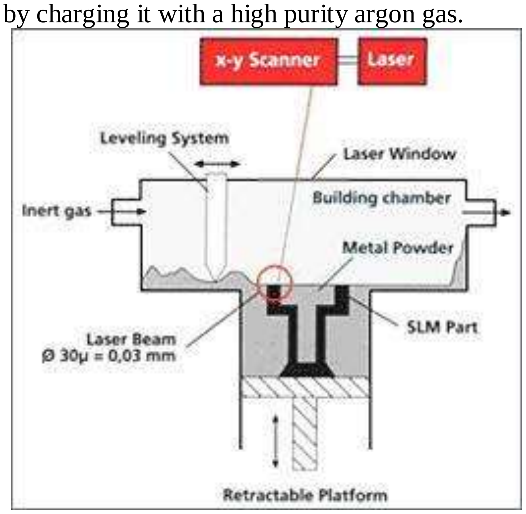

Figure 9 The SLM process.

Applications of Rapid Prototyping

Rapid prototyping is widely used in the automotive, aerospace, medical, and consumer products industries. Although the possible applications are virtually limitless, nearly all fall into one of the following categories: prototyping, rapid tooling, or rapid manufacturing.

- *Prototyping*

As its name suggests, the primary use of rapid prototyping is to quickly make prototypes for communication and testing purposes. Prototypes dramatically improve communication because most people, including engineers, find three-dimensional objects easier to understand than two-dimensional drawings. Such improved understanding leads to substantial cost and time savings. By exchanging prototypes early in the design stage, manufacturing can start tooling up for production while the art division starts planning the packaging, all before the design is finalized. Prototypes are also useful for testing a design, to see if it performs as desired or needs improvement. Engineers have always tested prototypes, but RP expands their capabilities. First, it is now easy to perform iterative testing build a prototype, test it, redesign, build and test, etc. Such an approach would be far too time-consuming using traditional prototyping techniques, but it is easy using RP.

In addition to being fast, RP models can do a few things metal prototypes cannot. For example, Porsche used a transparent stereolithography model of the 911 GTI transmission housing to visually study oil flow. Snecma, a French turbo machinery producer, performed photo elastic stress analysis on a SLA model of a fan wheel to determine stresses in the blades.

- *Rapid Tooling*

A much-anticipated application of rapid prototyping is rapid tooling, the automatic fabrication of production quality machine tools. Tooling is one of the slowest and most expensive steps in the manufacturing process, because of the extremely high quality required. Tools often have complex geometries, yet must be dimensionally accurate to within a hundredth of a millimeter. In addition, tools must be hard, wear resistant, and have very low surface roughness (about 0.5 micrometers root mean square). To meet these requirements, molds and dies are traditionally made by CNC-machining, electro-discharge machining, or by hand. All are expensive and time consuming, so manufacturers would like to incorporate rapid prototyping techniques to speed the process. Peter Hilton, president of Technology Strategy Consulting in Concord, MA, believes that "tooling costs and development times can be reduced by 75 percent or more" by using rapid tooling and related technologies. Rapid tooling can be divided into two categories, indirect and direct.

➢ *Indirect Tooling*

Most rapid tooling today is indirect: RP parts are used as patterns for making molds and dies. RP models can be indirectly used in a number of manufacturing processes:

- Vacuum Casting: In the simplest and oldest rapid tooling technique, a RP positive pattern is suspended in a vat of liquid silicone or room temperature vulcanizing (RTV) rubber. When the rubber hardens, it is cut into two halves and the RP pattern is removed. The resulting rubber mold can be used to cast up to 20 polyurethane replicas of the original RP pattern. A more useful variant, known as the Keltool powder metal sintering process, uses the rubber molds to produce metal tools. Developed by 3M and now owned by 3D Systems, the Keltool process involves filling the rubber molds with powdered tool steel and epoxy binder. When the binder cures, the "green" metal tool is removed from the rubber mold and then sintered. At this stage the metal is only 70% dense, so it is infiltrated with copper to bring it close to its theoretical maximum density. The tools have fairly good accuracy, but their size is limited to 25 centimeters.
- Sand Casting: A RP model is used as the positive pattern around which the sand mold is built. LOM models, which resemble the wooden models traditionally used for this purpose, are often used. If sealed and finished, a LOM pattern can produce about 100 sand molds.
- Investment Casting: Some RP prototypes can be used as investment casting patterns. The pattern must not expand when heated, or it will crack the ceramic shell during autoclaving. Both Stratasys and Cubital make investment casting wax for their machines. Paper LOM prototypes may also be used, as they are dimensionally stable with temperature. The paper shells burn out, leaving some ash to be removed.
- To counter thermal expansion in stereolithography parts, 3D Systems introduced Quick Cast, a build style featuring a solid outer skin and mostly hollow inner structure. The part collapses inward when heated. Likewise, DTM sells True form polymer, a porous substance that expands little with temperature rise, for use in its SLS machines.
- Injection molding: CEMCOM Research Associates, Inc. has developed the NCC Tooling System to make metal/ceramic composite molds for the injection molding of plastics. [18] First, a stereolithography machine is used to make a match-plate positive pattern of the desired molding. To form the mold, the SLA pattern is plated with nickel, which is then reinforced with a stiff ceramic material. The two mold halves are separated to remove the pattern, leaving a matched die set that can produce tens of thousands of injection moldings.

➢ *Direct Tooling*

To directly make hard tooling from CAD data is the Holy Grail of rapid tooling. Realization of this objective is still several years away, but some strong strides are being made:

- Rapid Tool: A DTM process that selectively sinters polymer-coated steel pellets together to produce a metal mold. The mold is then placed in a furnace where the polymer binder is burned off and the part is infiltrated with copper (as in the Keltool process). The resulting mold can produce up to 50,000 injection moldings.

- In 1996 Rubbermaid produced 30,000 plastic desk organizers from a SLS-built mold. This was the first widely sold consumer product to be produced from direct rapid tooling. [19] Extrude Hone, in Irwin PA, will soon sell a machine, based on MIT's 3D Printing process, that produces bronze-infiltrated PM tools and products. [20]
- Laser-Engineered Net Shaping (LENS) is a process developed at Sandia National Laboratories and Stanford University that can create metal tools from CAD data. Materials include 316 stainless steel, Inconel 625, H13 tool steel, tungsten, and titanium carbide cermets. A laser beam melts the top layer of the part in areas where material is to be added. Powder metal is injected into the molten pool, which then solidifies. Layer after layer is added until the part is complete. Unlike traditional powder metal processing, LENS produces fully dense parts, since the metal is melted, not merely sintered. The resulting parts have exceptional mechanical properties, but the process currently works only for parts with simple, uniform cross sections. The system has been commercialized by MTS corporation
- Direct AIM (ACES Injection Molding): A technique from 3D Systems in which stereolithography-produced cores are used with traditional metal molds for injection molding of high and low density polyethylene, polystyrene, polypropylene and ABS plastic. Very good accuracy is achieved for fewer than 200 moldings. Long cycle times (~ five minutes) are required to allow the molding to cool enough that it will not stick to the SLA core.
- In another variation, cores are made from thin SLA shells filled with epoxy and aluminum shot. Aluminum's high conductivity helps the molding cool faster, thus shortening cycle time. The outer surface can also be plated with metal to improve wear resistance. Production runs of 1000-5000 moldings are envisioned to make the process economically viable.
- LOM Composite: Helysis and the University of Dayton are working to develop ceramic composite materials for Laminated Object Manufacturing. LOM Composite parts would be very strong and durable, and could be used as tooling in a variety of manufacturing processes.
- Sand Molding: At least two RP techniques can construct sand molds directly from CAD data. DTM sells sand-like material that can be sintered into molds. Soligen uses 3DP to produce ceramic molds and cores for investment casting, (Direct Shell Production Casting).

MEDICAL APPLICATION

Medical Imaging

CT Scanning

A CT scan, also known as CAT (Computer Axial Tomography) is a non-invasive medical scanning technique. It uses x-ray technology to obtain geometric data of a body from different positions. A CT scan uses modified x-ray technology, selectively exposing sections of the patient to radiation. The data is then processed to generate a cross-section of the human body's tissues and organs . In order to facilitate the tomography of certain organs, x-ray opaque material may be ingested or injected. Radiologists interpret tomography, identifying trauma, diseases and determining the existence and impact of various pathologies.

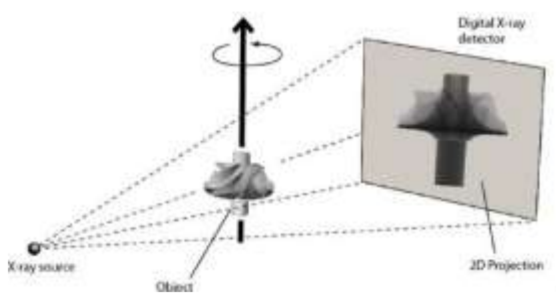

Figure 10 Working of CT scanning.

The CT Process

The X-ray tube emits a conic beam of electromagnetic radiation that selectively penetrates the part of the body being examined; the attenuated radiation is then encoded by a 2D detector and sent to the processing equipment as a digital

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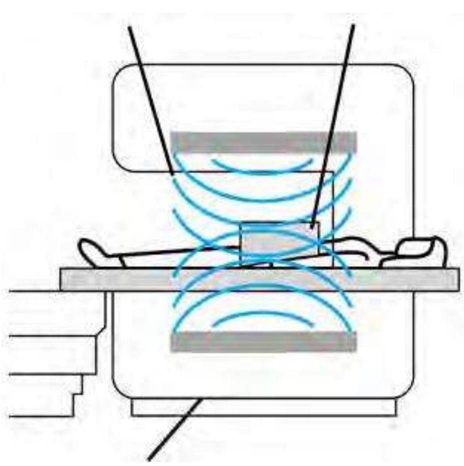
radiograph image. The body is positioned and a precision rotational stage device rotates. An image is generated one step at a time at intervals between 0.250 and 10. This produces 360 to 1440 images and covers a scan of 3600.
3D CT is a method that employs conventional 2D CT data to recreate an image that can be viewed in all three planes. Viewing these images in three different orientations throughout the body provides greater flexibility than conventional planar X-rays more importantly a 3D reconstruction can be generated which provides precise anatomical features. This is due to recent developments in 2D CT equipment and CAD software. The development of 3D CT data is primarily intended to simulate real life anatomical parts and is currently been used in areas such as trauma, tumours and craniofacial deformities. 3D rendering is also possible which lends to high quality 3D CT images.

Advantages of CT Scanning
1. The process is non-invasive and accurate.
2. CT scanning can produce high quality images of bone, blood vessels and soft tissue.
3. The examination and diagnosis of CT scans are fast and facilitate short response times.
4. More tolerant to patient movement than MRI.
5. Tolerant to in vivo medical devices.
6. Accurate imagery often obviates exploratory surgery.

Figure 11 C.A.T scan machine.

MRI Scanning
In 1993 the first functional MRI machine was developed which displayed an image of the brain.
The MRI scanning technique generates pulsed radio frequency (RF) EMR via magnetic coils. The realignment time of displaced hydrogen atoms contained in the tissues is determined and processed to produce an image of the tissue.

Step2 Step1



Step3

Figure 12 The working principle of an MRI Scanner.

MRI Process

- A magnetic field aligns the hydrogen protons in the body.
- RF waves are absorbed by the protons and then emitted as a signal.

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- A RF coil picks up the signal and transmits it to the computer.
- The computer processes the data and generates an image.

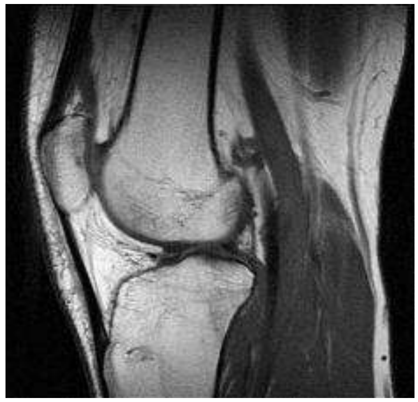

Figure 13 2D image of the knee taken by MRI machine.

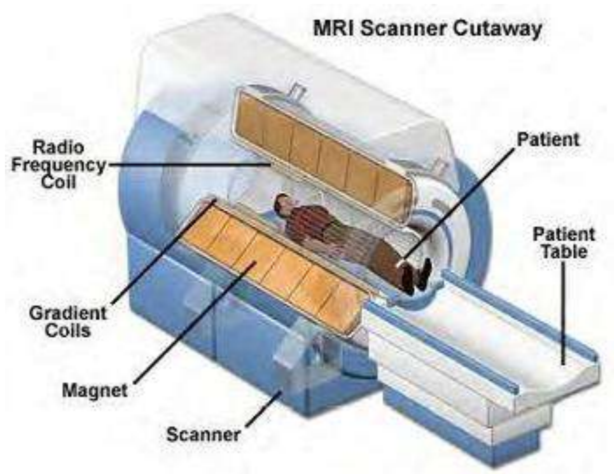

Figure 14 Essential parts of a modern MRI machine.

Ultrasound

This technique uses the analysis of sound waves reflected within the human body to generate an image. In 1962 Joseph Holmes designed the first contact B-mode scanner.

Ultrasound Process

The ultrasound device emits ultrasonic sound waves when in contact with the body. These Waves, partially reflected at anatomical interfaces, are received by a microphone in the device. The amplitude, frequency and interference profile of the reflected waves is a function of the anatomy under study. This profile is processed and displayed as an image. An interface gel may be used to enhance sound transmission.

Figure 15 The Ultrasound Scanning Process and a modern Ultrasound Scanning Device.

RP PROCESS

3D Modeling

Advanced 3D CAD modeling is a general prerequisite in the RP process and is usually the most time consuming part of the entire process chain. It is important that these 3D geometric models can be viewed by the entire design team for reasons such as form and fit, stress analyses, Finite Element Method (FEM) analysis, detailed design, drafting, design for manufacture and assembly (DFMA).

Data Conversion and Transmission

The solid or surface model built is converted into an STL file format. The STL file format approximates the surfaces of the model using triangulation. The data transmission must take place under agreed data formats such as Standard Triangle Language (STL) or Initial Graphics Exchange Specification (IGES).

File Processing

The STL file must be checked for flaws within the file. This can be caused by errors within CAD models or the non robustness of the CAD-STL interface. Materialize Magic's and 3-matic software can be used to produce a watertight solid model.

Building

It is good practice to build as many parts as possible at the same time, this utilizes the build area of the platform. When complete the part should be handled carefully until post processing has taken place. [26]

Post Processing

This includes manual preparation and cleanup. Depending on the process used it could involve removing resin, powder or some other support material.

CONCLUSIONS

It can be concluded that the rapid prototype process is time saving and safe process in medical science. By using different methods of rapid prototyping implant development will be more efficient and accurate. It can also observed that the by using implants developed by rapid prototyping will not only improve life quality of paitient also these implants has very less possibilities of infection and disease.

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