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A Review on Development of Medical Implants by Rapid PrototypingTechnology

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Abstract

Rapid prototyping / manufacturing is computer operated manufacturing technique, builds parts directly from CAD data by additive sequence layer-by-layer, unlike traditional manufacturing process where material is removed in sequence to obtain a desired part. Rapid prototype plays a crucial role in development of medical implants. As medical implants have complex design and vary from patient to patient. It is easy to make custom made medical implants by rapid prototyping at very less cost and time, compared to conventional manufacturing techniques. The present article showcases the significance of rapid prototyping applications in medical industry with suitable bio-compatible materials and manufacturing techniques used to fabricate the complex medical models.

Key Words: Rapid prototyping, medical implants, bio-materials, 3D printing.

1. Introduction

A medicinal insert is a created structure produced for metals, polymers, pottery are prompted to, of the human body through surgical methods, will restore those shape, structure of the muscle/bone Furthermore give backing to the body weights without any uneasiness of the patients [1]. Bio-Medical implants can be inserted to human body temporarily or permanently depending up on the patient compulsion.The performance of a medical device is quite complicated as there are several contributing and related factors, including the implant design, material selection, structural requirements of the device, processing or manufacturing modality of the implant, and clinical issues.

Implantable Medical Devices (IMD) can be characterized as active and passive devices depending on whether they want a power source or not, respectively. At Present, a host of chronic diseases have been addressed using implantable medical devices throughout the body, as in figure. 1[2]. Advanced biomaterials have enabled miniaturized sensors and biocompatible devices that could be implanted in vivo in humans and animal models, allowing diagnosis, prognosis and biological investigations.Many implants can be susceptible to premature failures due to biological attack, and this limits the choice of materials that can be safely used in the body.

In order to properly assess the state-of-the-art in tissue replacement and augmentation, it is first necessary to carefully review the physiology, anatomy, biochemistry and biomechanics of normal tissues as well as the pathophysiological changes that require intervention to restore normal function. In addition, since most medical implants require surgical intervention for installation, it is necessary to be familiar with the repair and regeneration responses that result before it is possible to define the biocompatibility of an implant material.

The bio-compatibility and engineering uses of devices are intimately associated with the chemical and mechanical properties of the materials used in device construction. Therefore, we will briefly review the relationship between chemical and physical structures and mechanical properties of implant materials prior to establishing the utility of each type of material in medical applications. After reviewing this material, it will be easier to understand the types of preclinical biocompatibility tests that are required before clinical tests can begin.

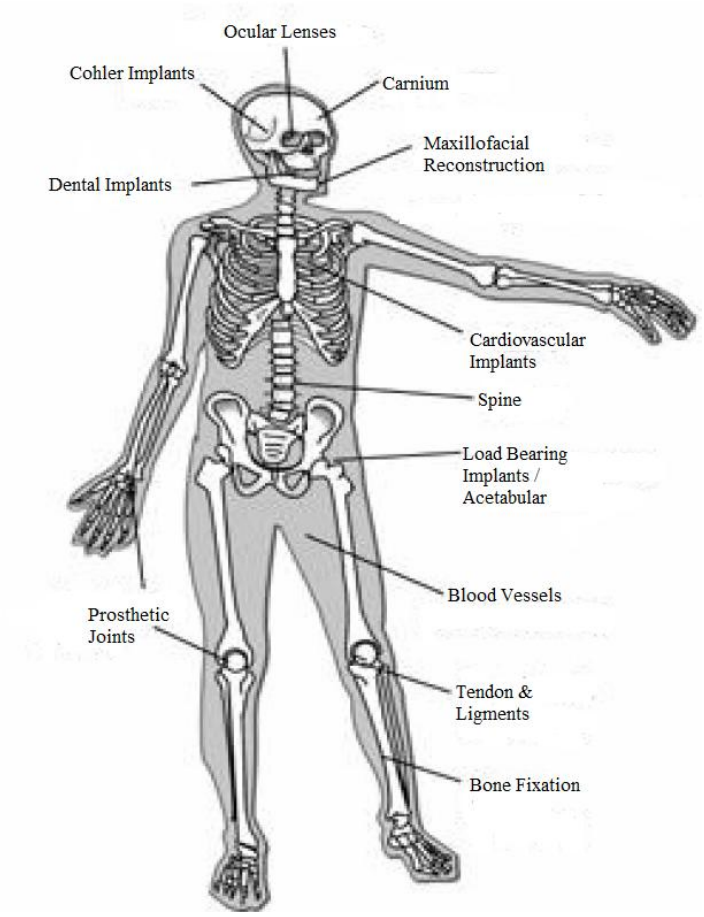

Figure 1: Medical Implants in Human Body

There are some risks and complications associated with medical implantation, such as infections, surgical risks, and implant failure. Rising aging population and increasing prevalence of chronic diseases are some of the major driving factors for the medical implants market. Aged people are more susceptible to chronic diseases such as cardiovascular diseases, orthopedic disorders, endovascular diseases, and dental disorders, this being the major users of medical implants, such as kidney and heart implants, artificial joints implants, and eye implants.

Like all manufacturers, those producing medical implants face the constant challenge to accelerate product development. That pressure is further compounded by the need to create increasingly innovative products. Medical implant manufacturers must balance this race to market—quality; design, materials, and performance must be at the top of the list. Computer generated models are a valuable tool in validating new designs. But, physical product testing remains the key to product integrity. Testing allows the experts to guide product development with years of practical experience. For example, metal plates and rods are being used with great success in stabilizing broken bones

and supporting spinal injuries. Implants are fastened to the bone with screws. Although relatively simple by comparison, bone screw designs must undergo the same scrutiny and rigorous testing as any other more complex device. Self-tapping screws have been prone to tip breakage. Broken tips are not retrievable and may pose subsequent health risks. Additionally, when screws fail, the device fails. Screws and fasteners are tested for tip breakage, break angle, torque, and bending fatigue. Testing ensures that ASTM A540 standards are met and that the product meets structural and metallurgical specifications[3]. In surgery provide a torque limiting screwdriver with fasteners as you never know how much torque might applied by the surgeon.

Medical device manufacturing is a regulated industry in which specialty metals are used for the production of high-performance components. With its costs and time advantages, Rapid prototyping / Manufacturing (RP/M) is an ideal solution for applications including the development, prototyping and production of specialty surgical instruments and orthopedic implants, such as hip, knee and spinal devices[4]. Rapid prototyping is the automatic construction of physical objects using solid freeform fabrication.Ittakes virtual designs from Computer Aided Design (CAD) or animation modelling software, transforms them into thin, virtual, horizontal cross-sections and then creates each cross-section in physical space, one after the next until the model is finished. The steps involved in product development using rapidprototyping are shown in Figure 2[5].Rapid prototyping / Manufacturing (RP/M) is also known as additive manufacturing or 3D Printing.

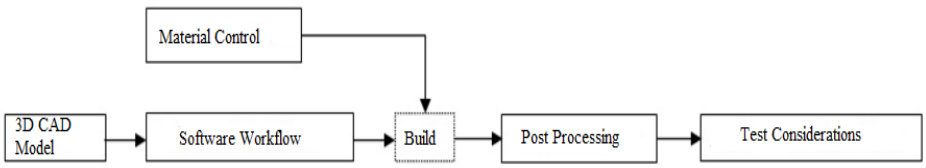

Figure 2: Steps Involved in RP/M

Many of the medical sectors have adopted the 3D printed elements as part of the technological revolution that the 3D technology is bringing. Some of the main advantages of rapid prototyping techniquesare, it does not require multi-steps production operations or any additional tooling and that it minimizes the need for having an inventory. These advantages are highly appreciated for small volumes and complex parts products, such as orthopaedic implants, prosthetic joints and load bearing implants[6].

Next to traditional manufacturing, the 3D printing of implants is a flexible process. The capital required to achieve a certain scope is reduced, enabling individual customization. Customized products provide superior comfort that leads to a faster recovery. Failure risks are much reduced, just like surgical time and overall costs, overall.Compared to traditional manufacturing techniques, such as casting, the 3D printing process creates unique microstructures. Refined grains are obtained due to the rapid heat extraction in the process. For this

reason, the patient's discomfort decreases, without sacrificing the possibility for freeform and complex near-net shapes.

In conclusion, well tailored medical devices lead to fewer downside effects and successful patient recovery. The new applications and quality improvements are surely yet to come. 3D printing is about to reshape current supply chains for numerous orthopaedic implants, minimizing high-costs and long lead-times.

2. Bio-Compatible Materials

In the field of biomaterials there are a number of challenges that must be addressed for successful design of a medical implant[7]. Biocompatibility is a complex issue in that both the composition and size scale of the biomaterial can dictate the cellular response in vivo. Many implants can be susceptible to premature failures due to biological attack, and this limits the choice of materials that can be safely used in the body.Biomaterials are artificial or natural materials used in biological systems. Researches in the scope of biomaterials are multidisciplinary and include various aspects of materials science, chemistry, biology and medicine[8].Figure 3. Shows the classification of bio-materials and their applications in human body. Biomaterial is any material that is an integral part of a living organism. The material can be natural or synthetic and includes metals, ceramics and polymers. They mainly are used in the medical field for tissue repair, heart valves and implants. Table 1. Indicates the types of bio-materials[9].

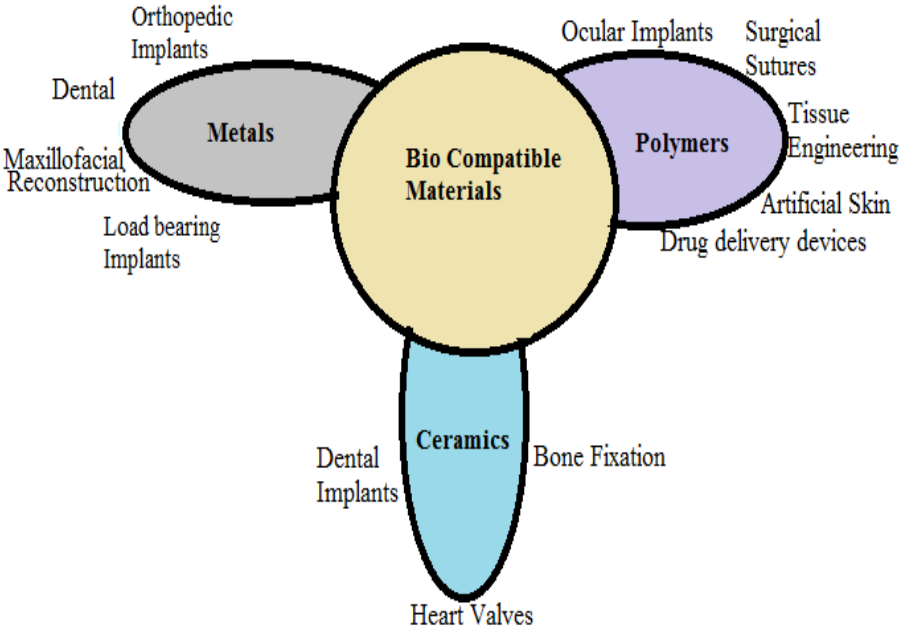

Figure 3: Classifications of Bio-Compatible Materials and their Application

Table 1: Types of Bio- Compatible Materials

Metals	Ceramics	Polymers	Natural Polymers
Stainless steel	Aluminum	Silicones	Collagen
Titanium alloys	oxide	Poly ethylene	Gelatin
Tantalum alloys	zirconia	Poly vinyl chloride	Elastin
Cobalt alloys	Calcium	Polyurethanes	Silk
Gold / Platinum	phosphates	Polylactides	Polysaccharide

Metals

Metals and metal alloys are commonly used for medical implant applications as they are strong enough to bear weight of the body so they are used for load bearing implants applications. Metal implants must exhibit high strength, minimal wear and corrosion. Finally, bio-compatible to the human body without any allergic reaction to the patients and smooth functioning of the implants for a long run. A very few existing metals and metal alloys such as stainless steel, gold, titanium alloys, tantalum alloys, zirconium alloys and cobalt alloys are suitable for medical implants. Still there is a huge space for the researchers to develop new metals and metal alloys. Metals and metal alloys are commonly used at dental applications, load bearing implants, bone fixations, knee joints and maxillofacial reconstruction. As their application need high strength to bear the body weight. Metals exhibit sufficient density as low as that of bone, high mechanical strength and fatigue resistance, low elastic modulus and good wear resistance. It is very difficult to combine all these properties in only one material, so metal alloys come into picture to satisfy the above properties.

Titanium alloys–Titanium and its alloys are recognized as the best biocompatible materials as they are resistance to body fluids, exhibits high strength and minimum density. These alloys come with combination of biocompatible and good strength makes them sufficient for medical applications. Titanium is used to fabricate the load bearing implants, knee joints, dental applications as they improve the growth of osseointegration necessary for implants durability[10]. Among all titanium alloys Ti-6Al-4V is commonly used in load bearing implants and knee prosthesis as they show low wear rate on sliding and contact. Elasticity modulus of Ti-6Al-4V is 110 GPa is very low compared to stainless steel (210 GPa), cobalt alloys (240 GPa) makes them widely used for medical implant applications. NiTi alloys are been using in medical applications, studies show that Ni can corrode in body fluids it may cause cancerous tumours, hence very low quantity of Ni can be used such as stainless steel, pure titanium or cobalt alloys.NiTi implants display a peripheral defensive Ti-based oxide layer, which enhances erosion resistance of this material, and goes about as a viable boundary to Ni particle discharge[11].

Stainless steel–Stainless steel used in surgical implants (316L) made with shifting measures of iron, chromium, and nickel is utilized in making of prostheses. The low carbon (L) in stainless steel lessens consumption and abatements antagonistic tissue reactions and metal hypersensitivities. Maximum medical implants are yet too made from stainless steel. Its main disadvantage is

high corrosion rate, hence not suitable for replacing knee and joints[12]. Stainless steels are commonly used for dental applications.

Cobalt based alloys – Cobalt alloys can be utilized as a part of different diverse permeable structures to consider biologic obsession by in growth. Large number of prostheses are being fabricated from cobalt base alloys for total hip replacements, knee joints as these alloys show a negligible wear rate on sliding and contact of implant. Cr presence in the alloy make it stronger and corrosion resistance to the body fluids[13].Cobalt-base alloys with Polyethylene are most commonly used in total hip replacement (THR), knee joints and other bone implants because of their good healing with the body and fast recovery of the patients, these implants can serve patients jot less than 25 years without any wear rates and osteolysis[14]. polyethylene is organically inactive in the body all in all, minute particles of polyethylene may release toxic to body due to longevity of implants, this leads to wear failure and osteolysis.

There are two types depending on the carbon content in the alloy during casting process as low carbon (< 0.06 Wt%) and high carbon (0.15-0.25 Wt%). Addition of carbon content in the alloy is in the range of 0.1-0.3 Wt% results significant wear properties [15].The alloy surface is protected from wear as a thin carbide film is formed on alloy surface with high hardness [16].Investigations on low carbon content of Co-Cr-Mo alloy results high wear rate correlated with material with high carbon content Normally 5-7 wt% molybdenum is added to the alloy to enhance the mechanical properties, high corrosion resistance[17]. The compound has an oxide layer on its surface, thus forms a narrow film 1-4 μm thickness which improves the corrosion resistance.

Gold / Platinum – Gold and Platinum are very high cost comparatively with the above listed alloys, common patients cannot afford the implants made of gold and platinum even though they are biocompatible. These metals are commonly used for dental applications.

Ceramics

Ceramic materials have been used for artificial joints since the 1970s when the first generation of alumina products demonstrated superior resistance to wear, compared to the traditional metal and polyethylene materials. Advances in material quality and processing techniques and a better understanding of ceramic design led to the introduction of second generation alumina components in the 1980s that offered even better wear performance[18]. Advances in the use of ceramics for artificial joints have received a great deal of attention. Ceramic-on-ceramic hip joints received FDA approval in 2003.

Traditional metal-polyethylene hip system wear generates polyethylene particulate debris, inducing osteolysis, weakening of surrounding bone, and results in loosening of the implant, a primary cause of costly revision operations. Ceramic materials generate significantly less polyethylene debris when used in conjunction with polyethylene acetabular components in bearing

couples. Wear performance extends the life of artificial joints, giving ceramic-on-ceramic joints a predicted life of well over 20 years. Serving the needs of the increasing numbers of younger patients for whom such surgery is now a viable operation, these ceramic-on-ceramic joints allow them to continue leading active lifestyles.

Polymers

Polymers offer the benefit of being intrinsically resistant to environmental attack; however, polymeric biomaterials face unique demands when utilized in load-bearing medical devices in that the mechanical stresses in which they function often put them at direct risk for yield, fatigue, wear, creep, and fracture.Medical devices composed of polymers, like other biomaterial systems, are not immune to mechanically induced biological failures. Medical polymers are used in a broad range of applications including tissue repair and replacement, drug delivery, and wound healing[19].

Polymers exhibit time-dependent mechanical behaviour and are known to be viscoelastic. For example, the elastic modulus and yield strength of a polymer generally increases with increasing strain rate while the strain to failure typically decreases with increased loading rates. Similarly, sustained loads can result in time-dependent strain or creep in polymers. Time-dependent material properties render the prediction of in-vivo performance challenging, particularly when the load conditions become complex. In fact, load-bearing medical devices often subject the polymer components to their limits of yield, fracture, wear, and fatigue resistance.

3. Existing Problems in Medical Implants

The ensuing in vivo degradation and loss of integrity may be detrimental to the performance of the device, potentially leading to the Implant failure. The implanted device and its degradation by-products may stimulate activation of a range of immune mechanisms, leading to inflammation, which in turn may further contribute to the implant degradation. The toxicity of the leaching ions and fragments may hinder the recovery of damaged tissues adjacent to the implanted device. Surface fouling and infections are also of great concern. The abiotic surface of the implant presents a suitable ground for colonization by human pathogenic bacteria. Once attached to the surface of the device, the bacterial cells may form a three-dimensional bio film, which serves as a protection barrier against detachment, predation by host immune cells and significantly reduces the efficacy of most systemic antibiotics.

One of the major concerns in cases of this nature is the statute of limitations (the time limit for bringing a lawsuit). All states allow a fixed period of time in which to bring a suit, but in many cases involving defective medical products a significant period of time can elapse between a patient's exposure to a defective product and the patient's awareness of the injury. Because of that problem, many states have adopted a discovery rule, under which the time limit for

bringing suit does not begin to run at the time of the injury, but rather when the injured person knows or should have become aware of the resulting illness or other damage.

Given the high cost and time associated with the surgical implantation of the device and the recovery of the patient, long-term reliability of the device is crucial. Peri-implant space is a chemically harsh environment, with the surface of the implant being continuously attacked by the highly conductive and corrosive physiological medium which also carries a variety of biochemically reactive organic molecules. The drive towards small, light and flexible devices may undermine mechanical robustness of the implant; aggressive cleaning procedures used on the devices prior to implantation may further contribute to weakening of the organic layers and adhesives.

The Food and Drug Administration (FDA) regulates the safety and effectiveness of medical devices. The amount of control the FDA exercises over the manufacturers depends on how likely the goods being produced are to cause injury. The FDA has promulgated standards and practices with which manufacturers must comply. Evidence of compliance may bolster a defendant's case that it was not negligent, and evidence of failure to comply can support a plaintiff's claim that the injury-causing product was defective. The FDA also prescribes labelling requirements for certain medical products. A manufacturer's compliance with these requirements, however, does not itself relieve the manufacturer from failure-to-warn liability.

4. Manufacturing Techniques

Unlike traditional manufacturing process additive manufacturing is easy to build parts directly from CAD data; it doesn't require any casting, milling, mould preparation, lathe and material removing process as in traditional process. Here parts are built in additive manner, adding material layer by layer sequentially with limited heat to melt or solidify the material. Additive manufacturing processes are grouped in three categories based on the type of the material used as liquid, solid and powder based processes. Table.2 [20] shows the different additive manufacturing techniques based on type of material used to build parts. Some of the popular techniques are discussed below in brief.

Table 2: Classification Rapid Prototyping Techniques based on Raw Material Use

Rapid Prototyping / Manufacturing Techniques		
Liquid based	**Solid based**	**Powder based**
Stereolithography Direct Light Processing Technology High Viscosity Jetting	Fused deposit modelling Laminated Object Manufacturing	Laser Engineered Net Shaping Direct Metal Laser Sintering Selective Laser Sintering

Stereo Lithography (SLA)

Stereolithography (SLA) is most popular additive manufacturing process among liquid based processes; it uses liquid (resin) to build parts directly from CAD data through computer programmed software externally connected to the SLA equipment. Stereolithography is an enclosed substance amassing or 3-dimensional printing developments used for convincing models, model's illustrations and creation components up one layer instantly by action a photograph responsive leave with an ultraviolet light optical device or another equivalent power supply[21].Figure 4. Represents the Stereolithography process layout. The expression "stereolithography" was begun in 1986 by Charles (Chuck) W. Body.

One of the advantages of stereolithography is its speed; functional parts can be manufactured within a day. The length of time it takes to produce one particular part depends on the size and complexity of the project and can last from a few hours to more than a day. Most stereolithography machines can produce parts with a maximum size of approximately 50×50×60 cm (20"×20"×24") and some, such as the Mammoth stereolithography machine (which has a build platform of 210×70×80 cm)[22],are capable of producing single parts of more than 2 meter in length. Prototypes made by stereolithography are strong enough to be machined and can be used as master patterns for injection molding, thermoforming, blow molding, and various metal casting processes.

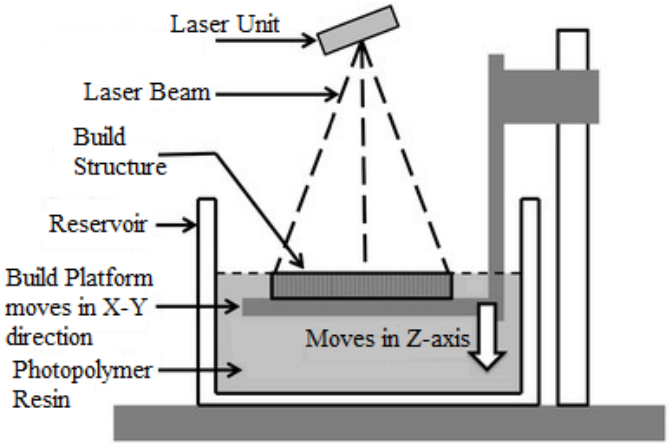

Figure 4:Stereolithography (SLA) Courtesy CoustomPartNetInc

Although stereolithography can produce a wide variety of shapes, it has often been expensive; the cost of photo-curable resin has long ranged from $80 to $210 per litre, and the cost of stereolithography machines has ranged from $100,000 to more than $500,000.

Fused Deposition Modelling (FDM)

Fused deposition modelling (FDM) is a solid based process, which uses solid wire as process material. It is commonly used rapid manufacturing technique for

the fabrication of CAD models with polymer materials[23]. Bio compatible materials utilized as a part of this procedure are polycarbonate (PC), acrylonitrile butadiene styrene (ABS), polyphenylsulfone (PPSF). The product developed on FDM is highly cost effective as there is no post processing such as curing of resin. The cost of FDM machine vary between 75-200 USD is very low compare to other additive machines[24]. The CAD model is produced by extruding small beads of thermoplasticmaterial to form layers as the material hardens immediately after extrusion from the nozzle. A schematic representation of FDM shown in figure 5. A plastic filament or metal wire is unwound from a coil and supplies material to an extrusion on nozzle which can turn the flow on and off. There is typically a worm-drive that pushes the filament into the nozzle at a controlled rate. The nozzle is heated to melt the material.

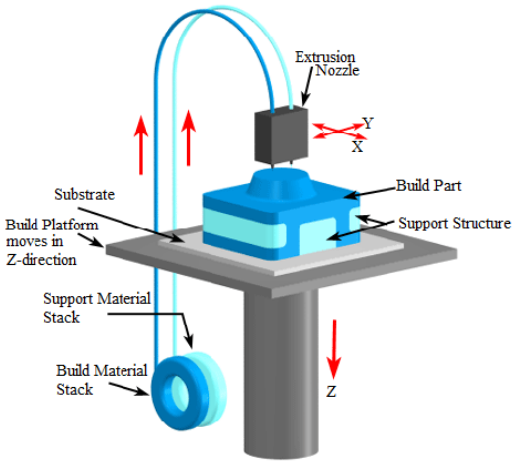

Figure 5: Schematic of Fused Deposit Modelling (FDM)Courtesy Stratasys

The thermoplastics are heated past their glass transition temperature and are then deposited by an extrusion head. The nozzle can be moved in both horizontal and vertical directions by a numerically controlled mechanism. The nozzle follows a tool-path controlled by a computer-aided manufacturing (CAM) software package, and the part is built from the bottom up, one layer at a time. Stepper motors or servo motors are typically employed to move the extrusion head. The mechanism used is often an X-Y-Z rectilinear design, although other mechanical designs such as deltabothave been employed. Although as a printing technology FDM is very flexible, and it is capable of dealing with small overhangs by the support from lower layers, FDM generally has some restrictions on the slope of the overhang, and cannot produce unsupported stalactites.

Laminated Object Manufacturing

Laminated Object Manufacturing is a very fast and inexpensive way to 3D print objects in several kinds of materials. Sheets are bonded together and cut in the right geometry according to the 3D model[25]. Laminated Object

Manufacturing is mainly used for prototyping, not for production. This technology is very versatile as almost any material can be glued. The more common material used is paper as it is easily cut. Plastic can also be used, using a blade or a laser during the cutting stage. Metallic sheets are more unusual because the cutting stage is more complicated.

LOM apparatus uses a continuous sheet of material as plastic, paper or (less commonly) metal, which is drawn across a build platform by a system of feed rollers. Plastic and paper build materials are often coated with an adhesive. To form an object, a heated roller is passed over the sheet of material on the build platform, melting its adhesive and pressing it onto the platform. A computer-controlled laser or blade then cuts the material into the desired pattern. The laser also slices up any excess material in a crosshatch pattern, making it easier to remove once the object is fully printed. New material is then pulled across the platform and the heated roller again passes over the material, binding the new layer to the one beneath it, the process layout of laminated object manufacturing shows in figure 6. This process is repeated until the entire object has been formed. Once an object is done "printing," it is removed from the build platform, and any excess material is cut away. Objects printed in paper take on wood-like properties, and can be sanded or finished accordingly. Paper objects are usually sealed with a paint or lacquer to keep out moisture.

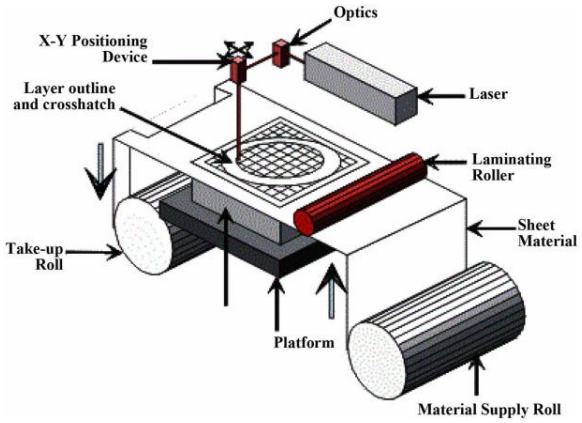

Figure 6: Laminated Object Manufacturing (LOM)Courtesy CoustomPartNet Inc.

While LOM does not create models that are as accurate as those created with other 3D printing methods like Stereo lithography(SLA) or Selective Laser Sintering (SLS). It does offer certain advantages. Because the LOM process doesn't involve any chemical reactions, no enclosed chamber is needed, making it easier to build large models. The materials used during LOM are also inexpensive, consistent, readily available and well understood.However, LOM is not ideal for creating objects with complex geometries, and it can't create hollow objects. Because this process doesn't produce highly accurate parts, it can't be used to create functional prototypes. For this reason, LOM is used primarily for creating scaled models and conceptual prototypes that can be

tested for form or design. It can also be used to make patterns for use in traditional manufacturing, such as sand molded casting, a metal casting process.The technology has been brought to public by Cubic Technologies (formerly Helisysinc.) that propose a plastic LOM machine. Recently, MCor launched their paper based machine adding color to the technology.

Laser Engineered Net Shaping (LENS™)

Laser engineered net shaping (LENS™)is a powder based additive manufacturing technique developed by Sandia National Laboratories, USA[26]. Powder material particle size ranging from 38-150 μm is used on LENS machine to fabricate the models. It is a metal 3D printing technology which prints the physical prototypes directly from computer aided design (CAD) models rapidly. A high powerNd:YAG laser is used to melt the powder particles, are forced to deposit on the metal pool formed on the substrate by the laser poweras in figure 7 [27]. The substrate is fixed on a CNC tables moves in X – Y direction and laser head moves in Z – direction to print the model layer by layer. A computerised program is utilised to control the deposition in X-Y-Z directions to achieve the desired build model. The build chamber is continuously supplied argon gas to maintain less than 10 ppm atmosphere pressure to avoid oxidation at high weld power.CAD models are converted into .STL file format and sliced to layer by layer; a computer controlled program drives the process of depositing solid models. The process parameter like laser power, scan speed, feed rate plays a pivotal role in defining the quality of build model. If the lower laser power is used powder particles are partially melt and exhibits high layer thickness and forms porous deposition, similarly for high laser power, the powder particles are fully melted and forms dens deposit models with thin layer thickness. We observe that not only laser power influences the deposition but scan speed and powder feed rate too influence the quality of deposition of models.

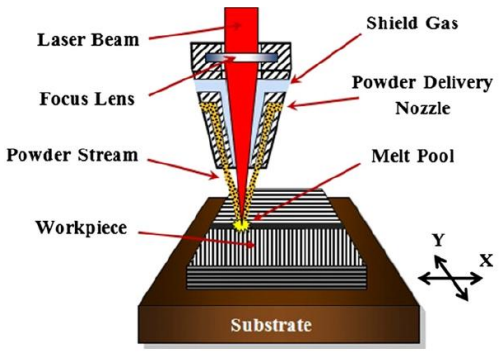

Figure 7: Illustration of LENSTMCourtesy Sandia National Laboratories

Selective Laser Sintering (SLS)

Selective Laser Sintering (SLS) is an additivemanufacturing technique that uses a laser as the power source to sinter powdered material (typically metal), aiming the laser automatically at points in space defined by a 3D model, binding

the material together to create a solid structure[28].Selective laser sintering (SLS) was developed and patented by Dr. Carl Deckard and academic adviser, Dr. Joe Beaman at the University of Texas at Austin in the mid-1980s, SLS involves the use of a high power laser (for example, a carbon dioxide laser) to fuse small particles of plastic, metal, ceramic, orglass powders into a mass that has a desired three-dimensional shape. The laser selectively fuses powdered material by scanning cross-sections generated from a 3-D digital description of the part (for example from a CAD file or scan data) on the surface of a powder bed as in figure 8. After each cross-section is scanned, the powder bed is lowered by one-layer thickness, a new layer of material is applied on top, and the process is repeated until the part is completed.

Due to finished part density depends on peak laser power, rather than laser duration, a SLS machine typically uses a pulsed laser. The SLS machine preheats the bulk powder material in the powder bed somewhat below its melting point, to make it easier for the laser to raise the temperature of the selected regions the rest of the way to the melting point.

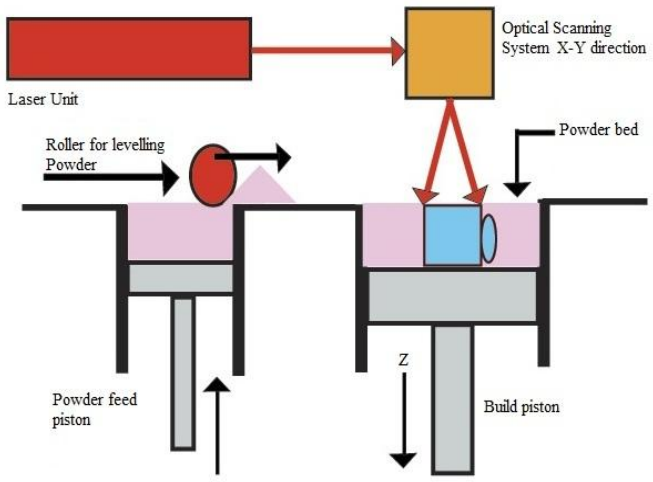

Figure 8: Representation of Selective Laser Sintering (SLS)Courtesy: CustomPartNet Inc.

Unlike some other additive manufacturing processes, suchas stereolithography (SLA) and fused deposition modeling (FDM), SLS does not require support structures due to the fact that the part being constructed is surrounded by unsintered powder at all times, this allows for the construction of previously impossible geometries.SLS technology is in wide use around the world due to its ability to easily make very complex geometries directly from digital CAD data. While it began as a way to build prototypeparts early in the design cycle, it is increasingly being used in limited-run manufacturing to produce end-use parts. One less expected and rapidly growing application of SLS is its use in art.

5. Market Analysis

Medical implant global market was valued at $72,575 million, and is expected to reach $215,500 million by 2025, supported by a CAGR of 7.1%[29]. An implant is a medical device, which is used to replace or support any damaged body organs, improve the functioning of body organs, or treat defects in normal body functions. These can be surgically implanted either permanently or temporarily in the human body, and can be removed when dispensable. These implantable devices comprise bones, tissues, skin, ceramics, metals, plastics, and other natural materials[30].

The global medical implants market is categorized based on types, origin, materials, and end users. Based on types, the report covers cardiovascular implants, spinal implants, orthopedics and trauma, dental implants, ophthalmic implants, neurostimulators implants, and others. Cardiovascular implants include pacing devices, stents and related implants and structural cardiac implants. Orthopedics and trauma implants comprise reconstructive joint replacements, orthobiologics, trauma implants, and sports medicine. Major dental implants include plate-form dental implants and root-form dental implants. Ophthalmic implants comprise intraocular lens and glaucoma implants. Neurostimulators implants are further categorized into deep brain stimulators, sacral nerve stimulators, spinal cord stimulators, vagus nerve stimulators, and others. Other implants include gynecological devices, drug implants, dental implants, cosmetic implants, gastroenterological implants, urological implants, and skin and wound care implants. Based on origin, the market covers synthetic and biological implants. Based on materials, the market covers polymers, alloys, and ceramics. Based on end users, the market covers medical device manufacturing companies, pharmaceutical companies, research institutes, and academic institutes.

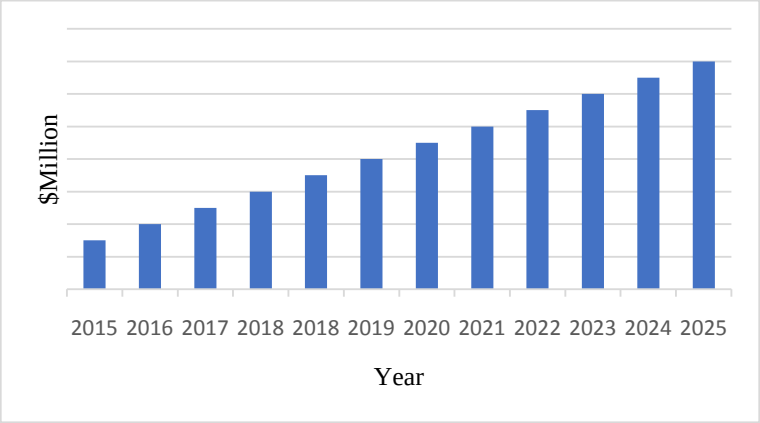

Figure 9: Comparison of Global Medical Implants Market, 2015-2025 ($Million)

Source: Primary Research, Government Publications, Company Releases, and AMR Analysis

Medical implants are used in areas such as cardiovascular, orthopedic, neurological disorders, dental, and others. Rising aging population and increasing prevalence of chronic diseases are some of the major driving factors for the medical implants market. Aged people are more susceptible to chronic diseases such as cardiovascular diseases, orthopedic disorders, endovascular diseases, and dental disorders, this being the major users of medical implants, such as kidney and heart implants, artificial joints implants, and eye implants.

The number of patients opting for orthopedic implant surgeries has increased among in the age group of less than 55 years to over 80 years. Moreover, increase in awareness about the benefits of such surgeries on the quality of life has fuelled the adoption of these devices, especially in developing countries such as India and China. In addition, improvement of healthcare infrastructure in the developing countries has boosted the growth of the orthopedic implants market. New technologies, such as patient-specific implants, especially in knee arthroplasty, using 3D technology and sculptural CAD are being developed, which have numerous benefits over off-the-shelf implants. Clearly implants have improved the quality of life for millions. But when these devices fail or pose health hazards, the ramifications can be disastrous for the recipient and manufacturer alike. Metal ions from artificial hips seeping into the blood stream has been linked to increased cancer risk, problems with eyesight and hearing, immune function disorder, cognitive impairment, and more have been linked to faulty medical implants.

The global medical implants market is growing at a steady pace which is attributed to factors such as the rising incidence of chronic diseases worldwide. Rising prevalence of chronic diseases coupled with the rapidly aging population worldwide is set to increase the demand for medical implants. The above graph shows the growth of global market of medical implants for the next decade.

6. Conclusion

Rapid prototyping technology can make significant impact in the field ofbiomedical engineering and surgery. Physical models enablecorrect identification of bone abnormality, intuitiveunderstanding of the anatomical issues for a surgeon, implantdesigners and patients as well. Rapid prototyping is transforming the practice of medicine; now it is possible to have a precise model of a bone before a surgery and the possibility of creating an accurate transplant.

Custom implants for orthopaedic, joints, load bearing, dental applications can be made instantaneously with MRI scan images. There are few types of bio-materials available based on implant applications such as bone fixations, knee, dental, load bearing, cardiovascular implants metal alloys, ceramics polymers are used to fabricate appropriate medical implants. The present work delivers the bio-compatible materials processed on rapid prototyping technology for the application of bio-medical implants.

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