Healthcare Applications of 3D Printing in Human Implants: A Review

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***Abstract*— 3D printing also known as additive manufacturing technology has been the major development in every field of science in the past few decades. 3D printing has shown its utility in medical science tremendously. It prints objects from a digital template to a real 3-dimensional physical object. The printing is done layer by layer using plastic, nylon, and bioactive materials. It has been found to be a quick and cost effective solution in the field of implants. The applications of 3D printing are rapidly ascendant. 3D printed ventilator parts, PPE and respirators are of great significance during COVID-19 pandemic. In this paper, we attempt to review and investigate the major applications of 3D printing in human implants and its development. The focus of this paper is on recent advancements in different types of 3D printed implants and its gain in health care sector. The review also reports the future and challenges that the technology of 3D printing for human implants is facing.**

Keywords—Additive manufacturing, Bio-printing, Prosthesis, Implants, COVID-19

I. Introduction

[1]According to the ASTM (American Society for Testing and Materials) 3D printing is based on the principle of additive manufacturing which can be elaborated as, *"a process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive/reductive manufacturing methodologies"* [1]. The process of 3D printing generally referred as fused deposition modelling offers us to convert the bioactive component into 3D printed geometries. This technology promises appropriate customization of the drug, implants instruments according to the patient's need [2]. The 3D printing industry associated with the healthcare sector aims in providing aids for hearing, dental implants and prostheses which can be customized according to the end user. Customized digital information provides a blueprint for further solutions in the health care field 3D printing industry, including knee implants, hip implants, prostheses and 3D printed hearing aids. The major factor that has boosted the industry is the quick increase in the population rate as most of the disorders require advance healthcare techniques [3]. 3D printed devices provides adequate designing methodologies and effective cost is also reduced. Today, using 3D printing one can manufacture human as well as animal implants to replicate and replace an organ and even for treating an illness. Therefore, 3D printing is comparatively a better methodology used for designing and manufacturing for healthcare sector [4].

A. *Evolution and Development of 3D printed Implants and Prosthesis*

H. Philippe et al. reported in their work regarding the evidence of the use of prosthesis since the ancient Egyptian times. Prosthetics were known to be manufactured basically for the cosmetic purposes. Amputation is a process which was frequently feared among people even more than natural death 5]. The mummy that has been exposed to view in the Cairo Museum has had the amputated toe of the right foot. It was believed that it was further replaced by a prosthetic produced from wood and leather. The first ever utilized rehabilitation help that got recognition as prosthesis was developed during the Greece and Rome civilizations [6]. The metals used in the metal implants that were utilized in healthcare sector include gold, tantalum, stainless steel, shape memory alloy, titanium alloy, and cobalt chromium alloy. They have been used as permanent prostheses, including knee, hip prosthesis, cranial prosthesis, and dental implants or were used as temporary implants such as rods, screws, and plates used for fixing the bone fractures. Orthopaedic implants in alloplastic material were generally preferred when manufactured using additive manufacturing [7, 8]. Although, the high modulus of elasticity and high mechanical strength was not found to be suitable to be placed with the human tissues and resulted in stress shielding effect. Additionally, the metals highly absorb the X-rays during computed tomography [7]. Implants are used to record various signals of brains of primates by the electrophysiologists. The implants are used with some recording chambers that provide protection from environmental perturbations during the experiments [9, 10]. Implant electrode arrays can be used for chronic multi-cellular recordings that involve various sites to record signals of the brain [11-13]. Kunming University Hospital and 3D thermoplastic printer manufacturer IEMAI 3D manufactured the first 3D printed clavicle implant using PEEK [4].

B. *Recent Status of 3D Printed Implants in Healthcare*

3D printing has been establishing great opportunities in the healthcare sector. Mostapha Tarfaoui et al. surveyed in their review that many 3D printing companies as well as institutes related to academics that were earlier involved in the manufacturing medical devices and their various accessories using 3D printing are now helping the government and medicals to provide personal protection equipment (PPE) to fight against COVID-19 [14]. The report of the market research firm presented statistics of the SmarTech Analysis, that the industry of 3D printing for medical purposes has been estimated to be around $1.25 billion. It is estimated that the market price would be $6.08 billion by 2027 [15]. It is clear from the studies done by researchers and the development of various devices that the scope of 3D printing is vast in medical industry. The Fig.1 shows the statistics of the healthcare 3D printing market based on the technology from 2012 to 2020. According to the reports of the CSIR-Central Scientific Instruments Organization (CSIR-CSIO) has been transferred to the industry. Titanium or other suitable materials can be utilized for obtaining "3D Printed Patient Specific Medical Implants" for patient specific devices using the data of CT-Scan [16]. McDougal et al., reported the current practical clinical applications of 3D printing in the fields of neuroscience that involves the models of neurons that are 3D printed for characterization of the morphological properties [17] and 3D printed lab based devices like micromanipulators [18, 19], perfusion chambers and cortical platform to record for experiments carried out on gnawing mammals including rats, mice and squirrels [20].

Specific programs such as NIH 3D Print Exchange have been setup by the National Institutes of Health to enhance and promote various 3D printed model studies. Some free and easily available respiratory models were also made accessible in the medical and biological sector [21]. S K Malyala et al. reported the development of a basal osseo-integrated implant that has the ability to be patient specific and provided mass customization for nerves treatment. They reported the analysis of the structure that worked as support for the dental patients [22]. In 2017, AIIMS performed the diagnosis of a patient who needed an immediate implant surgery. Therefore, various 3D printed models for the proper visualization of the implant. However, they then switched to EOS' metal technology which resulted into a successful titanium vertebra [4]. At the Tsinghua University, the researchers analyzed and developed 3D printed personalized cervical implant. They utilized polyurethane (PU) which was deposited using the low-temperature deposition manufacturing (LDM) with drug release function [23]. Che Tu et al. aimed in designing a new dental implant to adjust the huge bone dsynfunction occurred due to the previous implant failure which is bioactive in nature. There were new bone generation and good osseo-integration near the gap between the bones within the dental implants while the morphological characterization and Micro-CT evaluation was done [24]. Mika Salmi et al. discussed the potential of 3D printing technology to manufacture equipment required for COVID-19 pandemic period. 3D printing has emerged as a savior globally. It has provided medical supplies in the fight against COVID-19 [25].

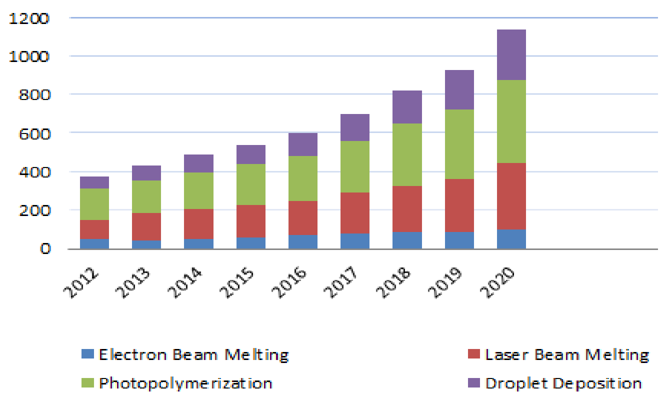

Fig. 1. Healthcare Applications of 3D Printing Industry from year 2012-2020 [3]

C. *Flowchart of 3D Printing of Implants*

The advancements in the 3D printing technology have brought tremendous change in medical applications. It provides a particular flowchart resulting in better accuracy of the work. This ultimately reduces the price of surgical guides which provides an accurate surgery as compared to the non-guided one. 3D printing involves designing of different implant fixtures, different drill sizes and protocols [26]. There are various parameters that need to be optimized while operating the implants such as the spectrum of dimensional deviation and angle deviation from the guided positions of the implants which is generally known as placement accuracy. In medical applications, generally the principle of additive manufacturing is applied rather than subtractive manufacturing in which the extra material is removed until the desirable product is achieved [27]. The flowchart of development of 3D printed implant is illustrated in Figure 2.

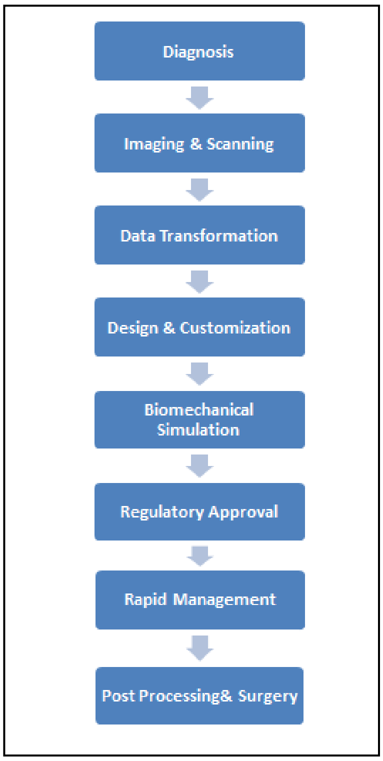

Fig. 2. Flowchart of Manufacturing of 3D printed Implants

II. Types of 3D Printed Implants

There are various types of 3D printed implants in the sector of healthcare. Some of the implants that are manufactured using 3D printing are elaborated below.

A. Cochlear Implant

According to the National Institutes of Health, a cochlear implant is a medically electronic diagnostic tool that recovers partial auditory, and serves as a sensory support and an alternative for deaf as well as those who suffer from profound sensory disabilities due to damage to the tiny hair cells in the inner ear termed as the cochlea [28]. The procedure of cochlear implant needs a multidisciplinary approach and a quality regulated framework that extends from acknowledgement to life-long monitoring and is set out in the AWMF guideline on cochlear implant [29]. The implant comprises of an outer element which resides behind the ear and an inner element which is inserted surgically. The anterior portion of the cochlear implant consists of a microphone and transmitter attached by a speech processor that further transforms the sound signal captured form the microphone into an electrical impulse carried into the transmitter. The transmitter then passes the coded signals to a receiver that is placed just below the surface. The receiver collects the transmitter's coded electrical signals and sends them to the array of electrodes that have been surgically mounted within the cochlea [28].

B. Tracheal Implants

J. Park et al. attempted to develop a successful artificial trachea through tissue engineering utilizing 3D bio-printing [30]. Congenital tracheomalacia is considered as an unusual abnormality having a mortality rate of 99.05%. This condition can develop in infants with fragile cartilage near the trachea or if the trachea is underdeveloped and delicate. The windpipe can be minor and demands no care with most children outgrowing the defect by turning 3 years of age. It can even get damaged due to breathing. This medical disorder can be mild and may not need any treatment, with most children outgrowing the defect by the time they turn 3 years old. However, some cases have been reported as severe and life-threatening that required immediate surgery [28].

C. Cardiovascular Implants

Heart valves developed mechanically are manufactured from tough materials that have high strength. It involves an alloy of steel that have an exterior suture ring made of cloth and two semi-circle shaped leaflets that have a hinge in the centre. All materials are pyrolytic carbon coated, which reduces the risks of blood clotting. Cardiovascular implants are considered as the most reliable implants till date such as defibrillators and pacemakers [31]. Other equipments like implantable pressure monitoring system or implantable blood glucose level monitoring system has the ability to diagnose blood pressure and glucose level exhibit early detection of blood pressure or blood glucose levels for providing personalized care for patients according to the symptoms [28].

D. Gastrointestinal Implants

Abnormalities from birth including the gastrointestinal tract are quite unusual but cases ranges from medium to extreme. It can appear anywhere in the body form the mouth to the anal opening. The gastrointestinal abnormalities can be operated via surgery. A gastrostomy tube is introduced via the abdomen for immediate delivery of nutrients to the stomach of patient. On an average 7 out of 10,000 babies are diagnosed with gastrointestinal defects on an annual basis. The three insertion techniques that are involved are percutaneous endoscopic gastrostomy, laparoscopic method and an open surgery gastrostomy tube placement technique. The PEG technique is the most approachable method that is widely used amongst the other three methods. The procedure utilizes an endoscope that is applied to the stomach to track the position of the G-tube through mouth [28]. Yi Kai Lo et al. reported the development of IFES for gastrointestinal tract modulation. The major limitation that has been lacking in the technique was poor GI neural network [32].

E. Renal Implants

According to the United States Renal Data System, 2015, renal vascular disease is generally diagnosed new born babies in the first few months after birth. However, the cases have increased in the last 20 years [28]. The commonness of laststage renal disorder is that it needs quick transplant surgery which, in India, is approximately in between 151 and 232 per million the population [33]. Renal implants helps in prevention of chronic kidney diseases. Mostly, of renal implants are often managed by angioplasty along with stenting. Angioplasty is a technical terminology which is done to bring back normal flow of blood in the blocked arteries [28]. International Society of Nephrology (ISN), American Nephrologists of Indian Origin (ANIO) and Indian Society of Nephrology have tremendously engaged in promoting advances in renal transplantation on India [34].

F. Bionic Ear Implants

Other than loss of hearing, abnormalities include the malformation of the outer part of the ear known as microtia or anotia. Studies report that around 0.83-17.4 out of 10,000 new born were diagnosed has with microtia birth defects. Visual examinations or CT Scanning images can be utilized to diagnose hearing loss. This helps in examine the precise situation and functioning of the inner ear and to direct further care. A 3D printing of the bionic ear based on a computer aided design was recently analyzed and introduced [28].

Researchers at the University of Utah and case Western Reserve University manufactured the “bionic ear” and analyzed their study in the Journal Transactions on Biomedical Engineering in 2012. The research was performed on four cadavers. The output in the form of sound waves from the microphones is transmitted to the speakers [35].

G. Dental Implants

Dental implant acts as an artificial substitute for the tooth or over crowns of teeth. A dental implant is generally considered as reliable and successful since many years. Samy Tunchel et al. performed a review analysis on 82 patients for 3 years. Out of all the patients 44 were males and 38 were females from the age group ranging from 26 to 67 years. 110 3DP/AM dental implants made from titanium were tested and implanted. Out of 110 implants, 6 implants failed and 104 implants were successful implants [36]. Recent studies reported a novel dental implant that is bioactive in nature. It adjusted the huge bone abnormality due to the removal of previous implant failure [37]. A survey demonstrated the applications of 3D printed models at the Department of Periodontology and Implant Dentistry at New York University College of Dentistry. It was reported that all features of implant training were enhanced utilizing three-dimensional models. Utilizing the models in dental implant, training was considered significant for analysis of complex anatomy conditions for the purpose of treatment planning [24].

H. Cranial Implants

Cranio-Maxillofacial (CMF) surgery requires extremely prudent surgical planning. The strength of the implant is certified by the osteosynthesis screws. The placement of the plates is ensured by positioning guides, which are helpful in indicating the osteotomy sites. Porous Titanium 3D printed cranial implants are reported to be inclusive result for craniofacial reconstructions considering the patient’s anatomy [38]. De La Peña A et al. describes a case study of two patients with cranial defects utilizing three-dimensional (3D) printing technique for cranial reconstruction. A digital prosthesis model is designed and construction using 3D computed tomography [39].

TABLE I. 3D PRINTED IMPLANTS USED IN HEALTHCARE SECTOR

Reference	Type of Implants	Interpretation
Thomas Lenarz et al. [29]	Cochlear Implant	The article explores the study of implantation of the cochlear implant. The diagnostic and surgical technique has been optimized that can be adapted to the anatomical and physiological needs.
Yi Kai Lo et al. [29]	Gastrointestinal Implant	This paper addresses the design requirements for an implant to study GI dysmotility and also presents a miniaturized wireless implant capable of modulating GI motility.
Santosh Kumar Malyala et al. [22]	Osseo-integrated Implant	The authors report the development of a basal osseo-integrated implant. They reported the analysis of the structure that worked as support for the dental patients.
Che Tu et al. [24]	Dental Implant	The authors aimed in designing a novel bioactive dental implant to adjust the huge bone abnormality caused due to the previous implant failure.
J. Park et al. [30]	Tracheal Implant	The authors attempted to develop a successful artificial trachea through tissue engineering utilizing 3D bio-printing.
Sunil Shroff et al. [33]	Renal Implant	The article aims in providing study and state of renal transplantation in India. It also discussed the challenges and the problems associated with it.
Chiara Gardin et al. [31]	Cardiovascular Implant	The article describes some applications of 3D printing in the development and testing of cardiovascular implants.

CONCLUSION

The review seeks to focus and explore the role of 3D printing in the development of human implants. However, the 3D printing technology for the manufacture of medical implants will divert towards patient-specific cell based biomimetic designs termed as bio-printing. There is an urgent need of significant reformation and advancements in the design and development of inks for bio-printing and compounded implant materials having high quality mechanical and biological functions. The mass customization of 3D printed implants is unpractical, as the cost of 3D printers is quite high for the. Therefore, with the analytical work linked with the production of medical implants, the engineering of economic 3D printers is of great significance too. Additionally, the major aim of personalized, 3D bio-printed organs could change personalized care of the patient. Currently, there are around 1 million participants for cochlear implantation in Germany. Out of which about 50,000 are already implanted [29]. The Healthcare 3D printing market is forecast to observe important growth, overdue to the mediation of the government for the betterment healthcare infrastructure and expanded investments in the R&D field. Moreover, healthcare professionals are continuously exploring 3D printing because it decreases the threat associated with anesthesia during surgeries [35]. 3D printing firms whose focus has been on jewelleries, furniture and medical implants are now racing to make PPE face shields and 3D-printed circuit splitters that will allow multiple patients to use a single ventilator especially during the period of COVID-19 [40]. The major challenges associated with the production of personalize 3D printed implants in a hospital environment, from medical, organizational and legal outlook.

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